UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 5/8/06

SUBJECT: Glyphosate: Chronic Dietary Exposure Assessment for the Section 3 Registration Action

PC Code: 103601
DP Number: 321666

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Executive Summary

A chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCIDJ, Version 2.03), which uses food consumption data from the USDA=s Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analysis was performed to support the Section 3 request for the registration and use of glyphosate on safflower for weed control and as a harvest aid.

Acute Dietary Exposure Results and Characterization

No toxicological endpoint attributable to a single dose of glyphosate was identified by HED=s Hazard Identification Assessment Review Committee (HIARC); therefore an acute dietary exposure assessment was not conducted.

Chronic Dietary Exposure Results and Characterization

The Tier 1 chronic dietary analysis for glyphosate is a conservative estimate of dietary

exposure that used tolerance level residues and 100% crop treated. The risk estimate from chronic dietary exposure estimates for food and drinking water to glyphosate as represented by the %PAD is below EPA=s level of concern for the U.S. population and all population subgroups. The exposure estimate of the U.S. population is 2% of the chronic PAD (cPAD). The exposure estimate for the most highly exposed subpopulation (Non-nursing infants <1 year old)) is 9% of the cPAD.

Cancer Dietary Exposure Results and Characterization

Glyphosate is classified as a Anot likely@ human carcinogen. A cancer dietary exposure analysis is not required.

Water Contribution

EFED calculated the surface water Tier I estimated EEC=s for glyphosate using the GENEEC and SCI-GROW models. EECs in ground water were estimated as 0.0038 ppb. The greatest EECs in surface water, 230 ppb, were estimated from the use patterns for AquaMaster®, a glyphosate formulation registered for control of aquatic weeds and directly applied to various bodies of water. A residue value of 230 ppb was entered into the DEEM® data file and used directly in the chronic dietary risk assessment.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which EPA has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by any special FQPA Safety Factor.

For acute and non-cancer chronic exposures, EPA is concerned when estimated dietary risk exceeds 100% of the PAD. EPA is generally concerned when estimated cancer risk exceeds one in one million (i.e., the risk exceeds 1×10^{-6}). References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: AAvailable Information on Assessing Exposure from Pesticides, A User=s Guide,@ 6/21/2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf; or see SOP 99.6 (8/20/99).

The most recent dietary risk assessment for glyphosate was conducted in support of a section 3 tolerance request on grasses, Roundup Ready® wheat and nongrass animal feeds (DP Barcode: D280830, W. Donovan, 2/15/02).

II. Residue Information

Dietary Exposure

This chronic dietary risk assessment was based on the assumption of tolerance-level residues for all commodities with existing and proposed tolerances. The existing glyphosate tolerances are listed in 40 CFR ' 180.364. The Interregional Research Project No. 4 (IR-4) is proposing tolerances for safflower and sunflower at 85.0 ppm. Glyphosate does not concentrate in either safflower or sunflower oil (DP Barcode D321667, J. R. Tomerlin, in progress). For this analysis 100%CT for all commodities was assumed. DEEM default processing factors from DEEM (Version 7.76) were used for all processed commodities that do not have individual tolerances. Revised tolerances for animal commodities are not required as a result of the proposed safflower and sunflower uses. A listing of the residue file used in the chronic dietary risk assessment is provided in Attachment 1.

Water

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for glyphosate in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of glyphosate.

EFED used the SCI-GROW (Screening Concentration In Ground Water) Model to estimate the EEC of glyphosate residues in ground water. The EECs estimated for glyphosate in ground water using SCI-GROW is 0.0038 ppb for both acute and chronic exposures. EFED used the Generic Estimated Environmental Concentration (GENEEC) Model to estimate acute and chronic EECs of glyphosate residues in surface water, calculating 21 ppb for acute exposures and 0.83 ppb for chronic exposures. However, an EEC of 230 ppb was estimated for chronic exposures with the use pattern data for AquaMaster®, a formulation that may be applied to water for controlling aquatic weeds.

III. DEEM-FCIDJ Program and Consumption Information

The glyphosate chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDJ, Version 2.03), which incorporates consumption data from USDA=s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods Aas consumed@ (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and

within population subgroups. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, EPA concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old. The glyphosate chronic dietary risk assessment also reports risk for non-nursing infants <1 year old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the chronic Population Adjusted Dose (cPAD). This procedure is performed for each population subgroup.

IV. Toxicological Information

On November 20, 2001, HED=s HIARC met to consider the endpoints of toxicological concern for acute and chronic dietary exposure as well as for occupational and residential exposure pursuant to the Food Quality Protection Act (FQPA) of 1996 (TXR No. 0050428, W. Dykstra, 1/22/02). No acute dietary toxicity endpoints were identified; therefore, no risk assessments for acute exposure were performed. For chronic dietary exposure, the HIARC selected a NOAEL of 175 mg/kg/day, which was established in the rabbit developmental toxicity study. There were observations of diarrhea, nasal discharge and death in maternal animals at the LOAEL of 350 mg/kg/day. Using an uncertainty factor of 100, the chronic RfD was calculated to be 1.75 mg/kg/day. The FQPA Safety Factor Committee determined that the 10x factor to account for enhanced sensitivity of infants and children be removed for all population subgroups and scenarios (HED Document Number 012584, B. Tarplee, 4/17/98). Therefore, the cPAD is equivalent to the chronic RfD for glyphosate. The HIARC classified glyphosate as Anot likely to be a human carcinogen.@ Therefore, a risk assessment for carcinogenicity is not required. A summary of the glyphosate toxicity endpoints is shown in Table 1.

Table 1 – Summary of Toxicological Dose and Endpoints for Glyphosate for Use in Human Risk Assessment

Exposure	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age and the general population)	None	None	An acute dietary endpoint was not selected for the general population or females 13-50, since an appropriate endpoint attributable to a single exposure was not identified in the toxicology data base
Chronic Dietary (All populations)	NOAEL= 175 mg/kg/day UF = 100 Chronic RfD = 1.75 mg/kg/day	Special FQPA SF = 1 cPAD = cRfD ÷ FQPA SF = 1.75 mg/kg/day	Developmental toxicity study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Short- and intermediate-term incidental oral (Residential)	NOAEL=175 mg/kg/day	LOC for MOE = 100	Developmental toxicity study - rabbit LOAEL = 350 mg/kg/day based on diarrhea, nasal discharge and death in maternal animals
Cancer (oral, dermal, inhalation)	Cancer classification (Group E)	Risk Assessment is not required	No evidence of carcinogenicity

V. Results/Discussion

As stated above, for chronic assessments, EPA is concerned when dietary risk exceeds 100% of the cPAD. The DEEM-FCIDJ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Table 2 are for the general U.S. Population, all infants (<1 year old), non-nursing infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years. The dietary risk estimates for food and drinking water in Table 2 are all below 100% of the cPAD. The most highly exposed population subgroup is non-nursing infants <1year old at 9% of the cPAD.

This analysis is a highly conservative, Tier 1 dietary exposure assessment. Further refinement to the analysis could be made through the use of anticipated residues, incorporation of percentages of crops treated with glyphosate, processing factors instead of DEEM's default factors, and/or monitoring data that better reflect residues at the time of consumption. Since risk estimates are well below EPA=s level of concern, a more highly refined analysis is not needed at

this time. The results of the chronic dietary exposure and risk analysis are shown in Table 2. The complete analysis is provided in Attachment 2.

