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

FEB 21 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ACCESSION NUMBER #071950
ACCESSION NUMBER #071951
ACCESSION NUMBER #071952
ACCESSION NUMBER #071953

PP3F2964/FAP4H5415: Iprodione in or on Grapes and Grape Fractions, Meat, Milk, Kidney and Liver, and Eggs. Evaluation of analytical methods and residue data. Submission of 9/15/83 and amendments of 10/3/83 and 11/4/83.

TO: H. Jacoby, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

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

FROM: R. W. Cook
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Agrochemical Division, Rhone-Poulenc Inc. proposes tolerances for combined residues of the fungicide iprodione [3-(3,5-dichlorophenyl) -N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboximide (tradename Rovral® Fungicide)] and 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-imidazolidinecarboxamide in or on the raw agricultural commodities grapes at 60 ppm, raisin waste at 1000 ppm, raisins at 300 ppm, and dry grape pomace at 225 ppm. The petitioner also proposes tolerances for combined residues of iprodione, its des-isopropyl metabolite and its hydroxylated metabolite 1-(3,5-dichloro-4-hydroxyphenyl)-biuret in milk at 0.3 ppm. Further, the petitioner proposes tolerances for combined residues of iprodione and its des-isopropyl metabolite in liver and kidney at 3 ppm; in meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.4 ppm; and in eggs at 0.8 ppm. No poultry tissue tolerances are proposed.

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We have recently recommended for establishment of tolerances of combined residues of iprodione and its non-hydroxylated

metabolites in or on almond nutmeats at 0.05 ppm, and at 0.25 ppm in almond hulls; for combined residues of iprodione and its non-hydroxylated metabolites in or on meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.1 ppm; and for combined residues of iprodione and its hydroxylated and non-hydroxylated metabolites in milk at 0.02 ppm. See M. Kovacs review of PP2F2728, 9/29/83.

Tolerances for combined residues of iprodione and its isomer and metabolite (as above) have been established under 40 CFR 180.399 in or on kiwifruit at 10 and on various stone fruits at 20 ppm.

Conclusions:

1a). The metabolism of iprodione in plants is adequately understood and the residue of concern in plants is iprodione, its isomer RP-30228, and its des-isopropyl metabolite RP-32490.

1b). The metabolism of iprodione in animals is not adequately understood. The residue of concern in livestock animals (except poultry) consists of iprodione, its isomer RP-30228, and its non-hydroxylated des-isopropyl metabolite RP-32490. In poultry liver and kidney, the residue consists of iprodione, RP-30228, RP-32490, RP-44247 (3,5-dichlorophenylurea), and Unknown Z. We defer to TOX regarding the need for further identification of Unknown Z, which comprised 26% of the ^{14}C-residue in chicken liver.

2. Adequate analytical methods are available for enforcement purposes.

3a) The residue data reasonably reflect the proposed use. Residues of iprodione and its non-hydroxylated metabolite, expressed as iprodione, are not likely to exceed the proposed tolerances of 60 ppm in or on grapes, 300 ppm in raisins, and 225 ppm in dry grape pomace. The proposed tolerance of 1000 ppm in raisin waste appears too high. We recommend that the tolerance for residues of iprodione in raisin waste be proposed at 300 ppm.

3b) Based upon the reviewed data, residues in grape juice are not expected to exceed the levels expected in whole grapes and therefore, no concentration is expected in wine. A food additive tolerance for the grape fraction, juice, is not required.

4a) Combined residues of iprodione and its non-hydroxylated metabolite RP-32490 and its hydroxylated metabolite in milk are not likely to exceed the proposed tolerance level of

0.3 ppm. Further, combined residues of iprodione and its non-hydroxylated metabolite RP-32490 in meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep are not likely to exceed the proposed tolerance level of 0.4 ppm. Combined residues of iprodione and its non-hydroxylated metabolite RP-32490 in liver and kidney of cattle, goats, hogs, horses, and sheep are not likely to exceed the proposed tolerance level of 3 ppm.

