

US EPA ARCHIVE DOCUMENT



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

FEB -5 1996

**MEMORANDUM**

**SUBJECT:** Dietary Exposure Analysis for Glyphosate-trimesium in/on Pome Fruit and Wheat PP# 5F04554 and PP# 5H05727.

**FROM:** Brian Steinwand *BS*  
Dietary Risk Evaluation Section  
Science Analysis Branch/HED (7509C)

**Through:** Elizabeth Doyle, Section Head *E.A. Doyle*  
Dietary Risk Evaluation Section  
SAB/Health Effects Division

**TO:** R. Taylor/T. Stowe, PM Team 25 *TS*  
Registration Division (7505C)

**Action Requested**

Provide a dietary exposure analysis for the use of glyphosate-trimesium in/on pome fruit and wheat. The petition requests but CBTS recommends against a tolerance of 0.05 ppm be established on pome fruit and 10 ppm on wheat.

**Discussion**

The proposed tolerance on pome fruit and wheat would require the establishment of animal commodity tolerances (See memo, G. Kramer, 11/28/95). However, with the exception of meat and poultry by-products, proposed animal commodity tolerances currently exist (PP# OF03860) at equal or higher levels than those proposed for this petition. Thus, the higher existing levels were used for the purposes of this analysis. Tolerance levels for meat and poultry by-products were raised accordingly.

### Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.1 mg/kg bwt/day, based on a NOEL of 10.0 mg/kg bwt/day) from a one year dog feeding study with an uncertainty factor of 100 that demonstrated emesis and salivation (See memo, G. Ghali, 6/26/94). The RfD has been approved by the HED RfD committee (3/10/94), but has not been reviewed by the joint Committee meeting of the WHO/FAO. Glyphosate-trimesium is classified as a Group E carcinogen.

### Residue Information

As a new chemical, tolerances for glyphosate-trimesium have yet to be published in the CFR. Tolerance level residues and 100 percent crop treated assumptions were made for the proposed commodities. Anticipated residues and percent crop treated information were not available for this analysis.

Prior new tolerances for grapes and bananas were upgraded to pending status for this analysis.

### Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

### Chronic Exposure Analysis

Exposure from Pending Tolerances for glyphosate-trimesium:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.005542	5.5
Children (1-6 years)	0.012601	12.6

Proposed new Tolerances on pome fruit and wheat:

U.S. Population	0.014219	14.2
Children (1-6 years)	0.031860	31.9

If the new tolerances on pome fruit and wheat are approved:

U.S. Population	0.019760	19.8
Children (1-6 years)	0.044461	44.5

## Conclusions

The chronic analysis for glyphosate-trimesium is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with glyphosate-trimesium. Even without refinements, the chronic dietary risk exposure to glyphosate-trimesium appears to be minimal for this petition on pome fruit at 0.05 ppm and wheat at 10 ppm and does not exceed the RfD for any of the DRES subgroups.

## Attachments

cc: DRES; Caswell 893C; RCAB; CBTS (G. Kramer); Tox I

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glyphosate trimesium Caswell #893C CAS No. 81591-81-3 A.I. CODE: 128501 CFR No.	1yr feeding- dog NOEL = 10.0000 mg/kg LEL = 0.00 ppm 50.0000 mg/kg 0.00 ppm	Emesis & salivation. Effects were also seen in a 3-month dog study: NOEL = 10 mg/kg; LEL=50 mg/kg. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.100000 EPA RfD= 0.000000	No data gaps. [Syn. Sulfosate]	RfD/PR reviewed 03/10/94