Table 2. Summary of Chronic Dietary Exposure and Risk for Glyphosate

Population Subgroup	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.040948	2
All Infants (< 1 year old)	0.127442	7
Non-Nursing Infants (<1 year old)	0.157626	9
Children 1-2 years old	0.094701	5
Children 3-5 years old	0.087772	5
Children 6-12 years old	0.059403	3
Youth 13-19 years old	0.036570	2
Adults 20-49 years old	0.033380	2
Adults 50+ years old	0.028298	2
Females 13-49 years old	0.030591	2

VII. Conclusions

Glyphosate does not possess acute or cancer dietary endpoints; consequently, the results of the chronic analysis only are given in Table 2. The Tier 1 analysis demonstrates that the requested uses for glyphosate result in chronic dietary risk estimates that do not exceed EPA=s level of concern for any of the regulated population subgroups, including those comprised of infants and children.

VIII. List of Attachments

Attachment 1: Residue Listing for the Chronic Dietary Risk Assessment
Attachment 2: Chronic Dietary Risk Assessment Summary

Attachment 1: Residue Listing for the Chronic Dietary Risk Assessment

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for GLYPHOSATE 1994-98 data
Residue file: C:\Documents and Settings\Bob\My Documents\work\glyphosate\deem\gly-saff-sunf-95 R98

Adjust. #2 NOT used
Analysis Date 04-17-2006 Residue file dated: 03-10-2006/11:12:33/8
Reference dose (RfD) = 1.75 mg/kg bw/day
Comment:THIS R98 FILE WAS GENERATED USING THE CONVERT TO R98 UTILITY VERSION 1.1.2.

Food Crop EPA Code	Grp	Food Name	Residue (ppm)	Adj.Factors #1	#2
95000010	O	Acerola	0.200000	1.000	1.000
18000020	18	Alfalfa, seed	0.500000	1.000	1.000
14000030	14	Almond	1.000000	1.000	1.000
14000031	14	Almond-babyfood	1.000000	1.000	1.000
14000040	14	Almond, oil	1.000000	1.000	1.000
14000041	14	Almond, oil-babyfood	1.000000	1.000	1.000
04010050	4A	Amaranth, leafy	0.200000	1.000	1.000
11000070	11	Apple, fruit with peel	0.200000	1.000	1.000
11000080	11	Apple, peeled fruit	0.200000	1.000	1.000
11000081	11	Apple, peeled fruit-babyfood	0.200000	1.000	1.000
11000090	11	Apple, dried	0.200000	8.000	1.000
11000091	11	Apple, dried-babyfood	0.200000	8.000	1.000
11000100	11	Apple, juice	0.200000	1.300	1.000
11000101	11	Apple, juice-babyfood	0.200000	1.300	1.000
11000110	11	Apple, sauce	0.200000	1.000	1.000
11000111	11	Apple, sauce-babyfood	0.200000	1.000	1.000
12000120	12	Apricot	0.200000	1.000	1.000
12000121	12	Apricot-babyfood	0.200000	1.000	1.000
12000130	12	Apricot, dried	0.200000	6.000	1.000
12000140	12	Apricot, juice	0.200000	1.000	1.000
12000141	12	Apricot, juice-babyfood	0.200000	1.000	1.000
01030150	1CD	Arrowroot, flour	0.200000	1.000	1.000
01030151	1CD	Arrowroot, flour-babyfood	0.200000	1.000	1.000
95000160	O	Artichoke, globe	0.200000	1.000	1.000
01030170	1CD	Artichoke, Jerusalem	0.200000	1.000	1.000
04010180	4A	Arugula	0.200000	1.000	1.000
95000190	O	Asparagus	0.500000	1.000	1.000
95000200	O	Avocado	0.200000	1.000	1.000
09020210	9E	Balsam pear	0.500000	1.000	1.000
95000220	O	Bamboo, shoots	0.200000	1.000	1.000
95000230	O	Banana	0.200000	1.000	1.000
95000231	O	Banana-babyfood	0.200000	1.000	1.000
95000240	O	Banana, dried	0.200000	3.900	1.000
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000
15000250	15	Barley, pearled barley	20.000000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	20.000000	1.000	1.000
15000260	15	Barley, flour	20.000000	1.000	1.000
15000261	15	Barley, flour-babyfood	20.000000	1.000	1.000
15000270	15	Barley, bran	30.000000	1.000	1.000
19010280	19A	Basil, fresh leaves	0.200000	1.000	1.000
19010281	19A	Basil, fresh leaves-babyfood	0.200000	1.000	1.000
19010290	19A	Basil, dried leaves	0.200000	1.000	1.000
19010291	19A	Basil, dried leaves-babyfood	0.200000	1.000	1.000
06030300	6C	Bean, black, seed	5.000000	1.000	1.000
06020310	6B	Bean, broad, succulent	5.000000	1.000	1.000
06030320	6C	Bean, broad, seed	5.000000	1.000	1.000
06020330	6B	Bean, cowpea, succulent	5.000000	1.000	1.000

06030340	6C	Bean, cowpea, seed	5.000000	1.000	1.000
06030350	6C	Bean, great northern, seed	5.000000	1.000	1.000
06030360	6C	Bean, kidney, seed	5.000000	1.000	1.000
06020370	6B	Bean, lima, succulent	5.000000	1.000	1.000
06030380	6C	Bean, lima, seed	5.000000	1.000	1.000
06030390	6C	Bean, mung, seed	5.000000	1.000	1.000
06030400	6C	Bean, navy, seed	5.000000	1.000	1.000
06030410	6C	Bean, pink, seed	5.000000	1.000	1.000
06030420	6C	Bean, pinto, seed	5.000000	1.000	1.000
06010430	6A	Bean, snap, succulent	5.000000	1.000	1.000
06010431	6A	Bean, snap, succulent-babyfood	5.000000	1.000	1.000
21000480	M	Beef, kidney	4.000000	1.000	1.000
21000490	M	Beef, liver	0.500000	1.000	1.000
21000491	M	Beef, liver-babyfood	0.500000	1.000	1.000
01010500	1AB	Beet, garden, roots	0.200000	1.000	1.000
01010501	1AB	Beet, garden, roots-babyfood	0.200000	1.000	1.000
02000510	2	Beet, garden, tops	0.200000	1.000	1.000
01010520	1A	Beet, sugar	10.000000	1.000	1.000
01010521	1A	Beet, sugar-babyfood	10.000000	1.000	1.000
01010530	1A	Beet, sugar, molasses	10.000000	1.000	1.000
01010531	1A	Beet, sugar, molasses-babyfood	10.000000	1.000	1.000
13010550	13A	Blackberry	0.200000	1.000	1.000
13010560	13A	Blackberry, juice	0.200000	1.000	1.000
13010561	13A	Blackberry, juice-babyfood	0.200000	1.000	1.000
13020570	13B	Blueberry	0.200000	1.000	1.000
13020571	13B	Blueberry-babyfood	0.200000	1.000	1.000
13010580	13A	Boysenberry	0.200000	1.000	1.000
14000590	14	Brazil nut	1.000000	1.000	1.000
95000600	O	Breadfruit	0.200000	1.000	1.000
05010610	5A	Broccoli	0.200000	1.000	1.000
05010611	5A	Broccoli-babyfood	0.200000	1.000	1.000
05010620	5A	Broccoli, Chinese	0.200000	1.000	1.000
05020630	5B	Broccoli raab	0.200000	1.000	1.000
05010640	5A	Brussels sprouts	0.200000	1.000	1.000
15000650	15	Buckwheat	0.100000	1.000	1.000
15000660	15	Buckwheat, flour	0.100000	1.000	1.000
01010670	1AB	Burdock	0.200000	1.000	1.000
14000680	14	Butternut	1.000000	1.000	1.000
05010690	5A	Cabbage	0.200000	1.000	1.000
05020700	5B	Cabbage, Chinese, bok choy	0.200000	1.000	1.000
05010710	5A	Cabbage, Chinese, napa	0.200000	1.000	1.000
05010720	5A	Cabbage, Chinese, mustard	0.200000	1.000	1.000
95000730	C	Cactus	0.500000	1.000	1.000
95000740	C	Canistel	0.200000	1.000	1.000
09010750	9A	Cantaloupe	0.500000	1.000	1.000
04020760	4B	Cardoon	0.200000	1.000	1.000
01010780	1AB	Carrot	0.200000	1.000	1.000
01010781	1AB	Carrot-babyfood	0.200000	1.000	1.000
01010790	1AB	Carrot, juice	0.200000	1.000	1.000
09010800	9A	Casaba	0.500000	1.000	1.000
14000810	14	Cashew	1.000000	1.000	1.000
01030820	1CD	Cassava	0.200000	1.000	1.000
01030821	1CD	Cassava-babyfood	0.200000	1.000	1.000
05010830	5A	Cauliflower	0.200000	1.000	1.000
01010840	1AB	Celeriac	0.200000	1.000	1.000
04020850	4B	Celery	0.200000	1.000	1.000
04020851	4B	Celery-babyfood	0.200000	1.000	1.000
04020860	4B	Celery, juice	0.200000	1.000	1.000
09020880	9B	Chayote, fruit	0.500000	1.000	1.000
95000890	O	Cherimoya	0.200000	1.000	1.000
12000900	12	Cherry	0.200000	1.000	1.000
12000901	12	Cherry-babyfood	0.200000	1.000	1.000
12000910	12	Cherry, juice	0.200000	1.500	1.000
12000911	12	Cherry, juice-babyfood	0.200000	1.500	1.000