4b) Combined residues of iprodione and its non-hydroxylated metabolite RP-32490 in poultry meat (except liver and kidney) will not exceed 0.4 ppm; combined residues of iprodione, its des-isopropyl metabolite, and its non-hydroxylated metabolites RP-36112 and RP-36115 in eggs will not exceed the proposed 0.8 ppm tolerance; combined residues of iprodione, RP-30228, RP-32490, RP-44247 (3,5-dichlorophenylurea), and Unknown Z (if TOX is concerned) in poultry liver will not exceed 3 ppm; and combined residues of iprodione and its metabolite RP-32490 in poultry fat are likely to exceed 0.4 ppm. A tolerance of 2 ppm for combined residues of iprodione and its metabolite RP-32490 in poultry fat is more appropriate and should be proposed.

5. Codex limits for residues of the parent compound iprodione in grapes are 10 ppm. Since available data indicate residue levels up to 45 ppm of parent compound per se, we cannot recommend for the Codex limit for parent compound only. The Canadian limit is 10 ppm of combined residues of iprodione and its metabolites in grapes. There are no Mexican tolerances for iprodione in grapes.

Recommendations:

We recommend against the establishment of the proposed tolerance, for the reasons cited in Conclusions 1b, 3a, and 4b.

1. RCB is unable to make a favorable recommendation until resolution of our deferral to TOX Branch regarding the need for further identification of UNKNOWN Z in chicken liver.

Further, for a favorable recommendation, the petitioner should be advised that the following information is needed.

2. A tolerance of 300 ppm for combined residues of iprodione and its metabolite RP-32490 in raisin waste should be proposed.

3. Tolerances for combined residues of iprodione and its metabolites in poultry tissues and should be proposed as stated in conclusion 4(b) above.

4. The petitioner should be advised that residue data reflecting aerial application will be required if and when such use is proposed.

NOTE to PM:

The petitioner's expression of the tolerance is incorrect. The petitioner proposes a tolerance for residues in unspecified liver and kidney at 3 ppm, while at the same time proposes 0.4 ppm in meat byproducts. Since liver and kidney are meat byproducts, the petitioner is in effect asking for two different tolerances/ levels for the same commodity. For clarity, if and when tolerances proposed in this petition are established, they should be specified in terms of meat, fat (except poultry fat), and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, poultry, and sheep; for liver and kidney of cattle, goats, hogs, horses, and sheep; for poultry liver; and for poultry fat.

DETAILED CONSIDERATIONS

Formulation:

The formulation proposed for use on grapes is Rovral® Fungicide, EPA Reg. No. 359-685, a wettable powder formulation containing 50% of the active ingredient iprodione. The inert ingredients in this formulation are cleared under 40 CFR 180.1001(c). We have previously concluded that no residue problems are expected from the manufacturing impurities (A. Rathman, 3/2/79, PP0G2087).

Directions for Use:

For control of bunch rot (Botrytis sp.) on grapes, apply 1.5 - 2.0 pounds (0.75 to 1.0 lbs. a.i.) /acre/treatment of Rovral® Fungicide as a foliar spray application in 50 - 200 gallons of water per acre. Apply at:

1. early - midbloom;
2. prior to bunch closing;
3. beginning of fruit ripening (veraison); and
4. final application prior to harvest as needed.

The last application may be may up to and including the day of harvest. Thorough coverage of bunches is essential. Under severe disease conditions the higher rate is recommended. The only restriction is: Do not make more than 4 applications per season.

Based on the volume of spray (50 - 200 gallons per acre), we presume the directions apply to ground equipment only.