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PENDING PUBLISHED
01014AA	GRAPES-FRESH	1F03950		0.100000
01014DA	GRAPES-RAISINS	1F03950		0.200000
01014JA	GRAPES- JUICE	1F03950		0.100000
03002AA	BRAZIL NUTS	4F04343		0.050000
03003AA	CASHEWS	4F04343		0.050000
03004AA	CHESTNUTS	4F04343		0.050000
03005AA	FILBERTS, HAZELNUTS	4F04343		0.050000
03006AA	HICKORY NUTS	4F04343		0.050000
03007AA	MACADAMIA NUTS (BUSH NUTS)	4F04343		0.050000
03008AA	PECANS	4F04343		0.050000
03009AA	WALNUTS	4F04343		0.050000
03010AA	BUTTER NUTS	4F04343		0.050000
03013AA	BEECHNUTS	5F04554		0.050000
04001AA	APPLES-FRESH	5F04554		0.050000
04001DA	APPLES-DRIED	5F04554		0.050000
04001JA	APPLES- JUICE	5F04554		0.050000
04002AA	CRABAPPLES	5F04554		0.050000
04003AA	PEARS-FRESH	5F04554		0.050000
04003DA	PEARS-DRIED	5F04554		0.050000
04004AA	QUINCES	5F04554		0.050000
05001AA	APRICOTS-FRESH	3F04238		0.050000
05001DA	APRICOTS-DRIED	3F04238		0.050000
05002AA	CHERRIES-FRESH	3F04238		0.050000
05002DA	CHERRIES-DRIED	3F04238		0.050000
05002JA	CHERRIES- JUICE	3F04238		0.050000
05003AA	NECTARINES	3F04238		0.050000
05004AA	PEACHES-FRESH	3F04238		0.050000
05004DA	PEACHES-DRIED	3F04238		0.050000
05005AA	PLUMS(DAMSONS)-FRESH	3F04238		0.200000
05005DA	PLUMS-PRUNES(DRIED)	3F04238		0.200000
05005JA	PLUMS, PRUNE- JUICE	3F04238		0.200000
06002AA	BANANAS-UNSPECIFIED	5E04479		0.050000
06002AB	BANANAS-FRESH	5E04479		0.050000
06002DA	BANANAS-DRIED	5E04479		0.050000
06016AA	PLANTAINS	5E04479		0.050000
15004AA	CORN, POP	9F03796		0.050000
15029AA	SOYBEANS-SPROUTED SEEDS	0F03860		3.000000
24002EA	CORN, GRAIN- ENDOSPERM	9F03796		0.050000
24002HA	CORN, GRAIN-BRAN	9F03796		0.050000
24002SA	CORN SUGAR	9F03796		0.050000

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glyphosate trimesium Caswell #893C CAS No. 81591-81-3 A.I. CODE: 128501 CFR No.	1yr feeding- dog NOEL= 10.0000 mg/kg LEL= 0.00 ppm 50.0000 mg/kg 0.00 ppm	Emesis & salivation. Effects were also seen in a 3-month dog study: NOEL =10 mg/kg; LEL=50 mg/kg. No evidence of carcinog- enicity in rats or mice.	ADI UF -->100 OPP RfD= 0.1000000 EPA RfD= 0.0000000	No data gaps. [Syn. Sulfosate]	RfD/PR reviewed 03/10/94

