4-7-88

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

APR 7 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Revised Dietary Exposure Analysis for Iprodione on Caneberries (7F3542)

FROM: J. Robert Tomerlin, Ph.D.
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 revised dietary exposure analysis for Iprodione on caneberries (7F3542) (Tomerlin to Rossi memo, 3/29/88) taking into account newly published tolerances of which the TAS staff were unaware.

Discussion

1. The TAS staff learned after distribution of the cited memorandum (Mario Fiol, personal communication) that tolerances for lettuce which were designated as pending tolerances had been recently published. Consequently, the analysis was repeated classifying all lettuce tolerances as published and including all other pending tolerances.

2. A TAS routine chronic exposure analysis was conducted using reference doses as specified in the cited memorandum.

3. Food uses evaluated include published tolerances from CFR 180.399, the proposed action for caneberries (Nelson to Rossi memo, 7/28/87), and food additive tolerances from CFR 193.253. In this analysis, published tolerances for lettuce are: 25 ppm for leaf lettuce and unspecified lettuce, and 15 ppm for head lettuce. In addition, all pending tolerances have been included in the analysis. A summary of the tolerance information used in the analysis is attached as Table 1.

4. The TAS routine chronic exposure analysis estimates the Theoretical Maximum Residue Contribution (TMRC) for the general

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U.S. population and 22 population sub-groups. The TMRC for the overall U.S. population is 0.042 mg/kg/day, which occupies 124.7 per cent of the ADI. A summary of the TMRC's for all the population sub-groups is given in Table 2.

5. Current published tolerances exceed 100 per cent of the ADI for the U.S. population, non-nursing infants, and children 1 to 6 years old (Table 3). However, the proposed action on caneberries is negligible, contributing from 0.04 to 1.0 per cent of the ADI. Other pending tolerances contribute from 21.4 to 44.6 per cent of the ADI.

cc: TAS Files
Reading File
circ.
PMSD

TOX (Rathman)
Iprodione SF
PP#7F3542

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A DATE: 04/06/88 PAGE: 1

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 oncogeni- city in rats or mice.	ADI SF --> 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	
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	
01016AA	STRAWBERRIES	7F3510		15.0000		
03001AA	ALMONDS	5F3241			0.3000	
05001AA	APRICOTS-FRESH	3F2810			20.0000	
05001DA	APRICOTS-DRIED	3F2810			20.0000	
05002AA	CHERRIES-FRESH				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	
11005AA	TOMATOES-WHOLE	7F3545		3.0000		
11005JA	TOMATOES-JUICE	7F3545		3.0000		
11005RA	TOMATOES-PUREE	7F3545		3.0000		
11005TA	TOMATOES-PASTE	7F3545		3.0000		
11005UA	TOMATOES-CATSUP	7F3545		3.0000		
13002AA	CELERY	7F3554		25.0000		
13005AA	BROCCOLI	6F3305			25.0000	
13013AA	LETTUCE-LEAFY VARIETIES	7F3481			25.0000	
13016AA	FENNEL	7F3554		25.0000		
13020AA	LETTUCE-UNSPECIFIED				25.0000	
13045AA	LETTUCE-HEAD VARIETIES	3F2840			15.0000	
14003AA	CARROTS	7E3474			5.0000	
14007AA	GARLIC	3F2841			0.1000	

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Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A DATE: 04/06/88 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 SF --> 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
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
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
24004AA	RICE-ROUGH	6F3443		10.0000	
24004AB	RICE-MILLED	6F3443		10.0000	
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

Table 1, continued

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A DATE: 04/06/88 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 SF --> 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
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
53003AA	HORSE			3.0000	
53005BA	SHEEP-MEAT BYPRODUCTS	4F3129			0.5000
53005BB	SHEEP(ORGAN MEATS)-OTHER	4F3129			0.5000
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: 04/06/88 PAGE: 1

CHEMICAL INFORMATION	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.

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	0.041061	0.049894	124.735728	22.083250		
U.S. POPULATION - SPRING SEASON	0.038328	0.047471	118.677667	22.856832		
U.S. POPULATION - SUMMER SEASON	0.044939	0.053807	134.517735	22.169440		
U.S. POPULATION - FALL SEASON	0.040928	0.049401	123.503060	21.182452		
U.S. POPULATION - WINTER SEASON	0.040070	0.048606	121.515393	21.339775		
NORTHEAST REGION	0.047330	0.056748	141.871030	23.545482		
NORTH CENTRAL REGION	0.039718	0.048302	120.754210	21.460053		
SOUTHREN REGION	0.030132	0.038037	95.093653	19.763920		
WESTERN REGION	0.053549	0.063135	157.838715	23.966165		
HISPANICS	0.039889	0.051442	128.605613	28.883855		
NON-HISPANIC WHITES	0.043137	0.051818	129.543945	21.701900		
NON-HISPANIC BLACKS	0.028961	0.036161	90.403437	18.001018		
NON-HISPANIC OTHERS	0.034445	0.049505	123.762422	37.649613		
NURSING INFANTS (< 1 YEAR OLD)	0.053051	0.060325	150.812865	18.185635		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.128562	0.146407	366.017493	44.612422		
FEMALES (13+ YEARS, PREGNANT)	0.032007	0.038974	97.433808	17.415390		
FEMALES 13+ YEARS, NURSING	0.047962	0.056257	140.641287	20.736617		
CHILDREN (1-6 YEARS OLD)	0.101659	0.117692	294.228813	40.082368		
CHILDREN (7-12 YEARS OLD)	0.054049	0.066516	166.289175	31.166520		
MALES (13-19 YEARS OLD)	0.027358	0.036111	90.278385	21.883690		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.026848	0.034335	85.837605	18.718473		
MALES (20 YEARS AND OLDER)	0.029453	0.036813	92.032885	18.400315		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.032866	0.039712	99.279230	17.115005		

*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: 04/05/88
CASWELL #470A

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.041061	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	102.652478	% 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:	0.041330	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	103.325588	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.008564	MG/KG/DAY
THIS TMRC WILL OCCUPY	21.410140	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.049894	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	124.735728	% OF THE ADI.

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.128562	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	321.405070	% 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:	0.128580	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	321.448920	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.017827	MG/KG/DAY
THIS TMRC WILL OCCUPY	44.568573	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.146407	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	366.017493	% OF THE ADI.

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.101659	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	254.146445	% 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:	0.102056	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	255.138938	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.015636	MG/KG/DAY
THIS TMRC WILL OCCUPY	39.089875	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.117692	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	294.228813	% OF THE ADI.