Nature of the Residue:

Plants:

No new plant metabolism studies are submitted in this petition. The metabolism of iprodione in plants has been previously discussed

in our reviews of PP8G2087 (strawberries and wheat, A. Rathman, 3/2/79), and PP2F2596 (peaches, R. Perfetti, 5/13/82). In ring-^{14}C--iprodione plant metabolism studies in strawberries, wheat, and peaches, the primary residue from foliar application was the parent compound iprodione and smaller amounts of its isomer RP-30228. Soil applications resulted in these same two materials plus small amounts of the des-isopropyl metabolite RP-32490. Although there are no grape metabolism data, we see no reason to expect different metabolic pathways in grapes. Therefore, we conclude that the residue of concern in grapes is iprodione, its isomer RP-30228, and its des-isopropyl metabolite RP-32490.

Animals:

The metabolism of iprodione in cows, goats, and rats has been evaluated in our review of PP2F2728 (M. Kovacs, 10/25/82, almonds). The currently submitted goat metabolism study focuses on previously unidentified metabolites in goat urine, liver and kidney.

Unknown X was identified by mass spectra as 3,5-dichloro-4-hydroxyphenylurea. Unknown Y was identified as 3,5-dichlorophenylurea and designated as RP-44247. These 2 metabolites were not apparent in the cattle tissue studies, possibly due to low extractability of ^{14}C from cattle liver or kidney. Unknown Y, RP-44247, 3,5-dichlorophenylurea, was subsequently found as a major metabolite in poultry liver, kidney, and eggs.

In goat urine, the major metabolites were RP-32114, RP-36115, and RP-32490, at 23%, 11%, and 14%, respectively. Eight other metabolites were identified in amounts <4% each, and two unidentified metabolites comprised 10.5%. Unknown X was 2.5% and Unknown Y was 8%. Identified metabolites account 67% of total ^{14}C. In goat liver, the major residues were iprodione (13%) and RP-32490 (20%). Nine other metabolites were identified in amounts <3% each, and two unidentified metabolites comprised 14.6%. Unknown X was 8.9% and Unknown Y was 5.7%. About 55% of the total ^{14}C in liver is now identified. For goat kidney, the major metabolites were RP-36115, and RP-32490, at 12% and 7.5%, respectively. Nine other metabolites were identified in amounts <4% each, and one unidentified metabolite, Unknown X, comprised 22.7%. About 55% of the total extractable residue in kidney is now identified. While 55% identification is less than desirable, the similarity between goat and cattle metabolism data and the rapid depuration of iprodione residues upon withdrawal of dietary burden permits the conclusion that the metabolism of iprodione is adequately understood for the current purposes.

Additionally, poultry metabolism and feeding studies are now available. In the metabolism study, four groups (one control) of 5 White Leghorn hens each were fed phenyl ring ^{14}C-iprodione for 15 consecutive days. The dose level was about 10 ppm of the feed intake and equivalent to about 0.7 mg/kg body weight. Samples were

obtained at 2 hours, 3 and 7 days after last dose. Tissue samples including liver, kidney, heart, gizzard, breast muscle, thigh muscle, fat, skin, and blood were collected at sacrifice. Eggs and excreta were sampled daily. All samples were analysed for total ^{14}C and certain samples were extracted and ^{14}C-metabolites identified by TLC.

Total ^{14}C Residues (as ppm)

	2 hrs.	3 days	7 days
Liver	2.81	0.08	0.02
Kidney	1.76	0.06	0.01
Heart	0.55	0.01	<0.01
Gizzard	0.23	<0.01	<0.01
Breast muscle	0.21	<0.01	<0.01
Thigh muscle	0.27	<0.01	<0.01
Fat	1.24	0.03	<0.02
Skin	0.35	0.02	<0.01
Blood	0.31	0.03	0.01

Recovered ^{14}C in excreta accounted 78% - 85% of the applied radioactivity, showing rapid elimination from the hens within 7 days.

