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

MAY 1 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Iprodione (109801), Reregistration Case No. 2335.
Special Review, Anticipated Residues.
CBRS No. 15099, DP Barcode No. 211975, No MRID No.

FROM: John Abbotts, Chemist
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and

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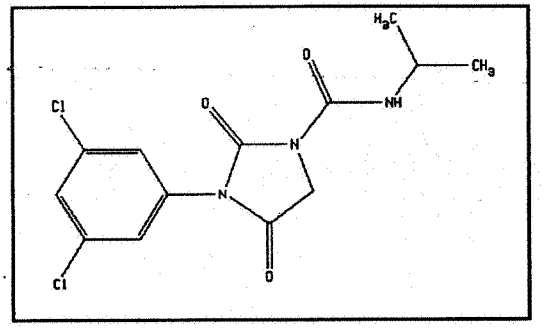
Special Review Branch requested anticipated residues for dietary risk evaluation of iprodione. Assignment instructions are for anticipated residues for chronic (cancer) and acute dietary risks.

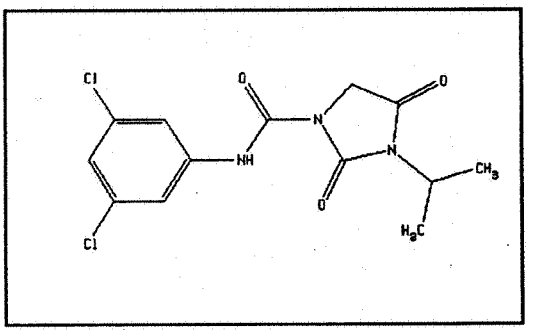
Tolerances are established for the combined residues of the fungicide iprodione parent, its isomer, and one metabolite in or on plant commodities, food commodities, and feed commodities (40 CFR 180.399(a) and (c), 185.3750, 186.3750). Tolerances are established for the combined residues of iprodione parent, its isomer, and two metabolites, all expressed as iprodione equivalents, in or on animal commodities (40 CFR 180.399(b)). Chemical structures and full chemical names of residues in tolerance expressions are given in Figure 1. Iprodione is a List B Chemical; Phase 4 Review was completed 3/15/91.

Figure 1. Iprodione Tolerance Residues:

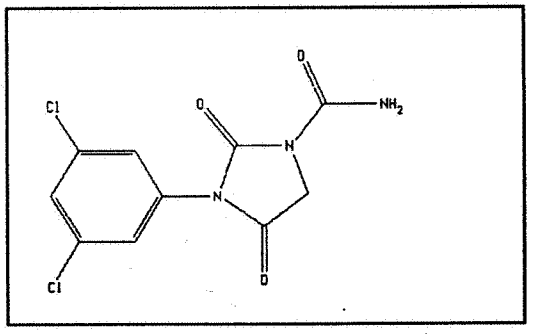
Iprodione parent;
3-(3,5-dichlorophenyl)-
N-(1-methylethyl)-2,4-dioxo-
1-imidazolidine-carboxamide



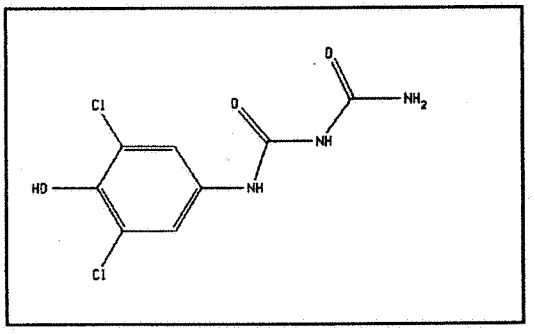
Iprodione isomer, RP30228;
3-(1-methylethyl)-
N-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP32490
(animals and plants);
3-(3,5-dichlorophenyl)-2,4-dioxo-
1-imidazolidine-carboxamide



Iprodione metabolite RP36114
(animals); N-(3,5-dichloro-
4-hydroxyphenyl)-ureido-carboxamide



Conclusions

1. For the purposes of this assignment, anticipated residues will be determined for residues in the tolerance expressions presently established: Iprodione, its isomer, and its metabolite RP32490 for plant commodities; and iprodione, its isomer, and metabolites RP32490 and RP36114 in animal commodities (see Figure 1 for full chemical names and structures)

Commodities in the tables below are arranged in approximately the same order as the previous DRES analysis (CBTS Memo, 4/29/93, R. Griffin). Anticipated residues for cancer risk are given in Table 1:

Table 1. Combined Iprodione Anticipated Residues, Cancer Risk

Commodity	Anticipated Residues, ppm	Basis for Anticipated Residues
Unspecified crop group:		
Kiwifruit	0.18	Monitor
Wine and sherry	0.83	Monitor
Root and tuber vegetables:		
Carrots	0.021	Monitor
Potatoes, whole	0.0023	Monitor
Potatoes, peeled	0.0023	Monitor + Proc
Potatoes, peel	0.0023	Monitor + Proc
Bulb vegetables:		
Garlic	0.0088	Monitor, Trans
Onion, dry	0.0088	Monitor
Shallot	0.0088	Monitor, Trans
Leafy vegetables:		
Lettuce, leaf	0.040	Monitor
Lettuce, unspecified	0.040	Monitor, Trans
Lettuce, head	0.0048	Monitor
Brassica vegetables:		
Broccoli	0.0016	Monitor

Table 1. Combined Iprodione Anticipated Residues, Cancer Risk		
Commodity	Anticipated Residues, ppm	Basis for Anticipated Residues
Legumes:		
Beans, dry	0.00005	Monitor
Beans, succulent, green	0.0016	Monitor
Beans, succulent, other	0.0016	Monitor, Trans
Peanuts, whole	0.075	Field
Peanut, oil	0.012	Field + Proc
Stone fruits:		
Apricot	0.041	Monitor
Apricot, dried	0.23	Monitor + Conc
Cherries, fresh	0.34	Monitor
Cherries, dried	2.07	Monitor + Conc
Cherries, juice	0.34	Monitor + Proc, Trans
Nectarine	0.22	Monitor
Peaches, fresh	0.245	Monitor
Peaches, dried	1.67	Monitor + Conc
Plums, fresh	0.069	Monitor
Plums, prunes, dried	0.276	Monitor + Proc
Plums, prune, juice	0.276	Monitor + Proc, Trans
Small fruits and berries:		
Blackberries	0.361	Monitor
Boysenberries, Dewberries, Loganberries, Youngberries, Currants	0.198	Monitor, Trans
Raspberries	0.198	Monitor
Blueberries	0.023	Monitor
Grapes, fresh	0.054	Monitor
Grapes, raisins	0.243	Monitor + Proc

Table 1. Combined Iprodione Anticipated Residues, Cancer Risk		
~~Commodity~~	Anticipated ~~Residues, ppm~~	Basis for ~~Anticipated Residues~~
Grapes, juice	0.054	Monitor + Proc
Strawberries	0.266	Monitor
Cereal grains:		
Rice, rough	0.57	Field
Rice, milled	0.063	Field + Proc
Tree nuts:		
Almond, nutmeat	0.10	Field
Additional crops:		
Ginseng	2.0	Tol
Ginseng, dried	4.0	Tol
Chinese mustard (FL only)	15.0	Tol
Animal commodities:		
Meat of cattle, goats, and sheep	0.00087	All determined from calculated dietary burden and animal feeding studies.
Meat byproducts of cattle, goats, and sheep	0.00087	
Fat of cattle, goats, and sheep	0.0026	
Kidney of cattle, goats, and sheep	0.0099	
Liver or cattle, goats, and sheep	0.0082	
Meat, organ, other, of cattle, goats, and sheep	0.0099	
Milk, whole	0.0073	
Meat of hogs	0.00037	
Meat byproducts of hogs	0.00037	
Fat of hogs	0.0011	

Table 1. Combined Iprodione Anticipated Residues, Cancer Risk		
~~Commodity~~	Anticipated ~~Residues, ppm~~	Basis for ~~Anticipated Residues~~
Kidney of hogs	0.0043	
Liver of hogs	0.0035	
Meat, organ, other, of hogs	0.0043	
Meat of poultry	0.00057	
Meat byproducts of poultry	0.00057	
Fat of poultry	0.0044	
Liver of poultry	0.0104	
Eggs	0.0024	
Horse	3.0	Tol

Table notes:
Basis for Anticipated residues:
Tol = Tolerance value;
Field = Field trial data;
Proc = Processing data;
Monitor = Monitoring data from FDA and/or FOODCONTAM;
Conc = concentration factor based on wet weight or other information;
Trans = data translated from a similar commodity.

2. Anticipated residues for acute risk should be tolerance values, unless otherwise indicated for the commodities in Table 2:

Table 2. Combined Iprodione Anticipated Residues, Acute Risk, Other than RAC Tolerances		
Commodity	Anticipated Residues, ppm	Basis for Anticipated Residues
Unspecified crop group:		
Wine and sherry	60	Tol, Monitor + Proc
Root and tuber vegetables:		
Potatoes, peeled	0.5	Tol + Proc
Potatoes, peel	0.5	Tol + Proc

Table 2. Combined Iprodione Anticipated Residues, Acute Risk, Other than RAC Tolerances		
Commodity	~~Anticipated~~ Residues, ppm	~~Basis for~~ Anticipated Residues
Legumes:		
Peanut, oil	0.155	Tol + Proc
Stone fruits:		
Apricot, dried	112	Tol + Conc
Cherries, dried	122	Tol + Conc
Cherries, juice	20	Tol + Proc, Trans
Peaches, dried	136	Tol + Conc
Plums, prunes, dried	80	Tol + Proc
Plums, prune, juice	80	Tol + Proc, Trans
Small fruits and berries:		
Raspberries, Boysenberries, Dewberries, Loganberries, Youngberries,	25	Group Tol
Grapes, fresh	10	Field
Grapes, raisins	50	Field + Proc
Grapes, juice	10	Field + Proc
Cereal grains:		
Rice, rough	10	Tol
Rice, milled	1.1	Tol + Proc
Additional crops:		
Ginseng	2.0	Tol
Ginseng, dried	4.0	Tol
Chinese mustard (FL only)	15.0	Tol

Table 2 notes: RAC = raw agricultural commodity
Basis for Anticipated residues:
Tol = Tolerance value;
Tol, Monitor = Tolerance, supported by monitoring data

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Field = Field trial data;
Proc = Processing data;
Conc = concentration factor based on wet weight;
Trans = data translated from a similar commodity.

3. Further details on the determination of anticipated residues are provided below under ANTICIPATED RESIDUES, CROPS and ANTICIPATED RESIDUES, ANIMAL COMMODITIES.

