2-15-85

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

FEB 15 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA ACCESSION NUMBER 072864, 072865 [RCB # 225, 226]
PP4F3129/FAP4H5440: Iprodione in or on Peanuts and Peanut Fractions, Meat, Milk, Kidney and Liver, and Eggs. Evaluation of Analytical Method and Residue Data.

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, Chemist RWCook
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-imidazolidinecarboxamide (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:

peanuts at 0.5 ppm,
peanut forage and hay at 150 ppm, and
peanut hulls at 7 ppm.

Note: Established tolerances are "(expressed as iprodione equivalents)". We presume the petitioner intended to express the residues as above, but a revised Section F including this expression is needed.

Tolerance is proposed for combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione] and its hydroxylated and non-hydroxylated metabolites (expressed as iprodione equivalents) in milk at 0.4 ppm.

1/14

Tolerances are proposed for combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione] and its non-hydroxylated metabolites (expressed as iprodione equivalents):

in meat, fat, and meat byproducts (excluding liver and kidney) of cattle, goats, hogs, horses, and sheep at 0.6 ppm;

in kidney of cattle, goats, hogs, horses, and sheep at 3 ppm;

in liver of cattle, goats, hogs, horses, and sheep at 2 ppm;

in meat, fat, and meat by-products of poultry at 0.05 ppm;

and in eggs at 0.01 ppm.

Tolerances are proposed for combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [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 (expressed as iprodione equivalents) in or on:
crude oil at 1 ppm; and
soapstock at 10 ppm.

Tolerances for combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione] 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 (expressed as iprodione equivalents) have been established under 40 CFR 180.399(a) in or on the raw agricultural commodities:

- kiwifruit (10 ppm);
- apricots, cherries, nectarines, peaches, plums, prunes (20 ppm);
- almond nutmeats (0.05 ppm), almond hulls (0.25 ppm);
- in grapes (60 ppm);

Tolerances have been established under 40 CFR 180.399(b) for combined residues of 3-(3,5-dichlorophenyl)-N(-1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione] and its nonhydroxylated metabolites (expressed as iprodione equivalents) in or on:

- meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep at 0.4 ppm;
- liver and kidney of cattle, goats, hogs, horses, and sheep at 3 ppm;
- in eggs at 0.8 ppm;
- in poultry meat and meat byproducts (except liver) at 0.4 ppm;
- in poultry fat at 2 ppm;
- in poultry liver at 3 ppm.

Tolerances have been established under 40 CFR 180.399(c) for combined residues of iprodione and its hydroxylated and nonhydroxylated metabolites (expressed as iprodione equivalents) in or on the raw agricultural commodity:

° milk at 0.3 ppm.

We have recommended for tolerances on grape pomace, raisin waste, etc., however, due to administrative error, the proposed tolerances were not promulgated concurrently with establishment of the tolerance on grapes.

Proposed tolerances for eggs of 0.01 ppm, and meat, fat, and meat byproducts of poultry at 0.05 ppm are not appropriate since tolerances have been established at 0.8 ppm for eggs and 0.4 ppm for poultry meat and meat byproducts, 2 ppm for poultry fat, and 3 ppm for poultry liver. The proposed tolerance of 2 ppm in liver of cattle, goats, hogs, horses, and sheep is not appropriate since tolerances are established at 3 ppm. These inappropriate proposals should be withdrawn. A revised Section F is needed.

Petition No. 4F3150 proposing tolerances for iprodione on beans (succulent and dry) and bean forage and hay is under review.

Conclusions:

1a. The residues of concern in peanuts and other plants are 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione, RP-26019], 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-30228], and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [RP-32490].

1b. The residues of concern in poultry tissue and in eggs are 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione, RP-26019], and its non-hydroxylated metabolites.

1c. The residues of concern in meat, fat, and meat byproducts of cattle, goats (except liver and kidney), hogs, horses, and sheep are 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione, RP-26019], and its non-hydroxylated metabolites.

1d. The residues of concern in milk are 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide [iprodione, RP-26019], and its hydroxylated and non-hydroxylated metabolites.

2. Adequate methods are available for enforcement purposes.

3a. Combined residues of iprodione, RP-30228 and RP-32490 are not likely to exceed the proposed tolerances of 0.5 ppm in or on peanuts, 7 ppm in or on peanut hulls, and 150 ppm in or on peanut forage and hay, and 10 ppm in soapstock.

