RF
3-29-88

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

MAR 29 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Iprodione on Caneberries, PP#7F3542

FROM: J. Robert Tomerlin, Ph.D. 3/29/88
Tolerance Assessment System Staff
HED/RCB (TS 769C)

THRU: Karl Arne, Ph.D.
Branch Senior Scientist
HED/RCB (TS 769C)

TO: Lois Rossi, PM 21
Registration Division (TS 767)

Action Requested

Provide a dietary exposure analysis for the proposed crop group tolerance on caneberries (7F3542).

Discussion

1. A routine chronic TAS analysis was conducted with a reference dose (ADI) of 0.04 mg/kg body weight/day, based upon a NOEL of 4.2 mg/kg body weight/day from a 1 year dog feeding study. This value has been approved by TOX branch (12/19/86) and ORD (7/15/86).

2. Food uses evaluated include published tolerances from CFR 180.399, the proposed action for caneberries (Nelson to Rossi memo, 7/28/87), food additive tolerances from CFR 193.253, and pending actions on eggs, lettuce, and potatoes. Note that published tolerances of 15 ppm currently exist on boysenberries and raspberries; consequently, the new action for these two foods is an additional 10 ppm to bring the total to 25 ppm as specified in the petition. A summary of the tolerance information used in the analysis is attached as Table 1.

3. The TAS routine chronic analysis estimates the Theoretical Maximum Contribution (TMRC) for the general U.S. population and 22 population sub-groups. The TMRC for the overall U.S. population is 0.043 mg/kg/day, which occupies 108.4 per cent of the ADI. The two most highly affected sub-groups are non-nursing

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infants less than 1 year old and children 1 to 6 years old. A summary of the TMRC for each population sub-group is given in Table 2.

4. An examination of Table 3 shows that for the U.S. population, current published tolerances result in a TMRC of 0.04 mg/kg/day (99% of the ADI), to which the new action would add 0.0003 mg/kg/day (0.7% of the ADI). The TMRC for published and new tolerances would therefore be 0.04 mg/kg/day (99.7% of the ADI). Current pending tolerances on eggs, lettuce, and potato would add an additional 0.003 mg/kg/day (8.7% of the ADI), bringing the total TMRC to 0.043 mg/kg/day (108.4% of the ADI).

5. As stated previously (Tomerlin to Rossi memo, 3/25/88), the major contributors to the Iprodione TMRC, particularly for the two juvenile sub-groups, are grapes, milk, and peaches. The effect of the current action on caneberries is negligible.

cc: TAS Files
Reading file
circ.
PMSD
TOX (Rathman)
Iprodione SF
PP#7F3542

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A DATE: 03/29/88 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene)	1yr feeding- dog	Increased number of RBC	ADI 100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000	(under review).	ORD verified 7/15/87.
CAS No. 36734-19-7	100.00 ppm	prostate weights. NOEL	EPA RfD= 0.040000		WHO last reviewed 1977.
A.I. CODE: 109801	LEL= 15.0000 mg/kg	based on calc. dose.			
CFR No. 180.399	600.00 ppm	No evidence of oncogeni-	WHO RfD 0.300000		
	ONCO: Negative- 2 species	city in rats or mice.	Type: ADI		

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED	
01002AA	BLACKBERRIES	7F3542	25.0000			
01003AA	BOYSENBERRIES	5F3214			15.0000	
01003AA	BOYSENBERRIES	7F3542	10.0000			
01004AA	DEWBERRIES	7F3542	25.0000			
01005AA	LOGANBERRIES	7F3542	25.0000			
01006AA	RASPBERRIES	5F3214			15.0000	
01006AA	RASPBERRIES	7F3542	10.0000			
01007AA	YOUNGBERRIES	7F3542	25.0000			
01009AA	BLUEBERRIES	5F3214			15.0000	
01011AA	CURRANTS	5F3214			15.0000	
01014AA	GRAPES-FRESH	3F2964			60.0000	
01014DA	GRAPES-RAISINS	4H5415			300.0000	H
01014JA	GRAPES-JUICE	3F2964			60.0000	
03001AA	ALMONDS	5F3241			0.3000	
05001AA	APRICOTS-FRESH	3F2810			20.0000	
05001DA	APRICOTS-DRIED	3F2810			20.0000	
05002DA	CHERRIES-DRIED	2F2596			20.0000	
05002JA	CHERRIES-JUICE	2F2596			20.0000	
05003AA	NECTARINES	2F2596			20.0000	
05004AA	PEACHES-FRESH	2F2596			20.0000	
05004DA	PEACHES-DRIED	2F2596			20.0000	
05005AA	PLUMS(DAMSONS)-FRESH	3F2810			20.0000	
05005DA	PLUMS-PRUNES(DRIED)	3F2810			20.0000	
05005JA	PLUMS/PRUNE-JUICE	3F2810			20.0000	
06018AA	KIWI	2F2596			10.0000	
13005AA	BROCCOLI	6F3305			25.0000	
13013AA	LETTUCE-LEAFY VARIETIES	7F3481		25.0000		
13020AA	LETTUCE-UNSPECIFIED			25.0000		
13045AA	LETTUCE-HEAD VARIETIES	3F2840			15.0000	
13045AA	LETTUCE-HEAD VARIETIES			10.0000		
14003AA	CARROTS	7E3474			5.0000	
14007AA	GARLIC	3F2841			0.1000	
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	4F3111			0.5000	
14011DA	ONIONS-DEHYDRATED OR DRIED	4F3111			0.5000	
14013AA	POTATOES(WHITE)-WHOLE	6F3366		0.5000		
14013AB	POTATOES(WHITE)-UNSPECIFIED	6F3366		0.5000		
14013AC	POTATOES(WHITE)-PEELED	6F3366		0.5000		
14013DA	POTATOES(WHITE)-DRY	6H5496		0.5000		
14013HA	POTATOES(WHITE)-PEEL ONLY	6F3366		0.5000		
14017AA	SHALLOTS	4F3111			0.5000	

Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A DATE: 03/29/88 PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene) Caswell #470A CAS No. 36734-19-7 A.I. CODE: 109801 CFR No. 180.399	1yr feeding- dog NOEL= 4.2000 mg/kg 100.00 ppm LEL= 15.0000 mg/kg 600.00 ppm ONCO: Negative- 2 species	Increased number of RBC Heinz bodies, decreased prostate weights. NOEL based on calc. dose. No evidence of oncogenicity in rats or mice.	ADI 100 OPP RfD= 0.040000 EPA RfD= 0.040000 WHO RfD 0.300000 Type: ADI	Teratology- rat (under review).	TOX complete 12/19/86. ORD verified 7/15/87. WHO last reviewed 1977.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
15001AA	BEANS-DRY-GREAT NORTHERN				2.0000
15001AB	BEANS-DRY-KIDNEY				2.0000
15001AC	BEANS-DRY-LIMA				2.0000
15001AD	BEANS-DRY-NAVY (PEA)				2.0000
15001AE	BEANS-DRY-OTHER				2.0000
15001AF	BEANS-DRY-PINTO				2.0000
15002AA	BEANS-SUCCULENT-LIMA				2.0000
15003AA	BEANS-SUCCULENT-GREEN	4F3150			2.0000
15003AB	BEANS-SUCCULENT-OTHER	4F3150			2.0000
15003AC	BEANS-SUCCULENT-YELLOW,WAX	4F3150			2.0000
15006AA	PEANUTS-WHOLE	4F3129			0.5000
15013AA	MUNG BEANS (SPROUTS)				2.0000
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)				2.0000
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	4F3150			2.0000
15023AA	BEANS-DRY-PIGEON BEANS	4F3150			2.0000
15027AA	BEANS-UNSPECIFIED				2.0000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	4F3150			2.0000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	4F3150			2.0000
15031AA	BEANS-DRY-BLACKEYE PEAS(COWPEAS)				2.0000
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	4F3150			2.0000
27007OA	PEANUTS-OIL	4F3129			0.5000
43058AA	WINE AND SHERRY				60.0000
50000DB	MILK-NON-FAT SOLIDS	4F3129			0.5000
50000FA	MILK-FAT SOLIDS	4F3129			0.5000
50000SA	MILK SUGAR (LACTOSE)	4F3129			0.5000
53001BA	BEEF-MEAT BYPRODUCTS	4F3129			0.5000
53001BB	BEEF(ORGAN MEATS)-OTHER	4F3129			0.5000
53001DA	BEEF-DRIED	4F3129			0.5000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	4F3129			0.5000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	3F2964			3.0000
53001LA	BEEF(ORGAN MEATS)-LIVER	3F2964			3.0000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129			0.5000
53002BA	GOAT-MEAT BYPRODUCTS	4F3129			0.5000
53002BB	GOAT(ORGAN MEATS)-OTHER	4F3129			0.5000
53002FA	GOAT(BONELESS)-FAT	4F3129			0.5000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	3F2964			3.0000
53002LA	GOAT(ORGAN MEATS)-LIVER	3F2964			3.0000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129			0.5000
53005BA	SHEEP-MEAT BYPRODUCTS	4F3129			0.5000
53005BB	SHEEP(ORGAN MEATS)-OTHER	4F3129			0.5000