Recommendations

We recommend DRES evaluation for cancer risk from iprodione using the anticipated residues provided in Table 1. For anticipated residues, cancer risk, where the basis for determining anticipated residues includes monitoring data (indicated by Monitor in Table 1), percent crop treated data have already been taken into account. For anticipated residues, cancer risk, for all animal commodities except horse, anticipated residues were based on calculated dietary burdens that took percent crop treated data into account. For both these situations, we recommend for the purposes of DRES evaluation that percent crop treated be set to the default value of 100%.

Anticipated residues, acute risk, should be based on present tolerance values, except for the commodities indicated in Table 2 where field trial data, processing data, or other considerations indicate that a different value is more appropriate. Table 2 also includes anticipated residues for some commodities for which specific tolerances have not been established. Anticipated residues in Table 2 have not been adjusted by percent crop treated data.

For commodities in the DRES run, residue data are not available specifically on dried beef, poultry skin, milk fat solids, milk non-fat solids, or milk sugar. For commodities with these components, we recommend using the most appropriate commodity for which anticipated residues have been determined, adjusted by any default value built into DRES.

Background

In response to a request from Registration Division, Dietary Exposure Branch previously determined combined anticipated residues of iprodione, its isomer, and its metabolites, in or on milk, lettuce, tomatoes, grapes, stone fruits, and strawberries (DEB 5254-56, 5322-23, 5/24/89, J. Smith). In this determination, anticipated residues for each crop commodity were based on the maximum residue value from field trial data where crops were treated at the maximum allowable application rate. Anticipated residues on milk were based on average residues from field trial data for feed commodities, and maximum residues from a cattle feeding study (Ibid.).

In response to a Section 18 request for use of iprodione on apples, CBTS conducted a Dietary Risk Evaluation System (DRES) analysis, using toxicological endpoints for chronic non-cancer effects and carcinogenicity, (CBTS Memo, 4/29/93, R. Griffin). This evaluation used anticipated residues as previously determined (DEB 5254ff, 5/24/89), and percent crop treated values for grapes, stone fruits, lettuce, and carrots. The results of the evaluation for the overall U.S. population were an exposure of 33% RfD (111% RfD for non-nursing infants, the group with highest exposure) and a cancer risk of 1.5×10^{-3}. The use of anticipated residues and percent crop treated data had the effect of reducing overall estimated exposure by about 3-fold, compared to an evaluation with tolerance values. The CBTS Memo reporting the DRES analysis included as an attachment the oncogenic risk by food name, based on analysis using tolerance values only. The estimated risk by crop group from that analysis is summarized in Table 3. As a consequence of this DRES evaluation, CBRS has been requested to determine anticipated residues for acute and cancer risks.

Table 3. Estimated chronic dietary risk by crop group.

Crop group	%RfD	Cancer risk
Unspecified	12.7	5.6×10^{-4}
Roots and tubers	3.6	1.6×10^{-4}
Bulb vegetables	0.1	5.9×10^{-6}
Leafy vegetables	14.1	6.2×10^{-4}
Brassica	3.1	1.4×10^{-4}
Legumes	2.1	9.3×10^{-5}
Stone fruits	18.1	8.0×10^{-4}
Small fruits and berries	35.2	1.5×10^{-3}
Cereal grains	4.0	1.7×10^{-4}
Tree nuts	0.0021	9.3×10^{-8}
Red meat	3.0	1.3×10^{-4}
Poultry	4.0	1.8×10^{-4}
Milk and eggs	15.3	6.8×10^{-4}
Population total	115.2	5.2×10^{-3}

Source: DRES run for the U.S. population based on iprodione tolerances, CBTS Memo, 4/29/93, R. Griffin.
Totals may not seem consistent due to rounding.

Residues of concern

Phase 4 review concluded that similar metabolism on three dissimilar crops has been demonstrated and no further data are required for the purposes of conducting Phase 5 review. Most of the residue was iprodione, but its isomer, two metabolites, and the isomer of one metabolite were also identified in plant metabolism studies. Animal metabolism studies are considered adequate for determination of the metabolites of interest, although an additional ruminant metabolism study is required to validate the enforcement analytical method. (Iprodione List B File, C.L. Olinger, 3/15/91) For the purposes of this assignment, anticipated residues will be determined for residues in the tolerance expressions presently established: Iprodione, its isomer, and its metabolite RP32490 for plant commodities; and iprodione, its isomer, and metabolites RP32490 and RP36114 in animal commodities (see Figure 1 for structures).

ANTICIPATED RESIDUES, CROPS

Residue data sources

Chemistry Branch Guidelines for Anticipated Residues (3/25/91, E. Zager) note that anticipated residue values for carcinogenic risk are estimates of the average residue levels in foods at the time of consumption. For acute risk, anticipated residues will be tolerance levels or the best estimates of the maximum residues in foods at the time of consumption.

For iprodione, sources of residue data include data from field trials and data from FDA monitoring, and from monitoring by states through the FOODCONTAM data base. No data are available on residue degradation or reduction during events between harvest and food consumption. The Guidelines for Anticipated Residues (Ibid.) indicate that FDA monitoring data may be used for determining anticipated residues for chronic risk if 100 samples or more of a particular commodity have been analyzed.

Agency policy on residue data for acute risk is in the process of development. However, the present CBRS position is that even FDA monitoring data are not likely to be extensive enough nor targeted enough to provide confidence that the highest residues on a single sample will be determined. Tolerance values should be used for acute risk, unless processing data, residue data submitted in support of reregistration, or other considerations indicate that a value other than the tolerance is more appropriate (M.S. Metzger, personal communication).

CBRS has received monitoring data for iprodione, its isomer, and metabolite in the tolerance expression for crop commodities

(B.O. Bohannon, FDA, to S. Hummel, CBRS, 3/4/94). Data were provided from the FDA surveillance (non-targeted) monitoring program during FY 90-FY 93 year to date, indicating counts, or total number of samples analyzed by methods capable of determining the regulated residues, and data on individual samples with detectable residues. Table 4 summarizes the FDA monitoring data, with commodities arranged in approximate order in which they appear in the DRES run (Memo, 4/29/93, R. Griffin).

Table 4. Summary of FDA Surveillance Monitoring, FY 90-93, for Combined Iprodione Residues.

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
Unspecified group:					
Kiwi; 21S/11	90	0		0	
	91	90		18	1
	92	90		32	8
	93	20		46	13
	Totals:	200	0	96	22
Wine, white; 32B/01	90	13	5	179	1
	91	34	19	83	
	92	15	10	13	
	93	0		46	
	Totals:	62	34	321	1
Wine, red; 32B/02	90	42	15	144	
	91	28	11	61	3
	92	11	4	13	
	93	0		3	
	Totals:	81	30	221	3
Root and tuber vegetables:					
Carrot; 25J/01	90	75		67	
	91	121		47	
	92	80	3	55	
	93	69	2	40	

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
	Totals:	345	5	209	0
Potato; 25J/06	90	302		30	
	91	230		38	
	92	204		5	
	93	161		35	
	Totals:	897	0	108	0
Bulb vegetables:					
Garlic, bulb; 25J/21	90	0		0	
	91	1		3	
	92	1		3	
	93	0		6	
	Totals:	2	0	12	0
Onion, bulb; 25J/25	90	0		0	
	91	59		39	
	92	69		40	
	93	40		43	
	Totals:	169	0	122	0
Shallots; 25J/11	90	0		15	
	91	0		16	
	92	1		10	
	93	1		11	
	Totals:	2	0	52	0
Leafy vegetables:					
Lettuce/ Romaine; 24T/19	90	892	8	57	
Lettuce, leaf; 24T/32	91	397		22	1
	92	429	8	34	1

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
	93	121	2	34	
	Totals:	947	10	90	2
Lettuce, head; 24T/31	91	283	1	16	
	92	255		18	1
	93	94	1	23	
	Totals:	632	2	57	1
Brassica vegetables:					
Broccoli; 24T/05	90	166		83	
	91	153		59	
	92	146		69	
	93	41		78	
	Totals:	506	0	289	0
Legumes:					
Bean, Dry, Kidney; 24B/07	90	18		0	
	91	12		2	
	92	8		1	
	93	7		0	
	Totals:	45	0	3	0
Bean, Dry, Lima; 24B/08	90	9		0	
	91	18		0	
	92	11		0	
	93	9		0	
	Totals:	47	0	0	0
Bean, Dry, Navy; 24B/10	90	2		0	
	91	1		0	
	92	0		0	
	93	0		0	
	Totals:	3	0	0	0

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
Bean, Dry, Pinto; 24B/11	90	0		3	
	91	2		0	
	92	0		0	
	93	0		0	
	Totals:	2	0	3	0
Beans, String (Green); 24A/14	90	72		168	
	91	96		108	
	92	51		84	
	93	51		61	
	Totals:	270	0	421	0
Beans, Wax; 24A/15	90	1		4	
	91	2		1	
	92	0		1	
	93	2		3	
	Totals:	5	0	9	0
Peanuts; 23A/07	90-93 Totals	0	0	1	0
Beans, dry, pigeon; 24B/17	90	0		1	
	91	0		1	
	92	0		0	
	93	0		0	
	Totals:	0	0	2	0
Beans, dry, blackeye peas; 24B/50	90	3		0	
	91	17		0	
	92	3		0	
	93	7		1	
	Totals:	30	0	1	0

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; ~~FDA Code~~	~~FY~~	Domestic ~~Counts~~	Domestic ~~Detects~~	Import ~~Counts~~	Import ~~Detects~~
Beans, dry, garbanzo; 24B/06	90	1		0	
	91	0		0	
	92	0		2	
	93	2		3	
	Totals:	3	0	5	0
Stone fruits:					
Apricot; 21G/01	90	42		34	9
	91	41		33	8
	92	45	1	18	6
	93	28		4	1
	Totals:	156	1	89	24
Apricot, Dried/ paste; 21H/01	90	1		5	
	91	0		4	
	92	0		3	
	93	0		2	
	Totals:	1	0	14	0
Cherry; 21G/03	90	87	26	40	6
	91	175	38	48	14
	92	86	12	18	4
	93	62	29	25	5
	Totals:	410	105	131	29
Nectarine; 21G/07	90	66	7	48	7
	91	51		95	16
	92	41	5	46	6
	93	35	5	21	4
	Totals:	193	17	210	33
Peach; 21G/13	90	118	8	132	26
	91	100	9	113	22

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
	92	106	11	73	19
	93	88	15	54	24
	Totals:	412	43	372	91
Plums; 21G/14	90	57	1	69	10
	91	54	1	105	27
	92	46	5	49	10
	93	2	1	42	10
	Totals:	159	8	265	57
Prunes; 21G/15	90	10		0	
	91	0		1	
	92	0		0	
	93	3		1	
	Totals:	13	0	2	0
Small fruits and berries:					
Berries, Black; 20A/01	90	26	13	43	12
	91	9		32	4
	92	6		53	10
	93	7	1	52	11
	Totals:	48	14	180	37
Berries, Logan; 20A/11	90	9		0	
	91	1		0	
	92	0		2	1
	93	0		1	
	Totals:	10	0	3	1
Berries, Red Rasp; 20A/13	90	43	10	93	11
	91	31	8	130	8
	92	21	4	59	3
	93	17	3	79	4

