



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

MAY 31 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Estimate of upper-bound to carcinogenic risk from metolachlor. (Related to PP0E3854, rotational crop tomatoes, and associated draft Federal Register notice)

FROM: James P. Kariya *JKariya*
Dietary Exposure Section
Science Analysis and Coordination Branch
Health Effects Division

TO: Steve Robinson/Joanne Miller
Registration Division

Due to an oversight in R. Engler's December 5, 1990 "List of chemicals evaluated for carcinogenic potential" which the Dietary Exposure Section relies on for values of q^* s, metolachlor has not recently been evaluated for carcinogenic risk. Specifically, with regard to PP0E3854, rotational crop tomatoes, no estimate of upper-bound carcinogenicity appeared to be appropriate at the time of the last DRES run (S. Schaible memo of 3-4-91 to J. Miller).

However, it has recently been discovered that a memo from G. Burin to R. Mountfort, dated 1-8-85, recommended a q^* of 2 E-3 . This value was approved verbally by R. Engler, Chief of the Science Analysis and Coordination Branch, on 5-30-91 for use in evaluating the carcinogenic potential of metolachlor. The attached outputs from the Dietary Risk Evaluation System document the upper-bound estimate of carcinogenic risk expected from metolachlor using this value. The upper-bound estimate is 3 E-6 , when tolerance-level residues are assumed. DRES does not have estimates of percents of crops treated with metolachlor, nor does it have information on anticipated residues.

In light of these developments, I remove my objection to the draft Federal Register notice for the proposed rule on rotational crop tomatoes, which I returned to the Registration Division on April 22, 1991. As noted on the attached sheet, I concur with the document as it currently is written.

Please be aware that metolachlor underwent Peer Review in April of 1991, but that the decisions made at that meeting have not been written up, nor has a new q^* been derived. A new value for

EXPOSURE and NON-CANCER CHRONIC RISK

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 05/30/91 PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Metolachlor		2-yr feeding- rat		Decreased body weight gain.		ADI UF -->100		New chronic dog study is under review.		HED complete 03/21/86.	
Caswell #188DD		NOEL= 15.0000 mg/kg		Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.		OPP RfD= 0.150000		OPP to reevaluate 6-month dog feeding study and report conclusions to RfD Workgroup.		EPA verified 04/22/86.	
CAS No. 51218-45-2		300.00 ppm				EPA RfD= 0.150000				HED reassess 04/07/88.	
A.I. CODE: 108801		LEL= 150.0000 mg/kg								EPA verified 06/22/88.	
CFR No. 180.368		3000.00 ppm								On IRIS.	
		ONCO: Class C- pending									

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC		DIFFERENCE		EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**	AS PERCENT OF RFD	AS PERCENT OF RFD	AS PERCENT OF RFD	ARC	%RFD	
U.S. POPULATION - 48 STATES	0.001164	0.001315	0.876933	0.101046				
U.S. POPULATION - SPRING SEASON	0.001107	0.001251	0.834283	0.096018				
U.S. POPULATION - SUMMER SEASON	0.001168	0.001325	0.883103	0.104491				
U.S. POPULATION - FALL SEASON	0.001175	0.001328	0.885107	0.101595				
U.S. POPULATION - WINTER SEASON	0.001168	0.001321	0.880869	0.102117				
NORTHEAST REGION	0.001069	0.001225	0.816466	0.104079				
NORTH CENTRAL REGION	0.001163	0.001322	0.881178	0.105939				
SOUTHERN REGION	0.001228	0.001364	0.909015	0.090177				
WESTERN REGION	0.001131	0.001294	0.862574	0.108659				
HISPANICS	0.001266	0.001444	0.962458	0.118326				
NON-HISPANIC WHITES	0.001129	0.001287	0.857814	0.104866				
NON-HISPANIC BLACKS	0.001259	0.001363	0.908824	0.069539				
NON-HISPANIC OTHERS	0.001205	0.001339	0.892705	0.089501				
NURSING INFANTS (< 1 YEAR OLD)	0.001050	0.001077	0.718157	0.018119				
NON-NURSING INFANTS (< 1 YEAR OLD)	0.003274	0.003373	2.248956	0.066318				
FEMALES (13+ YEARS, PREGNANT)	0.000811	0.000945	0.630183	0.089758				
FEMALES 13+ YEARS, NURSING	0.000921	0.001063	0.708663	0.094971				
CHILDREN (1-6 YEARS OLD)	0.002499	0.002788	1.858713	0.192565				
CHILDREN (7-12 YEARS OLD)	0.001787	0.002021	1.347204	0.155801				
MALES (13-19 YEARS OLD)	0.001205	0.001371	0.914142	0.110969				
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000988	0.001126	0.750871	0.092462				
MALES (20 YEARS AND OLDER)	0.000892	0.001013	0.675574	0.080935				
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000786	0.000903	0.602138	0.078160				

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

CANCER RISK

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

PAGE: 1

DATE: 05/30/91

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
Metolachlor		2-yr feeding- rat	Decreased body weight gain.	ADI	UF -->100	New chronic dog study is under review.	HED complete 03/21/86.
Caswell #1880D		NOEL= 15.0000 mg/kg	Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.	OPP Rfd= 0.150000	OPP Rfd= 0.150000	OPP to reevaluate 6-month dog feeding study and report conclusions to Rfd Workgroup.	EPA verified 04/22/86.
CAS No. 51218-45-2		LEL= 150.0000 mg/kg					HED reassess 04/07/88.
A.I. CODE: 108801		3000.00 ppm					EPA verified 06/22/88.
CFR No. 180.368		ONCO: Class C- pending					On IRIS.