3b Combined residues of iprodione, RP-30228 and RP-32490 in peanut oil do not exceed levels in the raw agricultural commodity peanuts, no food additive tolerance for peanut oil is indicated at this time. The petitioner should withdraw the proposal on crude oil. A revised Section F is needed.

3c. Combined residues of iprodione, RP-30228 and RP-32490 in peanut meal are not likely to exceed the level in the raw agricultural commodity peanuts, and therefore feed additive tolerances are not required for the animal feed peanut meal.

3d. Combined residues of iprodione and its non-hydroxylated metabolites (expressed as iprodione equivalents) in meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep are not likely to exceed the established tolerance level of 0.4 ppm. However, we recommend using the expression and levels of Conclusion 5 below.

3e. Combined residues of iprodione, and its hydroxylated and non-hydroxylated metabolites in milk are not likely to exceed the proposed tolerance level of 0.4 ppm. However, for reasons of regulatory consistency, the tolerance level should be 0.5 ppm. The tolerance should be expressed in terms of combined residues of iprodione and its metabolites containing the 3,5-dichloroaniline moiety.

3f. Combined residues of iprodione and its non-hydroxylated metabolites (expressed as iprodione equivalents) are not likely to exceed the established tolerances of 0.8 ppm in eggs; 0.4 ppm in poultry meat and meat byproducts (except poultry liver); and 2 ppm in poultry fat and 3 ppm in poultry liver. See Conclusion 5.

4. Proposed tolerances for eggs of 0.01 ppm, and meat, fat, and meat by-products of poultry at 0.05 ppm are not appropriate since tolerances are established at 0.8 ppm for eggs and 0.4 ppm for poultry meat and meat byproducts, 2 ppm for poultry fat, and 3 ppm for poultry liver. The proposed tolerance of 2 ppm in liver of cattle, goats, hogs, horses, and sheep is not appropriate since tolerances are established at 3 ppm. These inappropriate proposals should be withdrawn. A revised Section F is needed. The proposals for meat, fat, and meat byproducts at 0.6 ppm need to be revised as suggested in Conclusion 5.

5. We believe the tolerance expression for 180.399(b) and (c) should be combined and simplified to read:

> "for combined residues of iprodione and its metabolites containing the 3,5-dichloroaniline moiety (expressed as iprodione equivalents)."

TOX considerations permitting, we believe that a tolerance level of 0.5 ppm is appropriate for residues of iprodione (as described above) in milk, and in the meat, fat (except poultry fat) and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, poultry, and sheep. Since the tolerance expression for 40 CFR 180.380 already includes metabolites containing the 3,5-dichloroaniline moiety, a new Section of 40CFR 180.3 is needed. This new Section should read:

( ) Where a tolerance is established for more than one pesticide having as metabolites compounds containing the 3,5-dichloroaniline moiety found in or on a raw agricultural commodity, the total amount of such residues shall not exceed the highest established tolerance for a pesticide having these metabolites.

6. There are no Codex, Mexican or Canadian tolerances for iprodione on peanuts, therefore no compatibility problems are expected.

Recommendations:

We recommend against the establishment of the proposed tolerances, for the reasons cited in Conclusions 4 and 5. For a favorable recommendation, the petitioner should be advised that the following information is needed.

1. Proposed tolerances for eggs of 0.01 ppm, and meat, fat, and meat by-products of poultry at 0.05 ppm are not appropriate since tolerances are established at 0.8 ppm for eggs and 0.4 ppm for poultry meat and meat byproducts, 2 ppm for poultry fat, and 3 ppm for poultry liver. The proposal at 2 ppm in liver of cattle, goats, hogs, horses, and sheep is not correct since tolerance is established at 3 ppm. These inappropriate proposals should be withdrawn. A revised Section F is needed.

2. A revised Section F proposing tolerances in the following terms is needed for iprodione residues in raw agricultural commodities of animal origin:

   "for combined residues of iprodione and its metabolites containing the 3,5-dichloroaniline moiety (expressed as iprodione equivalents)."

   TOX considerations permitting, a tolerance 0.5 ppm is appropriate for combined residues of iprodione (as above) in milk, and in the meat, fat (except poultry fat) and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep. A revised Section F is needed.

