

US EPA ARCHIVE DOCUMENT



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

NOV 27 1995

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MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Glyphosate-trimesium
in/on Imported Bananas PP# 5EO4479 and Grapes PP#
1FO3950/FAP# 1HO5606.

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

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

E.A. Doyle
W. Stowe

Action Requested

Provide a dietary exposure analysis for the use of
glyphosate-trimesium in/on imported bananas and in/on grapes.
The petition requests that a tolerance of 0.05 ppm be established
on imported bananas and 0.1 ppm on grapes (0.2 ppm on raisins).

Discussion

The proposed tolerance on grapes would require the
establishment of animal commodity tolerances (See memo, G.
Kramer, 10/18/95). However, proposed animal commodity tolerances
currently exist (PP# OFO3860) at equal or higher levels than
those proposed for this petition. Thus, the higher existing
levels were used for the purposes of this analysis.

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.



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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 the tree nut group 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	0.005505	5.5
Non-nursing infants	0.020486	20.5

Proposed new Tolerances on bananas and grapes:

U.S. Population	0.000037	.037
Non-nursing infants	0.000079	.078

If the new tolerances on bananas and grapes are approved:

U.S. Population	0.005542	5.5
Non-nursing infants	0.020565	20.6

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 this petition on bananas at 0.05 ppm and grapes at 0.1 ppm and does not exceed the RfD for any of the DRES subgroups.

Attachments

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

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TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

DATE: 11/22/95

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Glyphosate trimesium Caswell #893C CAS No. 81591-81-3 A.I. CODE: 128501 CFR No.	1yr feeding- dog NOEL= 10.0000 mg/kg 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.	OPR RfD= 0.100000 EPA RfD= 0.000000	-->100	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
03002AA	BRAZIL NUTS	4F04343		
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	4F04343	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	0.050000	
05005DA	PLUMS- PRUNES(DRIED)	3F04238	0.050000	
05005JA	PLUMS, PRUNE- JUICE	3F04238	0.050000	
06002AA	BANANAS- UNSPECIFIED	5E04479	0.050000	
06002AB	BANANAS- FRESH	5E04479	0.050000	
06002DA	BANANAS- DRIED	5E04479	0.050000	
06016AA	PLANTAINS	9F03796	0.050000	
15004AA	CORN, POP	0F03860	3.000000	
15029AA	SOYBEANS-SPROUTED SEEDS	0F03860	0.050000	
24002EA	CORN, GRAIN- ENDOSPERM	9F03796	0.050000	
24002HA	CORN, GRAIN- BRAN	9F03796	0.050000	
24002SA	CORN SUGAR	9F03796	0.050000	
27002OA	CORN, GRAIN- OIL	0F03860	3.000000	
28023AA	SOYBEANS- UNSPECIFIED	0F03860	3.000000	
28023AB	SOYBEANS- MATURE, SEEDS DRY	0F03860	3.000000	
28023JA	SOYBEANS- FLOUR, FULL FAT	0F03860	3.000000	
28023MB	SOYBEANS- FLOUR, LOW FAT	0F03860	3.000000	
28023WC	SOYBEANS- FLOUR, DEFAITED	0F03860	3.000000	

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CHEMICAL INFORMATION FOR CASSELL NUMBER 893C

DATE: 11/22/95

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glyphosate tri-mesilum 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
43058AA	VINE 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		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 TALLON)	0F03860		1.000000		
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0F03860		1.000000		
53001LA	BEEF(ORGAN MEATS)-LIVER	0F03860		1.000000		
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVABLE FAT)	0F03860		1.000000		
53002BA	GOAT-MEAT BYPRODUCTS	0F03860		1.000000		
53002BB	GOAT(ORGAN MEATS)-OTHER	0F03860		1.000000		
53002FA	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 (W/O REMOVABLE FAT)	0F03860		0.200000		
53003AA	HORSE	0F03860		1.000000		
53003BA	SHEEP-MEAT BYPRODUCTS	0F03860		1.000000		
53003BB	SHEEP(ORGAN MEATS)-OTHER	0F03860		1.000000		
53003FA	SHEEP(BONELESS)-FAT	0F03860		1.000000		
53003KA	SHEEP(ORGAN MEATS)-KIDNEY	0F03860		1.000000		
53003LA	SHEEP(ORGAN MEATS)-LIVER	0F03860		1.000000		
53003MA	SHEEP(BONELESS)-LEAN (W/O REMOVABLE FAT)	0F03860		1.000000		
53006BA	PORK-MEAT BYPRODUCTS	0F03860		1.000000		
53006BB	PORK(ORGAN MEATS)-OTHER	0F03860		1.000000		
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0F03860		1.000000		
53006KA	PORK(ORGAN MEATS)-KIDNEY	0F03860		1.000000		
53006LA	PORK(ORGAN MEATS)-LIVER	0F03860		1.000000		
53006MA	PORK(BONELESS)-LEAN (W/O REMOVABLE FAT)	0F03860		0.100000		
55008BA	TURKEY-BYPRODUCTS	0F03860		0.100000		
55008LA	TURKEY-GIBLETS (LIVER)	0F03860		0.100000		
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	0F03860		0.100000		
55008MB	TURKEY-FLESH(+SKIN, W/O BONES)	0F03860		0.100000		
55008MC	TURKEY-UNSPECIFIED	0F03860		0.100000		
55013BA	POULTRY, OTHER-BYPRODUCTS	0F03860		0.100000		
55013LA	POULTRY, OTHER-GIBLETS(LIVER)	0F03860		0.100000		
55013MA	POULTRY, OTHER-FLESH (+SKIN, W/O BONES)	0F03860		0.100000		
55014AA	EGGS-WHOLE	0F03860		0.100000		
55014AB	EGGS-WHITE ONLY	0F03860		0.100000		