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)-----		---EXISTING TOLERANCES---		---NEW & PENDING TOLERANCES--		TOTAL ONCOGENIC RISK
		NEW	PENDING	TMRC (UG/KG/DAY)	%RFD	TMRC (UG/KG/DAY)	%RFD	
15015AA	OKRA	0.30000		0.004391	0.0029			0.000000009
26011AA	GUAR BEANS	0.30000		0.000000	0.0000			0.000000000
270030A	COTTONSEED-OIL	0.10000		0.002041	0.0013			0.000000004
270030A	COTTONSEED-MEAL	0.10000		0.000012	0.0000			0.000000000
270080A	SAFFLOWER-SEED	0.10000		0.000000	0.0000			0.000000000
270080A	SAFFLOWER-OIL	0.10000		0.000157	0.0001			0.000000000
CROP GROUP TOTALS FOR UNSPECIFIED:								
				0.006601	0.0044			0.000000013
GRAND TOTAL TMRC:	0.006601	GRAND TOTAL % OF THE Rfd:		0.0044				

14013AA	POTATOES(WHITE)-WHOLE	0.20000		0.068012	0.0453			0.000000136
14013AB	POTATOES(WHITE)-UNSPECIFIED	0.20000		0.000016	0.0000			0.000000000
14013AC	POTATOES(WHITE)-PEELED	0.20000		0.156851	0.1045			0.000000314
14013DA	POTATOES(WHITE)-DRY	0.20000		0.001689	0.0011			0.000000003
14013HA	POTATOES(WHITE)-PEEL ONLY	0.20000		0.000004	0.0000			0.000000000
CROP GROUP TOTALS FOR ROOT AND TUBER VEGETABLES:								
				0.226572	0.1510			0.000000453
GRAND TOTAL TMRC:	0.226572	GRAND TOTAL % OF THE Rfd:		0.1510				

13002AA	CELERY	0.10000				0.006096	0.0040	0.000000012
CROP GROUP TOTALS FOR LEAFY VEGETABLES (EXCL. BRASSICAE):								
						0.006096	0.0041	0.000000012
GRAND TOTAL TMRC:	0.006096	GRAND TOTAL % OF THE Rfd:		0.0041				

13007AA	CABBAGE-GREEN AND RED	1.00000		0.093640	0.0624			0.000000187
CROP GROUP TOTALS FOR BRASSICA (COLE) LEAFY VEGETABLES:								
				0.093640	0.0624			0.000000187
GRAND TOTAL TMRC:	0.093640	GRAND TOTAL % OF THE Rfd:		0.0624				

15001AA	BEANS-DRY-GREAT NORTHERN	0.30000		0.000000	0.0000			0.000000000
15001AB	BEANS-DRY-KIDNEY	0.30000		0.004089	0.0027			0.000000008
15001AC	BEANS-DRY-LINA	0.30000		0.002397	0.0015			0.000000005
15001AD	BEANS-DRY-NAVY (PEA)	0.30000		0.011222	0.0074			0.000000022

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

PAGE: 2

DATE: 05/30/91

CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metolachlor		2-yr feeding- rat	Decreased body weight	ADI UF -->100	New chronic dog study is	HED complete 03/21/86.
Caswell #18800		NOEL= 15.0000 mg/kg	gain.	OPP RfD= 0.150000	under review.	EPA verified 04/22/86.
CAS No. 51218-45-2		300.00 ppm	Positive for oncogenicity	EPA RfD= 0.150000	OPP to reevaluate 6-month	HED reassess 04/07/88.
A.I. CODE: 108801		LEL= 150.0000 mg/kg	in male rats. Class C		dog feeding study and	EPA verified 06/22/88.
CFR No. 180.368		3000.00 ppm	(probable C). Final wt of		report conclusions to Rfd	
		ONCO: Class C- pending	the evidence pending.		Workgroup.	On IRIS.