The maximum residue of ^{14}C equivalent to iprodione in eggs was about 0.9 ppm, while the average or plateau level appears to be about 0.6 ppm. The ^{14}C in eggs was fractionated and examined by TLC. The primary metabolites found in eggs were the des-isopropyl metabolite RP-32490 at about 37%, RP-36112 at 20%, RP-36115 at 13%, Unknown Y at 11.5%, and the parent iprodione at about 5%. Unknown Y has been identified in goat urine as 3,5-dichlorophenylurea (RP-44247). We conclude the residue of concern in eggs are iprodione, its des-isopropyl metabolite, and its non-hydroxylated metabolites RP-36112 and RP-36115.

In chicken liver, parent iprodione was <2%, the des-isopropyl metabolite RP-32490 was 22% and Unknown Y and Unknown Z each accounted about 26%. As above, Unknown Y has been identified as 3,5-dichlorophenylurea (RP-44247). Unknown Z, a major metabolite in chicken liver, has not been identified yet. Other components of the residue in liver were each less than 4% of the ^{14}C. In chicken kidney, the same major metabolites were present: 33% RP-32490, 15% Unknown Y, and 15% Unknown Z. However, in muscle tissue and fat, Unknowns Y and Z were not found and the residue consisted primarily of RP-32490 (74% in muscle, 63% in fat) and iprodione (5% in muscle, 30% in fat).

In the chicken feeding study, four groups of 10 White Leghorn hens each were dosed with capsules containing technical iprodione for 28 consecutive days. We are not objecting to this protocol since previous plant and animal studies have shown metabolism to the common des-isopropyl metabolite. Therefore it is expected that this study would give similar results compared to feeding of animal feed items bearing iprodione and its metabolites. Treatment levels were 0, 2, 20, and 100 ppm of the diet, or about 0.0, 0.15, 1.5, and 7.5 mg/kg

body weight. Eggs were collected every third day and depuration samples were taken at 6 hrs, 14 days, and 28 days after last treatment.

Analytical Method No. 164 was used for extraction and detection of iprodione and its non-hydroxylated metabolites in eggs and chicken tissue. Method No. 164 is essentially similar to Method ADC #623A and ADC #623B which have been tried in EPA laboratory in conjunction with PP 2F2728 (5/24/83, M. Kovacs) and determined to be adequate for our purposes. Method No. 164 is a common moiety method which is based upon the basic hydrolysis to dichloroaniline and derivatized to the heptafluorobutyrate for gas chromatography.

While the petitioner uses the average residue value, we prefer to base our calculations on the highest residue. Maximum residues of iprodione and its non-hydroxylated metabolites in muscle tissue at 28 days were <0.05, 0.32, and 1.68 ppm at the 2, 20, and 100 ppm feeding level. Comparable residues in fat were 0.18, 2.57, and 8.62 ppm at the same interval and feeding levels, respectively. Residues in liver were 0.61, 4.10, and 13.4 ppm and in kidney were 0.33, 2.30, and 6.87 ppm at these feeding levels, respectively. Total iprodione residues were <0.05 ppm in all 14 day depuration samples of fat, muscle, kidney, and liver.

In eggs, the 2 ppm feeding level resulted in maximum detectable residues of 0.137 ppm at 7 days through 28 days. At the higher feeding levels of 20 and 100 ppm, the maximum detected residues were 0.75 and 2.17 ppm respectively. These levels are apparently constant, i.e. plateau levels, during 7 to 28 days. The data indicate that it is unlikely that residue levels would exceed these levels no matter how long the feeding was continued. During depuration, residue levels fell to <0.01 ppm at the two lower feeding levels within 9 days of withdrawal, and at the highest feeding level, to <0.01 ppm within 12 days of withdrawal.