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PENDING PUBLISHED
24007AA	WHEAT-ROUGH	5F04554	10.000000	0.050000
24007GA	WHEAT-GERM	5F04554	10.000000	3.000000
24007HA	WHEAT-BRAN	5F04554	10.000000	3.000000
24007MA	WHEAT-FLOUR	5F04554	10.000000	3.000000
270020A	CORN, GRAIN-OIL	9F03796		3.000000
270100A	SOYBEANS-OIL	0F03860		3.000000
28023AA	SOYBEANS-UNSPECIFIED	0F03860		3.000000
28023AB	SOYBEANS-MATURE, SEEDS DRY	0F03860		3.000000
28023WA	SOYBEANS-FLOUR, FULL FAT	0F03860		3.000000
28023WB	SOYBEANS-FLOUR, LOW FAT	0F03860		3.000000
28023WC	SOYBEANS-FLOUR, DEFATTED	0F03860		3.000000
43058AA	WINE AND SHERRY	1F03950		0.100000
50000DB	MILK-NON-FAT SOLIDS	0F03860		0.200000
50000FA	MILK-FAT SOLIDS	0F03860		0.200000
50000SA	MILK SUGAR (LACTOSE)	0F03860		0.200000
53001BA	BEEF-MEAT BYPRODUCTS	5F04554	1.500000	1.000000
53001BA	BEEF-MEAT BYPRODUCTS	0F03860		1.000000
53001BB	BEEF(ORGAN MEATS)-OTHER	0F03860		1.000000
53001DA	BEEF-DRIED	0F03860		1.000000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	0F03860		1.000000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0F03860		1.000000
53001LA	BEEF(ORGAN MEATS)-LIVER	0F03860		1.000000
53001MA	BEEF(BONELESS)-LEAN (M/O REMOVEABLE FAT)	0F03860		1.000000
53002BA	GOAT-MEAT BYPRODUCTS	0F03860		1.000000
53002BA	GOAT-MEAT BYPRODUCTS	5F04554	1.500000	1.000000
53002BB	GOAT(ORGAN MEATS)-OTHER	0F03860		1.000000
53002FB	GOAT(BONELESS)-FAT	0F03860		1.000000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	0F03860		1.000000
53002LA	GOAT(ORGAN MEATS)-LIVER	0F03860		1.000000
53002MA	GOAT(BONELESS)-LEAN (M/O REMOVEABLE FAT)	0F03860		1.000000
53003AA	HORSE	0F03860		0.200000
53003BA	SHEEP-MEAT BYPRODUCTS	0F03860		1.000000
53005BA	SHEEP-MEAT BYPRODUCTS	5F04554	1.500000	1.000000
53005BB	SHEEP(ORGAN MEATS)-OTHER	0F03860		1.000000
53005FA	SHEEP(BONELESS)-FAT	0F03860		1.000000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	0F03860		1.000000
53005LA	SHEEP(ORGAN MEATS)-LIVER	0F03860		1.000000
53005MA	SHEEP(BONELESS)-LEAN (M/O REMOVEABLE FAT)	0F03860		1.000000
53006BA	PORK-MEAT BYPRODUCTS	0F03860		1.000000
53006BA	PORK-MEAT BYPRODUCTS	5F04554	1.500000	1.000000

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glyphosate trimesium Caswell #893C CAS No. 81591-81-3 A.I. CODE: 128501 CFR No.	1yr feeding- dog NOEL= 10.0000 mg/kg 0.00 ppm LEL= 50.0000 mg/kg 0.00 ppm ONCO: E (Rfd/PR Committee)	Emesis & salivation. Effects were also seen in a 3-month dog study: NOEL =10 mg/kg; LEL=50 mg/kg. No evidence of carcinog- enicity in rats or mice.	ADI UF -->100 Opp Rfd= 0.100000 EPA Rfd= 0.000000	No data gaps. [Syn. Sulfosate]	Rfd/PR reviewed 03/10/94

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
530068B	PORK(ORGAN MEATS)-OTHER	OF03860		1.000000		
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	OF03860		1.000000		
53006KA	PORK(ORGAN MEATS)-KIDNEY	OF03860		1.000000		
53006LA	PORK(ORGAN MEATS)-LIVER	OF03860		1.000000		
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	OF03860		1.000000		
55008BA	TURKEY-BYPRODUCTS	OF03860		0.100000		
55008BA	TURKEY-BYPRODUCTS	5F04554		0.100000		
55008LA	TURKEY-GIBLETS (LIVER)	OF03860		0.100000		
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	OF03860		0.100000		
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	OF03860		0.100000		
55008MC	TURKEY-UNSPECIFIED	OF03860		0.100000		
55013BA	POULTRY, OTHER-BYPRODUCTS	5F04554		0.100000		
55013BA	POULTRY, OTHER-BYPRODUCTS	OF03860		0.100000		
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	OF03860		0.100000		
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	OF03860		0.100000		
55014AA	EGGS-WHOLE	OF03860		0.100000		
55014AB	EGGS-WHITE ONLY	OF03860		0.100000		
55014AC	EGGS-YOLK ONLY	OF03860		0.100000		
55015BA	CHICKEN-BYPRODUCTS	OF03860		0.100000		
55015BA	CHICKEN-BYPRODUCTS	5F04554		0.100000		
55015LA	CHICKEN-GIBLETS(LIVER)	OF03860		0.100000		
55015MA	CHICKEN-FLESH(W/O SKIN, W/O BONES)	OF03860		0.100000		
55015MB	CHICKEN-FLESH(+SKIN, W/O BONES)	OF03860		0.100000		