14000920	14	Chestnut	1.000000	1.000	1.000
40000930	F	Chicken, meat	0.100000	1.000	1.000
40000931	F	Chicken, meat-babyfood	0.100000	1.000	1.000
40000940	F	Chicken, liver	1.000000	1.000	1.000
40000950	F	Chicken, meat byproducts	1.000000	1.000	1.000
40000951	F	Chicken, meat byproducts-babyfoo	1.000000	1.000	1.000
06030980	6C	Chickpea, seed	5.000000	1.000	1.000
06030981	6C	Chickpea, seed-babyfood	5.000000	1.000	1.000
06030990	6C	Chickpea, flour	5.000000	1.000	1.000
01011000	1AB	Chicory, roots	0.200000	1.000	1.000
02001010	2	Chicory, tops	0.200000	1.000	1.000
09021020	9B	Chinese waxgourd	0.500000	1.000	1.000
19011030	19A	Chive	0.200000	1.000	1.000
04011040	4A	Chrysanthemum, garland	0.200000	1.000	1.000
19021050	19B	Cinnamon	7.000000	1.000	1.000
19021051	19B	Cinnamon-babyfood	7.000000	1.000	1.000
10001060	10	Citrus citron	0.500000	1.000	1.000
10001070	10	Citrus hybrids	0.500000	1.000	1.000
10001080	10	Citrus, oil	0.500000	1.000	1.000
95001090	O	Cocoa bean, chocolate	0.200000	1.000	1.000
95001100	O	Cocoa bean, powder	0.200000	1.000	1.000
95001110	O	Coconut, meat	0.100000	1.000	1.000
95001111	O	Coconut- meat-babyfood	0.100000	1.000	1.000
95001120	O	Coconut, dried	0.100000	2.100	1.000
95001130	O	Coconut, milk	0.100000	1.000	1.000
95001140	O	Coconut, oil	0.100000	1.000	1.000
95001141	O	Coconut, oil-babyfood	0.100000	1.000	1.000
95001150	O	Coffee, roasted bean	1.000000	1.000	1.000
95001160	O	Coffee, instant	1.000000	1.000	1.000
05021170	5B	Collards	0.200000	1.000	1.000
19011180	19A	Coriander, leaves	0.200000	1.000	1.000
19011181	19A	Coriander, leaves-babyfood	0.200000	1.000	1.000
19021190	19B	Coriander, seed	7.000000	1.000	1.000
19021191	19B	Coriander, seed-babyfood	7.000000	1.000	1.000
15001200	15	Corn, field, flour	1.000000	1.000	1.000
15001201	15	Corn, field, flour-babyfood	1.000000	1.000	1.000
15001210	15	Corn, field, meal	1.000000	1.000	1.000
15001211	15	Corn, field, meal-babyfood	1.000000	1.000	1.000
15001220	15	Corn, field, bran	1.000000	1.000	1.000
15001230	15	Corn, field, starch	1.000000	1.000	1.000
15001231	15	Corn, field, starch-babyfood	1.000000	1.000	1.000
15001240	15	Corn, field, syrup	1.000000	1.500	1.000
15001241	15	Corn, field, syrup-babyfood	1.000000	1.500	1.000
15001250	15	Corn, field, oil	1.000000	1.000	1.000
15001251	15	Corn, field, oil-babyfood	1.000000	1.000	1.000
15001260	15	Corn, pop	0.100000	1.000	1.000
15001270	15	Corn, sweet	0.100000	1.000	1.000
15001271	15	Corn, sweet-babyfood	0.100000	1.000	1.000
95001280	O	Cottonseed, oil	35.000000	1.000	1.000
95001281	O	Cottonseed, oil-babyfood	35.000000	1.000	1.000
11001290	11	Crabapple	0.200000	1.000	1.000
95001300	O	Cranberry	0.200000	1.000	1.000
95001301	O	Cranberry-babyfood	0.200000	1.000	1.000
95001310	O	Cranberry, dried	0.200000	1.000	1.000
95001320	O	Cranberry, juice	0.200000	1.100	1.000
95001321	O	Cranberry, juice-babyfood	0.200000	1.100	1.000
04011330	4A	Cress, garden	0.200000	1.000	1.000
04011340	4A	Cress, upland	0.200000	1.000	1.000
09021350	9B	Cucumber	0.500000	1.000	1.000
13021360	13B	Currant	0.200000	1.000	1.000
13021370	13B	Currant, dried	0.200000	1.000	1.000
04011380	4A	Dandelion, leaves	0.200000	1.000	1.000
01031390	1CD	Dasheen, corm	0.200000	1.000	1.000
02001400	2	Dasheen, leaves	0.200000	1.000	1.000