We have previously concluded that the metabolism of iprodione in animals is adequately understood, for the purposes of establishing tolerances in meat and milk as a result of the use on almonds. While almond hulls are fed to livestock, the residue levels and dietary intake from such feed are much less than possible residue levels and dietary burdens due to proposed use on grapes. Further, no poultry feed items were involved in almond hulls. Currently submitted data indicate that while the metabolism of iprodione in cattle, goats, hogs, horses, and sheep is adequately understood, the presence of a major unidentified metabolite in chicken liver precludes the same conclusion in regard to poultry metabolism. Therefore, we defer to TOX Branch in regard to the need for further identification of Unknown Z, found in chicken liver at 25% of the ^{14}C-residue.

Analytical Methods:

The analytical method for iprodione, entitled "DETERMINATION OF RP26019 AND ITS METABOLITES IN/ON STONE FRUIT AND NUT CROPS BY

GLC AND TLC" (Analytical Method No. 151) is similar to the method successfully tested in EPA labs. (PP3F2810, R. Perfetti, 3/21/83).

In principle, the method for iprodione in whole grapes, raisin waste, juice, and dry pomace involves extraction by blending with acetone or aqueous acetone (dry substrates), liquid-liquid partition using ethyl acetate/methylene chloride to extract aqueous acetone (for oily materials use hexane/acetonitrile), Florisil column chromatography, and GLC with ^{63}Ni electron capture detection. Detection limits of the method are reportedly 0.05 ppm. The method was modified for raisins and raisin waste, and wet or dry pomace. These samples were hydrated by soaking prior to extraction.

Untreated control samples showed 0.0 - 0.07 ppm of RP-26019 in whole grapes, and consequently, 0.0 - 0.09 ppm in juice, 0.0 - 0.16 ppm in wet pomace, 0.0 - 0.14 ppm in dry pomace, 0.0 - 0.19 ppm in raisins, and 0.0 - 0.30 ppm in raisin waste. These control values are not excessive, in view of the magnitude of the proposed tolerances (>60 ppm on grapes + fractions). Reported recovery values for iprodione, RP-30228, and RP-32490 in grapes and various grape fractions ranged from 72 to 123% at 0.2 to 600 ppm fortification levels.

We conclude that adequate methods are available for enforcement purposes.

Residue Data:

Previously submitted residue data are available for 11 trials: CA (6), NY (3), OH, and PA (N. Dodd, 3/21/83, PP3G2787). In general, these previous studies showed 16 - 45 ppm of parent iprodione and small amounts of metabolites in fresh grapes harvested on day of last application.

Currently submitted residue studies total 2, both in CA desert region. In both locations, 1 replicate of 12 vines of Thompson Seedless grapes were treated with 3 treatments of 1 lb.a.i./A at 14, 7 and 0 days preharvest. This treatment rate is 0.75 X maximum recommended rate but we are not raising this issue since the omitted application was the early-mid bloom treatment. Samples of grapes were collected 0 - 14 days after last application, while some grapes were field-dried for 16 - 19 days for raisins. Pilot plant equipment at University of California was used for grape fraction processing into juice and wet and dry pomace fractions, while raisin samples were processed by air cleaning (no water wash) into raisins and raisin waste. A full description of the processing is not provided.

Samples were analyzed by Method No. 151, as modified for juice, pomace, and raisins, for residues of iprodione, its isomer RP-30228, and its metabolite RP-32490. Residues of iprodione in the 2 fresh grape samples showed levels of 1.75 to 2.45 ppm iprodione, 0.07 to 0.12 ppm of its isomer RP-30228, and <0.05 ppm of RP-32490.

For the record, we note the proposed EUP (PP3G2787) totaled 9720 pounds of Rovral® (4860 lbs. a.i.) on 355 acres of grapes. We believe that an EUP of this size and scope could produce more than two residue trials totaling 24 grape vines. We note the petitioner's claim that the currently submitted studies are "large plot trials" (page 1, Summary, Book 5, Section D, PP3F2964). We do not consider 12 vines in two locations to be "large plots". The petitioner notes that residue levels reported in current studies are significantly lower than levels previously considered in PP3G2787/ FAP3H5379 (N. Dodd, 3/21/83). The petitioner ascribes differences to use of commercial equipment versus handgun or backpack application, and further notes that similar differences in residue levels in or on stone fruit were noted (PP2F2596, PP3F2810).

