2-6-95
R.F.

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

FEB 6 1995

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 6 1995

MEMORANDUM

Subject: PP#2F04111. Iprodione on Cottonseed. Response from Rhone-Poulenc dated 10/6/94 to Deficiencies Cited in the Memo of N. Dodd dated 6/24/93.
MRID#s: 433971-01 thru -03 (3 vols).
DP Barcode#: D209023.
CBTS#: 14677.

From: G. Jeffrey Herndon, Chemist
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

G. Jeffrey Herndon

Through: Edward Zager, Acting Chief
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

Edward Zager

To: Susan Lewis/Carl Grable, PM #21
Fungicide/Herbicide Branch
Registration Division (7505C)

and

Jane Smith, Acting Head
Registration Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Rhone-Poulenc proposes the establishment of a permanent tolerance for 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, and its metabolite 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide in/on cottonseed at 0.10 ppm.

CBTS recommended for a temporary tolerance of 0.10 ppm for combined residues of iprodione, its isomer, and its metabolite on cottonseed provided a revised label for Start 15G was submitted (PP#1G3998, M. Peters, 5/10/93).

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Permanent tolerances have been established for combined residues of iprodione, its isomer and its metabolite on various raw agricultural commodities at levels ranging from 0.1 to 150.0 ppm (40 CFR 180.399). Food additive tolerances have been established for iprodione, its isomer and its metabolite on dried ginseng (4.0 ppm) and raisins (300 ppm) (40 CFR 185.3750). Feed additive tolerances have been established for iprodione, its isomer, and its metabolite on dried grape pomace (225 ppm), raisin waste (300 ppm), rice bran (30.0 ppm), rice hulls (50.0 ppm), and soapstock (10.0 ppm) (40 CFR 186.3750).

Permanent tolerances for animal commodities have also been established for iprodione, its isomer, its metabolite, and an additional metabolite N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide at levels ranging from 0.5 to 5.0 ppm (40 CFR 180.399).

Iprodione is a List B chemical. A Phase IV review of iprodione has been completed (C. Olinger, 3/15/91).

Conclusions

1a. The language on the proposed label concerning crop rotation should be changed to the following (see CBTS's Comments and Conclusions to Deficiency 5 for the rationale):

CROP ROTATION RESTRICTIONS FOR BEANS, BROCCOLI, CARROTS, CHINESE MUSTARD, COTTON, DRY BULB ONIONS, GARLIC, LETTUCE, PEANUTS, AND POTATOES.

The following crops may be rotated after harvest: Beans, Broccoli, Carrots, Chinese Mustard, Cotton, Dry Bulb Onions, Garlic, Lettuce, Peanuts, and Potatoes.

1b. The heading " The following crops may be rotated 1 month after the last iprodione application", and the crops listed under it should be deleted from the proposed label (see CBTS's Comments and Conclusions to Deficiency 5 for the rationale).

2a. The petitioner should explain how they calculated the 3,5-DCPA/ECD interaction to be non-linear and why the high spikes (0.25 and 0.50 ppm) exhibited low apparent recoveries.

2b. The petitioner should provide copies of the pertinent extraction log pages (i.e. information on sample weights, extraction volumes, etc.) for the samples and spikes analyzed.

2c. Since a validated method already exists for recovering iprodione, its isomer, and its metabolite from cottonseed (Rhone-Poulenc SOP 90277, which employs benzene), additional validation of the new common moiety method will not be required at this time.

3. Normally, the lack of adequate storage stability data past one year (samples were stored up to 2.8 years) would become a deficiency. However, based on the relative stability of the three regulated iprodione moieties coupled with the predominately non-quantifiable residue levels (even from the cottonseed harvested in conjunction with the 5X processing study), CBTS will not require additional storage stability data **to support this proposed, at-plant use of Rovral® 4 Flowable on cotton.** This does not free the petitioner from performing proper storage stability data of adequate duration to support other uses of iprodione (different crops, use patterns, or formulations) which result in measurable residues.

4. CBTS notes that CBRS should be aware of on the following issues that can be addressed by the reregistration process (see the Detailed Considerations for additional explanation):

a. iprodione rotational crop issue.
b. the need for the common moiety method to be validated at Beltsville.
c. the need for the common moiety method to be examined in regard to interference with other pesticides containing the dichloroaniline moiety, such as vinclozlin, iprodione, procymidone, propanil, methazole, and potentially oxadiazon and dichloronitroaniline.
d. the need to examine the appropriateness of the petitioner's claimed LOQ of 0.05 ppm.