95001410	C	Date	0.200000	1.000	1.000
13011420	13A	Dewberry	0.200000	1.000	1.000
19021430	19B	Dill, seed	7.000000	1.000	1.000
19011440	19A	Dillweed	0.200000	1.000	1.000
70001450	P	Egg, whole	0.050000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.050000	1.000	1.000
70001460	P	Egg, white	0.050000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.050000	1.000	1.000
70001470	P	Egg, yolk	0.050000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.050000	1.000	1.000
08001480	8	Eggplant	0.050000	1.000	1.000
13021490	13E	Elderberry	0.200000	1.000	1.000
04011500	4A	Endive	0.200000	1.000	1.000
95001510	O	Feijoa	0.200000	1.000	1.000
04021520	4B	Fennel, Florence	0.200000	1.000	1.000
95001530	O	Fig	0.200000	1.000	1.000
95001540	O	Fig, dried	0.200000	1.000	1.000
14001550	14	Filbert	1.000000	1.000	1.000
14001560	14	Filbert, oil	1.000000	1.000	1.000
80001570	F	Fish-freshwater finfish	0.250000	1.000	1.000
80001580	F	Fish-freshwater finfish, farm ra	0.250000	1.000	1.000
80001590	F	Fish-saltwater finfish, tuna	0.250000	1.000	1.000
80001600	F	Fish-saltwater finfish, other	0.250000	1.000	1.000
80001610	F	Fish-shellfish, crustacean	3.000000	1.000	1.000
80001620	F	Fish-shellfish, mollusc	3.000000	1.000	1.000
20001630	20	Flaxseed, oil	4.000000	1.000	1.000
03001640	3	Garlic	0.200000	1.000	1.000
03001650	3	Garlic, dried	0.200000	1.000	1.000
03001651	3	Garlic, dried-babyfood	0.200000	1.000	1.000
01031660	1CD	Ginger	0.200000	1.000	1.000
01031661	1CD	Ginger-babyfood	0.200000	1.000	1.000
01031670	1CD	Ginger, dried	0.200000	1.000	1.000
01011680	1AB	Ginseng, dried	0.200000	1.000	1.000
23001720	M	Goat, kidney	4.000000	1.000	1.000
23001730	M	Goat, liver	0.500000	1.000	1.000
13021740	13B	Gooseberry	0.200000	1.000	1.000
95001750	O	Grape	0.200000	1.000	1.000
95001760	O	Grape, juice	0.200000	1.200	1.000
95001761	O	Grape, juice-babyfood	0.200000	1.200	1.000
95001770	O	Grape, leaves	0.200000	1.000	1.000
95001780	O	Grape, raisin	0.200000	4.300	1.000
95001790	O	Grape, wine and sherry	0.200000	1.000	1.000
10001800	10	Grapefruit	0.500000	1.000	1.000
10001810	10	Grapefruit, juice	0.500000	2.100	1.000
06031820	6C	Guar, seed	5.000000	1.000	1.000
06031821	6C	Guar, seed-babyfood	5.000000	1.000	1.000
95001830	O	Guava	0.200000	1.000	1.000
95001831	O	Guava-babyfood	0.200000	1.000	1.000
19011840	19A	Herbs, other	0.200000	1.000	1.000
19011841	19A	Herbs, other-babyfood	0.200000	1.000	1.000
14001850	14	Hickory nut	1.000000	1.000	1.000
09011870	9A	Honeydew melon	0.500000	1.000	1.000
95001880	O	Hop	7.000000	1.000	1.000
01011900	1AB	Horseradish	0.200000	1.000	1.000
13021910	13B	Huckleberry	0.200000	1.000	1.000
95001920	O	Jaboticaba	0.200000	1.000	1.000
95001930	O	Jackfruit	0.200000	1.000	1.000
05021940	5B	Kale	0.200000	1.000	1.000
95001950	O	Kiwifruit	0.200000	1.000	1.000
05011960	5A	Kohlrabi	0.200000	1.000	1.000
10001970	10	Kumquat	0.500000	1.000	1.000
03001980	3	Leek	0.200000	1.000	1.000
10001990	10	Lemon	0.500000	1.000	1.000
10002000	10	Lemon, juice	0.500000	2.000	1.000

10002001	1B	Lemon, juice-babyfood	0.500000	2.000	1.000
10002010	1B	Lemon, peel	0.500000	1.000	1.000
19012020	19A	Lemongrass	0.200000	1.000	1.000
06032030	6C	Lentil, seed	5.000000	1.000	1.000
04012040	4A	Lettuce, head	0.200000	1.000	1.000
04012050	4A	Lettuce, leaf	0.200000	1.000	1.000
10002060	1C	Lime	0.500000	1.000	1.000
10002070	1C	Lime, juice	0.500000	2.000	1.000
10002071	1C	Lime, juice-babyfood	0.500000	2.000	1.000
13012080	13A	Loganberry	0.200000	1.000	1.000
95002090	O	Longan	0.200000	1.000	1.000
11002100	11	Loquat	0.200000	1.000	1.000
95002110	O	Lychee	0.200000	1.000	1.000
95002120	O	Lychee, dried	0.200000	1.850	1.000
14002130	14	Macadamia nut	1.000000	1.000	1.000
95002140	O	Mamey apple	0.200000	1.000	1.000
95002150	O	Mango	0.200000	1.000	1.000
95002151	O	Mango-babyfood	0.200000	1.000	1.000
95002160	O	Mango, dried	0.200000	1.000	1.000
95002170	O	Mango, juice	0.200000	1.000	1.000
95002171	O	Mango, juice-babyfood	0.200000	1.000	1.000
19012200	19A	Marjoram	0.200000	1.000	1.000
19012201	19A	Marjoram-babyfood	0.200000	1.000	1.000
15002260	15	Millet, grain	0.100000	1.000	1.000
05022290	5B	Mustard greens	0.200000	1.000	1.000
12002300	12	Nectarine	0.200000	1.000	1.000
15002310	15	Oat, bran	20.000000	1.000	1.000
15002320	15	Oat, flour	20.000000	1.000	1.000
15002321	15	Oat, flour-babyfood	20.000000	1.000	1.000
15002330	15	Oat, groats/rolled oats	20.000000	1.000	1.000
15002331	15	Oat, groats/rolled oats-babyfood	20.000000	1.000	1.000
08002340	8	Okra	0.500000	1.000	1.000
95002350	O	Olive	0.200000	1.000	1.000
95002360	O	Olive, oil	0.200000	1.000	1.000
03002370	3	Onion, dry bulb	0.200000	1.000	1.000
03002371	3	Onion, dry bulb-babyfood	0.200000	1.000	1.000
03002380	3	Onion, dry bulb, dried	0.200000	9.000	1.000
03002381	3	Onion, dry bulb, dried-babyfood	0.200000	9.000	1.000
03002390	3	Onion, green	0.200000	1.000	1.000
10002400	1C	Orange	0.500000	1.000	1.000
10002410	1C	Orange, juice	0.500000	1.800	1.000
10002411	1C	Orange, juice-babyfood	0.500000	1.800	1.000
10002420	1C	Orange, peel	0.500000	1.000	1.000
95002430	O	Palm heart, leaves	0.200000	1.000	1.000
95002440	O	Palm, oil	0.100000	1.000	1.000
95002441	O	Palm, oil-babyfood	0.100000	1.000	1.000
95002450	O	Papaya	0.200000	1.000	1.000
95002451	O	Papaya-babyfood	0.200000	1.000	1.000
95002460	O	Papaya, dried	0.200000	1.800	1.000
95002470	O	Papaya, juice	0.200000	1.500	1.000
04012480	4A	Parsley, leaves	0.200000	1.000	1.000
19012490	19A	Parsley, dried leaves	0.200000	1.000	1.000
19012491	19A	Parsley, dried leaves-babyfood	0.200000	1.000	1.000
01012500	1AB	Parsley, turnip rooted	0.200000	1.000	1.000
01012510	1AB	Parsnip	0.200000	1.000	1.000
01012511	1AB	Parsnip-babyfood	0.200000	1.000	1.000
95002520	O	Passionfruit	0.200000	1.000	1.000
95002521	O	Passionfruit-babyfood	0.200000	1.000	1.000
95002530	O	Passionfruit, juice	0.200000	1.000	1.000
95002531	O	Passionfruit, juice-babyfood	0.200000	1.000	1.000
95002540	O	Pawpaw	0.200000	1.000	1.000
06022550	6B	Pea, succulent	5.000000	1.000	1.000
06022551	6B	Pea, succulent-babyfood	5.000000	1.000	1.000
06032560	6C	Pea, dry	5.000000	1.000	1.000

