

8430



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

FEB 16 1996

**MEMORANDUM**

**SUBJECT:** Dietary Exposure Analysis for Glyphosate-trimesium in/on Bananas PP# 5FO4554, Grapes PP# 1FO3950, Tree Nuts PP# 4FO4343, Citrus PP# OFO3890, and Stone Fruit 3FO4238

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

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

*E.A. Doyle*  
*W.D.*

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

**Action Requested**

Provide a dietary exposure analysis for the use of glyphosate-trimesium in/on bananas, grapes, tree nuts, citrus and stone fruits. The petition requests and CBTS recommends that a tolerance of 0.05 ppm be established on bananas, 0.1 ppm on grapes (0.2 ppm on raisins), 0.05 ppm on tree nuts, 0.05 ppm on citrus and 0.05 ppm on stone fruit (0.2 ppm on prunes).

**Discussion**

**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.



Recycled/Recyclable  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

## 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 apples, wheat and meat byproducts 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	0.019699	19.7
Children (1-6 years)	0.044279	44.3

Proposed new Tolerances:

U.S. Population	0.000126	.126
Children (1-6 years)	0.000346	.346

If the new tolerances are approved:

U.S. Population	0.019825	19.9
Children (1-6 years)	0.044625	44.6

### 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 these petitions and does not exceed the RfD for any of the DRES subgroups.

### Attachments

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

2

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C.

DATE: 02/12/96

PAGE: 1

3

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glychosate 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.	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		H
01014JA	GRAPES- JUICE	1F03950	0.100000		H
02001AA	CITRUS CITRON	0F03840	0.050000		
02002AA	GRAPEFRUIT-UNSPECIFIED	0F03840	0.050000		
02002AB	GRAPEFRUIT-PULP	0F03840	0.050000		
02002JA	GRAPEFRUIT- JUICE	0F03840	0.050000		H
02003AA	KUMQUATS	0F03840	0.050000		
02004AA	LEMONS-UNSPECIFIED	0F03840	0.050000		
02004AB	LEMONS-PULP	0F03840	0.050000		
02004HA	LEMONS-PEEL	0F03840	0.050000		H
02004JA	LEMONS- JUICE	0F03840	0.050000		
02005AA	LIMES-UNSPECIFIED	0F03840	0.050000		
02005A	LIMES-PULP	0F03840	0.050000		
02005HA	LIMES-PEEL	0F03840	0.050000		H
02005JA	LIMES- JUICE	0F03840	0.050000		
02006AA	ORANGES-UNSPECIFIED	0F03840	0.050000		
02006AB	ORANGES-PULP	0F03840	0.050000		
02006HA	ORANGES-PEEL	0F03840	0.050000		H
02006JA	ORANGES- JUICE	0F03840	0.050000		
02007AA	TANGELLOS	0F03840	0.050000		
02008AA	TANGERINES	0F03840	0.050000		
02008JA	TANGERINE- JUICE	0F03840	0.050000		H
03001AA	ALMONDS	4F04343	0.050000		
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	3F04258	0.050000		
04001AA	APPLES-FRESH	3F04258	0.050000		
04001DA	APPLES-DRIED	3F04258	0.050000		
04001JA	APPLES- JUICE	3F04238	0.050000		H
05001AA	APRICOTS-FRESH	3F04238	0.050000		
05001DA	APRICOTS-DRIED	3F04238	0.050000		
05002AA	CHERRIES-FRESH	3F04238	0.050000		

CHEMICAL INFORMATION FOR CASSELL NUMBER 893C

DATE: 02/12/96

PAGE: 2

<p>CHEMICAL Glyphosate trimesium Caswell #893C CAS No. 81591-81-3 A.I. CODE: 128501 CFR No.</p>	<p>STUDY TYPE 1yr feeding- dog NOEL= 10.0000 mg/kg LEL= 0.00 ppm 50.0000 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)</p>	<p>EFFECTS Emesis &amp; 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.</p>	<p>REFERENCE DOSES ADI UF --&gt;100 Opp RfD= 0.100000 EPA RfD= 0.000000</p>	<p>DATA GAPS/COMMENTS No data gaps. [Syn. Sulfosate]</p>	<p>STATUS RfD/PR reviewed 03/10/94</p>
---	--	--	---	--	--

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		STATUS
			NEW	PENDING	
05002DA	CHERRIES-DRIED	3F04238	0.050000		
05002JA	CHERRIES-JUICE	3F04238	0.050000		H
05003AA	NECTARINES	3F04238	0.050000		
05004AA	PEACHES-FRESH	3F04238	0.050000		
05004DA	PEACHES-DRIED	3F04238	0.050000		
05005AA	PLUMS(DAWSONS)-FRESH	3F04238	0.200000		H
05005AA	PLUMS(DAWSONS)-FRESH	3F04238	0.200000		H
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		
24007AA	WHEAT-ROUGH	5F04554	10.000000		
24007GA	WHEAT-GERM	5F04554	10.000000		
24007HA	WHEAT-BRAN	5F04554	10.000000		
24007MA	WHEAT-FLOUR	5F04554	0.050000		
270020A	CORN, GRAIN-OIL	9F03796	0.050000		
270100A	SOYBEANS-OIL	0F03860	3.000000		
28023AA	SOYBEANS-UNSPECIFIED	0F03860	3.000000		
28023AB	SOYBEANS-MATURE, SEEDS DRY	0F03860	3.000000		
28023UA	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	0F03860	1.000000		
53001BA	BEEF-MEAT BYPRODUCTS	5F04554	1.500000		
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		