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)		EXISTING TOLERANCES--		NEW & PENDING TOLERANCES--		TOTAL ONCOGENIC RISK
		NEW	PENDING	THMRC (UG/KG/DAY)	%Rfd	THMRC (UG/KG/DAY)	%Rfd	
15001AE	BEANS-DRY-OTHER	0.30000		0.011948	0.0079			0.000000024
15001AF	BEANS-DRY-PINTO	0.30000		0.010905	0.0072			0.000000022
15002AA	BEANS-SUCCULENT-LIMA	0.30000		0.007699	0.0051			0.000000015
15003AA	BEANS-SUCCULENT-GREEN	0.30000		0.060015	0.0400			0.000000120
15003AB	BEANS-SUCCULENT-OTHER	0.30000		0.007915	0.0052			0.000000016
15003AC	BEANS-SUCCULENT-YELLOW,WAX	0.30000		0.001639	0.0010			0.000000003
15006AA	PEANUTS-WHOLE	0.50000		0.034789	0.0231			0.000000070
15007AA	PEAS(GARDEN)-MATURE SEEDS,DRY	0.30000		0.000525	0.0003			0.000000001
15009AA	PEAS(GARDEN)-GREEN IMMATURE	0.30000		0.051600	0.0344			0.000000103
15011AA	LENTILES-WHOLE	0.30000		0.000361	0.0002			0.000000001
15011AB	LENTILES-SPLIT	0.30000		0.000002	0.0000			0.000000000
15013AA	MUNG BEANS (SPROUTS)	0.30000		0.001996	0.0013			0.000000004
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	0.30000		0.000000	0.0000			0.000000000
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	0.30000		0.000000	0.0000			0.000000000
15023AA	BEANS-DRY-PIGEON BEANS	0.30000		0.000011	0.0000			0.000000000
15027AA	BEANS-UNSPECIFIED	0.30000		0.001570	0.0010			0.000000003
15029AA	SOYBEANS-SPROUTED SEEDS	0.20000		0.000000	0.0000			0.000000000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	0.30000		0.000000	0.0000			0.000000000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	0.30000		0.000000	0.0000			0.000000000
15031AA	BEANS-DRY-BLACKEYE PEAS(COMPEAS)	0.30000		0.000742	0.0004			0.000000001
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	0.50000		0.000158	0.0001			0.000000000
270070A	PEANUTS-OIL	0.20000		0.002613	0.0017			0.000000005
270100A	SOYBEANS-OIL	0.20000		0.064431	0.0429			0.000000129
28023AA	SOYBEANS-UNSPECIFIED	0.20000		0.000104	0.0000			0.000000000
28023AB	SOYBEANS-MATURE,SEEDS DRY	0.20000		0.000180	0.0001			0.000000000
28023BA	SOYBEANS-FLOUR, FULL FAT	0.20000		0.000584	0.0003			0.000000001
28023BB	SOYBEANS-FLOUR, LOW FAT	0.20000		0.000190	0.0001			0.000000000
28023BC	SOYBEANS-FLOUR,DEFATTED	0.20000		0.002492	0.0016			0.000000005
CROP GROUP TOTALS FOR LEGUME VEGETABLES:				0.280177	0.1867			0.000000560

GRAND TOTAL THMRC: 0.280177 GRAND TOTAL % OF THE RfD: 0.1868

11003AA	PEPPERS,SWEET,GARDEN	0.10000		0.002155	0.0014			0.000000004
11003AB	CHILI PEPPERS	0.50000		0.002054	0.0013			0.000000004
11003AD	PEPPERS-OTHER	0.10000		0.000436	0.0002			0.000000001
11005AA	TOMATOES-WHOLE	0.10000				0.049202	0.0328	0.000000098
11005JA	TOMATOES- JUICE	0.10000				0.008270	0.0055	0.000000017
11005RA	TOMATOES-PUREE	0.10000				0.056176	0.0374	0.000000112
11005TA	TOMATOES-PASTE	0.10000				0.021317	0.0142	0.000000043

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Metolachlor		2-yr feeding- rat		Decreased body weight gain.		ADI UF -->100		New chronic dog study is under review.		HED complete 03/21/86.	
CAS No. 51218-45-2		NOEL= 15.0000 mg/kg		Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.		OPP RfD= 0.150000		dog feeding study and report conclusions to RfD Workgroup.		EPA verified 04/22/86.	
A.I. CODE: 108801		300.00 ppm				EPA RfD= 0.150000				HED reassess 04/07/88.	
CFR No. 180.368		3000.00 ppm								EPA verified 06/22/88.	
		ONCO: Class C- pending								On IRIS.	

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)-----		---EXISTING TOLERANCES---		-NEW & PENDING TOLERANCES-		TOTAL ONCOGENIC RISK
		NEW	PENDING	TMRC (UG/KG/DAY)	%RfD	TMRC (UG/KG/DAY)	%RfD	
11005UA	TOMATOES-CATSUP	0.10000				0.010508	0.0070	0.000000021
CROP GROUP TOTALS FOR FRUITING VEGETABLES (EXCL. CUCURBITS):					0.0030	0.145473	0.0970	0.000000300
GRAND TOTAL TMRC:		0.150118		0.1001				