06032561	6[illegible]	Pea, dry-babyfood	5.000000	1.000	1.000
06012570	6[illegible]	Pea, edible podded, succulent	5.000000	1.000	1.000
06032580	6[illegible]	Pea, pigeon, seed	5.000000	1.000	1.000
06022590	6[illegible]	Pea, pigeon, succulent	5.000000	1.000	1.000
12002600	12	Peach	0.200000	1.000	1.000
12002601	12	Peach-babyfood	0.200000	1.000	1.000
12002610	12	Peach, dried	0.200000	7.000	1.000
12002611	12	Peach, dried-babyfood	0.200000	7.000	1.000
12002620	12	Peach, juice	0.200000	1.000	1.000
12002621	12	Peach, juice-babyfood	0.200000	1.000	1.000
95002630	O	Peanut	0.100000	1.000	1.000
95002640	O	Peanut, butter	0.100000	1.890	1.000
95002650	O	Peanut, oil	0.100000	1.000	1.000
11002660	11	Pear	0.200000	1.000	1.000
11002661	11	Pear-babyfood	0.200000	1.000	1.000
11002670	11	Pear, dried	0.200000	6.250	1.000
11002680	11	Pear, juice	0.200000	1.000	1.000
11002681	11	Pear, juice-babyfood	0.200000	1.000	1.000
14002690	14	Pecan	1.000000	1.000	1.000
08002700	8	Pepper, bell	0.100000	1.000	1.000
08002701	8	Pepper, bell-babyfood	0.100000	1.000	1.000
08002710	8	Pepper, bell, dried	0.100000	1.000	1.000
08002711	8	Pepper, bell, dried-babyfood	0.100000	1.000	1.000
08002720	8	Pepper, nonbell	0.100000	1.000	1.000
08002721	8	Pepper, nonbell-babyfood	0.100000	1.000	1.000
08002730	8	Pepper, nonbell, dried	0.100000	1.000	1.000
19022740	19B	Pepper, black and white	7.000000	1.000	1.000
19022741	19B	Pepper, black and white-babyfood	7.000000	1.000	1.000
95002750	O	Peppermint	200.000000	1.000	1.000
95002760	O	Peppermint, oil	200.000000	1.000	1.000
95002770	O	Persimmon	0.200000	1.000	1.000
95002780	O	Pine nut	1.000000	1.000	1.000
95002790	O	Pineapple	0.100000	1.000	1.000
95002791	O	Pineapple-babyfood	0.100000	1.000	1.000
95002800	O	Pineapple, dried	0.100000	5.000	1.000
95002810	O	Pineapple, juice	0.100000	1.700	1.000
95002811	O	Pineapple, juice-babyfood	0.100000	1.700	1.000
14002820	14	Pistachio	1.000000	1.000	1.000
95002830	O	Plantain	0.200000	1.000	1.000
95002840	O	Plantain, dried	0.200000	3.900	1.000
12002850	12	Plum	0.200000	1.000	1.000
12002851	12	Plum-babyfood	0.200000	1.000	1.000
12002860	12	Plum, prune, fresh	0.200000	1.000	1.000
12002861	12	Plum, prune, fresh-babyfood	0.200000	1.000	1.000
12002870	12	Plum, prune, dried	0.200000	5.000	1.000
12002871	12	Plum, prune, dried-babyfood	0.200000	5.000	1.000
12002880	12	Plum, prune, juice	0.200000	1.400	1.000
12002881	12	Plum, prune, juice-babyfood	0.200000	1.400	1.000
95002890	O	Pomegranate	0.200000	1.000	1.000
25002940	M	Pork, kidney	4.000000	1.000	1.000
25002950	M	Pork, liver	0.500000	1.000	1.000
01032960	1C	Potato, chips	0.200000	1.000	1.000
01032970	1C	Potato, dry (granules/ flakes)	0.200000	4.520	1.000
01032971	1C	Potato, dry (granules/ flakes)-b	0.200000	4.520	1.000
01032980	1C	Potato, flour	0.200000	1.000	1.000
01032981	1C	Potato, flour-babyfood	0.200000	1.000	1.000
01032990	1C	Potato, tuber, w/peel	0.200000	1.000	1.000
01032991	1C	Potato, tuber, w/peel-babyfood	0.200000	1.000	1.000
01033000	1C	Potato, tuber, w/o peel	0.200000	1.000	1.000
01033001	1C	Potato, tuber, w/o peel-babyfood	0.200000	1.000	1.000
60003010	P	Poultry, other, meat	0.100000	1.000	1.000
60003030	P	Poultry, other, meat byproducts	1.000000	1.000	1.000
10003070	10	Pummelo	0.500000	1.000	1.000
09023080	9B	Pumpkin	0.500000	1.000	1.000

09023090	9B	Pumpkin, seed	0.500000	1.000	1.000
11003100	11	Quince	0.200000	1.000	1.000
95003110	O	Quinoa, grain	5.000000	1.000	1.000
04013130	4A	Radicchio	0.200000	1.000	1.000
01013140	1AB	Radish, roots	0.200000	1.000	1.000
02003150	2	Radish, tops	0.200000	1.000	1.000
01013160	1AB	Radish, Oriental, roots	0.200000	1.000	1.000
02003170	2	Radish, Oriental, tops	0.200000	1.000	1.000
05023180	5B	Rape greens	0.200000	1.000	1.000
20003190	20	Rapeseed, oil	10.000000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	10.000000	1.000	1.000
13013200	13A	Raspberry	0.200000	1.000	1.000
13013201	13A	Raspberry-babyfood	0.200000	1.000	1.000
13013210	13A	Raspberry, juice	0.200000	1.000	1.000
13013211	13A	Raspberry, juice-babyfood	0.200000	1.000	1.000
04023220	4B	Rhubarb	0.200000	1.000	1.000
15003230	15	Rice, white	0.100000	1.000	1.000
15003231	15	Rice, white-babyfood	0.100000	1.000	1.000
15003240	15	Rice, brown	0.100000	1.000	1.000
15003241	15	Rice, brown-babyfood	0.100000	1.000	1.000
15003250	15	Rice, flour	0.100000	1.000	1.000
15003251	15	Rice, flour-babyfood	0.100000	1.000	1.000
15003260	15	Rice, bran	0.100000	1.000	1.000
15003261	15	Rice, bran-babyfood	0.100000	1.000	1.000
01013270	1AB	Rutabaga	0.200000	1.000	1.000
15003280	15	Rye, grain	0.100000	1.000	1.000
15003290	15	Rye, flour	0.100000	1.000	1.000
20003300	20	Safflower, oil	85.000000	1.000	1.000
20003301	20	Safflower, oil-babyfood	85.000000	1.000	1.000
01013310	1AB	Salsify, roots	0.200000	1.000	1.000
02003320	2	Salsify, tops	0.200000	1.000	1.000
95003330	O	Sapote, Mamey	0.200000	1.000	1.000
19013340	19A	Savory	0.200000	1.000	1.000
95003360	O	Sesame, seed	0.100000	1.000	1.000
95003361	O	Sesame, seed-babyfood	0.100000	1.000	1.000
95003370	O	Sesame, oil	0.100000	1.000	1.000
95003371	O	Sesame, oil-babyfood	0.100000	1.000	1.000
03003380	3	Shallot	0.200000	1.000	1.000
26003420	M	Sheep, kidney	4.000000	1.000	1.000
26003430	M	Sheep, liver	0.500000	1.000	1.000
15003440	15	Sorghum, grain	15.000000	1.000	1.000
15003450	15	Sorghum, syrup	15.000000	1.000	1.000
95003460	O	Soursop	0.200000	1.000	1.000
06003470	6	Soybean, seed	20.000000	0.330	1.000
06003480	6	Soybean, flour	20.000000	1.000	1.000
06003481	6	Soybean, flour-babyfood	20.000000	1.000	1.000
06003490	6	Soybean, soy milk	20.000000	1.000	1.000
06003491	6	Soybean, soy milk-babyfood or in	20.000000	1.000	1.000
06003500	6	Soybean, oil	20.000000	1.000	1.000
06003501	6	Soybean, oil-babyfood	20.000000	1.000	1.000
95003510	O	Spanish lime	0.200000	1.000	1.000
95003520	O	Spearmint	200.000000	1.000	1.000
95003530	O	Spearmint, oil	200.000000	1.000	1.000
19023540	19B	Spices, other	7.000000	1.000	1.000
19023541	19B	Spices, other-babyfood	7.000000	1.000	1.000
04013550	4A	Spinach	0.200000	1.000	1.000
04013551	4A	Spinach-babyfood	0.200000	1.000	1.000
09023560	9B	Squash, summer	0.500000	1.000	1.000
09023561	9B	Squash, summer-babyfood	0.500000	1.000	1.000
09023570	9B	Squash, winter	0.500000	1.000	1.000
09023571	9B	Squash, winter-babyfood	0.500000	1.000	1.000
95003580	O	Starfruit	0.200000	1.000	1.000
95003590	O	Strawberry	0.200000	1.000	1.000
95003591	O	Strawberry-babyfood	0.200000	1.000	1.000