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
	Totals:	112	25	361	26
Berries, Boysen; 20A/03	90	3	1	14	2
	91	7		8	3
	92	3		2	1
	93	2		1	
	Totals:	15	1	25	6
Berries, Blue; 20A/02	90	33	2	59	16
	91	27		70	6
	92	24		73	5
	93	9		48	4
	Totals:	93	2	250	31
Berries, Currants; 20A/05	90	0		7	
	91	0		2	
	92	0		3	
	93	0		0	
	Totals:	0	0	12	0
Berries, Grapes; 20A/09	90	204	7	189	26
	91	189	10	177	37
	92	176	9	141	28
	93	39	3	108	29
	Totals:	608	29	615	120
Berry Juice, Grapes; 20D/09	90	1		0	
	91	0		5	
	92	2		6	
	93	10		4	
	Totals:	13	0	15	0

Table 4. Summary, FDA Surveillance Monitoring Data					
Commodity; FDA Code	FY	Domestic Counts	Domestic Detects	Import Counts	Import Detects
Berries, Straw; 20A/14	90	227	45	170	1
	91	242	58	140	5
	92	209	52	102	11
	93	87	19	102	9
	Totals:	765	174	514	26
Cereal Grains:					
Rice, Grain; 02A/05	90	12		1	
	91	2		1	
	92	34		5	
	93	24		2	
	Totals:	72	0	9	0
Rice, processed and milled; 02D/	90	0		5	
	91	28		6	
	92	6		13	
	93	9		42	
	Totals:	41	0	66	0
Tree nuts:					
Almonds	90-93 Totals:	0	0	0	0

Table note: In the columns for detects, blank spaces indicate years with zero detects.

Data from the FOODCONTAM data base are also available for FY 90-93. These data sets for counts and detects have each been sorted by commodity, allowing determination of total counts and total detects for each commodity during FY 90-93. Table 5 summarizes state monitoring data for combined residues of iprodione in the FOODCONTAM data base. This information was generated from sampling by individual state agencies, and data apply to domestic samples unless otherwise indicated.

Table 5. Summary of FOODCONTAM Monitoring Data, FY 90-93, for Combined Iprodione Residues.

Table 5. Summary, State Monitoring Data		
Commodity	Counts	Detects
Kiwifruit	5	2
Kiwi (New Zealand)	21	1
Carrots	173	31
Potatoes	174	2
Onions	166	1
Lettuce	862	11
Broccoli	261	2
Green Beans	201	2
Wax Beans	3	0
Peanuts	4	0
Apricots	75	13
Cherries	69	44
Nectarines	126	78
Peaches	311	130
Plums	130	46
Prunes	7	2
Black Berries	9	6
Logan Berries	1	1
Raspberries	28	5
Blue Berries	18	1
Boysen Berries	1	0
Grapes	371	101
Grape Juice	10	0
Strawberries	285	101
Rice	3	0
Almonds	5	0

It should be noted that both FDA monitoring data and state monitoring data for FY 90-93 reported occasional samples with detectable combined iprodione residues on commodities for which iprodione tolerances are not established. For the purposes of this assignment, it is assumed that these samples with over-tolerance residues were seized, and these commodities will be ignored in determining anticipated residues.

For FDA monitoring data and for FOODCONTAM data, the limits of quantitation for iprodione residues is not stated. For the FDA data, other than residues reported as trace (designated T0.0), the lowest residues reported were 0.01 ppm; for the FOODCONTAM data, the lowest residues reported as detectable were 0.016 ppm. FDA multiresidue methods detect total combined residues of iprodione/isomer/metabolite (B.O. Bohannon, FDA, personal communication, 2/2/95). For the purposes of this assignment, it will be assumed that the limit of quantitation for combined iprodione residues will be 0.01 ppm, and half the combined limit of quantitation will be 0.005 ppm.

Percent crop treated data have also been provided for many crops by BEAD (Alan Halvorson, 3/95). These data are provided as ranges for the percent crop treated with iprodione. For the purposes of this assignment, the higher limit of the range will be used; where percent crop treated is reported as less than 1%, then 1% will be used. Where (average) anticipated residues for cancer risk can be determined from FDA monitoring data, residues will be assumed to be zero on the percent of the crop <u>not</u> treated, and will be assumed to be half the combined limit of quantitation (0.005 ppm) on samples representing the portion of the crop treated, but where no residues were detected. For cases where anticipated residues can be determined from FDA monitoring data, let:
d = the number of samples with detectable residues,
Σ = the sum of all residues in ppm over d samples,
p = the portion of the crop treated, expressed as a decimal,
1-p = the portion of the crop not treated, and
n = the total number of samples (counts), with or without detectable residues.
Then average anticipated residues, a, in ppm will be determined from the equation:

$$a = [n(1-p)(0) + (n(p)-d)(0.005) + \Sigma]/n$$

The first term within the brackets will be zero in all cases, so this reduces to equation (1):

$$a = [(np-d)(0.005) + \Sigma]/n \qquad (1)$$

In cases where the number of samples with detectable residues, compared to the total counts, is similar to the reported portion of the crop treated with iprodione, then the first term within

the brackets in equation (1), to correct for samples treated but with residues not detected, will be ignored. It can also be seen that where the sum of detectable residues is large, the first term within the brackets of equation (1) will be insignificant compared to the second term.

Anticipated residues for individual commodities are given below:

Unspecified crop group

For kiwi fruit, Phase 4 Review reported that the label contains no use directions, so the established tolerance must represent an import tolerance. No percent crop treated data were provided for kiwi fruit, so a default of 100% will be assumed. Import counts from FDA and FOODCONTAM (Tables 4 and 5) together are 117, so these data will be combined. The single FOODCONTAM detect was for residues of 0.05 ppm; the sum of residues over 22 FDA samples with detectable residues was 20.151 ppm, and the combined sum was 20.201 ppm. Substituting in equation (1) above gives:
$a = [(117-23)(0.005) + 20.201]/117 = 0.18$ ppm.

For wine, there were no samples from FOODCONTAM, and residues were much lower in FDA import samples (a sum of 0.46 ppm over 4 detects, for both red and white wine). According to Agricultural Statistics, 1990, U.S. Department of Agriculture, U.S. production of grapes crushed for wine in 1989 was 2.85 million tons. This publication did not have data on wine imports into the U.S. but data on imports have been obtained from USDA; for 1992, imports of table wine were 2.63 million hectoliters (CBTS 15364, 4/7/95, B.A. Schneider). According to the Food and Food Production Encyclopedia, 1982, wine grapes contain 70 to 80 percent water. Assuming that 70% of the weight of crushed grapes is converted to wine, this gives 1.99 million tons of U.S. wine production. A hectoliter is 100 liters, or 0.1 metric ton, which means that wine imports into the U.S. in 1992 were 0.26 million metric tons. Ignoring the difference between tons and metric tons, and recognizing that data were obtained for different years, imports represent approximately 10% of U.S. wine consumption. Anticipated residues for wine will therefore be based on the domestic monitoring data.

For domestic monitoring, the sum over 34 white wine samples with detectable residues was 12.702 ppm, and over 30 red wine samples with detects was 105.481 ppm. Total domestic counts for red and white wine combined were 143, so data will be combined. For wine grapes in CA, the upper range of percent crop treated was 19%. Because the percentage of detects in FDA samples is higher than this value, the detect samples will be assumed to represent the portion of the crop that is treated. Combining residues from red and white wine gives
$a = [12.702 + 105.481]/143 = 0.83$ ppm.

For wine and sherry, the single monitoring sample with the highest residues contained 100 ppm. This is greater than the present tolerance for grapes of 60 ppm, and there is no food additive tolerance for grape juice, the closest grape processed commodity to wine. Anticipated residues for wine and sherry will therefore be assumed to be 60 ppm, the present tolerance value for grapes.

Summary, unspecified crop group. Anticipated residues, cancer risk, for commodities in this group, based on monitoring data, are:
kiwifruit, 0.18 ppm;
wine and sherry, 0.83 ppm.

Anticipated residues, acute risk, should be based on the tolerance value for kiwi fruit, and should be 60 ppm for wine and sherry, based on the present tolerance for grapes and processing data.

Root and tuber vegetables

For carrots, there were no FDA detects in import samples, and total domestic counts were greater than 100; FDA monitoring data and FOODCONTAM data will be combined. The sum of residues over 5 FDA detects was 2.32 ppm; the sum over 31 FOODCONTAM detects was 8.048 ppm. Reported upper range of percent crop treated is 18%. Anticipated residues are determined as:
a = [{(345+173)(0.18)-36}(0.005) + (2.32+8.048)]/(345+173)
= 0.021 ppm.

For potatoes, there were no detects in any FDA samples, and 2 detects in FOODCONTAM samples for a sum of 2.04 ppm. The upper range of percent crop treated is 8%. Anticipated residues are:
a = [{(897+174)(0.08)-2}(0.005) + 2.04]/(897+174) = 0.0023 ppm.

The DRES run of 4/29/93 listed the commodities potatoes, whole; potatoes, peeled; potatoes, peel only. Tolerances on potatoes were established as a registration action subsequent to Phase 4 Review. Review of potato processing data concluded that at exaggerated rates, combined residues of iprodione did not concentrate in potato chips, flakes, granules, or potato processing waste (RCB 4016, 4017, 9/9/88, R.W. Cook, PP6F3366). The data provided were not sufficient to determine if residues differ consistently between potato pulp and potato peel. Anticipated residues for these commodities will be identical to anticipated residues for whole tubers. For acute risk, the tolerance value of 0.5 ppm should be used for all potato commodities.

Summary, root and tuber vegetables. Anticipated residues, cancer risk, are based on monitoring data for carrots and whole potatoes, and the values for other potato commodities were

obtained by adjusting monitoring data for processing data. Anticipated residues, cancer risk, are:
carrots, 0.021 ppm;
potatoes, whole, 0.0023 ppm;
potatoes, peeled, 0.0023 ppm;
potatoes, peel, 0.0023 ppm.

For acute risk, anticipated residues should be based on tolerance values, and the tolerance for potatoes, 0.5 ppm, should be translated to processed potato commodities.

Bulb vegetables

For onions, the number of FDA samples is sufficient to determine anticipated residues. There were no detects among FDA samples, and one detect, at 2.6 ppm, among the FOODCONTAM samples. Reported percent crop treated is 21%. Combining the domestic FDA and FOODCONTAM samples gives:
$a = [\{(169+166)(0.21)-1\}(0.005) + 2.6]/(169+166) = 0.0088$ ppm.