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CHEMICAL INFORMATION FOR CASWELL NUMBER 893C

DATE: 11/22/95

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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= 10,000 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.	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
55014AC	EGGS-YOLK ONLY	0F03860		0.100000		
55015BA	CHICKEN-BYPRODUCTS	0F03860		0.100000		
55015LA	CHICKEN-GIBLETS(LIVER)	0F03860		0.100000		
55015MA	CHICKEN-FLESH(W/O SKIN,W/O BONES)	0F03860		0.100000		
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	0F03860		0.100000		

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

TABLE 2

DATE: 11/22/95

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	UF		
Glyphosate trimesium Caswell #893C CAS No. 81591-81-3 A.I. CODE: 128501 CR No.	1yr feeding- dog NOEL= 10.0000 mg/kg LEL= 0.00 ppm 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 carcinogenicity in rats or mice.	OPp RfD= 0.100000 EPA RfD= 0.000000	No data gaps.	RfD/PR reviewed 03/10/94	
POPULATION SUBGROUP						
U.S. POPULATION - 48 STATES	0.000000	0.005542	5.541596	5.541596		
U.S. POPULATION - SPRING SEASON	0.000000	0.005340	5.339716	5.339716		
U.S. POPULATION - SUMMER SEASON	0.000000	0.005555	5.555203	5.555203		
U.S. POPULATION - FALL SEASON	0.000000	0.005703	5.702763	5.702763		
U.S. POPULATION - WINTER SEASON	0.000000	0.005569	5.569403	5.569403		
NORTHEAST REGION	0.000000	0.005544	5.544280	5.544280		
NORTH CENTRAL REGION	0.000000	0.005727	5.727192	5.727192		
SOUTHERN REGION	0.000000	0.005180	5.179502	5.179502		
WESTERN REGION	0.000000	0.005895	5.894955	5.894955		
HISPANICS	0.000000	0.006667	6.666529	6.666529		
NON-HISPANIC WHITES	0.000000	0.005508	5.508335	5.508335		
NON-HISPANIC BLACKS	0.000000	0.005180	5.180118	5.180118		
NON-HISPANIC OTHERS	0.000000	0.005936	5.938320	5.938320		
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.005282	5.281615	5.281615		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.020564	20.564194	20.564194		
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.003921	3.921238	3.921238		
FEMALES 13+ YEARS, NURSING	0.000000	0.004628	4.627638	4.627638		
CHILDREN (1-6 YEARS OLD)	0.000000	0.012601	12.600914	12.600914		
CHILDREN (7-12 YEARS OLD)	0.000000	0.008581	8.581017	8.581017		
MALES (13-19 YEARS OLD)	0.000000	0.006033	6.032723	6.032723		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.004737	4.737392	4.737392		
MALES (20 YEARS AND OLDER)	0.000000	0.004164	4.163627	4.163627		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.003503	3.503046	3.503046		
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	XRFD

*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: 11/22/95

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:	0.000037 0.037	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	0.000037 0.037	MG/KG/DAY % OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.005505 5.505	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	0.005542 5.542	MG/KG/DAY % OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR 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:	0.000079 0.078	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	0.000079 0.078	MG/KG/DAY % OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE CURRENT NEW PETITION HAVE A TMRC OF: THIS TMRC WILL OCCUPY	0.020486 20.486	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	0.020565 20.564	MG/KG/DAY % OF THE ADI.

See Table 1.

check about
concentration factors
in juices other
than grape

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Glyphosate-trimesium in/on Imported Bananas PP# 5E04479 and Grapes PP# 1F03950/FAP# 1H05606.

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

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

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 imported bananas and in/on grapes. The petition requests that a tolerance of 0.05 ppm be established on imported bananas and 0.1 ppm on grapes (0.2 ppm on raisins).

Discussion

The proposed tolerance on grapes would require the establishment of animal commodity tolerances (See memo, G. Kramer, 10/18/95). However, 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.

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.

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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 the tree nut group 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 ~~Existing~~ ^{Pending} Tolerances for glyphosate-trimesium:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.000000	0.0 5.5
Non-nursing infants	0.000000	0.0 20.5

Proposed new Tolerances on bananas and grapes:

U.S. Population	0.000050	.050
Non-nursing infants	0.000086	.085

If the new tolerances on bananas and grapes are approved:

U.S. Population	0.005509	5.56
Non-nursing infants	0.020516	20.56

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 bananas at 0.05 ppm and grapes at 0.1 ppm and does not exceed the RfD for any of the DRES subgroups.

Attachments

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