95003600	O	Strawberry, juice	0.200000	1.000	1.000
95003601	O	Strawberry, juice-babyfood	0.200000	1.000	1.000
95003610	O	Sugar apple	0.200000	1.000	1.000
95003620	O	Sugarcane, sugar	2.000000	1.000	1.000
95003621	O	Sugarcane, sugar-babyfood	2.000000	1.000	1.000
95003630	O	Sugarcane, molasses	30.000000	1.000	1.000
95003631	O	Sugarcane, molasses-babyfood	30.000000	1.000	1.000
20003640	20	Sunflower, seed	85.000000	1.000	1.000
20003650	20	Sunflower, oil	85.000000	1.000	1.000
20003651	20	Sunflower, oil-babyfood	85.000000	1.000	1.000
01033660	1CE	Sweet potato	0.200000	1.000	1.000
01033661	1CE	Sweet potato-babyfood	0.200000	1.000	1.000
04023670	4B	Swiss chard	0.200000	1.000	1.000
95003680	O	Tamarind	0.200000	1.000	1.000
10003690	10	Tangerine	0.500000	1.000	1.000
10003700	10	Tangerine, juice	0.500000	2.300	1.000
01033710	1CD	Tanier, corm	0.200000	1.000	1.000
95003720	O	Tea, dried	1.000000	1.000	1.000
95003730	O	Tea, instant	7.000000	1.000	1.000
08003740	8	Tomatillo	0.100000	1.000	1.000
08003750	8	Tomato	0.100000	1.000	1.000
08003751	8	Tomato-babyfood	0.100000	1.000	1.000
08003760	8	Tomato, paste	0.100000	5.400	1.000
08003761	8	Tomato, paste-babyfood	0.100000	5.400	1.000
08003770	8	Tomato, puree	0.100000	3.300	1.000
08003771	8	Tomato, puree-babyfood	0.100000	3.300	1.000
08003780	8	Tomato, dried	0.100000	14.300	1.000
08003781	8	Tomato, dried-babyfood	0.100000	14.300	1.000
08003790	8	Tomato, juice	0.100000	1.500	1.000
15003810	15	Triticale, flour	5.000000	1.000	1.000
15003811	15	Triticale, flour-babyfood	5.000000	1.000	1.000
50003820	P	Turkey, meat	0.100000	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.100000	1.000	1.000
50003840	P	Turkey, meat byproducts	1.000000	1.000	1.000
50003841	P	Turkey, meat byproducts-babyfood	1.000000	1.000	1.000
01033870	1CD	Turmeric	0.200000	1.000	1.000
01013880	1AB	Turnip, roots	0.200000	1.000	1.000
05023890	5B	Turnip, greens	0.200000	1.000	1.000
14003910	14	Walnut	1.000000	1.000	1.000
86010000	O	Water, direct, all sources	0.230000	1.000	1.000
86020000	O	Water, indirect, all sources	0.230000	1.000	1.000
95003980	O	Watercress	0.200000	1.000	1.000
09013990	9A	Watermelon	0.500000	1.000	1.000
09014000	9A	Watermelon, juice	0.500000	1.000	1.000
15004010	15	Wheat, grain	5.000000	1.000	1.000
15004011	15	Wheat, grain-babyfood	5.000000	1.000	1.000
15004020	15	Wheat, flour	5.000000	1.000	1.000
15004021	15	Wheat, flour-babyfood	5.000000	1.000	1.000
15004030	15	Wheat, germ	20.000000	1.000	1.000
15004040	15	Wheat, bran	20.000000	1.000	1.000
15004050	15	Wild rice	0.100000	1.000	1.000
01034060	1CE	Yam, true	0.200000	1.000	1.000
01034070	1CE	Yam bean	0.200000	1.000	1.000

Attachment 2: Chronic Dietary Risk Assessment Summary

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U.S. Environmental Protection Agency                                  Ver. 2.00
DEEM-FCID Chronic analysis for GLYPHOSATE                          (1994-98 data)
Residue file name: C:\Documents and Settings\Bob\My
Documents\work\glyphosate\deem\gly-saff-sunf-85.R98
                                                  Adjustment factor #2 NOT used.
Analysis Date 03-10-2006/11:13:28     Residue file dated: 03-10-2006/11:12:33/8
Reference dose (RfD, Chronic) = 1.75 mg/kg bw/day
COMMENT 1: THIS R98 FILE WAS GENERATED USING THE CONVERT TO R98 UTILITY VERSION 1.1.2.
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Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.040948	2.3%
U.S. Population (spring season)	0.041580	2.4%
U.S. Population (summer season)	0.040882	2.3%
U.S. Population (autumn season)	0.040507	2.3%
U.S. Population (winter season)	0.040857	2.3%
Northeast region	0.039938	2.3%
Midwest region	0.042443	2.4%
Southern region	0.039454	2.3%
Western region	0.042626	2.4%
Hispanics	0.041986	2.4%
Non-hispanic whites	0.040549	2.3%
Non-hispanic blacks	0.041367	2.4%
Non-hisp/non-white/non-black	0.043857	2.5%
All infants (< 1 year)	0.127442	7.3%
Nursing infants	0.047930	2.7%
Non-nursing infants	0.157626	9.0%
Children 1-6 yrs	0.087996	5.0%
Children 7-12 yrs	0.056558	3.2%
Females 13-19 (not preg or nursing)	0.032553	1.9%
Females 20+ (not preg or nursing)	0.028708	1.6%
Females 13-50 yrs	0.032676	1.9%
Females 13+ (preg/not nursing)	0.033369	1.9%
Females 13+ (nursing)	0.041177	2.4%
Males 13-19 yrs	0.040339	2.3%
Males 20+ yrs	0.034384	2.0%
Seniors 55+	0.027783	1.6%
Children 1-2 yrs	0.094701	5.4%
Children 3-5 yrs	0.087772	5.0%
Children 6-12 yrs	0.059403	3.4%
Youth 13-19 yrs	0.036570	2.1%
Adults 20-49 yrs	0.033380	1.9%
Adults 50+ yrs	0.028298	1.6%
Females 13-49 yrs	0.030591	1.7%

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 5/6/06

Subject: Glyphosate: Safflower and Sunflower; Summary of Analytical Chemistry and Residue Data. Petition Number 4E6878.