Note to the PM:

If and when these proposed tolerances are promulgated, a new Section of 40 CFR 180.3 is needed. The new section must be compatible with the expression of 40 CFR 180.380 which already includes metabolites containing the 3,5-dichloroaniline moiety. This new Section should read:

( ) Where a tolerance is established for more than one pesticide having as metabolites compounds containing the 3,5-dichloroaniline moiety found in or on a raw agricultural commodity, the total amount of such residues shall not exceed the highest established tolerance for a pesticide having these metabolites.

DETAILED CONSIDERATIONS

Formulation:

The formulation proposed for use is Rovral® Fungicide, EPA Reg. No. 359-685, a wettable powder formulation containing 50% iprodione. Formulation inerts are cleared under 40 CFR 180.1001. We have previously concluded residue problems are not anticipated from either inert ingredients or manufacturing impurities.

Directions for Use:

For Sclerotinia blight, apply 2.0 lbs. Rovral® (1.0 lbs. a.i.) per acre. Rovral® should be applied in 40 gallons of water per acre. Make an initial application when conditions first become favorable for disease development. Up to 2 subsequent applications should be made at 4 week intervals. Do not apply within 10 days of harvest. Apply Rovral® using a tractor mounted boom sprayer equipped with low pressure nozzles that produce large droplets. A single nozzle should be centered and adjusted to provide complete coverage of the row.

Nature of the Residue:

Plants:

Plant metabolism studies have been reported on strawberries and wheat (A. Rathman, 3/2/79, PP8G2087), peaches (R. Perfetti, 5/13/84, PP2F2596), lettuce (N. Dodd, 4/11/83, PP3G2801), and peanuts (N. Dodd, 5/31/84, PP4G3037). In ^{14}C-iprodione plant metabolism studies in strawberries, wheat, peaches, and peanuts, the primary residue from foliar application was the parent compound iprodione and smaller amounts of its isomer RP-30228. Soil applications resulted in these two compounds plus small amounts of the metabolite RP-32490.

We reiterate our conclusion that the residues of concern in peanuts and other plants are iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide]; 3-(1-methylethyl)-N(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidine-carboxamide [RP-30228]; and 3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide [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). Poultry studies have been reviewed. (R. Cook, 2/21/84, PP3F2964 /FAP4H5415). TOX is not concerned with Unknown Z, a substituted 3,5-dichloroaniline metabolite in chicken liver (see memos of A. Arce, 5/30/84; R. Cook, 7/26/84, PP3F2964/FAP4H5415).

We have previously concluded the metabolism of iprodione in livestock animals is adequately understood for purposes of establishing tolerances in meat and milk as a result of the use on almonds. We have deferred to TOX Branch the question of their concern about the presence of Unknown X in goat kidney and liver. In this case, a total of 23% of the total ^{14}C in goat kidney was found as Unknown X, which has subsequently been determined to be 3,4-dichloro-4-hydroxyaniline. The petitioner estimated the body weight percentage of the liver and kidney tissue as 1.2 and 0.2% respectively. Other information available to us indicates that the weight of a beef cattle kidney would be about 1.5 pounds from an live animal weighing 1000 pounds; beef liver from such an animal would be 8 to 10 pounds. Goat organs probably weigh proportionally less than cattle organs. Unknown X was not detected in previously reviewed cow metabolism study, possibly due to the low extractability of ^{14}C from cattle tissues (M. Kovacs, 2F2728, 10/25/82). Unknown X is structurally related to hydroxylated urinary metabolites found in goat urine, and the finding of hydroxylated precursors in excretory organs is not surprising. We now consider resolved the questions regarding the metabolite Unknown X in goat liver and kidney.

We have previously concluded that the residues of concern in poultry tissue and in eggs are iprodione RP-26019, its metabolites RP-32490, RP-36112 and RP-36115. We reiterate that finding.

Analytical Methods:

The analytical method for iprodione, marked "CONFIDENTIAL", is entitled "DETERMINATION OF IPRODIONE AND ITS METABOLITES IN/ON GRAIN AND HAY BY GLC AND TLC" (Analytical Method No. 162). The method determines RP26019, RP30228, and RP32490.