FDA monitoring samples are insufficient to determine anticipated residues in garlic and shallots. However, anticipated residues for onions will be translated to these crops.

Summary, bulb vegetables. Anticipated residues, cancer risk, based on monitoring data on onions, translated to garlic and shallot, are:
garlic, 0.0088 ppm;
onion, dry, 0.0088 ppm;
shallot, 0.0088 ppm.

Anticipated residues for acute risk should be based on tolerances.

Leafy vegetables

Lettuce is the only commodity with iprodione tolerances in this crop group. FDA monitoring data were for the category lettuce in FY90, and were divided by leaf lettuce and head lettuce in subsequent years; FOODCONTAM data are for the generic category lettuce. FDA monitoring data were for more than 100 samples for domestic surveillance only, so these samples will be used for anticipated residues. The upper ranges for percent crop treated are 19% for head lettuce, 16% for leaf lettuce in CA, and 19% for lettuce overall. For leaf lettuce, the sum of residues over 10 detects was 36.86 ppm, and anticipated residues are:
$a = [\{947(0.16)-10\}(0.005) + 36.86]/947 = 0.040$ ppm.

For head lettuce, the sum of residues over 2 detects was 2.45 ppm, and anticipated residues are:
$a = [\{632(0.19)-2\}(0.005) + 2.45]/632 = 0.0048$ ppm.

For the generic category lettuce, the sum of residues over 8 FDA detects was 12.63 ppm, the sum of residues over 11 FOODCONTAM detects was 12.18 ppm, and anticipated residues are:
a = [{892(0.19)-8}(0.005)+{862(0.19)-11}(0.005)+24.81]/(892+862)
= 0.015 ppm.
Since anticipated residues for leaf lettuce are higher, the value of 0.040 ppm will be translated to the DRES commodity lettuce, unspecified.

Summary, leafy vegetables. Anticipated residues, cancer risk, based on monitoring data for leaf and head lettuce, with the values for leaf lettuce were translated to lettuce, unspecified, are:
lettuce, leaf, 0.040 ppm;
lettuce, unspecified, 0.040 ppm;
lettuce, head, 0.0048 ppm.
For acute risk, anticipated residues should be based on tolerances.

Brassica vegetables

Broccoli is the only crop with an iprodione tolerance in this group. There were no detects among FDA samples, and two detects among FOODCONTAM samples for a sum of residues of 1.12 ppm. Percent crop treated is reported as <1%. Anticipated residues are:
a = [(506)(0.01)(0.005) + {261(0.01)-1}(0.005) + 1.12]/(506+261)
= 0.0016 ppm.

Summary, brassica vegetables. Anticipated residues, cancer risk, based on monitoring data, are
broccoli, 0.0016 ppm.
For acute risk, anticipated residues should be based on tolerances.

Legumes

For dry beans, there were no samples with detectable residues among FDA monitoring, and FOODCONTAM did not report any samples for dry beans. Percent crop treated data are reported as <1%. FDA domestic surveillance samples will be combined, and anticipated residues on dry beans are:
a = [(45+47+3+2+30+3)(0.01)(0.005)]/(45+47+3+2+30+3)
= (0.01)(0.005) = 0.00005 ppm.

For green beans, there were no samples with detectable residues among FDA monitoring, and two samples, for a sum of residues of 0.76 ppm, among the FOODCONTAM samples. Percent crop treated data are reported as <1%. Combining monitoring data from FDA and FOODCONTAM gives anticipated residues of:
a = [{(270+201)(0.01)-2}(0.005) + 0.76]/(270 + 201) = 0.0016 ppm.

Monitoring samples are insufficient to determine anticipated residues for wax beans or other succulent beans, so the value for green beans will be translated to other succulent beans.

Peanuts. For this crop, Tables 4 and 5 show that FDA monitoring data are insufficient, and FOODCONTAM data are minimal for determining anticipated residues. Data from field trials are necessary. Phase 4 Review (3/15/91, C.L. Olinger) found that no additional field trial data or processing data were required, contingent upon submission of adequate storage stability data. A recent review concluded that storage stability data are adequate for crop commodities (CBRS 14162, 12/27/94, S.A. Knizner). Application rates, retreatment intervals, and PHIs reflected the currently registered use. Residues on all samples of peanut nutmeats were ≤0.05 ppm for each of parent, isomer, and metabolite (PP4F3129, 2/15/85, R.W. Cook). Taking half the combined limit of detection gives average combined residues of 0.075 for cancer risk for peanuts, whole.

Phase 4 Review also found residue data from a processing study adequate, contingent on adequate storage stability data. Residue data from this study are summarized in Table 6 (Ibid.):

Table 6. Peanut processing data.

	Residues, ppm, of:					
	Parent		Isomer		RP32490	
	with three applications each, at 1b ai/A:					
Commodity	1	2	1	2	1	2
Nutmeats	0.21	0.27	0.11	0.18	≤0.05	≤0.05
Refined Oil	≤0.05	≤0.05	≤0.05	≤0.05	≤0.05	≤0.05
Meal	--	≤0.05	--	≤0.05	--	≤0.05

Residues were nondetectable for oil and meal in both trials. The dilution factors during concentration will be a maximum of 0.31 (0.15/0.48) for acute risk, and an average of 0.16 (.075/0.48) for cancer risk. Applying the latter factor to anticipated residues for peanuts gives 0.012 ppm for cancer risk for refined peanut oil and peanut meal. Peanut oil is a commodity listed in the DRES run; peanut meal is an animal feed commodity.

Applying the factor of 0.31 ppm to the tolerance for peanuts, 0.5, gives 0.155 ppm for anticipated residues, acute risk, for peanut oil.

Summary, legumes. Anticipated residues are
for cancer risk:
beans, dry, 0.00005 ppm;
beans, succulent, green, 0.0016 ppm;
beans, succulent, other, 0.0016 ppm;
peanuts, whole, 0.075 ppm;
peanut, oil, 0.012 ppm.

For cancer risk, anticipated residues were based on monitoring data for dry beans and green beans, and translation from green beans to other succulent beans. Anticipated residues, cancer risk, for peanuts were based on field trial data, adjusted for processing data for peanut oil; anticipated residues for peanuts have not been adjusted for percent crop treated data.

Anticipated residues, acute risk, should be the tolerance value for beans and peanuts, and the tolerance value adjusted by processing data for peanut oil, at 0.155 ppm.

Stone fruits.

For apricots, FDA monitoring data found detectable residues in imported samples more frequently than in domestic samples. According to Agricultural Statistics, 1990, U.S. production of apricots in 1989 was 117,000 tons, of which 2,515 metric tons was exported. This publication did not have data on imports, but data on imports have been obtained from USDA; for 1993, apricot imports into the U.S. were 19,000 hundredweight (CBTS 15364, 4/7/95, B.A. Schneider). A hundredweight is 100 pounds, or 0.05 ton, so apricot imports were 950 tons. Although data were obtained from different years, apricot imports represent less than 1% of U.S. consumption.

FDA domestic surveillance monitoring found one sample with detectable residues of 1.20 ppm among 156 samples; for FOODCONTAM data, the sum of residues over 13 detects was 6.90 ppm. The upper range of reported percent crop treated data is 86%. Combining FDA domestic data and FOODCONTAM data gives anticipated residues of:
a[domestic] = [{(156+75)(0.86)-14}(0.005) + 1.2 + 6.9]/(156+75)
= 0.039 ppm.
For import samples, the sum of residues over 24 detects was 16.98 ppm. Assuming a default value of 100% crop treated gives anticipated residues of:
a[import] = [(89-24)(0.005) + 16.98]/89 = 0.194 ppm.
Giving this a weighting of 1% compared to domestic production gives weighted anticipated residues of
a[overall] = 0.039(0.99) + 0.194(0.01) = 0.041 ppm.

For the DRES commodity dried apricot, monitoring samples are insufficient to determine anticipated residues. According to the Food and Food Production Encyclopedia, 1982, raw apricots contain

85.3% water (14.7% dry matter), and sun-dried apricots contain 15-20% water (80-85% dry matter). The maximum concentration factor is therefore 5.6X, and this will be applied to anticipated residues for apricots to give 0.23 ppm for cancer risk. For acute risk, this concentration factor will be applied to the tolerance value, 20 ppm, to give 112 ppm.

For cherries, FDA monitoring data found detectable residues in both domestic and imported samples, with about the same frequency. According to Agricultural Statistics, 1990, U.S. Department of Agriculture, U.S. production of cherries in 1988 was 276,000 tons. Also during 1988, the most recent year for which exports and imports were reported, U.S. exports were 29,273 tons, and imports were 3,440 tons. The upper range of reported percent crop treated data is 38%. Even if 100% of imported cherries were treated with iprodione, imports would represent less than 4% of the U.S. diet of treated cherries, so FDA import data will be ignored in determining anticipated residues. For FDA domestic surveillance data, the sum of residues over 105 detects was 119.796 ppm; for FOODCONTAM data, the sum of residues over 44 detects was 41.046 ppm. The portion of detects from FOODCONTAM samples is higher than the reported percent crop treated, so no adjustment will be made to those samples for percent crop treated but with undetectable residues. Anticipated residues are:

$$a = [\{410(0.38)-105\}(0.005) + 119.796 + 41.046]/(410+66)$$
$$= 0.34 \text{ ppm.}$$

No monitoring data are available for the DRES commodity cherry, dried. According to the Food and Food Production Encyclopedia, 1982, a fresh cherry contains a minimum of 16.3% dry matter; the maximum concentration factor for dried cherry compared to fresh cherry would be 6.1X. Applying this value to anticipated residues for fresh cherries gives for dried cherries, 2.07 ppm for cancer risk. Applying this value to the tolerance value of 20 ppm gives 122 ppm for acute risk. Processing data are not available for the DRES commodity cherry juice, but processing data on grapes (see below) indicate that iprodione residues in grape juice were approximately 1X the level in grapes; anticipated residues for cherry juice will therefore be the same as for fresh cherries.

For peaches, FDA monitoring data showed more detects in import samples than domestic samples. According to Agricultural Statistics, 1990, U.S. production of peaches in 1988 was 2.614 billion pounds, of which 74,311 metric tons (0.163 billion pounds) were exported. This publication does not have data on U.S. imports of peaches, but data have been obtained from USDA; for 1993, imports of peaches and nectarines combined into the U.S. were 917,000 hundredweight, which is 91.7 million pounds (CBTS 15364, 4/7/95, B.A. Schneider). Peach imports therefore represent about 4% of U.S. consumption.