Recommendations

CBTS recommends against the proposed use of iprodione on cotton until the deficiencies outlined in Conclusions 1a, 1b, 2a, and 2b are adequately resolved.

In addition, cotton gin byproducts are now considered a livestock feed item (see Table II, Subdivision O, June 1994). Data for this commodity can be provided later in conjunction with a time limited tolerance for cottonseed and a conditional registration for cotton once the above cited deficiencies have been resolved.

DETAILED CONSIDERATIONS

The Deficiencies listed below were cited by CBTS in the 6/24/93 memo of N. Dodd concerning PP#2F04111.

Deficiency 1 from the 6/24/93 Memo

Product Chemistry data gaps are 62-2, 62-3, and 63-11 as discussed in the R. B. Perfetti memo dated 9/9/92 (CBRS #9943; Barcode #D165907). These data gaps should be resolved.

Registrant's Response to Deficiency 1

The registrant claims that these data gaps have been resolved: the data for guideline 62-2 and 62-3 (MRID# 426982-01) were approved 5/17/94 and the study submitted to fulfill requirements for guideline 63-11 (MRID# 425336-01) was approved on 6/15/93.

CBTS's Comments and Conclusions to Deficiency 1

In a memo of R.B. Perfetti dated 9/10/93, CBRS concluded that, with the new CSF that Rhone-Poulenc submitted (dated 3/12/93), the requirements of Guideline 62-2 have been satisfied. In addition, Rhone-Poulenc submitted additional validation data (MRID# 426982-01) to determine the active ingredient. These additional data were determined to satisfy the remaining deficiencies concerning Guideline 62-3.

In a memo of F. Toghrol dated 6/4/93, CBRS concluded "the data gap to support reregistration of Rhone-Poulenc's iprodione 95% T/MP (EPA Reg.# 264-452) regarding octanol/water partition coefficient (Guideline# 63-11) has been resolved".

Deficiency 1 has been resolved.

Deficiency 4 from the 6/24/93 Memo

Chinese mustard is listed in the Section B/label as a crop with crop rotation restrictions but is not included in either the list of crops which may be rotated after harvest or the crops which may by rotated 1 month after the last application of iprodione. This is an omission which should be corrected on a revised Section B/label.

Registrant's Response to Deficiency 4

No response has been provided by the registrant.

CBTS's Comments and Conclusions to Deficiency 4

Additional language should be added to the label (see CBTS's Comments and Conclusions to Deficiency 5 below for guidance).

Deficiency 4 has not been resolved.

Deficiency 5 from the 6/24/93 Memo

The appropriateness of the proposed crop rotation restrictions will be evaluated when the package of crop rotation studies is submitted for CBTS review.

Registrant's Response to Deficiency 5

The registrant claims that a rotational crop study has been initiated, but will not be completed until the end of October (1994?). Rhone-Poulenc proposes to restrict the use of Rovral 4 Flowable on cotton to continuous culture only, until the confined rotational crop study is submitted and reviewed. The restriction is included on the proposed label.

CBTS's Comments and Conclusions to Deficiency 5

As noted in the memo of conference of R. Loranger from the 3/2/93 meeting (see Attachment I), the plantback intervals and likely establishment of rotational crop tolerances will need to be addressed for all currently registered uses. However, CBTS believes that these should be addressed during reregistration, not in conjunction with PP#2F04111. For the purposes of the proposed Section 3 registration on cotton, CBTS believes that the proposed Section B concerning the rotational crop restrictions for cotton should be relaxed from specifying continuous cotton culture only to allowing rotation to other iprodione-registered crops (as specified on the current Rovral 4 Flowable label).

In examining the proposed label, CBTS noticed that tomatoes are the only rotational crop listed for which iprodione is not registered. CBTS recommends that tomatoes be deleted from the "one month after last application" list of rotational crop list, along with the term "root crops", since all the iprodione-registered root crops are listed individually in the preceding list under "The following crops may be rotated after harvest".