DP Number: 321667 Decision: 364666
PC Code: 103601 MRID Numbers: 46408001 & 48408002
40 CFR 180.364 Chemical Class: Herbicide

From: J. R. Tomerlin, Ph.D., Plant Pathologist
Fungicide Branch
Registration Division (7505C)

Through: P. V. Shah, PhD., Branch Senior Scientist
Registration Acton Branch 1
Health Effects Division

and

W. Cutchin
Technical Review Branch
Registration Division (7505C)

To: S. Brothers/D. Rosenblatt PM 5
Risk Integration, Minor Use and Emergency Response Branch
Registration Division (7505C)

Executive Summary

The Interregional Research Project No. 4 (IR-4) has submitted field trial data for glyphosate (N-(phosphonomethyl)glycine) on safflower and sunflower. In all trials, Roundup Ultra® Herbicide was applied to preemergence plants, with a second foliar application to the physiologically mature crop; registration is being sought for Roundup WeatherMax®. The only difference between the test substance (Roundup Ultra® Herbicide) and the proposed registered product (Roundup WeatherMAX®) is the percent active ingredient in the formulated product. In

the residue trials, application of Roundup Ultra® Herbicide was adjusted to approximate the proposed application rate for Roundup WeatherMax®. A total of 6.0 lb a.i./A (6.7 kg a.i./hectare) of compound was applied per season in the safflower trials, approximately 109% of the proposed label rate for WeatherMAX®. The treatment interval was 106 days in all safflower trials. The number and locations of safflower field trials are not in accordance with OPPTS Guideline 860.1500. Based on the available data, TRB will extend the sunflower data to cover safflower even though it has a higher use rate. In each sunflower trial, Roundup Ultra® Herbicide was to be applied to preemergence sunflower, with a second foliar application to the physiologically mature crop. A total of 2.0 lb a.i./A (2.24 kg a.i./hectare) of compound was to be applied per treated plot, approximately 105% of the proposed label rate. In two trials, the initial preemergence treatment was not applied because the plots were too wet to spray before sunflower emergence. Applications in four trials were 1.22X to 1.33X higher than specified by the protocol because of calculation errors. The interval between treatments ranged from 105 to 118 days. The number and locations of sunflower field trials are not in accordance with OPPTS Guideline 860.1500 because no trials were conducted in Region 8 as required by the Guidelines. However, the two trials conducted in Scottsbluff, NE were 60 miles from Region 8 and this deviation from Guideline requirements is considered to be insignificant.

In previously submitted studies in plants and rotatational crops, residues of glyphosate were not detectable in crops planted 30 days after treatment. For purposes of this petition, the residue of concern for tolerance setting and risk assessment purposes is glyphosate *per se*. Amino-methylphosphonic acid (AMPA) is no longer of toxicological concern and is not included in either the tolerance expression or the risk assessment. No impact is expected on the dietary burdens to dairy or beef cattle, poultry or hogs since safflower and sunflower meal are minor contributors to livestock dietary burdens relative to other livestock feedstuffs.

Adequate enforcement methods are included in the Food and Drug Administration's Pesticide Analytical Methods, Volume II (PAM II). These methods include GLC (Method I in PAM II) and HPLC with fluorometric detection. However, recoveries are not likely for glyphosate under FDA Multiresidue Methods.

The method used for the analysis of glyphosate residues in safflower and sunflower samples, *Analytical method for glyphosate and AMPA in raw agricultural commodities, and their processed fractions*, Document RES-008-90, February, 1994: Monsanto Corp. is adequate for data collection. Minor modifications to the reference method did not negatively affect the performance of the method. The LOQ was 0.05 ppm; a LOD was not reported.

Glyphosate residues were quantitated in sample extracts of safflower and sunflower RACs and processed commodities using the method cited, a two-column-switching HPLC equipped with an o-phthalaldehyde post-column reactor and a fluorescence detector. The percent recovery of glyphosate during method validation in safflower seed ranged from 84 to 100%. During sample analysis, untreated safflower seed was fortified with glyphosate at levels of 0.05, 0.99 and 2.0 ppm for concurrent recovery spikes; concurrent recovery values ranged from 80% to 106%. Untreated control safflower meal was fortified at 4.0 ppm and untreated control safflower oil was fortified at 0.05 ppm for concurrent recovery spikes; concurrent recoveries for meal and oil were 83% and 76%, respectively. During sample analysis, untreated

sunflower seed was fortified with glyphosate at levels of 0.05, 0.1, 0.5, 1.0 and 10.0 ppm for concurrent recovery spikes; concurrent recovery values ranged from 72% to 113%. Untreated control sunflower meal and oil were fortified at 0.05 ppm for concurrent recovery spikes; concurrent recoveries were 93% in sunflower meal and 85% in sunflower refined oil.

Tolerances for the residues of glyphosate (N-(phosphonomethyl)glycine) are established on a wide range of crops (40 CFR 180.364). Although IR-4 proposed tolerances of 25.0 ppm in safflower and sunflower, TRB proposes tolerances of 85.0 ppm, based on the results of the new MRL/tolerance calculator, for safflower and sunflower. The residue field trial studies were adequate in number and geographic location, conducted in accordance with the proposed uses, and supported by appropriate storage stability data. There are adequate analytical methods available for tolerance enforcement. The analytical method used for data gathering is acceptable for that purpose. The residue chemistry data support the proposed tolerance for the residues of glyphosate at 85.0 ppm on safflower and sunflower. A glyphosate confined rotational crop study has previously been submitted and reviewed. The registrant should reinstate the 30-day PBI for crops on which use of glyphosate is not registered.

Regulatory Recommendations and Residue Chemistry Deficiencies

The petitioner should submit a revised supplemental label for the proposed uses on safflower and sunflower including a 30-day plant back restriction for rotational crops.

Pending submission of a revised supplemental label and the results of the forthcoming human health risk assessment, TRB recommends for the establishment of tolerances for the residues of glyphosate on/in safflower and sunflower at 85.0 ppm.

Background

Glyphosate is an herbicide, and its registration on safflower and sunflower would permit its use for weed control and as a harvest aid. The test material was Roundup Ultra®, the isopropylamine salt. Roundup Ultra® is 4 lb a.i./gal, or 3 lb/gal of acid equivalent. The nomenclature of the test substance is shown in Table 1. The physical and chemical characteristics of glyphosate are shown in Table 2.