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For FDA domestic surveillance of peaches, the sum of residues over 43 detects was 49.23 ppm; for import samples, the sum of residues over 91 detects was 165.04 ppm. For FOODCONTAM samples, the sum of residues over 130 detects was 121.002 ppm. The upper range of reported percent crop treated was 41%; for imports, a default assumption of 100% crop treated will be used. Combining FDA domestic and FOODCONTAM samples for domestic residues gives

a[domestic]=
[{(412+311)(0.41)-43-91}(0.005)+49.23+121.002]/(412+311)
= 0.237 ppm

a[import] = [(372-91)(0.005) + 165.04]/372 = 0.447 ppm

a[overall] = 0.237(0.96) + 0.447(0.04) = 0.245 ppm.

Monitoring samples were insufficient to determine anticipated residues for the DRES commodity dried peaches. According to the Food and Food Production Encyclopedia, 1982, fresh peaches contain 89.1% (11% dry matter) water, and dried peaches contain 25% water (75% dry matter); the maximum concentration factor from fresh to dried would be 6.8X. Applying this value to anticipated residues for fresh peaches gives for dried peaches 1.67 ppm for cancer risk. Applying this value to the tolerance of 20 ppm gives 136 ppm for acute risk.

For nectarines, FDA monitoring data showed more detects in import samples than domestic samples. Import data obtained from USDA are for peaches and nectarines combined, so imports will be assumed to represent similar proportions for nectarines as peaches, or about 4% of U.S. consumption. For FDA monitoring data, the sum of residues over 17 domestic detects is 20.53 ppm; the sum over 33 import detects is 34.334 ppm. For FOODCONTAM data, the sum of residues over 78 detects is 50.06 ppm. Reported percent crop treated for CA was 32%; the portion of detects among the FOODCONTAM data is higher than this value, so no correction will be made for crop treated with no detects. A default of 100% treated will be used for imports. FDA domestic data and FOODCONTAM data will be combined to determine domestic anticipated residues.

a[domestic] = [{(193(0.32)-17)}(0.005) + 20.53 + 50.06]/(193+126)
= 0.222 ppm

a[import] = [(210-33)(0.005) + 34.334]/210 = 0.168 ppm.

Because average residues on imports are lower than the value for domestic residues, and because imports represent a small portion of U.S. consumption, the domestic average, 0.22 ppm, will be used for cancer risk.

For plums, FDA monitoring data showed more detects in import samples than domestic samples. According to Agricultural Statistics, 1990, U.S. imports of fresh plums and prunes in 1988 were 21,879 tons, and exports were 39,862 tons. In 1988, California produced 216,000 tons of plums. Imports therefore represented about 11% of U.S. consumption of plums, and anticipated residues will be calculated with this assumption.

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The upper range for percent crop treated data in the U.S. is 25%; the portion of detects from FOODCONTAM samples is higher than this value, so no adjustment will be made to those samples for percent crop treated. For imports, a default of 100% percent crop treated will be used. The sum of residues over 8 FDA domestic detects was 4.737 ppm; the sum over 57 FDA import detects was 31.78 ppm; and the sum over 46 FOODCONTAM detects was 12.90 ppm. Combining FDA and FOODCONTAM data, and calculating a weighted average for domestic and import data, anticipated residues are:

a[domestic] = [{159(0.25)-8}(0.005) + 4.737 + 12.90]/(159+130)
= 0.062 ppm
a[import] = [(265-57)(0.005) + 31.78]/265 = 0.124 ppm, and
a[overall] = 0.062(0.89) + 0.124(0.11) = 0.069 ppm, indicating that the import data had a small effect on the weighted anticipated residues.

FDA and FOODCONTAM monitoring data together are insufficient to determine anticipated residues on prunes. Review of data submitted for reregistration concluded that for prunes processed from plums, the average concentration factor for combined iprodione residues was approximately 4X, as was the maximum theoretical concentration factor, and a food additive tolerance of 80 ppm on prunes would be appropriate (CBRS 13956, 1/24/95, S.A. Knizner). The concentration factor of 4X will be used for both cancer and acute risks, giving anticipated residues on prunes of 0.276 ppm and 80 ppm, respectively. Residue data are not available for the DRES commodity prune juice, but based on data from grapes, prune juice residues will be assumed to be 1X those in prunes.

Summary, stone fruits. Anticipated residues are
for cancer risk:
apricots, fresh, 0.041 ppm;
apricots, dried, 0.23 ppm;
cherries, fresh, 0.34 ppm;
cherries, dried, 2.07 ppm;
cherries, juice, 0.34 ppm;
nectarines, 0.22 ppm;
peaches, fresh, 0.245 ppm;
peaches, dried, 1.67 ppm;
plums, fresh, 0.069 ppm;
plums, prunes, dried, 0.276 ppm;
plums, prune, juice, 0.276 ppm.

for acute risk:
apricots, dried, 112 ppm;
cherries, dried, 122 ppm;
cherries, juice, 20 ppm;
peaches, dried, 136 ppm;
plums, prunes, dried, 80 ppm;
plums, prune, juice, 80 ppm.

Anticipated residues, cancer risk, for fresh commodities were based on monitoring data in all cases. For acute risk, anticipated residues should be tolerance values except for the commodities indicated. For cancer and acute risk, residues were adjusted by maximum concentration factors for dried commodities, adjusted for processing data for prunes, and adjusted for processing data translated from grapes for juices.

Small fruits and berries.

An iprodione tolerance is established for caneberries, which are defined as berries of the species Rubus (40 CFR 180.1); these include blackberries, boysenberries, loganberries, and raspberries. Of these berry categories, FDA monitoring data for both import and domestic samples are sufficient for anticipated residues for red raspberries only. According to Agricultural Statistics, 1990, U.S. production in 1989 was 27.3 million pounds of red raspberries, and 1.98 million pounds of black raspberries. This publication contains no data on raspberry imports, but data have been obtained from USDA; for 1993, imports of raspberries into the U.S. were 129,000 hundredweight, or 12.9 million pounds (CBTS 15364, 4/7/95, B.A. Schneider). Imports therefore represent approximately 30% of U.S. raspberry consumption.

For FDA domestic samples of red raspberries, the sum of residues over 25 detects was 20.37 ppm; the sum of residues over 26 import detects was 20.12 ppm. From FOODCONTAM data, the sum of residues over 5 detects was 15.26 ppm. Reported percent crop treated was 57%; the default of 100% crop treated will be used for imports. FDA domestic data and FOODCONTAM data will be combined to determine domestic residues. Anticipated residues are:

a[domestic] = [{(112+28)(0.57)-25-5}(0.005)+20.37+15.26]/(112+28)
= 0.256 ppm

a[import] = [(361-26)(0.005) + 20.37]/361 = 0.061 ppm

a[overall] = 0.256(0.7) + 0.061(0.3) = 0.198 ppm.

Anticipated residues for raspberries will be translated to caneberries for which monitoring data are insufficient, including boysenberries, loganberries, and the DRES commodities dewberries and youngberries.

For the additional caneberry category blackberries, FDA monitoring detected residues in domestic and import samples. The sum of residues over 14 FDA domestic detects was 9.34 ppm; the sum over 37 import detects was 59.24 ppm. For FOODCONTAM data, the sum of residues over 5 detects was 12.14 ppm. The upper range of percent crop treated was 30%; however, the proportion of detects among FDA domestic samples was comparable to this value and the proportion among FOODCONTAM samples was higher. Therefore, no correction will be made for samples treated but without detectable residues. The default of 100% crop treated will be used for imports. FDA domestic data and FOODCONTAM data

will be combined to determine domestic residues. Anticipated residues are:
a[domestic] = [9.34 + 12.14]/(48 + 9) = 0.373 ppm
a[import] = [(180-37)(0.005) + 59.24]/180 = 0.333 ppm
a[overall] = 0.373(0.7) + 0.333(0.3) = 0.361 ppm.

Recent review of residue data noted that boysenberries and raspberries are presently covered by two tolerances, caneberries at 25 ppm, and individual tolerances at 15 ppm. The individual tolerances should be deleted, and the group tolerance of 25 ppm should be used for boysenberries and raspberries, along with other caneberries. (CBRS 14497, 13955, 1/24/95, S.A. Knizner). The higher value will be used for anticipated residues, acute risk, for all caneberries.

For blueberries, the number of FDA import samples, and the number of FDA domestic and FOODCONTAM samples combined are sufficient to determine anticipated residues. According to Agricultural Statistics, 1990, U.S. production of blueberries in 1989 was 89.3 million pounds. This publication contains no data on blueberry imports, but data have been obtained from USDA; for 1993, imports of blueberries into the U.S. were 173,000 hundredweight, or 17.3 million pounds (CBTS 15364, 4/7/95, B.A. Schneider). Imports therefore represent approximately 16% of U.S. consumption of blueberries.

The sum of residues over 2 FDA domestic detects is 1.31 ppm; the sum over 31 import detects is 18.08 ppm. FOODCONTAM reported 1 detect, at 0.13 ppm. Percent crop treated is reported as uncertain but no more than a few percent; because the proportion of detects among FDA domestic samples and FOODCONTAM samples represent only a few percent, no correction will be made for samples treated but without detectable residues. For imports, the default of 100% crop treated will be assumed. FDA domestic samples and FOODCONTAM samples will be combined to determine domestic anticipated residues. Anticipated residues are:
a[domestic] = [1.31 + 0.13]/(93+18) = 0.013 ppm
a[import] = [(250-31)(0.005) + 18.08]/250 = 0.077 ppm
a[overall] = 0.013(0.84) + 0.077(0.16) = 0.023 ppm.

Monitoring data are insufficient to determine anticipated residues for currants. The present tolerance for currants is 15 ppm, the same as the tolerance for blueberries and raspberries. Anticipated residues for raspberries are higher than for blueberries, and these will be translated to currants: 0.198 ppm for cancer risk.

For FDA monitoring data on grapes, import samples had a higher frequency of detects than domestic samples. According to Agricultural Statistics, 1990, the U.S. in 1988 imported 280,902 metric tons of grapes, and exported 136,246 metric tons. During the same year, the U.S. produced 6.033 million tons of grapes.

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Imports therefore represented about 5% of U.S. consumption. The upper range for reported percent crop treated for U.S. grapes is 16%; the portion of detects from FOODCONTAM samples is higher than this value, so no adjustment will be made to those samples for percent crop treated. For imports, a default of 100% percent crop treated will be used. The sum of residues over 29 FDA domestic detects was 15.998 ppm; the sum over 120 FDA import detects was 62.761 ppm; and the sum over 101 FOODCONTAM detects was 34.668 ppm. Combining FDA and FOODCONTAM data, and calculating a weighted average for domestic and import data, anticipated residues are:

a[domestic] = [{608(0.16)-29}(0.005) + 15.998 + 34.668]/(608+371)
= 0.052 ppm
a[import] = [(615-120)(0.005) + 62.671]/615 = 0.101 ppm, and
a[overall] = 0.052(0.95) + 0.101(0.05) = 0.054 ppm, indicating that import residues had a small effect on weighted anticipated residues.