Additionally, the crop chinese mustard, which is listed as a potential rotational crop, should also be listed under the heading "The following crops may be rotated after harvest".

CBTS reiterates that the final decision on the rotational crop issue resides with CBRS as part of the reregistration process.

Deficiency 5 has <u>not</u> been resolved.

Deficiency 10 from the 6/24/93 Memo

For any new crop field trial studies, toluene should be substituted for benzene when the regulatory method is used for the determination of iprodione and its degradates in the samples. The concurrent fortification data from these studies should be submitted as validation of the substitution of toluene for benzene in the regulatory method.

Registrant's Response to Deficiency 10

The registrant has provided a new, common-moiety method that was used to analyze the new field trial data. The new method does not use benzene.

"Method for the Analysis of Rovral-Related Residues: Common Moiety Method, version 6.0 for Cottonseeds", Horizon Laboratories, Inc., 7/20/94 (MRID# 433971-01).

Cottonseed are ground and blended with acetone. The solution is filtered and the resulting acetone extract is evaporated. The dry residue is transferred to a glass hydrolysis vessel and reacted with hot aqueous alkali overnight. This converts residues of RP-26019, RP-30228, and RP-32490 to 3,5-dichloroaniline. The resulting 3,5-dichloroaniline is distilled from the reaction mixture, partitioned into methylene chloride, and reacted with 2-chloropropionyl chloride to yield N-(3,5-dichlorophenyl)-2-chloropropylamide (3,5-DCPA). The extract was purified in a Florisil® column and analyzed by GC/ECD using a 15 meter, 0.53 mm Supelco Sup-Herb® capillary column. The lab claims a limit of quantitation of 0.05 ppm iprodione-equivalents.

The method was validated by Horizon Labs. The lab claims that the GC/ECD response was non-linear versus 3,5-DCPA analyte concentration based on standards over a range from 10 to 200ng/mL. The lab used a log-log equation to plot the curve.

The petitioner provided the following recoveries of the three iprodione-related residues from cottonseeds, as shown in Tables 1, 2, and 3.

Table 1

Recovery of RP-26019 (Iprodione) from Cottonseed

lab ID	fortification level (ppm)	% recovery (expressed as RP-26019 equivalents)
10092-02	0.05	110.2
10092-05	0.25	97.8
10092-08	0.50	91.0
10092-12	0.05	97.7
10092-15	0.25	86.6
10092-18	0.50	90.9
		ave. = 95.7

Table 2

Recovery of RP-30228 (Iprodione isomer) from Cottonseed

lab ID	fortification level (ppm)	% recovery (expressed as RP-30228 equivalents)
10092-03	0.05	108.3
10092-06	0.25	82.8
10092-09	0.50	87.5
10092-13	0.05	97.5
10092-16	0.25	88.2
10092-19	0.50	100.6
		ave. = 94.2

Table 3

Recovery of RP-32490 (Iprodione metabolite) from Cottonseed

lab ID	fortification level (ppm)	% recovery (expressed as RP-32490 equivalents)
10092-04	0.05	103.6
10092-07	0.25	87.3
10092-10	0.50	78.0
10092-14	0.05	94.3
10092-17	0.25	98.1
10092-20	0.50	90.1
		ave. = 91.9

The recoveries above were generated with the validation of the method. Additional method recoveries were generated with the field trial data from 9 new field trials, and are discussed below.

CBTS's Comments and Conclusions to Deficiency 10

Based on past experience with the ECD, CBTS believes that the ECD is a linear detector, but standard curves using certain compounds (such as DDT) do not produce as good correlation coefficients as other compounds do (such as lindane). However, CBTS does not support the use of the log-log plot of the data when samples are analyzed on a linear detector.

Although the petitioner claimed the GC/ECD response was non-linear versus 3,5-DCPA analyte concentration, CBTS calculated a linear equation based on the standard curve (6 different standard concentrations from 10 to 200 ng/mL) provided on page 205 of MRID#433971-01, **and found the curve to be linear ($r = 0.9992$ and $r^2 = 0.9985$)**. Based on the extraction scheme employed (10 g. of sample extracted into 10 mL, then taking 4 of the 10 mL and bringing it up to a 5 mL final volume), CBTS calculated a dilution factor for calculating the actual sample concentration from the extract concentration of 1.25 mL/g, and a molecular weight conversion of 1.31 (MW of iprodione/MW of 3,5-DCPA). Plugging the height counts of the 3,5-DCPA peaks from the chromatograms of the spike samples into the line equation ($y = mx + b$, where $m = 1576$ and $b = 5502$), and using the extraction and MW factors above, CBTS calculated values shown in Table 1 below.

