

US EPA ARCHIVE DOCUMENT

6-14-88



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

JUN 14 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7G3525. Iprodione on Stored Corn Grain: TAS
Dietary Exposure Analysis.

FROM: Susan L. Stanton *Susan L. Stanton* 06/13/88
Tolerance Assessment Program
HED/RCB (TS-769C)

THRU: Karl Arne, Ph.D. *e. Fick farka*
Branch Senior Scientist 06/14/88
HED/RCB (TS-769C)

TO: Lois Rossi/Mario Fiol, PM 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

Action Requested

Provide TAS estimates of dietary exposure to the fungicide iprodione from the proposed experimental use on stored field corn grain.

RCB has reviewed the petition and, TOX considerations permitting, recommends that the proposed tolerance of 20 ppm be established to cover residues which may occur as a result of the proposed experimental use (memo L. Propst to L. Rossi, 06/08/88).

Discussion

1. A routine chronic exposure analysis was conducted using a Reference Dose (ADI) of 0.04 mg/kg body weight/day based on a NOEL of 4.2 mg/kg/day from a 1-year dog feeding study with a safety factor of 100. This value has been approved by the Tox Branch ADI Committee (12/19/86) and verified by the Agency reference dose committee (07/15/87).

2. The food uses evaluated were those established under 40 CFR 180.399 and 21 CFR 193.253, the proposed experimental use on stored field corn grain, and proposed uses on the following commodities: strawberries (7F3510), tomatoes (7F3545), celery (7F3554), and rice (6F3443). Since the last TAS analysis of exposure to iprodione (memo Tomerlin to Rossi, 04/21/88), tolerances have been established on caneberries at 25 ppm and

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potatoes at 0.5 ppm (Personal communication Mario Fiol, 06/13/88). Table 1 provides a complete listing of residues used in the analysis.

3. The TAS routine chronic analysis calculates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2) and compares this exposure estimate to the reference dose (ADI in this case).

The TMRC from all established and proposed food uses for the overall U.S. Population was calculated to be 0.058696 mg/kg body weight/day, which occupies approximately 147% of the ADI. The two most highly exposed population subgroups were non-nursing infants (TMRC = 0.165949 mg/kg/day or 415% of the ADI) and children, 1-6 years (TMRC = 0.136620 or 342% of the ADI). The effect of the current action (PP#7G3525; field corn grain) on exposure is shown below:

	<u>Established Tolerances</u>	<u>Current Action (Corn Grain)</u>	<u>Other Proposed Uses</u>	<u>Total Exposure</u>
U.S. Population	0.044019 ^a (110.0%) ^b	0.006679 (16.7%)	0.007998 (20.0%)	0.058696 (146.7%)
Infants (Non-Nurs)	0.129277 (323.2%)	0.019542 (48.9%)	0.017130 (42.8%)	0.165949 (414.9%)
Children, 1-6 yrs.	0.104793 (262.0%)	0.017316 (43.3%)	0.014511 (36.3%)	0.136620 (341.5%)

^aTMRC expressed as mg/kg body wt./day.

^bTMRC as a percent of the ADI.

4. These exposure estimates are based on the assumption that residues would be present at tolerance levels on foods as eaten and that 100% of crops would be treated with iprodione. Since the proposed EUP would involve treating a maximum of 160,000 bushels of corn, or less than 0.01% of the total U.S. corn production (from 1986 Agricultural Statistics), and since residues in foods as eaten are often reduced by processing (washing, cooking, etc.), the actual exposure would likely be considerably lower than that which is reported here.

CC: Stanton (RCB), Propst (RCB), TAS File, PP#7G3525, Iprodione SF, TOX, Circulation (7), RF, PMSD.

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A

DATE: 06/13/88

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DA. JAPS/COMMENTS	STATUS
			ADI	SF -->		
Iprodione (Glycophene)	1 yr feeding- dog	Increased number of RBC	100	100	Teratolgy- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RED= 0.040000		(under review).	EPA verified 7/15/87.
CAS No. 36734-19-7	NOEL= 100.00 ppm	prostate weights. NOEL	EPA RED= 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-				
	ONCO: Negative- 2 species	city in rats of mice				

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		PUBLISHED
			NEW	PENDING	
01002AA	BLACKBERRIES	7F3542			25.0000
01003AA	BOYSENBERRIES	7F3542			25.0000
01004AA	DEWBERRIES	7F3542			25.0000
01005AA	LOGANBERRIES	7F3542			25.0000
01006AA	RASPBERRIES	7F3542			25.0000
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			
03001AA	ALMONDS	5F3241	15.0000		
05001AA	APRICOTS-FRESH	3F2810			0.3000
05001DA	APRICOTS-DRIED	3F2810			20.0000
05002AA	CHERRIES-FRESH				20.0000
05002DA	CHERRIES-DRIED				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			
13020AA	LETTUCE-UNSPECIFIED				25.0000
13045AA	LETTUCE-HEAD VARIETIES	3F2840			25.0000
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

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Table 1 (con't.)