FDA and FOODCONTAM monitoring data together are insufficient to determine anticipated residues on grape processed commodities. Phase 4 Review found grape processing data sufficient for reregistration, contingent upon adequate storage stability data. A recent review concluded that storage stability data are adequate for crop commodities (CBRS 14162, 12/27/94, S.A. Knizner).

Data on grape processed commodities have been reviewed. Concentration factors from grapes to raisins ranged from 2.4 to 6.8X, and the theoretical concentration factor was 4.5X (PP3F2964, 2/21/84, R.W. Cook); the latter value will be used for cancer risk. Residues in the animal feed item raisin waste were comparable to those in raisins. Residues in grape juice and wet pomace were comparable (1X) to those in grapes, and residues in the animal feed item dry pomace showed a concentration factor of 3.4X from residues in grapes (Ibid.); these values will be used for cancer risk.

With regard to acute risk, residue data in support of reregistration were submitted on grapes and grape commodities, and review concluded that present tolerances for commodities in the DRES run should be reduced to 10 ppm for grapes, and 50 ppm for raisins (CBRS 14402, 12/27/94, S.A. Knizner). Because residues do not concentrate in grape juice, 10 ppm should be used for anticipated residues, acute risk, for this commodity as well.

It should be noted that anticipated residues determined above for wine (see Unspecified crop group) were higher than anticipated residues for grape juice. Because the higher values for wine were consistent with monitoring data, those anticipated residues are considered more appropriate.

FDA monitoring of strawberries detected residues on both domestic and import samples. According to Agricultural Statistics, 1990, U.S. production of strawberries in 1989 was 238 million pounds. This publication contains no data on strawberry imports, but data have been obtained from USDA; for 1993, imports of strawberries into the U.S. were 318,000 hundredweight, or 31.8 million pounds (CBTS 15364, 4/7/95, B.A. Schneider). Imports therefore represent approximately 12% of U.S. consumption of strawberries.

From FDA monitoring data, the sum of residues over 174 domestic detects was 197.458 ppm; the sum of residues over 26 import detects was 36.135 ppm. From FOODCONTAM data, the sum of residues over 101 detects was 107.946 ppm. The upper range of reported percent crop treated was 50%; for imports, a default value of 100% crop treated will be assumed. Data from FDA domestic monitoring will be combined with FOODCONTAM data. Anticipated residues are:

a[domestic] =
[{(765+285)(0.5)-174-101}(0.005) + 197.458 + 107.946]/(765+285)
= 0.292 ppm
a[import] = [(514-26)(0.005) + 36.135]/514 = 0.075 ppm
a[overall] = 0.292(0.88) + 0.075(0.12) = 0.266 ppm.

Summary, small fruits and berries. Anticipated residues for cancer risk are:
blackberries, 0.361 ppm;
raspberries, 0.198 ppm;
boysenberries, dewberries,
loganberries, youngberries,
and currants, each 0.198 ppm;
blueberries, 0.023 ppm;
grapes, 0.054 ppm;
grapes, raisins, 0.243 ppm;
grapes, juice, 0.054 ppm;
strawberries, 0.266 ppm.

Anticipated residues for animal feed items for cancer risk are:
wet pomace, 0.054 ppm;
dry pomace, 0.184 ppm;
raisin waste, 0.243 ppm.

For cancer risk, anticipated residues for blackberries, raspberries, blueberries, and strawberries were based on monitoring data; anticipated residues for raspberries were translated to boysenberries, dewberries, loganberries, youngberries, and currants. Anticipated residues, cancer risk, for grapes were based on monitoring data, adjusted for processing data for grape juice, raisins, and processed animal feed items.

For acute risk, anticipated residues should be based on tolerances, with these exceptions: For the group caneberries, the group tolerance should replace lower individual tolerances.

For grape commodities, field trial data, combined with processing data, indicate that lower tolerances are appropriate. For these specific commodities, anticipated residues, acute risk, are:
raspberries, 25 ppm;
boysenberries, dewberries,
loganberries, youngberries, each 25 ppm;
grapes, 10 ppm;
grapes, raisins, 50 ppm;
grapes, juice, 10 ppm;

Cereal grains

Rice is the only cereal grain for which iprodione tolerances have been established. The number of FDA samples is not sufficient to use monitoring data, so anticipated residues will be based on field trial data. Phase 4 Review found rice field trial data adequate for reregistration, contingent on storage stability data. A recent review concluded that storage stability data are adequate for crop commodities (CBRS 14162, 12/27/94, S.A. Knizner). Field trial data were previously reviewed (PP6F3443, 4/25/88, R.W. Cook). These data are reproduced in the table below, with half the stated limit of detection used in calculating total iprodione residues. Application rates were 2X 0.5 lb ai/A by aerial equipment, with both applications prior to heading; this was consistent with the maximum label rate:

Table 7. Rice field trial data

State	Iprodione residues in rice commodities, ppm:			
	Parent	Isomer	RP32490	Total
Rice Grain:				
AR	0.70	0.25	0.14	1.09
CA	0.24	0.05	≤0.05	0.32
MS	0.24	≤0.05	≤0.05	0.29
MS	0.15	≤0.05	0.05	0.22
AR	0.09	0.68	≤0.05	0.80
AR	0.08	0.86	≤0.05	0.96
LA	0.73	0.24	0.09	1.06
TX	0.20	0.07	≤0.05	0.29
LA	0.36	0.21	0.05	0.62
LA	0.07	0.07	≤0.05	0.16
LA	0.13	0.10	0.10	0.33

State	Iprodione residues in rice commodities, ppm:			
	Parent	Isomer	RP32490	Total
MS	0.41	0.10	≤0.05	0.54
MS	0.19	0.11	≤0.05	0.32
MS	0.18	0.19	≤0.05	0.40
LA	0.68	0.45	≤0.05	1.16
Rice Straw:				
AR	0.73	2.11	0.25	3.09
CA	0.34	0.30	≤0.05	0.66
MS	0.55	1.18	0.75	2.48
MS	0.56	0.94	0.89	2.39
AR	0.15	0.70	0.22	1.07
AR	0.63	0.75	0.18	1.56
MS	≤0.05	0.08	≤0.05	0.13
TX	0.31	0.35	0.07	0.73
LA	0.91	2.88	0.22	4.01
LA	0.86	0.93	0.21	2.00
LA	0.60	0.56	0.15	1.31
MS	0.52	1.29	≤0.05	1.84
MS	0.42	1.57	1.04	3.03
MS	0.42	0.80	1.05	2.27
LA	0.77	1.23	0.14	2.14

Table note: Rate for each trial was 2X 0.5 lb ai/A, both before heading.

From these data, average residue values, respectively, are 0.57 ppm for rice grain, and 1.91 ppm for the animal feed commodity rice straw.

Phase 4 Review found rice processing data adequate for reregistration, contingent on storage stability data. A subsequent review concluded that storage stability data are adequate for crop commodities (CBRS 14162, 12/27/94, S.A. Knizner). Rice processing data were reviewed as part of a petition (PP6F3443, 3/17/87, R.W. Cook). Concentration factors

during processing of rice grain, averaged for two determinations were 4.50 (4.23, 4.76) for hulls and 0.11 (0.08, 0.14) for polished rice. Since these averages are not significantly different from the maximum concentration factor for each commodity, the averages will be used in determining anticipated residues for acute and cancer risk.

Commodities in the DRES run of 4/29/93 were rice, rough; and rice, milled. The comparable commodities for which residue data are available are rice, grain; and rice, polished. The rice commodities grain, hulls, and straw are potential animal feed items.

For acute risk, the tolerance value of 10 ppm for rice grain will be used for rice, rough; and the factor from processing data will be applied to give anticipated residues of 1.1 ppm for polished rice.

Summary, rice. Anticipated residues, cancer risk, on rice commodities were based on field trials and processing data, as appropriate. Combined iprodione anticipated residues were determined for the food items rice, rough; and rice, milled; and for the animal feed items grain, hulls, and straw. Anticipated residues, cancer risk, are:
rice, rough, 0.57 ppm;
rice, milled, 0.063 ppm;

rice, grain, 0.57 ppm;
rice, hulls, 2.56 ppm;
rice, straw, 1.91 ppm.

Anticipated residues, acute risk, based on the tolerance for rice grain, adjusted by processing data, are
rice, rough, 10 ppm;
rice, milled, 1.1 ppm.

Almonds

The only tree nut crop for which iprodione tolerances are established is almonds. Data in Tables 4 and 5 indicate that FDA and FOODCONTAM sampling of almonds was minimal, so field trial data will be used to determine anticipated residues.

Phase 4 Review found that field trial data on almonds were adequate for ground application only, contingent on adequate storage stability data. As indicated above, subsequent review found storage stability data adequate to support all crop commodities (CBRS 14162, 12/27/94, S.A. Knizner). For reregistration, additional data are required for aerial and chemigation applications. For the purposes of this assignment, the available data will be used to determine anticipated residues.

The field trial data for ground application have been reviewed for a petition (PP5F3241, 6/26/85, M.P. Firestone). Trials were conducted in CA at rates at or above the maximum label application rate of 4X 0.5 lb ai/A, with applications made at times of the growing season specified by the label. The field trial data are reproduced below, with half the stated limit of detection used in calculating total iprodione residues.

Table 8. Almond field trial data.

Sample	Total applied, lb ai/A	Iprodione residues, ppm:			
		Parent	Isomer	RP32490	Total
Almond Nutmeat	2.0	≤0.05	≤0.05	≤0.05	0.075
	2.0	≤0.05	≤0.05	≤0.05	0.075
	2.0	≤0.05	≤0.05	≤0.05	0.075
	2.5	0.18	0.06	≤0.05	0.26
Almond Hulls	2.0	1.06	0.48	0.08	1.62
	2.0	1.20	0.07	≤0.05	1.30
	2.0	0.60	0.09	0.09	0.78
	2.5	1.29	0.06	0.28	1.63

Table note: All trials were conducted in CA; the maximum label rate is 4X 0.5 lb ai/A.

Using the data in the table above, and normalizing residues from the trail at 2.5 lb ai/A to the 1X label rate, gives average values of 0.10 ppm for nutmeat, and 1.25 ppm for the animal feed commodity almond hulls.

Summary, almonds. Anticipated residues, cancer risk, based on field trial data, for the food item almond nutmeat and the animal feed item almond hulls, are:
almond nutmeat, 0.10 ppm;
almond hulls, 1.25 ppm.

Anticipated residues, acute risk, should be based on the tolerance for almond nutmeat.

Additional crops.