05001AA	APRICOTS-FRESH	0.10000		0.003369	0.0022			0.000000007
05001DA	APRICOTS-DRIED	0.10000		0.000242	0.0001			0.000000000
05002AA	CHERRIES-FRESH	0.10000		0.003218	0.0021			0.000000006
05002DA	CHERRIES-DRIED	0.10000		0.000000	0.0000			0.000000000
05002JA	CHERRIES-JUICE	0.10000		0.000511	0.0003			0.000000001
05003AA	NECTARINES	0.10000		0.001297	0.0008			0.000000003
05004AA	PEACHES-FRESH	0.10000		0.021539	0.0143			0.000000043
05004DA	PEACHES-DRIED	0.10000		0.000035	0.0000			0.000000000
05005AA	PLUMS(DAMSONS)-FRESH	0.10000		0.002486	0.0016			0.000000005
05005DA	PLUMS-PRUNES(DRIED)	0.10000		0.001742	0.0011			0.000000003
05005JA	PLUMS,PRUNE-JUICE	0.10000		0.001926	0.0012			0.000000004
CROP GROUP TOTALS FOR STONE FRUITS:				0.036365	0.0242			0.000000073

GRAND TOTAL TMRC: 0.036365 GRAND TOTAL % OF THE RfD: 0.0242

15004AA	CORN,POP	0.10000		0.000677	0.0004			0.000000001
15005AA	CORN,SWEET	0.10000		0.023671	0.0157			0.000000047
24001AA	BARLEY	0.10000		0.005730	0.0038			0.000000011
24002EA	CORN,GRAIN-ENDOSPERM	0.10000		0.016540	0.0110			0.000000033
24002HA	CORN,GRAIN-BRAN	0.10000		0.000000	0.0000			0.000000000
24002SA	CORN SUGAR	0.10000		0.014575	0.0097			0.000000029
24003AA	OATS	0.10000		0.008257	0.0055			0.000000017
24004AA	RICE-ROUGH	0.10000		0.000306	0.0002			0.000000001
24004AB	RICE-MILLED	0.10000		0.015526	0.0103			0.000000031
24005AA	RYE-ROUGH	0.10000		0.000000	0.0000			0.000000000
24005GA	RYE-GERM	0.10000		0.000027	0.0000			0.000000000
24005WA	RYE-FLOUR	0.10000		0.000403	0.0002			0.000000001
24006AA	SORGHUM (INCLUDING MILO)	0.30000		0.007131	0.0047			0.000000014
24007AA	WHEAT-ROUGH	0.10000		0.014061	0.0093			0.000000028
24007GA	WHEAT-GERM	0.10000		0.000081	0.0000			0.000000000
24007HA	WHEAT-BRAN	0.10000		0.001216	0.0008			0.000000002
24007WA	WHEAT-FLOUR	0.10000		0.125725	0.0838			0.0000000251

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/30/91

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CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Metolachlor	Caswell #1880D	2-yr feeding- rat	Decreased body weight	ADI	UF -->100	New chronic dog study is					
CAS No. 51218-45-2	NOEL= 15.0000 mg/kg	gain.	Positive for oncogenicity	OPP RfD= 0.150000		under review.					
A.I. CODE: 108801	300.00 ppm	In male rats. Class C	(probable C). Final wt of	EPA RfD= 0.150000		dog feeding study and					
CFR No. 180.368	3000.00 ppm	the evidence pending.				report conclusions to RfD					
	ONCO: Class C- pending					Workgroup.					On IRIS.

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)-----		--EXISTING TOLERANCES--		--NEW & PENDING TOLERANCES--		TOTAL ONCOGENIC RISK
		NEW	PENDING	THRC (UG/KG/DAY)	%RfD	THRC (UG/KG/DAY)	%RfD	
24012AA	MILLET	0.10000		0.000002	0.0000			0.000000000
26001AA	BUCKWHEAT	0.10000		0.000099	0.0000			0.000000000
270020A	CORN, GRAIN-OIL	0.10000		0.002280	0.0015			0.000000005
CROP GROUP TOTALS FOR CEREAL GRAINS:				0.236307	0.1575			0.000000473
GRAND TOTAL THRC:	0.236307	GRAND TOTAL % OF THE RfD:		0.1575				

03001AA	ALMONDS	0.10000		0.000280	0.0001			0.000000001
03002AA	BRAZIL NUTS	0.10000		0.000005	0.0000			0.000000000
03003AA	CASHEWS	0.10000		0.000114	0.0000			0.000000000
03004AA	CHESTNUTS	0.10000		0.000018	0.0000			0.000000000
03005AA	FILBERTS, HAZELNUTS	0.10000		0.000040	0.0000			0.000000000
03006AA	HICKORY NUTS	0.10000		0.000001	0.0000			0.000000000
03007AA	MACADAMIA NUTS (BUSH NUTS)	0.10000		0.000005	0.0000			0.000000000
03008AA	PECANS	0.10000		0.000482	0.0003			0.000000001
03009AA	WALNUTS	0.10000		0.000482	0.0003			0.000000001
03010AA	BUTTER NUTS	0.10000		0.000000	0.0000			0.000000000
03013AA	BEECHNUTS	0.10000		0.000000	0.0000			0.000000000
CROP GROUP TOTALS FOR TREE NUTS:				0.001427	0.0009			0.000000003
GRAND TOTAL THRC:	0.001427	GRAND TOTAL % OF THE RfD:		0.0010				

08015AA	DILL	0.30000		0.000025	0.0000			0.000000000
CROP GROUP TOTALS FOR HERBS AND SPICES:				0.000025	0.0000			0.000000000
GRAND TOTAL THRC:	0.000025	GRAND TOTAL % OF THE RfD:		0.0000				