Table 1

		CBTS calculated values		Petitioner's calculated values	
spike ID	petitioner's claimed theoretical value (µg/g)	concentration (µg/g)	% recovery	concentration (µg/g)	% recovery
10093-2	0.25	0.127	50.8	0.2511	99.8
10093-7	0.05	0.0515	103.0	0.0546	105.0
10093-12	0.25	0.126	50.4	0.2590	103.0
10093-17	0.05	0.049	98.0	0.0515	99.7
10093-22	0.50	0.117	23.4	0.4703	94.1
10093-27	0.05	0.0500	100	0.0545	106.2
10093-32	0.25	0.125	50	0.2564	101.6
10093-37	0.05	0.046	92	0.0519	101.4
10093-42	0.25	0.117	46.8	0.2479	98.6

Based on the recalculated recovery methods, 3,5-DCPA's interaction with the ECD appears to be linear and the method gives adequate recoveries for the low spike (0.05 ppm). However, the higher spikes (0.25 and 0.50 ppm) give very poor recoveries that appear to be factors of 2X (0.25 ppm spikes) and 4X (0.50 ppm spike) below what they should be. How can the petitioner come up with a theoretical 0.50 ppm spike that exhibits a height count of 118217 and equates to a 0.47 ppm concentration (claimed 94.1% recovery) when the theoretical 0.25 ppm standards exhibit similar height counts and equate to concentrations near 0.25 ppm (also a claimed 100% recovery) which also achieve about 100% recovery? Since no extraction logs were provided with the petition, CBTS can only assume that all samples were extracted according to the method (10 g. of sample extracted into 10 mL, then taking 4 of the 10 mL and bringing it up to a 5 mL final volume).

The petitioner should explain how they calculated the 3,5-DCPA/ECD interaction to be non-linear and why the high spikes (0.25 and 0.50 ppm) exhibited low apparent recoveries. In addition, the petitioner should provide copies of the pertinent extraction log pages for the samples and spikes analyzed.

Since a validated method already exists for recovering iprodione, its isomer, and its metabolite from cottonseed (Rhone-

Poulenc SOP 90277, which employs benzene), additional validation of the new common moiety method will not be required at this time.

CBTS defers to CBRS to determine whether the method will need to be validated at Beltsville to support the reregistration of iprodione.

CBTS defers to CBRS to determine, as part of reregistration, if the common moiety method will need to be examined in regard to interference with other pesticides containing the dichloroaniline moiety, such as vinclozlin, iprodione, procymidone, propanil, methazole, and potentially oxadiazon and dichloronitroaniline.

CBTS defers to CBRS to determine whether the petitioner's claimed LOQ of 0.05 ppm should be examined as part of reregistration and tolerance reassessment. CBTS believes the actual method LOQ is closer to 0.01 ppm, but based on the high tolerances from late season use of iprodione (as compared to the 0.10 ppm tolerance from this at-plant use on cotton), redefining the LOQ may have little or no bearing on risk assessment.

Deficiency 10 has <u>not</u> been resolved.

<u>Deficiency 14b from the 6/24/93 Memo</u>

An analytical reference standard and Material Safety Data Sheet for the animal metabolite N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide (RP-36114) are not available at the repository and should be provided by the petitioner.

<u>Registrant's Response to Deficiency 14b</u>

An analytical reference standard for RP-36114 has been sent to the EPA Repository.

<u>CBTS's Comments and Conclusions to Deficiency 14b</u>

CBTS contacted Terry Bundy at the USEPA Pesticides and Industrial Chemicals Repository in RTP, NC (fax on 1/27/95) and found that the standard and MSDS are available.

Deficiency 14b has been resolved.

<u>Deficiency 15 from the 6/24/93 Memo</u>

The metabolites 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide (RP-32490) and N-(3,5-dichloro-4-hydroxyphenyl)-ureido-carboxamide (RP36114) must be tested through the appropriate multiresidue protocols.