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A DATE: 03/29/88 PAGE: 3

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene) Caswell #470A CAS No. 36734-19-7 A.I. CODE: 109801 CFR No. 180.399	1yr feeding- dog NOEL= 4.2000 mg/kg 100.00 ppm LEL= 15.0000 mg/kg 600.00 ppm ONCO: Negative- 2 species	Increased number of RBC Heinz bodies, decreased prostate weights. NOEL based on calc. dose. No evidence of oncogenicity in rats or mice.	ADI 100 OPP RfD= 0.040000 EPA RfD= 0.040000 WHO RfD 0.300000 Type: ADI	Teratology- rat (under review).	TOX complete 12/19/86. ORD verified 7/15/87. WHO last reviewed 1977.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
53005FA	SHEEP(BONELESS)-FAT	4F3129			0.5000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	3F2964			3.0000
53005LA	SHEEP(ORGAN MEATS)-LIVER	3F2964			3.0000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	4F3129			0.5000
53006BA	PORK-MEAT BYPRODUCTS	4F3129			0.5000
53006BB	PORK(ORGAN MEATS)-OTHER	4F3129			0.5000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	4F3129			0.5000
53006KA	PORK(ORGAN MEATS)-KIDNEY	3F2964			3.0000
53006LA	PORK(ORGAN MEATS)-LIVER	3F2964			3.0000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	4F3129			0.5000
55008BA	TURKEY-BYPRODUCTS	3F2964			2.0000
55008LA	TURKEY-GIBLETS (LIVER)	3F2964			3.0000
55008MA	TURKEY-FLESH(W/O SKIN & W/O BONES)	4F3129			0.5000
55008MB	TURKEY-FLESH(+SKIN & W/O BONES)	3F2964			2.0000
55008MC	TURKEY-UNSPECIFIED	4F3129			0.5000
55013BA	POULTRY/OTHER-BYPRODUCTS	4F3129			0.5000
55013LA	POULTRY/OTHER-GIBLETS(LIVER)	3F2964			3.0000
55013MA	POULTRY/OTHER-FLESH (+SKIN & W/O BONES)	4F3129			0.5000
55014AA	EGGS-WHOLE	3F2964		0.8000	
55014AB	EGGS-WHITE ONLY	3F2964		0.8000	
55014AC	EGGS-YOLK ONLY	3F2964		0.8000	
55015BA	CHICKEN-BYPRODUCTS	4F3129			0.5000
55015LA	CHICKEN-GIBLETS(LIVER)	3F2964			3.0000
55015MA	CHICKEN-FLESH(W/O SKIN & W/O BONES)	4F3129			0.5000
55015MB	CHICKEN-FLESH(+SKIN & W/O BONES)	3F2964			2.0000

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 03/29/88 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Iprodione (Glycophene)	1yr feeding- dog	Increased number of RBC	ADI 100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000	(under review).	ORD verified 7/15/87.
CAS No. 36734-19-7	100.00 ppm	prostate weights. NOEL	EPA RfD= 0.040000		WHO last reviewed 1977.
A.I. CODE: 109801	LEL= 15.0000 mg/kg	based on calc. dose.			
CFR No. 180.399	600.00 ppm	No evidence of oncogeni-	WHO RfD 0.300000		
	ONCO: Negative- 2 species	city in rats or mice.	Type: ADI		

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.039612	0.043376	108.439908	9.408980		
U.S. POPULATION - SPRING SEASON	0.036606	0.040534	101.335577	9.820242		
U.S. POPULATION - SUMMER SEASON	0.043401	0.047261	118.151377	9.649497		
U.S. POPULATION - FALL SEASON	0.039670	0.043103	107.758218	8.583877		
U.S. POPULATION - WINTER SEASON	0.038796	0.042338	105.845285	8.855405		
NORTHEAST REGION	0.045648	0.049462	123.654872	9.534137		
NORTH CENTRAL REGION	0.038407	0.042025	105.062300	9.044005		
SOUTHREN REGION	0.028953	0.032121	80.302062	7.918905		
WESTERN REGION	0.051744	0.056286	140.715693	11.356400		
HISPANICS	0.038516	0.042529	106.321765	10.032595		
NON-HISPANIC WHITES	0.041672	0.045527	113.818523	9.637645		
NON-HISPANIC BLACKS	0.027658	0.030148	75.370648	6.224838		
NON-HISPANIC OTHERS	0.032295	0.035897	89.742273	9.003593		
NURSING INFANTS (< 1 YEAR OLD)	0.052761	0.053161	132.902832	0.999967		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.126605	0.127888	319.719370	3.207155		
FEMALES (13+ YEARS, PREGNANT)	0.030977	0.034154	85.384955	7.942553		
FEMALES 13+ YEARS, NURSING	0.046454	0.050700	126.750225	10.615130		
CHILDREN (1-6 YEARS OLD)	0.098517	0.103114	257.785500	11.492515		
CHILDREN (7-12 YEARS OLD)	0.052233	0.056543	141.356310	10.773765		
MALES (13-19 YEARS OLD)	0.026106	0.029451	73.627752	8.362820		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.025799	0.029039	72.597215	8.099090		
MALES (20 YEARS AND OLDER)	0.028321	0.031674	79.184872	8.381447		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.031610	0.035389	88.473045	9.448812		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

Table 3

TOLERANCE ASSESSMENT SUMMARY FOR Iprodione (Glycophene) DATE: 03/29/88
CASWELL #470A

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.039612	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	99.030928	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000269	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.673110	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.039882	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	99.704038	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.003494	MG/KG/DAY
THIS TMRC WILL OCCUPY	8.735870	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.043376	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	108.439908	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.126605	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	316.512215	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000018	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.043850	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.126622	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	316.556065	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.001265	MG/KG/DAY
THIS TMRC WILL OCCUPY	3.163305	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.127888	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	319.719370	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.098517	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	246.292985	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000397	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.992492	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.098914	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	247.285478	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.004200	MG/KG/DAY
THIS TMRC WILL OCCUPY	10.500023	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.103114	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	257.785500	% OF THE ADI.