US EPA ARCHIVE DOCUMENT

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
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

CHEMICAL INFORMATION	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.

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	0.001164	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

DATE: 05/30/91 PAGE: 1

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

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	TOLERANCE (PPM) PENDING	TOLERANCE (PPM) PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	EXISTING TOLERANCES %RfD	NEW & PENDING TOLERANCES TMRC (UG/KG/DAY)	NEW & PENDING TOLERANCES %RFD	TOTAL ONCOGENIC RISK
15015AA	OKRA			0.30000	0.004391	0.0029			0.000000009
26011AA	GUAR BEANS			0.30000	0.000000	0.0000			0.000000000
27003OA	COTTONSEED-OIL			0.10000	0.002041	0.0013			0.000000004
27003WA	COTTONSEED-MEAL			0.10000	0.000012	0.0000			0.000000000
27008AA	SAFFLOWER-SEED			0.10000	0.000000	0.0000			0.000000000
27008OA	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-LIMA			0.30000	0.002397	0.0015			0.000000005
15001AD	BEANS-DRY-NAVY (PEA)			0.30000	0.011222	0.0074			0.000000022

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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(COWPEAS)			0.30000	0.000742	0.0004			0.000000001
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)			0.30000	0.000158	0.0001			0.000000000
27007OA	PEANUTS-OIL			0.50000	0.002613	0.0017			0.000000005
27010OA	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
28023WA	SOYBEANS-FLOUR, FULL FAT			0.20000	0.000584	0.0003			0.000000001
28023WB	SOYBEANS-FLOUR, LOW FAT			0.20000	0.000190	0.0001			0.000000000
28023WC	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 TMRC: 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

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11005UA	TOMATOES-CATSUP	0.10000					0.010508	0.0070	0.000000021
CROP GROUP TOTALS FOR FRUITING VEGETABLES (EXCL. CUCURBITS):					0.004645	0.0030	0.145473	0.0970	0.000000300

GRAND TOTAL TMRC: 0.150118 GRAND TOTAL % OF THE RfD: 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			0.000000251

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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 TMRC: 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 TMRC: 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 TMRC: 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

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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 TMRC: 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 TMRC: 0.010294 GRAND TOTAL % OF THE RfD: 0.0069

CHEMICAL INFORMATION	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.

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

FOOD CODE	FOOD NAME	TOLERANCE (PPM) NEW	TOLERANCE (PPM) PENDING	TOLERANCE (PPM) PUBLISHED	EXISTING TOLERANCES TMRC (UG/KG/DAY)	EXISTING TOLERANCES %RfD	NEW & PENDING TOLERANCES TMRC (UG/KG/DAY)	NEW & PENDING TOLERANCES %RfD	TOTAL ONCOGENIC RISK
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 TMRC: 0.222285 GRAND TOTAL % OF THE RfD: 0.1482

POPULATION SUBGROUP TOTALS	1.163831	0.7758	0.151569	0.1010	0.000002630

POPULATION TOTAL TMRC 1.315400 POPULATION TOTAL % OF THE RfD 0.8769

SUMMARY OF RESIDUES AND COMMODITIES

CHEMICAL INFORMATION FOR CASWELL NUMBER 188DD DATE: 05/30/91 PAGE: 1

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	PENDING	PUBLISHED
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	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	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(COWPEAS)	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	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	PENDING	PUBLISHED
24007WA	WHEAT-FLOUR	1E2563			0.100000
24012AA	MILLET	1E2563			0.100000
26001AA	BUCKWHEAT	1E2563			0.100000
26011AA	GUAR BEANS	1F2495			0.300000
27002OA	CORN,GRAIN-OIL	1F2521			0.100000
27003OA	COTTONSEED-OIL	1F2506			0.100000
27003WA	COTTONSEED-MEAL	1F2506			0.100000
27007OA	PEANUTS-OIL	2F2720			0.500000
27008AA	SAFFLOWER-SEED	2F2601			0.100000
27008OA	SAFFLOWER-OIL	2F2601			0.100000
27010OA	SOYBEANS-OIL	2F2720			0.200000
28023AA	SOYBEANS-UNSPECIFIED	2F2720			0.200000
28023AB	SOYBEANS-MATURE,SEEDS DRY	2F2720			0.200000
28023WA	SOYBEANS-FLOUR, FULL FAT	2F2720			0.200000
28023WB	SOYBEANS-FLOUR, LOW FAT	2F2720			0.200000
28023WC	SOYBEANS-FLOUR,DEFATTED	2F2720			0.200000
50000DB	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	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	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