In principle, the method for iprodione in peanut nutmeats, forage and hay, oil, meal, and soapstock involves extraction by shaking and blending with 10% aqueous acetone. A liquid-liquid partition step of ethyl acetate:methylene chloride at pH 3 is used to extract aqueous residue after acetone has been evaporated off. Remove solvent on rotary evaporator and take up residue in 10 ml. ethyl acetate. Then, gel permeation chromatography on Biobeads using mobile phase of ethyl acetate:toluene provides additional cleanup. Take collected fraction to dryness. Use 50 ml. each of acetonitrile:hexane as partition step on the residue from above step, use another 50 ml. acetonitrile and discard hexane. Take residue to dryness and dissolve in 10-15 ml. of 3% ethyl acetate: hexane. A Florisil column is eluted with 20% (Fraction I) and 30% (Fraction II) ethyl acetate:hexane. Fraction I contains RP-26019 and RP-30228, while Fraction II contains the metabolite RP-32490. Both fractions are analyzed by GLC with ^{63}Ni electron capture detection. The above method was modified for peanuts fractions as follows:

Nutmeats: extract with 2 X 200 ml acetone; use 150 ml. hexane (not 50 ml.); acetonitrile-hexane cleanup partition step repeated for 'dirty' samples.

Meal: use 20 grams and procedure as written.

Soapstock: dissolve in water, add sodium sulfate solution, and adjust <pH 4 with 5N HCl. The sample is partitioned in acetonitrile: hexane 4 times with 60 ml acetonitrile. Additional acetonitrile: hexane partition after gel permeation step if sample remains oily.

Peanut Oil: 10 gram samples and start with acetonitrile:hexane partition (no blending). Then follow method for soapstock.

Method detection limits are reportedly 0.05 ppm for iprodione, RP30228, and RP32490. The TLC procedure is confirmatory. The method is similar to Method AR/1710 successfully tested in our laboratories on kiwifruit.

Previously reported control and recovery data are:

Control values for iprodione in peanuts (ppm):

	RP26019	RP30228	RP32490
Peanuts (Nutmeats)	<0.05	<0.05	<0.05
Hulls	<0.05- 0.51	<0.05- 0.12	<0.05- 0.25
Hay	<0.05- 0.59	<0.05- 0.2	<0.05- 0.29

Recovery data for iprodione in peanuts (%):

	Fort.Lvl	RP26019	RP30228	RP32490
Peanuts	0.05-0.5	61-145	90-123	71-124
Hulls	0.1-0.5	87-131	68-121	82-106
Hay	5-100 *	81-116	91-98	69-106

* 1 ppm each of RP30228 and RP32490

We conclude that adequate plant analytical methods are available for enforcement purposes.

The analytical methods for animal products have been reviewed under PP2F2728 (M. Kovacs, 10/25/82) and PP3F2964 (R. Cook, 2/21/84). The methods for iprodione residues in animal tissue are Method ADC #623: Iprodione and its nonhydroxylated metabolites in milk (ADC #623-A) and tissues (ADC 623-B), and Rhone-Poulenc Method 159: hydroxylated metabolites in milk. These methods are based upon the hydrolysis of iprodione metabolites to either of the common moieties dichloroaniline (for nonhydroxylated metabolites) and dichloroaminophenol (as its methyl ester for hydroxylated metabolites). Residues are measured gas chromatographically as the heptafluorobutyryl derivative of these common moities.

Storage Stability: Data reflecting the storage stability of iprodione and major metabolites in milk and meat have been discussed in regard to PP 2F2728. Several studies showed minor degradation of iprodione residues during extended (6 months) storage.

Residue Data:

Residues in peanuts:

Residue data for peanuts, hulls, and forage and hay are reviewed in (N. Dodd, 5/31/84, PP4G3037). In brief, residues of iprodione in or on peanuts are reported from studies in six states, GA(3), TX(3), AL(3), VA, OK, and NC. Since these six states represent about 93% of the U.S. peanut production, we consider the geographic representation adequate. After 3 applications of 1.0 lb/A residues of RP-26019, RP-30228, or RP-32490 in peanuts (nutmeats) were not detectable (<0.05 ppm). This data and residue samples of hulls and hay are summarized below:

Iprodione and its metabolites in Peanuts (ppm):

	RP26019	RP30228	RP32490	Total
Peanuts (Nutmeats)	<0.05	<0.05	<0.05	<0.05
Hulls	0.26 - 5.25	<0.05- 1.38	<0.05- 0.73	<0.05-6.85
Hay	15.60-147.	0.16- 8.5	0.34- 6.42	16.23-148.54

No new residue data for peanut forage or hay are submitted.