The DRES run of 4/29/93 (R. Griffin) did not include the commodities ginseng, dried ginseng, or chinese mustard (regional registration) for which tolerances were established at the time. This may have been because these commodities represent a minimal portion of the human diet. If it would be appropriate to include

these commodities in the DRES run, CBRS recommends using the tolerance values, 2.0 ppm for ginseng, 4.0 ppm for dried ginseng, and 15.0 ppm for chinese mustard (FL only) (40 CFR 180.399(a) and 180.3750), for both acute and cancer risk. If residues from these commodities should prove to generate a significant estimated risk, then CBRS can refine anticipated residues based on field trial data at a later time.

Summary, additional crops. For both acute and cancer risk, the following values, based on tolerances, should be used for combined anticipated residues of iprodione:
ginseng, 2.0 ppm;
dried ginseng, 4.0 ppm;
chinese mustard (FL only), 15.0 ppm.

ANTICIPATED RESIDUES, ANIMAL COMMODITIES

Determination of residues

The number of samples from FDA monitoring and FOODCONTAM data together are too small to determine anticipated residues for animal feed items or animal commodities. USDA's Food Safety and Inspection Service has a program to monitor residues in animal commodities. The most recent material on file at CBRS on USDA's National Residue Program Plan is the 1990 report. As of 1990, iprodione residues were not evaluated in the USDA program, and iprodione was not ranked for consideration to be included in the program. Monitoring data therefore are not available to determine anticipated residues of iprodione in animal commodities. For cancer risk, anticipated residues in animals will be determined by calculating anticipated dietary burdens in animals and using data on transfer of residues during animal feeding studies. For acute risk, anticipated residues in animal commodities should be tolerances in all cases, uncorrected for percent crop treated data.

Crops with animal feed commodities for which iprodione tolerances are established are:
Almonds, beans, carrots, grapes, peanuts, potato, and rice (see Table 11 below on Iprodione feed commodities). In some cases described above, anticipated residues have been calculated for feed items as well as food items for a given crops. Where anticipated residues were determined from field trials, these will be adjusted for percent crop treated before calculating an animal diet for cancer risk. For other commodities, anticipated residues will be determined below:

Animal feed items.

Almonds. The applicable animal feed item is almond hulls. Anticipated residues determined above for hulls were 1.25 ppm for cancer risk, based on field trial data. The upper range for

reported percent crop treated data is 56%. Adjusting the value for cancer risk by percent treated gives 0.70 ppm for anticipated residues on the feed item hulls.

Beans. Animal feed items are seed, forage, and hay/straw. Bean seed is dried seed for dried shelled beans, succulent seed without pod for succulent shelled beans (such as limas), or succulent seed with pod for edible-pod beans (such as green beans). Anticipated residues were determined above for dry and succulent beans based on FDA monitoring data, and percent crop treated was already taken into account for cancer risk. The higher residues occurred in succulent beans, and will be used for the feed item bean seed: 0.0016 ppm for cancer risk.

For forage and hay/straw, field trial data will be used. Bean forage is the whole green plant; bean hay is the succulent plant, cut and dried, prior to bean harvest; bean straw is the dried plant, material remaining after bean harvest. Data on combined iprodione residues on beans, dry and succulent, were recently reviewed and found acceptable to support reregistration (CBRS 13730, 13960, 13959, 14496, 14134, 1/27/95, S.A. Knizner). Tolerances are established for bean forage and vine hay of dried beans (40 CFR 180.399). No tolerances are established for hay of succulent beans because there is a feeding restriction on current labels. However, the Updated Livestock Feeds Table, in Publication EPA 738-K-94-001, June 1994, concluded that restrictions against feeding bean forage or hay to livestock are no longer considered practical. The recent review of residue data on beans recommended a label restriction to specify that bean plants should not be cut for hay until 45 days after the last application; CBRS had previously required a label modification specifying a 45 day PHI for beans (CBRS 13730ff, 1/27/95, S.A. Knizner).

In the submission recently reviewed, residue data were provided for bean hay and forage (Ibid.). Data were also provided for residues on bean vines, a commodity no longer listed in the Updated Livestock Feeds Table. Because data on hay and forage were provided, and because these commodities include portions of the plant in addition to vines, the data on vines will not be used in determining anticipated residues. Data were also provided on succulent bean hay cut 7 days after treatment. Because these data are atypical considering the recommended label restriction or the present label restriction on feeding, they also will not be used in determining anticipated residues. The following table summarizes residue data for combined iprodione residues on bean hay and forage, for trials at the maximum label rate of two foliar applications, each at approximately 1.0 lb ai/A. Residue data were adjusted by converting nondetectable residues (≤0.05 ppm) to half the limit of detection.

Table 9. Combined iprodione residues in bean feed items.

Commodity	Application equipment	Posttreatment interval, days	Site	Combined residues, ppm
Dry beans, 50% WP formulation:				
Hay	Ground	45	ID	9.27
		46	NE	19.08
		49	NY	4.84, 7.22
		55	CA	86.09
		66	CA	23.54
		72	CA	13.00
Dry beans, 4 lb/gal FlC formulation:				
Hay	Ground	14	MI	5.0, 5.9, 7.0
	Chemigation	20	CO	2.6. 2.8, 3.3
	Ground	20	CO	16.6, 20.8, 20.9
	Chemigation	32	CA	1.5, 2.0, 2.1
Succulent beans, 50% WP:				
Forage	Ground	3	FL	11.56
		9	OR	13.32
		15	WI	11.38
		18	NY	15.00, 24.74
		19	MI	11.94
		21	DE	1.28
		21	MI	7.14
		33	WI	1.54
	Aerial	9	NY	1.79
		10	OR	3.36
		15	WI	3.00

Table notes: Application rate in all cases was 2X at about 1.0 lb ai/A. Residues are summarized from CBRS 13730ff, 1/27/95, S.A. Knizner.

Considering the variability of residues with location and pretreatment interval in the table above, anticipated residues for cancer will be determined from averages of each of bean hay and bean forage. Averages are 13.3 ppm for hay, and 8.84 ppm for forage. These will be adjusted for 1% crop treated to give anticipated residues for cancer risk on feed items of 0.133 ppm for bean hay and 0.0884 ppm for bean forage.

Anticipated residues on feed items for cancer risk then become:
bean seed, 0.0016 ppm;
bean forage, 0.0884 ppm;
bean hay, 0.133 ppm.

Carrots. The applicable animal feed item is carrot, culls. Anticipated residues were determined above for carrots based on FDA monitoring data, and percent crop treated has already been accounted for cancer risk. Anticipated residues on the feed item carrot, culls are 0.021 ppm for cancer risk.

Grapes. Animal feed items are cull raisins, wet pomace, dried pomace, and raisin waste. Anticipated residues were determined above for these items as the following, for cancer risk:
cull raisins, 0.243 ppm;
wet pomace, 0.054 ppm;
dry pomace, 0.184 ppm;
raisin waste, 0.243 ppm.

Because these values were determined from FDA monitoring data, residues for cancer risk have already taken percent crop treated data into account.

Peanut. Animal feed items are meal, hay, hulls. Anticipated residues on peanut meal, based on field trial and processing data, were determined above as the same values as peanut oil, 0.012 ppm for cancer risk and 0.046 ppm for acute risk. Field trial data on peanut commodities including hay and hulls were reviewed when submitted in support of a petition (PP4G3037, 3/31/84, N. Dodd). Field trials were conducted at the maximum label rate of 3X 1.0 lb ai/A. Data were submitted for PHIs of 0, 3, 4, 5, 9, and 11 days. Present registered use calls for a PHI of 10 days, and data for the registered PHI or less will be used to determine anticipated residues. Field trial data for hay and hulls are summarized in the following table.

Table 10. Field trial data on peanut hulls and hay.

Location	PHI, days	Iprodione residues, ppm:			
		Parent	RP30228	RP32490	Combined
Hulls:					
OK	0	5.23	0.43	≤0.05	5.68
NC	0	0.91	≤0.05	0.09	1.02
VA	0	0.57	≤0.05	0.14	0.74
GA	3	0.39	0.06	0.06	0.51
TX	4	2.01	0.39	0.28	2.68
TX	4	1.21	0.28	0.22	1.71
TX	4	5.25	1.38	0.22	6.85
GA	5	0.67	0.07	0.73	1.47
GA	9	0.61	≤0.05	0.05	0.68
Hay:					
OK	0	61.63	2.19	1.15	64.97
NC	0	146.70	0.41	1.43	148.54
VA	0	28.31	0.31	0.34	28.96
GA	3	56.72	0.41	1.69	58.82
TX	4	39.42	0.29	0.69	40.40
TX	4	76.75	0.98	0.57	78.30
TX	4	15.60	0.16	0.47	16.23
GA	5	56.14	0.59	0.96	57.69
GA	9	89.71	8.50	6.42	104.63

Table notes: Application rates were 3X 1.0 lb ai/A for all trials. Data summarized from PP4G3037.

From the data in the table above, average residues are 2.37 ppm for hulls and 66.5 ppm for hay. Average values for peanut feed commodities are corrected for the upper range of reported percent crop treated, 3%. Anticipated residues for feed items then become for cancer risk:
peanut meal, 0.00036 ppm;
peanut hulls, 0.071 ppm;
peanut hay, 2.00 ppm.

Potato. Animal feed items are culls and processed waste. Anticipated residues for potatoes were determined above based on monitoring data, so percent crop treated data have already been taken into account. Processing data did not show a significant difference between residues in pulp and peel, so residues in processed waste will be set at the same value as whole potatoes. Anticipated residues in animal feed items, culls and processed waste, are 0.0023 ppm for cancer risk for each commodity.

Rice. Anticipated residues were already determined above for the feed items grain, hulls, straw. Residues for cancer risk should be adjusted for percent crop treated, which was an upper range of 8%. Anticipated residues in the feed for cancer risk are:
rice grain, 0.046 ppm;
rice hulls, 0.205 ppm;
rice straw, 0.153 ppm.

Animal diets

The table below lists feed commodities with iprodione tolerances, along with the expected maximum portion of animal diets represented by a given commodity. The maximum dietary burden for each item is determined for cancer risk. Hypothetical animal diets are taken from the Updated Livestock Feeds Table, Publication EPA 738-K-94-001, June 1994. In accordance with the instructions accompanying the Updated Livestock Fees Table, dietary burdens are adjusted on a % dry matter basis. The text accompanying the Livestock Feeds Table notes that in general, such an adjustment is not necessary for poultry and swine because most of the feed items for these animals are dry. However, because only a small number of feed items for poultry and swine have iprodione tolerances and a few swine feed items have low dry matter percentages, the adjustment has been made for these animal diets as well for this assignment.

Table 11. Dietary burden, cancer risk, from Iprodione feed commodities.