53001BA	BEEF-MEAT BYPRODUCTS	0.02000		0.000353	0.0002			0.000000001
53001BB	BEEF(ORGAN MEATS)-OTHER	0.02000		0.000121	0.0000			0.000000000
53001DA	BEEF-DRIED	0.02000		0.000051	0.0000			0.000000000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	0.02000		0.007442	0.0049			0.000000015
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0.20000		0.000096	0.0000			0.000000000
53001LA	BEEF(ORGAN MEATS)-LIVER	0.05000		0.001035	0.0006			0.000000002
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.02000		0.023240	0.0154			0.000000046
53002BA	GOAT-MEAT BYPRODUCTS	0.02000		0.000000	0.0000			0.000000000

CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Metolachlor		2-yr feeding- rat		Decreased body weight gain.		ADI UF -->100		New chronic dog study is under review.		HED complete 03/21/86.	
Caswell #1880D		NOEL= 15.0000 mg/kg		Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.		OPP Rfd= 0.150000		OPP to reevaluate 6-month dog feeding study and report conclusions to Rfd Workgroup.		EPA verified 04/22/86.	
CAS No. 51218-45-2		LEL= 300.00 ppm				EPA Rfd= 0.150000				HED reassess 04/07/88.	
A.I. CODE: 108801		3000.00 ppm								EPA verified 06/22/88.	
CFR No. 180.368		ONCO: Class C- pending								On IRIS.	

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)-----		---EXISTING TOLERANCES---		-NEW & PENDING TOLERANCES-		TOTAL ONCOGENIC RISK
		NEW	PENDING	THMRC (UG/KG/DAY)	%Rfd	THMRC (UG/KG/DAY)	%Rfd	
53002BB	GOAT(ORGAN MEATS)-OTHER	0.02000		0.000000	0.0000			0.000000000
53002FA	GOAT(BONELESS)-FAT	0.02000		0.000001	0.0000			0.000000000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	0.20000		0.000000	0.0000			0.000000000
53002LA	GOAT(ORGAN MEATS)-LIVER	0.05000		0.000000	0.0000			0.000000000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.02000		0.000004	0.0000			0.000000000
53003AA	HORSE	0.02000		0.000000	0.0000			0.000000000
53005BA	SHEEP-MEAT BYPRODUCTS	0.02000		0.000001	0.0000			0.000000000
53005BB	SHEEP(ORGAN MEATS)-OTHER	0.02000		0.000000	0.0000			0.000000000
53005FA	SHEEP(BONELESS)-FAT	0.02000		0.000086	0.0000			0.000000000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	0.20000		0.000002	0.0000			0.000000000
53005LA	SHEEP(ORGAN MEATS)-LIVER	0.05000		0.000000	0.0000			0.000000000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.02000		0.000250	0.0001			0.000000001
53006BA	PORK-MEAT BYPRODUCTS	0.02000		0.000502	0.0003			0.000000001
53006BB	PORK(ORGAN MEATS)-OTHER	0.02000		0.000077	0.0000			0.000000000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0.02000		0.004164	0.0027			0.000000008
53006KA	PORK(ORGAN MEATS)-KIDNEY	0.20000		0.000002	0.0000			0.000000000
53006LA	PORK(ORGAN MEATS)-LIVER	0.05000		0.000241	0.0001			0.000000000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0.02000		0.007825	0.0052			0.000000016
CROP GROUP TOTALS FOR RED MEAT:				0.045493	0.0303			0.000000091
GRAND TOTAL THMRC:		0.045493						
GRAND TOTAL % OF THE Rfd:			0.0303					

55008BA	TURKEY-BYPRODUCTS	0.02000		0.000005	0.0000			0.000000000
55008LA	TURKEY-GIBLETS (LIVER)	0.05000		0.000003	0.0000			0.000000000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	0.02000		0.000159	0.0001			0.000000000
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	0.02000		0.000963	0.0006			0.000000002
55008MC	TURKEY-UNSPECIFIED	0.02000		0.000002	0.0000			0.000000000
55013BA	POULTRY, OTHER-BYPRODUCTS	0.02000		0.000000	0.0000			0.000000000
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	0.05000		0.000012	0.0000			0.000000000
55013MA	POULTRY, OTHER-FLESH (+SKIN,W/O BONES)	0.02000		0.000108	0.0000			0.000000000
55015BA	CHICKEN-BYPRODUCTS	0.02000		0.000000	0.0000			0.000000000
55015LA	CHICKEN-GIBLETS(LIVER)	0.05000		0.000253	0.0001			0.000000001
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	0.02000		0.001203	0.0008			0.000000002
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	0.02000		0.007586	0.0050			0.000000015
CROP GROUP TOTALS FOR POULTRY:				0.010294	0.0068			0.000000021
GRAND TOTAL THMRC:		0.010294						
GRAND TOTAL % OF THE Rfd:			0.0069					

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/30/91

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CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metolachlor	Caswell #18800	2-Yr feeding- rat	Decreased body weight gain.	ADI UF -->100	New chronic dog study is under review.	HED complete 03/21/86.
	CAS No. 51218-45-2	NOEL= 15.0000 mg/kg	Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.	OPP RfD= 0.150000	OPP to reevaluate 6-month dog feeding study and report conclusions to RfD Workgroup.	EPA verified 04/22/86.
	A.I. CODE: 108801	LEL= 150.0000 mg/kg		EPA RfD= 0.150000		HED reassess 04/07/88.
	CFR No. 180.368	ONCO: Class C- pending				EPA verified 06/22/88.

LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

FOOD CODE	FOOD NAME	TOLERANCE (PPM)-----		---EXISTING TOLERANCES---		--NEW & PENDING TOLERANCES--		TOTAL ONCOGENIC RISK
		NEW	PENDING	THRC (UG/KG/DAY)	%RfD	THRC (UG/KG/DAY)	%RfD	
50000DB	MILK-NON-FAT SOLIDS	0.02000		0.142257	0.0948			0.000000285
50000FA	MILK-FAT SOLIDS	0.02000		0.067672	0.0451			0.000000135
50000SA	MILK SUGAR (LACTOSE)	0.02000		0.000749	0.0004			0.000000001
55014AA	EGGS-WHOLE	0.02000		0.011290	0.0075			0.000000023
55014AB	EGGS-WHITE ONLY	0.02000		0.000184	0.0001			0.000000000
55014AC	EGGS-YOLK ONLY	0.02000		0.000133	0.0000			0.000000000
CROP GROUP TOTALS FOR DAIRY PRODUCTS:				0.222285	0.1481			0.000000445
GRAND TOTAL THRC:	0.222285	GRAND TOTAL % OF THE RfD:		0.1482				

POPULATION SUBGROUP TOTALS

POPULATION TOTAL THRC 1.315400 POPULATION TOTAL % OF THE RfD 0.8769

POPULATION SUBGROUP TOTALS 1.163831 0.7758 0.151569 0.1010 0.000002630

SUMMARY OF RESIDUES AND COMMODITIES

CHEMICAL INFORMATION FOR CASWELL NUMBER 18800

DATE: 05/30/91

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Metolachlor Caswell #18800 CAS No. 51218-45-2 A.I. CODE: 108801 CFR No. 180.368	2-yr feeding- rat NOEL= 15,0000 mg/kg 300.00 ppm LEL= 150,0000 mg/kg 3000.00 ppm ONCO: Class C- pending	Decreased body weight gain. Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.	OPP Rfd= 0.150000 EPA Rfd= 0.150000	-->100	New chronic dog study is under review. OPP to reevaluate 6-month dog feeding study and report conclusions to Rfd Workgroup.	HED complete 03/21/86. EPA verified 04/22/86. HED reassess 04/07/88. EPA verified 06/22/88. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PENDING
03001AA	ALMONDS	3F2958		0.100000
03002AA	BRAZIL NUTS	3F2958		0.100000
03003AA	CASHEWS	3F2958		0.100000
03004AA	CHESTNUTS	3F2958		0.100000
03005AA	FILBERTS, HAZELNUTS	3F2958		0.100000
03006AA	HICKORY NUTS	3F2958		0.100000
03007AA	MACADAMIA NUTS (BUSH NUTS)	3F2958		0.100000
03008AA	PECANS	3F2958		0.100000
03009AA	WALNUTS	3F2958		0.100000
03010AA	BUTTER NUTS	3F2958		0.100000
03013AA	BEECHNUTS	3F2958		0.100000
05001AA	APRICOTS-FRESH	3F2957		0.100000
05001DA	APRICOTS-DRIED	3F2957		0.100000
05002AA	CHERRIES-FRESH	3F2957		0.100000
05002DA	CHERRIES-DRIED	3F2957		0.100000
05002JA	CHERRIES-JUICE	3F2957		0.100000
05003AA	NECTARINES	3F2957		0.100000
05004AA	PEACHES-FRESH	3F2957		0.100000
05004DA	PEACHES-DRIED	3F2957		0.100000
05005AA	PLUMS(DAMSONS)-FRESH	3F2957		0.100000
05005DA	PLUMS-PRUNES(DRIED)	3F2957		0.100000
05005JA	PLUMS, PRUNE- JUICE	3F2957		0.100000
08015AA	DILL	1F2495		0.300000
11003AA	PEPPERS, SWEET, GARDEN	8E3616		0.100000
11003AB	CHILI PEPPERS	5E3236		0.500000
11003AD	PEPPERS-OTHER	9E3708		0.100000
11005AA	TOMATOES-WHOLE	0E3854	0.100000	
11005JA	TOMATOES-JUICE	0E3854	0.100000	
11005RA	TOMATOES-PUREE	0E3854	0.100000	
11005TA	TOMATOES-PASTE	0E3854	0.100000	
11005UA	TOMATOES-CATSUP	0E3854	0.100000	
13002AA	CELERY	0E3882	0.100000	
13007AA	CABBAGE-GREEN AND RED	8E3637		1.000000
14013AA	POTATOES(WHITE)-WHOLE	9F2203		0.200000
14013AB	POTATOES(WHITE)-UNSPECIFIED	9F2203		0.200000
14013AC	POTATOES(WHITE)-PEELED	9F2203		0.200000
14013DA	POTATOES(WHITE)-DRY	9F2203		0.200000
14013HA	POTATOES(WHITE)-PEEL ONLY	9F2203		0.200000
15001AA	BEANS-DRY-GREAT NORTHERN	1F2495		0.300000
15001AB	BEANS-DRY-KIDNEY	1F2495		0.300000