We conclude that the residue data reasonably reflect the proposed use and that combined residues of iprodione and its des-isopropyl metabolite RP-32490 are not likely to exceed the proposed 60 ppm tolerance in or on grapes.

Processed Commodities:

Raisins:

In 2 currently submitted raisin trials, treated fresh grapes containing residues of 1.75 to 2.45 ppm iprodione, 0.07 to 0.12 ppm RP-30228, and <0.05 ppm RP-32490 were field dried to raisins for 16 - 19 days. Raisins showed 8.35 to 10.25 ppm of iprodione, 0.18-0.28 ppm RP-30228, and 0.06-0.12 ppm RP-32490. The concentration factor for the conversion fresh grapes -> raisins ranged from 3.4 to 5.6 X. Previous data (N. Dodd, PP3G2787, 3/21/83) showed 2.4 to 6.8 X concentration. Using the theoretical concentration factor of 4.5, we conclude that residues in raisins are not likely to exceed the proposed 300 ppm level.

Raisin waste derived from these samples showed 22.4 to 31 ppm of iprodione plus 0.4 to 0.5 ppm RP-30228, and 0.4 ppm RP-32490, or about 9.5 to 16.8 X concentration compared to fresh grapes. There are no previous data for comparison purposes. However, it is unlikely that residues in raisin waste would exceed levels in raisins. Therefore, we recommend that the tolerance for residues of iprodione in raisin waste be proposed at 300 ppm.

Juice and Pomace:

When juice was made from grapes bearing residues of 1.75 to 2.45 ppm iprodione, 0.07 to 0.12 ppm RP-30228, and <0.05 ppm of RP-32490, the juice contained 1.9 to 2.44 ppm iprodione and small amounts of RP-30228 similar to its level in the fresh grape. Since grape juice does not concentrate iprodione, food additive tolerances are not required. By extension of this logic, residues of iprodione in wine will not exceed levels found in fresh grapes.

Treated grapes were processed to wet and dry pomace fractions under pilot plant conditions at the University of California. Wet pomace showed about the same levels and distribution of residues as fresh grapes. Dry pomace contained 6.1 - 7.3 ppm iprodione; 0.25 ppm RP-30228; and 0.06 ppm of RP-32490. The concentration factor for the conversion fresh grapes --> dry pomace is 3.4 X. Further, the proposed feed additive tolerance of 225 ppm in or on dry grape pomace is adequate to cover expected residues.

Meat, Milk, Poultry and Eggs:

The animal feed items of concern are cull grapes, raisin waste, and grape pomace. These feed items are used in moderate amounts (maximum of 30%) in the diets of beef cattle, poultry, and lambs, and lesser amounts (20%) of swine and dairy cattle diets.

In our previous considerations (M. F. Kovacs, 10/25/83, PP 2F2728), in cattle fed 200 ppm of iprodione for 28 days, the maximum residues were 0.329 ppm in milk, 0.13 ppm in muscle, 0.52 ppm in fat, 2.87 ppm in beef kidney, and 1.95 ppm in liver.

Considering the dietary burden of dairy cattle fed raisin waste at 300 ppm x 10% = 30 ppm or dry pomace at 225 ppm x 20% = 45 ppm, we can conclude that combined residues of iprodione, its non-hydroxylated metabolite RP-32490 and its hydroxylated metabolite in milk are not likely to exceed the proposed tolerance level of 0.3 ppm. Further, we conclude that combined residues of iprodione and its non-hydroxylated metabolite RP-32490 in meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep are not likely to exceed the proposed tolerance level of 0.4 ppm. Since the maximum ingestion level contemplated herein is 30 ppm, we conclude that combined residues of iprodione and its non-hydroxylated metabolite RP-32490 in liver and kidney of cattle, goats, hogs, horses, and sheep are not likely to exceed the proposed tolerance level of 3 ppm.