Crop	Feed item (Combined anticipated Residues, ppm)	% Dry Matter	Percent of livestock diet [animal dietary burden, ppm]:				
			Beef cattle	Dairy cattle	Poultry	Breeding Swine	Finishing Swine
Almond	Hulls (0.70)	90	25 [0.19]	15 [0.12]	NU	10 [0.078]	NU
Bean	Seed (0.0016)	88	15 [<0.001]	15 [<0.001]	10 [<0.001]	25 [<0.001]	15 [<0.001]
	Forage (0.0884)	35	30 [0.076]	60 [0.152]	NU	NU	NU
	Straw/Hay (0.133)	89	15 [0.022]	10 [0.015]	NU	NU	NU
Carrot	Culls (0.021)	12	40 [0.070]	25 [0.044]	NU	20 [0.035]	10 [0.017]
Grapes	Raisin, culls (0.243)	85	25 [0.071]	20 [0.057]	NU	20 [0.057]	NU
	Pomace, wet (0.054)	15	20 [0.072]	NU	NU	NU	NU
	Pomace, dried (0.184)	89	20 [0.041]	NU	NU	NU	NU
	Raisin waste (0.243)	79	25 [0.077]	10 [0.031]	NU	NU	NU
Peanut	Meal (0.00036)	85	15 [<0.001]	20 [<0.001]	25 [<0.001]	20 [<0.001]	15 [<0.001]
	Hay (2.00)	85	25 [0.588]	60 [1.41]	NU	10 [0.235]	NU
	Hulls (0.071)	95	15 [0.011]	NU	NU	NU	NU
Potato	Culls (0.0023)	20	75 [0.0086]	50 [0.0057]	NU	50 [0.0057]	50 [0.0057]
	Processed waste (0.0023)	12	75 [0.014]	50 [0.0096]	NU	25 [0.0048]	NU
Rice	Grain (0.046)	88	60 [0.031]	50 [0.026]	60 [0.031]	60 [0.031]	65 [0.034]
	Hulls (0.205)	90	10 [0.023]	10 [0.023]	15 [0.034]	10 [0.023]	NU
	Straw (0.153)	90	10 [0.017]	10 [0.017]	NU	NU	NU

Table note: NU=not used in a given animal diet.

Ensminger and Olentine, Feeds and Nutrition, 1978, identify three major categories for beef and dairy cattle feed: 1) grains, byproduct feeds, roots and tubers; 2) protein supplements; and 3) dry forages and silages. The preferred feed item for the first category is corn grain, with the following feed items with iprodione tolerances identified as substitutes: almond hulls, cull beans, cull carrots, potatoes, raisin cull and waste, and rice grain. The preferred item for protein supplements is soybean meal, with the following feed items with iprodione tolerances as substitutes: legume screenings and peanut meal. For the third category, the preferred item is alfalfa hay, with the following feed items with iprodione tolerances as substitutes: bean straw, grape pomace, grass-legume mixed hay, and rice straw.

Of commodities with iprodione tolerances, those expected to have the most widespread commercial distribution would be grains and legumes. For determining cancer risk, reasonable cattle diets can be constructed with rice grain and commodities of peanuts and beans. Other commodities, such as almond hulls, may contribute to local cattle diets. However, the iprodione dietary burden contributed by any local commodity is small compared to the burden from peanut hay (see Table 11), and separate local diets will therefore not be calculated. Cattle diets for cancer risk, consisting of grains and legumes, and with each major category described above represented, are given in the table below:

Table 12. Cattle diets, cancer risk

Commodity	Anticipated residues, ppm	% dry matter	% of animal diet	Dietary burden, ppm
Beef cattle				
Rice grain	0.046	88	60	0.031
Bean seed	0.0016	88	15	<0.001
Peanut hay	2.00	85	25	0.588
Total:			100	0.619
Dairy cattle				
Rice grain	0.046	88	45	0.024
Bean seed	0.0016	88	10	<0.001
Peanut hay	2.00	85	45	1.059
Total:			100	1.083

Ensminger and Olentine, Feeds and Nutrition, 1978, identify similar major feed categories for swine as for cattle, but describe fewer alternative commodities. The major categories are 1) grains, byproduct feeds, roots and tubers; 2) protein supplements; and 3) pastures and dry legumes. The preferred feed item for the first category is corn, with the following feed items with iprodione tolerances listed as substitutes: cull beans, carrots, peanuts, potatoes, rough rice, and rice polishings. Soybean meal is the preferred item for the second major category, with the following iprodione feed items as substitutes: peanut meal and peanuts. The third major category includes pasture grass and legume commodities. As with cattle, the single feed commodity contributing the highest dietary burden is peanut hay, and commodities with more local distribution make smaller contributions; separate local diets will therefore not be calculated for swine. For cancer risk a swine diet consisting of grain and legume commodities can be created as follows:

Table 14. Swine diet, cancer risk

Commodity	Anticipated residues, ppm	% dry matter	% of animal diet	Dietary burden, ppm
Rice grain	0.046	88	60	0.031
Bean seed	0.0016	88	25	<0.001
Peanut hay	2.00	85	10	0.235
Total:			95	0.266

For poultry, Ensminger and Olentine list two major feed categories: 1) grains and byproduct feeds, and 2) protein supplements. Corn and soybean meal, respectively, are again the preferred items for these categories. For the first category, cull beans, rough rice, and rice polishings (hulls) are listed as alternatives. For the second category, peanut meal is an alternative.

Table 11 lists only four poultry commodities with iprodione tolerances. The only commodities that contribute a significant dietary burden are rice grain or rice hulls. A diet including 15% of rice hulls would give a dietary burden of 0.034 ppm; this value will be used for determining anticipated residues. It should be noted that under the unexpected situation where poultry diet consisted of both 15% rice hulls and 60% rice grain, the iprodione dietary burden would be less than twice the value with hulls alone.

Animal feeding data

Animal feeding studies have been submitted in support of previous petitions. A cattle feeding study was submitted in support of

petition PP 2F2728. Lactating cows were fed iprodione at 5, 15, 50, and 200 ppm in the diet for 28 days. At the 5 ppm feeding level, residues in milk were not reported, and residues in other cattle samples were nondetectable. Maximum combined residues of iprodione in cattle tissues and milk at the three higher feeding levels are summarized in the following table (PP 2F2728, M.F. Kovacs, 10/25/82):

Table 15. Summary of Iprodione residues in cattle feeding study.

Sample	Combined residues, ppm (transfer ratio, tissue:feed), at feeding levels of:		
	15 ppm	50 ppm	200 ppm
Meat	<0.05 (<0.0033)	0.07 (0.0014)	0.13 (0.0006)
Kidney	0.16 (0.0107)	0.80 (0.016)	2.87 (0.014)
Fat	0.05 (0.0033)	0.21 (0.0042)	0.52 (0.0026)
Liver	0.13 (0.0087)	0.66 (0.0132)	1.95 (0.00975)
Milk	0.10 (0.0067)	0.20 (0.004)	0.39 (0.00195)

For the cattle feeding study, transfer ratios decrease from 50 ppm to 200 ppm, suggesting a plateau effect. Anticipated residues will be determined using the ratios from the 50 ppm feeding study, except for milk, where the ratio at the 15 ppm feeding level is slightly higher.

A poultry feeding study was submitted in support of petition PP 4F3129. Hens were fed iprodione at 2, 20, and 100 ppm in the diet for 28 days. The combined iprodione residues recovered from poultry tissues and eggs are summarized in the following table. Methods used to determine the residues in animal tissues from the feeding studies in cattle and poultry were the same ones which have been approved for publication in PAM II. Storage stability data were adequate for animal tissues. (PP 4F3129, 2/15/85, R.W. Cook):

Table 16. Summary, Iprodione residues in poultry feeding study.

Sample	Combined residues, ppm (transfer ratio, tissue:feed), at feeding levels of:		
	2 ppm	20 ppm	100 ppm
Meat	<0.05 (<0.025)	0.32 (0.016)	1.68 (0.0168)
Fat	0.18 (0.09)	2.57 (0.1285)	8.62 (0.0862)
Liver	0.61 (0.305)	4.10 (0.205)	13.40 (0.134)
Eggs	0.14 (0.07)	0.75 (0.0375)	2.17 (0.0217)

With the poultry feeding study, transfer ratios were generally lower at the 100 ppm feeding level compared to other feeding levels, suggesting a plateau. Highest transfer ratios were 0.0168 for meat, 0.129 for fat, 0.305 for liver, and 0.07 for eggs (human consumption of poultry kidney is negligible). These values will be used to determine anticipated residues in poultry.

Animal commodities

With the data above for anticipated animal dietary burdens and transfer ratios from feeding studies, anticipated residues can be determined for animal commodities. Anticipated residues for cattle commodities will be translated to commodities of goats and sheep. For swine, anticipated residues will be based on anticipated dietary burdens and transfer ratios from the cattle feeding studies. Because consumption, and calculated risk, of horse commodities is negligible, the tolerance value may still be used for horse. For the commodity meat byproducts, anticipated residues will be translated from meat; for the commodity organ meat, other, anticipated residues will be translated from the higher value of liver, kidney, or meat. For commodities in the DRES run, residue data are not available specifically on dried beef, poultry skin, milk fat solids, milk non-fat solids, or milk sugar. For commodities with these components, we recommend using the most appropriate commodity for which anticipated residues have been determined, adjusted by any default value built into DRES.

Anticipated residues in animal commodities are based on residues in animal feed items and transfer data from animal feeding studies, with the exception of horse, where anticipated residues are based on the highest tolerance. To determine anticipated residues for cancer risk, residues in feed items were adjusted for percent crop treated data. Anticipated residues for animal commodities for cancer risk are:

meat of cattle, goats, and sheep, 0.00087 ppm;
meat byproducts of cattle, goats, and sheep, 0.00087 ppm;
fat of cattle, goats, and sheep, 0.0026 ppm;
kidney of cattle, goats, and sheep, 0.0099 ppm;
liver of cattle, goats, and sheep, 0.0082 ppm;
meat, organ, other, of cattle, goats, and sheep, 0.0099 ppm;
milk, whole, 0.0073 ppm;
meat of hogs, 0.00037 ppm;
meat byproducts of hogs, 0.00037 ppm;
fat of hogs, 0.0011 ppm;
kidney of hogs, 0.0043 ppm;
liver of hogs, 0.0035 ppm;
meat, organ, other, of hogs, 0.0043 ppm;
horse, 3.0 ppm;
meat of poultry, 0.00057 ppm;
meat byproducts of poultry, 0.00057 ppm;
fat of poultry, 0.0044 ppm;
liver of poultry, 0.0104 ppm;
eggs, 0.0024 ppm.

For acute risk, anticipated residues for animal commodities should be tolerance values for all cases.

cc:Circ, Abbotts, RF, Iprodione List B File, SF, DRES (E. Doyle)
RDI:SVHummel:4/26/95:MSMetzger:4/27/95:FBSuhre:4/28/95
7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:4/28/95
JA11\iprodion.2a