CHEMICAL INFORMATION FOR CASWELL NUMBER 1880D

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF -->100		
Metolachlor Caswell #1880D CAS No. 51218-45-2 A.I. CODE: 108801 CFR No. 180.368	2-yr feeding- rat NOEL= 15.0000 mg/kg 300.00 ppm LEL= 150.0000 mg/kg 3000.00 ppm ONCO: Class C- pending	Decreased body weight gain. Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.	OPP RfD= 0.150000 EPA RfD= 0.150000		New chronic dog study is under review. OPP to reevaluate 6-month dog feeding study and report conclusions to RfD Workgroup.	HED complete 03/21/86. EPA verified 04/22/86. HED reassess 04/07/88. EPA verified 06/22/88. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PENDING PUBLISHED
15001AC	BEANS-DRY-LIMA	1F2495		0.300000
15001AD	BEANS-DRY-NAVY (PEA)	1F2495		0.300000
15001AE	BEANS-DRY-OTHER	1F2495		0.300000
15001AF	BEANS-DRY-PINTO	1F2495		0.300000
15002AA	BEANS-SUCCULENT-LIMA	1F2495		0.300000
15003AA	BEANS-SUCCULENT-GREEN	1F2495		0.300000
15003AB	BEANS-SUCCULENT-OTHER	1F2495		0.300000
15003AC	BEANS-SUCCULENT-YELLOW,WAX	1F2495		0.300000
15004AA	CORN,POP	1F2521		0.100000
15005AA	CORN,SWEET	8F2081		0.100000
15006AA	PEANUTS-WHOLE	2F2720		0.500000
15007AA	PEAS(GARDEN)-MATURE SEEDS,DRY	1F2495		0.300000
15009AA	PEAS(GARDEN)-GREEN IMMATURE	1F2495		0.300000
15011AA	LENTILES-WHOLE	1F2495		0.300000
15011AB	LENTILES-SPLIT	1F2495		0.300000
15013AA	MUNG BEANS (SPROUTS)	1F2495		0.300000
15015AA	OKRA	1F2495		0.300000
15022AA	BEANS-DRY-BROADBEANS(MATURE SEED)	1F2495		0.300000
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	1F2495		0.300000
15023AA	BEANS-DRY-PIGEON BEANS	1F2495		0.300000
15027AA	BEANS-UNSPECIFIED	1F2495		0.300000
15029AA	SOYBEANS-SPROUTED SEEDS	2F2720		0.200000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	1F2495		0.300000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	1F2495		0.300000
15031AA	BEANS-DRY-BLACKEYE PEAS(COMPEAS)	1F2495		0.300000
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	1F2495		0.300000
24001AA	BARLEY	1E2563		0.100000
24002EA	CORN, GRAIN-ENDOSPERM	1F2521		0.100000
24002HA	CORN, GRAIN-BRAN	1F2521		0.100000
24002SA	CORN SUGAR	1F2521		0.100000
24003AA	OATS	1E2563		0.100000
24004AA	RICE-ROUGH	1E2563		0.100000
24004AB	RICE-MILLED	1E2563		0.100000
24005AA	RYE-ROUGH	1E2563		0.100000
24005GA	RYE-GERM	1E2563		0.100000
24005WA	RYE-FLOUR	1E2563		0.100000
24006AA	SORGHUM (INCLUDING MILO)	8F2098		0.300000
24007AA	WHEAT-ROUGH	1E2563		0.100000
24007GA	WHEAT-GERM	1E2563		0.100000
24007HA	WHEAT-BRAN	1E2563		0.100000