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glyphosate tri-mesium Caswell #693C CAS No. 81591-81-3 A.I. CODE: 128501 CFR No.	1yr feeding- dog NOEL= 10,000 mg/kg 0.00 ppm LEL= 50,000 mg/kg 0.00 ppm ONCO: E (Rfd/PR Committee)	Emesis & salivation. Effects were also seen in a 3-month dog study: NOEL =10 mg/kg; LEL=50 mg/kg. No evidence of carcinog- enicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.100000 EPA Rfd= 0.000000	No data gaps.	Rfd/PR reviewed 03/10/94

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	
U.S. POPULATION - 48 STATES	0.000000	0.019760	19.759747	19.759747			%RFD
U.S. POPULATION - SPRING SEASON	0.000000	0.019138	19.137653	19.137653			
U.S. POPULATION - SUMMER SEASON	0.000000	0.019375	19.375328	19.375328			
U.S. POPULATION - FALL SEASON	0.000000	0.020388	20.388261	20.388261			
U.S. POPULATION - WINTER SEASON	0.000000	0.020139	20.138762	20.138762			
NORTHEAST REGION	0.000000	0.020389	20.388888	20.388888			
NORTH CENTRAL REGION	0.000000	0.020521	20.520504	20.520504			
SOUTHERN REGION	0.000000	0.018745	18.745474	18.745474			
WESTERN REGION	0.000000	0.019556	19.555564	19.555564			
HISPANICS	0.000000	0.020285	20.284618	20.284618			
NON-HISPANIC WHITES	0.000000	0.020012	20.011511	20.011511			
NON-HISPANIC BLACKS	0.000000	0.017921	17.920554	17.920554			
NON-HISPANIC OTHERS	0.000000	0.019458	19.457565	19.457565			
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.009868	9.868290	9.868290			
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.031389	31.388930	31.388930			
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.014224	14.224184	14.224184			
FEMALES 13+ YEARS, NURSING	0.000000	0.017425	17.424699	17.424699			
CHILDREN (1-6 YEARS OLD)	0.000000	0.044461	44.460600	44.460600			
CHILDREN (7-12 YEARS OLD)	0.000000	0.031819	31.818542	31.818542			
MALES (13-19 YEARS OLD)	0.000000	0.022654	22.653638	22.653638			
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.017411	17.411067	17.411067			
MALES (20 YEARS AND OLDER)	0.000000	0.015467	15.466908	15.466908			
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.012844	12.844018	12.844018			

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

TOLERANCE ASSESSMENT SUMMARY FOR Glyphosate trimesium  
CASWELL #893C

DATE: 01/25/96

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000000	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.000	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.014219	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	14.218	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.014219	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	14.218	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.005542	MG/KG/DAY
THIS TMRC WILL OCCUPY	5.542	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.019760	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	19.760	% OF THE ADI.

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

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000000	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.000	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.031860	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	31.860	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.031860	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	31.860	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.012601	MG/KG/DAY
THIS TMRC WILL OCCUPY	12.601	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.044461	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	44.461	% OF THE ADI.