Peanut Processing Study:

In 1983, "Florunner" peanuts in Voca, Texas, were treated 3 times with 1 or 2 lb ai/A. Final application was made just prior to harvest of mature peanuts, i.e., 0 days PHI (Label directs 10 day PHI). After 4 days of air-drying, the peanuts were passed through commercial thrasher, separating peanuts from hay. Fifty pounds of each treatment were frozen until processing and analysis. Treated peanuts were processed using pilot plant equipment at The Food Protein Research and Development Center (Texas A & M). Peanut fractions obtained this way are shelled nuts, hulls, crude oil (screwpressed and then solvent extracted), refined oil, meal, and soapstock. Peanut fractions analyzed in Rhone-Poulenc Laboratories by Method 162, modified as necesary to accomodate oily commodities.

Residues of Iprodione and its metabolites in Peanut Fractions:

Compound -->	RP26019		RP30228		RP32490	
Pounds/Acre -->	1	2	1	2	1	2
Nutmeats	0.21	0.27	0.11	0.18	<0.05	<0.05
Hulls	2.27	4.32	0.57	0.87	0.67	0.74
Crude Oil [1]	0.54	0.67	0.15	0.15	<0.05	<0.05
Crude Oil [2]	--	<0.05	--	<0.05	--	<0.05
Refined Oil	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Soapstock	1.33	2.65	0.32	0.32	<0.05	<0.05
Meal	--	<0.05	--	<0.05	--	<0.05

[1] (Screwpress extraction).
[2] (Solvent extraction after screwpress extraction).

Previously reported residue data for peanut nutmeats indicated that residues would be <0.05 ppm; however, currently submitted data from the peanut processing study show detectable residues of RP-26019 (0.27 ppm), RP-30028 (0.18 ppm) and RP-32490 (<0.05 ppm) in shelled peanut nutmeat. The petitioner explains these detectable residues are contamination during the shelling process, but proposes a 0.5 ppm tolerance level. Therefore, we conclude residues of iprodione, RP-30228 and RP-32490 are not likely to exceed the proposed tolerances of 0.5 ppm in or on peanuts, 7 ppm in peanut hulls, and 150 ppm in peanut forage and hay.

We conclude combined residues of iprodione, RP-30228 and RP-32490 are not likely to exceed the proposed tolerance of 10 ppm in soapstock. Residues in peanut meal are not likely to exceed levels in the raw agricultural commodity peanuts, and therefore a feed additive tolerance is not required for peanut meal.

Since residues in refined peanut oil do not exceed the proposed tolerance level in the raw agricultural commodity, no food additive tolerance for peanut oil is indicated at this time. The proposed 1 ppm tolerance for residues in crude oil is inappropriate and should be withdrawn. A revised Section F is needed.

Meat, Milk, Poultry and Eggs:

Animal feed items are meal, forage and hay, hulls and soapstock. Up to 25% of peanut meal is used in the diets of beef cattle, and 10% in poultry or swine diets, while soapstock is used up to 5% in animal diets. Peanut hulls are fed to beef cattle (5% maximum). Peanut forage and hay are fed to cattle up to 60% of the diet.

In our previous considerations (M. F. Kovacs, 10/25/83, PP 2F2728), in cattle fed 200 ppm of iprodione for 28 days, maximum residues were 0.389 ppm (of total hydroxylated and nonhydroxylated metabolites) in milk at 17 days. Maximum residues of nonhydroxylated metabolites were 0.13 ppm in muscle, 0.52 ppm in fat, 2.87 ppm in beef kidney, and 1.95 ppm in liver. The dietary burden of dairy cattle is about 90 ppm, mostly from peanut forage and hay (150 ppm x 60% = 90), and much smaller amounts from peanut meal (0.5 ppm x 25% = 0.12 ppm) and peanut hulls (7 ppm x 5% = 0.35 ppm).