Registrant's Response to Deficiency 15

The registrant has provided reports on multiresidue protocol testing (MRID# 433971-02 and 433971-03).

CBTS's Comments and Conclusions to Deficiency 15

The MRM reports have been forwarded to FDA (see memo of G.J. Herndon dated 1/24/95).

Deficiency 15 has been resolved.

Deficiency 19 from the 6/24/93 Memo

Additional residue data are needed from the major cotton producing state of CA, based on cotton production areas listed in Agricultural Statistics, 1990. At least one study should be conducted in CA. This study could be a bridging study required in Conclusion 20 below. (Toluene should be substituted for benzene in the analytical method as discussed in Conclusion #10 above.)

Registrant's Response to Deficiency 19

The registrant has provided a residue study in which 9 trials were conducted in 1991 in 6 states: CA (2), TX (2), MS (2), LA, GA, AR.

"Magnitude of Iprodione residue on Cottonseed After In-Furrow Spray Application of Rovral 4F", S. Murayama, 10/3/94
(MRID# 433971-01)

At time of planting, Rovral 4F was applied at a rate of about 1.0 fl.oz. (0.97 to 1.04) of formulated product per 1000 row-feet (2X the proposed rate), using in furrow spray equipment. Samples were harvested between 126 and 177 days after application. Three replicate samples of each treated plot were taken and the samples frozen and shipped to Rhone-Poulenc in RTP, NC. Samples were then shipped to Horizon Laboratories for analysis using the new common moiety method described above. The length of time the samples were stored frozen (from 2 hours after harvest until extraction) varied from 949 to 1018 days (maximum of 2.8 years).

Samples from all three replicates from all 9 field trial sites exhibited concentration that were less than the claimed lower limit of quantitation (0.05 ppm). In fact, for all samples that exhibited any peak in the retention time window of 3,5-DCPA, the maximum height of any peak was much less than one third (average was one seventh) the height of the lowest standard analyzed as part of the curve (0.016 ppm).

In MRID# 433971-01, the petitioner referenced a previous storage stability study (EC-91-172) that showed that after 12

months of frozen storage, relative levels of iprodione (100%), RP-30228 (iprodione isomer (112%)), and RP-32490 (iprodione metabolite (94%))

The new residue data generated using the common moiety method is in line with the previously reviewed residue data (PP#1G3998, J. Garbus, 6/8/92 and 12/15/92) that analyzed iprodione, its isomer, and its metabolite, separately (Rhone-Poulenc SOP 90277 with a claimed LOQ of 0.05 ppm for each compound). Residue data were generated from the application of flowable iprodione at 10 sites in the six states of AR (2), GA (1), LA (1), OK (1), TX (3), and MS (2). The application rate was 1.0 ounce Rovral® 4 Flowable per 1000 row feet (0.42 oz ai/1000 row feet or 2X) in 9 of the 10 trials and 1.67 ounce Rovral® 4 Flowable per 1000 row feet (0.70 oz ai per 1000 row feet or 3.3X) in the 10th trial. Cotton was harvested at PHI's of 129 to 169 days. The samples were frozen immediately after sampling and analyzed 17 to 85 days later. Residues in cottonseed were <0.05 ppm for iprodione, its isomer, and its metabolite except for one value of 0.05 ppm for the parent and one value of 0.06 ppm for the metabolite.

As noted in the review of PP#1G3998 (memo of J. Garbus dated 6/8/92), storage stability studies with cottonseed indicated that the isomer and metabolite were stable during 3 months of storage but that the parent decreased by 30 - 35%.

CBTS's Comments and Conclusions to Deficiency 19

Normally, the lack of adequate storage stability data past one year (samples were stored up to 2.8 years) would become a deficiency. However, based on the relative stability of the three regulated iprodione moieties coupled with the predominately non-quantifiable residue levels (even from the cottonseed harvested in conjunction with the 5X processing study), CBTS will not require additional storage stability data **to support this proposed, at-plant use of Rovral® 4 Flowable on cotton.** This does not free the petitioner from performing proper storage stability data of adequate duration to support other uses of iprodione (different crops, use patterns, or formulations) which result in measurable residues.

The additional field trial residue data satisfy the concerns raised in Deficiency 19.