Poultry:

Maximum residues of iprodione and its non-hydroxylated metabolites in poultry muscle tissue at 28 days were <0.05, 0.32, and 1.68 ppm at the 2, 20, and 100 ppm feeding levels. Comparable residues in fat were 0.18, 2.57, and 8.62 ppm, respectively. Residues in liver were 0.61, 4.10, and 13.4 ppm and in kidney were 0.33, 2.30, and 6.87 ppm, respectively.

In eggs, the 2 ppm feeding level resulted in maximum detectable residues of 0.137 ppm at 7 days through 28 days. At the higher feeding levels of 20 and 100 ppm, the maximum detected residues were 0.75 and 2.17 ppm respectively. During depuration, residue levels fell to <0.01 ppm at the two lower feeding levels within 9 days of withdrawal, and at the highest feeding level, to <0.01 ppm within 12 days of withdrawal.

Considering the dietary burden of poultry fed dry pomace at 225 ppm x 5% = 11 ppm and the above feeding data, we conclude that combined residues of iprodione in poultry meat (except liver) will not exceed 0.4 ppm; combined residues in eggs will not exceed the proposed 0.8 ppm tolerance; combined residues in liver will not exceed 3 ppm; and combined residues in poultry fat are likely to exceed 0.4 ppm. A tolerance of 2 ppm in poultry fat is appropriate and should be proposed.

We have deferred to TOX Branch the question of further identification of the metabolite designated Unknown Z, which has been found in chicken liver at a level of [redacted] 26% of the recovered ^{14}C. If TOX Branch is concerned with this unknown metabolite, we will require additional information.

OTHER CONSIDERATIONS:

International Tolerances:

Codex limits for residues of the parent compound iprodione in grapes are established at 10 ppm. The proposed U.S. tolerance is for 60 ppm of combined residues of iprodione and its metabolites. Since the available residue data indicate up to 45 ppm of parent iprodione, we cannot recommend for the Codex limits. The metabolites are included in the U.S. tolerance since they are significant portions of the residue on some commodities. The Canadian limit is 10 ppm of combined residues of iprodione and its metabolites in grapes. There are no Mexican tolerances for iprodione in grapes.

Removal of Residues:

Section E states that practical procedures for removing residues which exceed the proposed tolerance are not applicable to this petition.

cc: R.F., Circu, R. W. Cook, FDA, PP#3F2964/FAP4H5415, TOX
EEB, EAB, Robert E. Thompson
RDI:Section Head:RSQuick:Date:2/16/84:RDSchmitt:Date:2/16/84
TS-769:RCB:Reviewer:RWCook:Date:2/21/84:CM#2:RM:810:557-7377
Edited by GMK

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione

PETITION NO. 3F2964

CCPR NO. 111

R. W. Cook
12/20/83 T. Jones 12/21/83

Codex Status

| | No Codex Proposal Step 6 or above

Proposed U.S. Tolerances

Iprodione, 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-imidazolidinecarboxamide

Residue (if Step 9):

Iprodione 1/

Residue: (above)

Crop(s)	Limit (mg/kg)
grapes	10 1/

Crop(s)	Tol. (ppm)
Grapes (fresh)	60
Raisins	300
Raisin Waste	1000
Dried Grape Pomace	225

CANADIAN LIMIT

Residue: Iprodione including metabolites 3-isopropyl-N-(3,5-dichlorophenyl)-2,4-dioxoimadazolidine-1-carboxamide and 3-(3,5 dichlorophenyl)-2,4-dioxoimadozolidine-1-carboxamide.

Crop	Limit (ppm)
grapes	10

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm)
none	

Notes:

1/ Consideration needs to be given to expressing the U.S. tolerance as parent only, tox considerations permitting.