CHEMICAL INFORMATION FOR CASWELL NUMBER 1880D

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Metolachlor Caswell #1880D CAS No. 51218-45-2 A.I. CODE: 108801 CFR No. 180.368	2-yr feeding- rat NOEL= 15.0000 mg/kg 300.00 ppm LEL= 150.0000 mg/kg 3000.00 ppm ONCO: Class C- pending	Decreased body weight gain. Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.	OPP RfD= 0.150000 EPA RfD= 0.150000	-->100	New chronic dog study is under review. OPP to reevaluate 6-month dog feeding study and report conclusions to Rfd Workgroup.	HED complete 03/21/86. EPA verified 04/22/86. HED reassess 04/07/88. EPA verified 06/22/88. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			PENDING	PUBLISHED
24007MA	WHEAT-FLOUR	1E2563		0.100000
24012AA	MILLET	1E2563		0.100000
26001AA	BUCKWHEAT	1E2563		0.100000
26011AA	GUAR BEANS	1F2495		0.300000
270020A	CORN, GRAIN-OIL	1F2521		0.100000
270030A	COTTONSEED-OIL	1F2506		0.100000
27003WA	COTTONSEED-MEAL	1F2506		0.100000
270070A	PEANUTS-OIL	2F2720		0.500000
27008AA	SAFFLOWER-SEED	2F2601		0.100000
270080A	SAFFLOWER-OIL	2F2601		0.100000
270100A	SOYBEANS-OIL	2F2720		0.200000
28023AA	SOYBEANS-UNSPECIFIED	2F2720		0.200000
28023AB	SOYBEANS-MATURE, SEEDS DRY	2F2720		0.200000
28023AA	SOYBEANS-FLOUR, FULL FAT	2F2720		0.200000
28023WB	SOYBEANS-FLOUR, LOW FAT	2F2720		0.200000
28023WC	SOYBEANS-FLOUR, DEFATTED	2F2720		0.200000
500000B	MILK-NON-FAT SOLIDS	5F1606		0.020000
50000FA	MILK-FAT SOLIDS	5F1606		0.020000
50000SA	MILK SUGAR (LACTOSE)	5F1606		0.020000
53001BA	BEEF-MEAT BYPRODUCTS	5F1606		0.020000
53001BB	BEEF(ORGAN MEATS)-OTHER	5F1606		0.020000
53001DA	BEEF-DRIED	5F1606		0.020000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	5F1606		0.020000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	2F2720		0.200000
53001LA	BEEF(ORGAN MEATS)-LIVER	2F2720		0.050000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606		0.020000
53002BA	GOAT-MEAT BYPRODUCTS	5F1606		0.020000
53002BB	GOAT(ORGAN MEATS)-OTHER	5F1606		0.020000
53002FA	GOAT(BONELESS)-FAT	5F1606		0.020000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	2F2720		0.200000
53002LA	GOAT(ORGAN MEATS)-LIVER	2F2720		0.050000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606		0.020000
53003AA	HORSE	5F1606		0.020000
53005BA	SHEEP-MEAT BYPRODUCTS	5F1606		0.020000
53005BB	SHEEP(ORGAN MEATS)-OTHER	5F1606		0.020000
53005FA	SHEEP(BONELESS)-FAT	5F1606		0.020000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	2F2720		0.200000
53005LA	SHEEP(ORGAN MEATS)-LIVER	2F2720		0.050000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606		0.020000
53006BA	PORK-MEAT BYPRODUCTS	5F1606		0.020000

CHEMICAL INFORMATION FOR CASWELL NUMBER 188DD

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metolachlor Caswell #188DD CAS No. 51218-45-2 A.I. CODE: 108801 CFR No. 180.368	2-yr feeding- rat NOEL= 15.0000 mg/kg 300.00 ppm LEL= 150.0000 mg/kg 3000.00 ppm ONCO: Class C- pending	Decreased body weight gain. Positive for oncogenicity in male rats. Class C (probable C). Final wt of the evidence pending.	ADI UF -->100 OPP Rfd= 0.150000 EPA Rfd= 0.150000	New chronic dog study is under review. OPP to reevaluate 6-month dog feeding study and report conclusions to Rfd Workgroup.	HED complete 03/21/86. EPA verified 04/22/86. HED reassess 04/07/88. EPA verified 06/22/88. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
53006BB	PORK(ORGAN MEATS)-OTHER	5F1606		0.020000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	5F1606		0.020000
53006KA	PORK(ORGAN MEATS)-KIDNEY	2F2720		0.200000
53006LA	PORK(ORGAN MEATS)-LIVER	2F2720		0.050000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	5F1606		0.020000
55008BA	TURKEY-BYPRODUCTS	5F1606		0.020000
55008LA	TURKEY-GIBLETS (LIVER)	2F2720		0.050000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	5F1606		0.020000
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	5F1606		0.020000
55008MC	TURKEY-UNSPECIFIED	5F1606		0.020000
55013BA	POULTRY, OTHER-BYPRODUCTS	5F1606		0.020000
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	2F2720		0.050000
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	5F1606		0.020000
55014AA	EGGS-WHOLE	5F1606		0.020000
55014AB	EGGS-WHITE ONLY	5F1606		0.020000
55014AC	EGGS-YOLK ONLY	5F1606		0.020000
55015BA	CHICKEN-BYPRODUCTS	5F1606		0.020000
55015LA	CHICKEN-GIBLETS(LIVER)	2F2720		0.050000
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	5F1606		0.020000
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	5F1606		0.020000

the q* is likely to be derived, but will not be available until July, according to the executive secretary of the Peer Reviews for Carcinogenicity.

Finally, please note that it is highly irregular and undesirable for the Registration Division to incorporate risk estimates from dietary exposure into draft Federal Register notices without supporting documentation from the Dietary Exposure Section. This is the second case in the last few months in which RD has manufactured a paragraph containing quantitative risk estimates without DES' knowledge. In the future, please be sure to have documentation from DES before incorporating statements pertaining to dietary risk into draft Federal Register notices.

cc: J. Fleuchaus, OGC