Thus, we conclude that combined residues of iprodione, and its hydroxylated and non-hydroxylated metabolites in milk are not likely to exceed the proposed tolerance level of 0.4 ppm. However, for reasons of regulatory consistency, we recommend that the tolerance level be set at 0.5 ppm. We further recommend that the tolerances be expressed in terms of combined residues of iprodione and its metabolites containing the 3,5-dichloroaniline moiety.

The dietary burden of beef cattle is about 40 ppm, primarily from peanut forage at 150 ppm x 25% = 37.5 ppm (plus additional small amounts from peanut meal at 0.5 ppm x 15% = 0.075 ppm, and peanut hulls at 7 ppm x 5% = 0.35 ppm and soapstock at 10 ppm x 5% = 0.5 ppm). Based on the previously reviewed cattle feeding studies, we

conclude combined residues of iprodione and its 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 established tolerance level of 0.4 ppm. We conclude that combined residues of iprodione and its metabolite RP-32490 in liver and kidney of cattle, goats, hogs, horses, and sheep are not likely to exceed the established tolerance of 3 ppm. However, as discussed in Revision of the Tolerance (below), we recommend that the level be established at 0.5 ppm using the suggested tolerance expression.

The proposed tolerance of 2 ppm in liver of cattle, goats, hogs, horses, and sheep is not appropriate; a tolerance is established at 3 ppm. This proposal should be withdrawn. A revised Section F is needed.

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, 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 levels of 20 and 100 ppm, the maximum detected residues were 0.75 and 2.17 ppm, respectively.

Poultry are fed peanut meal (0.5 ppm x 10% = 0.05 ppm) and soapstock (10 ppm x 5% = 0.5 ppm), a dietary burden of 0.55 ppm. This burden from feed use of peanut meal and soapstock is lower than dietary burdens imposed by other feed items. We conclude combined residues of iprodione (RP-26019) and its metabolites will not exceed the established tolerances of 0.8 ppm in eggs; 0.4 ppm in poultry meat and meat byproducts (except poultry liver); and 2 ppm in poultry fat and 3 ppm in poultry liver.

The proposed tolerances for eggs of 0.01 ppm, and meat, fat, and meat byproducts of poultry at 0.05 ppm are not appropriate since tolerances has been established at 0.8 ppm for eggs and 0.4 ppm for poultry meat and meat byproducts, 2 ppm for poultry fat, and 3 ppm for poultry liver. These inappropriate proposals should be withdrawn. A revised Section F is needed.

OTHER CONSIDERATIONS:

International Tolerances:

There are no Codex, Canadian, or Mexican tolerances for residues of iprodione in or on peanuts or peanut byproducts. Therefore, we do not anticipate any compatibility problems.

Revision of the tolerance expression:

We believe the expression of the tolerance needs to be revised. TOX considerations permitting, the tolerance expression for 180.399(b) and (c) should be combined and simplified to read

> "for combined residues of iprodione and its metabolites containing the 3,5-dichloroaniline moiety (expressed as iprodione equivalents)."

There are several reasons for this action:
1) the possible presence of hydroxylated metabolites in animal tissues other than milk;
2) all animal commodities would be included in a single expression;
3) numerous other tolerances in 40 CFR 180 are expressed as proposed above; and
4) for clarity and brevity.

cc: R.F., Circu, R. W. Cook, FDA, PP#4F3129/FAP4H5440, TOX
EEB, EAB, Robert E. Thompson
TS-769:RCB:Reviewer:RWCook:Date:2/14/85:CM#2:RM:810:557-7377

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione [Rovral®]

PETITION NO. 4F3129 / 4H5440
R. W. Cook
11/9/84

J. Jones 11/9/84

CCPR NO. 111

Codex Status

☐ No Codex Proposal Step 6 or above

Residue (if Step 9):
Iprodione

Proposed U.S. Tolerances

Residue:
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

Crop(s)	Limit (mg/kg)
none (on peanuts or animal products)	

Crop(s)	Tol. (ppm)
Peanuts	0.5
Peanut hulls	7
Peanut forage and hay	150
Crude oil	1
Soapstock	10
MFMbyP (exc. K&L)	0.6
Kidney	3
Liver	2
Poultry MFMbyP	0.05
Eggs	0.01
Milk	0.4

CANADIAN LIMIT

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

Crop	Limit (ppm)
none (on peanuts or animal products)	

Comments:

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm)
none	