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

DATE: 02/12/96

PAGE: 3

10

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= 10,000 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 carcinogenicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.100000 EPA Rfd= 0.000000	No data gaps. [Syn. Sulfosates]	Rfd/PR reviewed 03/10/94

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM)	PENDING	PUBLISHED
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	OF03860		1.000000		
53002BA	GOAT-MEAT BYPRODUCTS	OF03860		1.000000		
53002BA	GOAT-MEAT BYPRODUCTS	5F04554		1.500000		
53002BB	GOAT(ORGAN MEATS)-OTHER	OF03860		1.000000		
53002FA	GOAT(BONELESS)-FAT	OF03860		1.000000		
53002KA	GOAT(ORGAN MEATS)-KIDNEY	OF03860		1.000000		
53002LA	GOAT(ORGAN MEATS)-LIVER	OF03860		1.000000		
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	OF03860		0.200000		
53003AA	HORSE	OF03860		1.000000		
53005BA	SHEEP-MEAT BYPRODUCTS	5F04554		1.500000		
53005BA	SHEEP-MEAT BYPRODUCTS	OF03860		1.000000		
53005BB	SHEEP(ORGAN MEATS)-OTHER	OF03860		1.000000		
53005FA	SHEEP(BONELESS)-FAT	OF03860		1.000000		
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	OF03860		1.000000		
53005LA	SHEEP(ORGAN MEATS)-LIVER	OF03860		1.000000		
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT)	OF03860		1.000000		
53006BA	PORK-MEAT BYPRODUCTS	OF03860		1.000000		
53006BA	PORK-MEAT BYPRODUCTS	5F04554		1.500000		
53006BB	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		0.100000		
55008BA	TURKEY-BYPRODUCTS	5F04554		0.100000		
55008BA	TURKEY-BYPRODUCTS	OF03860		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	OF03860		0.100000		
55013BA	POULTRY, OTHER-BYPRODUCTS	5F04554		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		

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

DATE: 02/12/96

PAGE: 4

9

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF -->100		
Glyphosate trimesium Caswell #893C 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 here 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.	OPP RFD= 0.100000 EPA RFD= 0.000000	No data gaps. [Syn. Sulfosate]	Rfd/PR reviewed 03/10/94	

FOOD CODE: 55015MB      FOOD NAME: CHICKEN-FLESH(+SKIN, W/O BONES)      PETITION NUMBER: OF03860      NEW:      TOLERANCE (PPM): 0.100000      PENDING:      PUBLISHED:

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 02/12/96

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glyphosate t-rimesium Caswell #893C 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. [Syn. Sulfosate]	RfD/PR reviewed 03/10/94

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	0.000000	0.019824	19.824452	19.824452				
U.S. POPULATION - SPRING SEASON	0.000000	0.019204	19.203793	19.203793				
U.S. POPULATION - SUMMER SEASON	0.000000	0.019441	19.440737	19.440737				
U.S. POPULATION - FALL SEASON	0.000000	0.020448	20.448302	20.448302				
U.S. POPULATION - WINTER SEASON	0.000000	0.020206	20.206118	20.206118				
NORTHEAST REGION	0.000000	0.020470	20.469806	20.469806				
NORTH CENTRAL REGION	0.000000	0.020586	20.585855	20.585855				
SOUTHERN REGION	0.000000	0.018796	18.795898	18.795898				
WESTERN REGION	0.000000	0.019622	19.622383	19.622383				
HISPANICS	0.000000	0.020377	20.376976	20.376976				
NON-HISPANIC WHITES	0.000000	0.020073	20.073014	20.073014				
NON-HISPANIC BLACKS	0.000000	0.017989	17.988766	17.988766				
NON-HISPANIC OTHERS	0.000000	0.019561	19.560538	19.560538				
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.009834	9.834434	9.834434				
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.031422	31.421771	31.421771				
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.014288	14.287912	14.287912				
FEMALES (13+ YEARS, NURSING)	0.000000	0.017476	17.476307	17.476307				
CHILDREN (1-6 YEARS OLD)	0.000000	0.044624	44.624172	44.624172				
CHILDREN (7-12 YEARS OLD)	0.000000	0.031917	31.916770	31.916770				
MALES (13-19 YEARS OLD)	0.000000	0.022710	22.709955	22.709955				
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.017466	17.465640	17.465640				
MALES (20 YEARS AND OLDER)	0.000000	0.015507	15.507165	15.507165				
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.012897	12.897002	12.897002				

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

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Glyphosate trimesium  
CASWELL #893C

DATE: 02/12/96

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

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.000000 0.000	MG/KG/DAY % OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) RESULT IN A TMRC OF: THESE NEW TOLERANCES WILL OCCUPY:	0.000126 0.126	MG/KG/DAY % OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE: THE NEW TMRC WILL OCCUPY	0.000126 0.126	MG/KG/DAY % OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.019699 19.699	MG/KG/DAY % OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE: THE TOTAL TMRC WILL OCCUPY	0.019825 19.824	MG/KG/DAY % OF THE ADI.

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

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.000000 0.000	MG/KG/DAY % OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) RESULT IN A TMRC OF: THESE NEW TOLERANCES WILL OCCUPY:	0.000346 0.346	MG/KG/DAY % OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE: THE NEW TMRC WILL OCCUPY	0.000346 0.346	MG/KG/DAY % OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.044279 44.278	MG/KG/DAY % OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED THE RESULTANT TMRC WILL BE: THE TOTAL TMRC WILL OCCUPY	0.044625 44.624	MG/KG/DAY % OF THE ADI.