CHEMICAL INFORMATION FOR CASWELL NUMBER 470A

DATE: 06/13/88

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->		
Iprodione (Glycophene)	1 yr feeding- dog	Increased number of RBC	100	100	Teratology- rat	1. TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000		(under review)	EPA verified 7/15/87.
CAS No. 36734-19-7	NOEL= 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-				
	ONCO: Negative- 2 species	city in rats or mice.				

FOOD CODE	FOOD NAME	PETITION NUMBER	NEM	TOLERANCE (PPM)	
				PENDING	PUBLISHED
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	6F3366			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	4F3150			2.0000
15003AA	BEANS-SUCCULENT-GREEN	4F3150			2.0000
15003AB	BEANS-SUCCULENT-OTHER	4F3150			2.0000
15003AC	BEANS-SUCCULENT-YELLOW, MAX	4F3129			2.0000
15006AA	PEANUTS-WHOLE				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 (COMPEAS)				2.0000
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	4F3150			2.0000
24002EA	CORN, GRAIN-ENDOSPERM	7G3525	20.0000		
24002HA	CORN, GRAIN-BRAN	7G3525	20.0000		
24002SA	CORN SUGAR	7G3525	20.0000		
24004AA	RICE-ROUGH	6F3443		10.0000	
24004AB	RICE-MILLED	6F3443		10.0000	
270020A	CORN, GRAIN-OIL	7G3525			
270070A	PEANUTS-OIL	4F3129	20.0000		
43058AA	WINE AND SHERRY				0.5000
50000DB	MILK-NON-FAT SOLIDS	4F3129			60.0000
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

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Table 1 (con't.)

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->		
Iprodione (Glycophene)	lyr feeding- dog	Increased number of RBC	100	100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4.2000 mg/kg	Heinz bodies, decreased	OPP RfD= 0.040000		(under review)	EPA verified 7/15/87.
CAS No. 36734-19-7	NOEL= 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-				
	ONCO: Negative- 2 species	cily in rats or mice.				

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	
				PENDING	PUBLISHED
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
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

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Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 06/13/88

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	SF -->		
Iprodione (Glycophene)	1 yr feeding- dog	Increased number of RBC		100	Teratology- rat	TOX complete 12/19/86.
Caswell #470A	NOEL= 4,2000 mg/kg	Heinz bodies, decreased			OPP RFD= 0.040000	EPA 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 uncogeni-				
	ONCO. Negative- 2 species	city in rats or mice.				
TOTAL TMRC (MG/KG BODY WEIGHT/DAY)						
POPULATION SUBGROUP		CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC
U.S. POPULATION - 48 STATES		0.044019	0.058696	146.740273	36.691587	
U.S. POPULATION - SPRING SEASON		0.041415	0.056226	140.564650	37.026695	
U.S. POPULATION - SUMMER SEASON		0.047997	0.062901	157.253640	37.261058	
U.S. POPULATION - FALL SEASON		0.043558	0.058142	145.355788	36.461935	
U.S. POPULATION - WINTER SEASON		0.042840	0.057224	143.060165	35.960760	
NORTHEAST REGION		0.050230	0.063705	159.262177	33.688097	
NORTH CENTRAL REGION		0.042671	0.056480	141.199645	34.522835	
SOUTHERN REGION		0.032527	0.047719	119.297768	37.979995	
WESTERN REGION		0.057171	0.073818	184.545223	41.618170	
HISPANICS		0.043017	0.065866	164.664370	57.121325	
NON-HISPANIC WHITES		0.046190	0.059983	149.956633	34.481160	
NON-HISPANIC BLACKS		0.030667	0.046477	116.193127	39.525272	
NON-HISPANIC OTHERS		0.037189	0.057791	144.477307	51.505345	
NURSING INFANTS (< 1 YEAR OLD)		0.053279	0.066671	166.676607	33.478902	
NON-NURSING INFANTS (< 1 YEAR OLD)		0.129277	0.165949	414.873633	91.681033	
FEMALES (13+ YEARS, PREGNANT)		0.034545	0.045776	114.439925	28.077935	
FEMALES 13+ YEARS, NURSING		0.051301	0.063205	158.011927	29.760218	
CHILDREN (1-6 YEARS OLD)		0.104793	0.136620	341.549890	79.567325	
CHILDREN (7-12 YEARS OLD)		0.057441	0.081291	203.227055	59.623870	
MALES (13-19 YEARS OLD)		0.029969	0.045499	113.747807	38.825783	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.029471	0.042538	106.346155	32.669475	
MALES (20 YEARS AND OLDER)		0.032107	0.042991	107.477400	27.210715	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.035899	0.045846	114.614855	24.868095	

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.