Deficiency 19 has been resolved.

Deficiency 20 from the 6/24/93 Memo

Bridging data from the flowable formulation to the granular formulation are needed. "Bridging data" refers to residue data from applications of the flowable formulation and granular formulation on side-by-side plots, using the same pre-harvest

interval and rate of application. (Toluene should be substituted for benzene in the analytical method as discussed in Conclusion #10 above.)

Registrant's Response to Deficiency 20

The registrant does not intend to register the granular formulation of iprodione on cotton at this time; the Rovral 4 Flowable is the only formulation for which the registrant is seeking a registration on cotton.

CBTS's Comments and Conclusions to Deficiency 20

Deficiency 20 has been resolved.

Deficiency 22 from the 6/24/93 Memo

The available rotational crop data are not adequate. The petitioner should submit all relevant rotational crop studies as a package for CBTS review when the on-going confined study is completed. Based on data summaries, CBTS has indicated that rotational crop tolerances will probably be required for the permanent tolerance.

Registrant's Response to Deficiency 22

See Registrant's Response to Deficiency 5 above.

CBTS's Comments and Conclusions to Deficiency 22

Provided the additional language listed under CBTS's Comments and Conclusions to Deficiency 5 is adopted, the concerns raised in Deficiency 22 will be resolved. CBTS reiterates that the final decision on the rotational crop issue resides with CBRS.

Deficiency 22 has been resolved.

Deficiency 27 from the 6/24/93 Memo

The Section F which proposes a permanent tolerance contains differences in nomenclature for the parent and metabolites compared to 40 CFR 180.399. This review uses the nomenclature in 40 CFR 180.399. The petitioner should revise the Section F to be consistent with the 40 CFR 180.399.

Registrant's Response to Deficiency 27

The registrant has submitted a new Section F.

CBTS's Comments and Conclusions to Deficiency 27

The new Section F language is consistent with that listed under 40 CFR 180.399.

Deficiency 27 has been resolved.

Attachment I - Rotational Crop Requirements for Iprodione on Cotton - memo of R. Loranger, 3/93.

cc (without Attachment I): circu., E. Haeberer.

cc (with Attachment I): List B File, RF, G. Herndon.

RDI: Section Head: E. Haeberer: 2/2/95,
Branch Senior Scientist: R. Loranger: 2/2/95,
Acting Branch Chief: E. Zager: 2/2/95.

H7509C: CBTS: G.J.Herndon: 305-6363: CM#2: Rm804C: 2/1/95.

Attachment I.

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

March, 93

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM OF CONFERENCE

SUBJECT: Iprodione on cotton - rotational crop requirements.

FROM: Richard Loranger, Ph.D., Branch Senior Scientist
Chemistry Branch Tolerance Support, HED (H7509C) R. Loranger

THRU: Debra Edwards, Ph.D., Chief Debra Edwards
Chemistry Branch Tolerance Support, HED (H7509C)

TO: Chemistry Branch Files

On March 2 Randy Perfetti and I met with representatives of Rhone-Poulenc to discuss the impact of rotational crop data requirements on an EUP for iprodione on cotton. EFGWB rejected earlier studies, primarily due to the absence of analyses for residues in soil.

We gave the Rhone-Poulenc representatives copies of our recent guidance on rotational crop studies. Summaries of the iprodione confined and field studies were then provided by the visitors. One confined study is in progress with submission to EPA planned next year. **We told them that restricting the experimental use to land that will be used only for continuous cotton culture would be acceptable in lieu of submitting additional rotational crop data.** This label restriction should be formally submitted to the Product Manager. Rhone Poulenc claims that 80% of cotton is monoculture. Therefore, there is no difficulty in their eyes to limiting the use in this manner. We stated we would consider a 12 month restriction with rotation limited to vegetables already having tolerances for iprodione. However, we would need to look over available rotational crop data for a final decision.

After glancing over the data summaries, we told the registrants that rotational crop tolerances are likely to be required for permanent registration. We are willing to review the 1988 (cold) field studies in terms of our own data requirements in light of their rejection being primarily due to the lack of soil analyses. We advised that all relevant rotational crop studies be submitted as a package when the present confined study is completed.

cc: Circu, RF, R. Loranger, R. Perfetti, M. Peters, PP#1G3998
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