TABLE 1. Test Compound Nomenclature	
Compound	Chemical Structure 
Common name	Glyphosate
Company experimental name	MON 65005
IUPAC name	N-(phosphonomethyl)glycine

CAS name	Glycine, N-(phosphonomethyl)
CAS #	1071-83-6
End-use product/EP	Roundup Ultra® Herbicide

TABLE 2. Physical and Chemical Properties of Glyphosate Technical Grade Active Ingredient	
Color	White
Physical State	Crystalline solid
Odor	Odorless
Melting Point[a]	184.5°C
pH[a]	2.5, 1% solution
Specific Gravity[b]	1.7 @ 20°
Solubility in water[b]	10,100 mg/L @ 20°C
Solvent solubility[c]	Insoluble in most organic solvents
Vapor Pressure[b]	$< 1 \times 10^{-5}$ Pa @ 25°C
Dissociation Constant[b]	<2, 2.6, 5.6, 10.6
Octanol/Water Coefficient[b]	-2.8
Absorption coefficient[c]	12,000
[b]Value obtained from International Programme on Chemical safety from data provided by Monsnato [c]Extoxnet	

860.1200 Directions for Use

Table 3. Summary of Directions for Use of Glyphosate.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate lb ai/A (kg ai/ha)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate lb ai/A (kg ai/ha)	PHI (days)	Use Directions and Limitations
Safflower						
Treatment 1 Preplant, preemergence, at-planting	524-537	Up to 2.75 (3.08)	1	2.75 (3.08) Treatments 1 and 2 combined	Not specified	See maximum seasonal rate
Treatment 2 In established crop: hooded or shielded sprayers in row middles, wiper applications in row middles	524-537	Up to 2.75 (3.08)	Not specified	2.75 (3.08) Treatments 1 and 2 combined	Not specified	See maximum seasonal rate

Table 3. Summary of Directions for Use of Glyphosate.						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate lb ai/A (kg ai/ha)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate lb ai/A (kg ai/ha)	PHI (days)	Use Directions and Limitations
Treatment 3 Preharvest	524-537	Up to 2.75 (3.08)	Not specified, more than 1 is unlikely	2.75 (3.08)	7	Apply to physiologically mature crop when seed has lost its opaqueness, 20 to 30 days after the end of flowering of the secondary branches
Post-harvest	524-537	According to "Weeds Tables" of the basic WeatherMAX® label			Not specified	
Sunflower						
Treatment 1 Preplant, preemergence, at-planting	524-537	Up to 0.95 (1.06)	1	0.95 (1.06) Treatments 1 and 2 combined	Not specified	See maximum seasonal rate
Treatment 2 In established crop: hooded or shielded sprayers in row middles, wiper applications in row middles	524-537	Up to 0.95 (1.06	Not specified	0.95 (1.06) Treatments 1 and 2 combined	Not specified	See maximum seasonal rate
Treatment 3 Preharvest	524-537	Up to 0.95 (1.06)	Not specified, more than 1 is unlikely	0.95 (1.06)	7	Apply to physiologically mature crop when the backsides of sunflower heads are yellow, bracts are turning brown and seed moisture content < 35%
Post-harvest	524-537	According to "Weeds Tables" of the basic WeatherMAX® label			Not specified	

The label is adequate to allow evaluation of the residue data relative to the proposed use.

860.1300 Nature of the Residue - Plants

PP# 2E04118 (formerly 2H05650), DP Barcodes: D242628, D245591, T. Bloem, 11/30/98
PP#s 0F06130, 0F06195 and 0F06273, DP Barcode: D280831, W. H. Donovan, W.G. Dykstra and J. T. Swackhammer, 2/20/02
5F04555, DP Barcodes: D217539 and D217541, G. Kramer, 3/14/96
Memorandum, R. B. Perfetti, 10/19/92
Memorandum, R. B. Perfetti, 10/27/92
Memorandum, R. B. Perfetti, 3/17/94

The qualitative nature of the residue in plants is adequately understood. Studies with a variety of plants including corn, cotton, soybeans, and wheat indicate that the uptake of glyphosate or its metabolite, aminomethylphosphonic acid (AMPA), from soil is limited. The

material that is taken up is readily translocated. Foliar-applied glyphosate is readily absorbed and translocated throughout the trees or vines to the fruit of apples, coffee, dwarf citrus (calamondin), pears and grapes. Metabolism via N-methylation yields N-methylated glycines and phosphonic acids. For the most part, the ratio of glyphosate to AMPA is 9 to 1 but can approach 1 to 1 in a few cases (e.g., soybeans and carrots). Much of the residue data for crops reflects a detectable residue of parent (0.05 - 0.15 ppm) along with residues below the level of detection (<0.05 ppm) of AMPA (Memo, R. B. Perfetti, 10/27/92). In an 8/19/92 meeting, the HED Metabolism Committee determined that, based on toxicological considerations, AMPA need not be regulated and should be dropped from the tolerance expression (Memo, R. B. Perfetti, 10/19/92). Furthermore, in a 3/17/94 meeting, the HED Metabolism Committee discussed whether uses that result in significantly higher residues of AMPA in plants and livestock commodities in the future would require that AMPA be reintroduced into the tolerance expression of glyphosate. The Committee determined that, based on toxicological considerations, AMPA need not be regulated regardless of levels observed in foods or feeds (Memo, R. B. Perfetti, 3/17/94).

Metabolism studies submitted for genetically engineered glyphosate-tolerant canola (D242628 and D245591, T. Bloem, 11/30/98) and glyphosate-tolerant corn (D217539, G. Kramer, 3/14/96) have indicated that metabolism in glyphosate-tolerant plants is essentially the same as that in normal plants. Thus, the terminal residue to be regulated in plants is glyphosate *per se*.

860.1300 Nature of the Residue – Livestock

PP#s 0F06130, 0F06195 and 0F06273, DP Barcode: D280831, W. H. Donovan, W.G. Dykstra and J. T. Swackhammer, 2/20/02
Memorandum, R. B. Perfetti, 10/19/92
Memorandum, R. B. Perfetti, 10/27/92
Memorandum, R. B. Perfetti, 3/17/94

The qualitative nature of glyphosate residues in livestock is adequately understood. Studies with lactating goats and laying hens fed a mixture of glyphosate and AMPA indicate that the primary route of elimination was by excretion (urine and feces). These results are consistent with metabolism studies in rats, rabbits, and cows. The terminal residues in eggs, milk, and livestock tissues are glyphosate and its metabolite AMPA; there was no evidence of further metabolism (Memo, R. Perfetti, 10/27/92). The conclusions of the HED Metabolism Committee on 10/19/92 and 3/17/94 apply to plant and livestock commodities. Thus, the terminal residue to be regulated in livestock is glyphosate *per se*.

860.1340 Residue Analytical Methods

0F06130, 0F06195, and 0F06273, DP Barcodes: D265970, D275014, and D275015, W. Donovan, 1/31/02
5F04555, DP Barcodes: D217539 and D217541, G. Kramer, 3/14/96
Memorandum, R. B. Perfetti, 10/27/92
MRID# 46408001, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06
MRID# 46408002, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06

Adequate enforcement methods are available for analysis of residues of glyphosate in or on plant and livestock commodities. These methods include GLC (Method I in Pesticides

Analytical Manual (PAM) II; the limit of detection is 0.05 ppm) and HPLC with fluorometric detection. Use of the GLC method is discouraged due to the lengthiness of the experimental procedure. The HPLC procedure has undergone successful Agency validation and was recommended for inclusion in PAM II (Memo, R. Perfetti, 10/27/92). A GC/MS method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL) (PP#5F04555, G. Kramer, 3/21/95). Thus, adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in/on the seed, meal, and oil of safflower and sunflower, and livestock commodities.

The HPLC method was used to analyze residues in safflower and sunflower (*Analytical method for glyphosate and AMPA in raw agricultural commodities, and their processed fractions*, Document RES-008-90, February, 1994: Monsanto Corp.). Minor modifications were made for use on safflower and sunflower that did not negatively affect the performance of the method. Modifications were made in the following areas:

- Preparation of iron (III) loaded Chelex® resin from resin in sodium form
- Sample preparation
- Amount of acidic aqueous extract
- The pH of the acidic aqueous extract
- Amount of 6 M HCl used for elution
- Anion exchange column resin
- Use of OPA solution instead of commercially prepared Fluoraldehyde®
- Chelex® column chromatography
- Instrumentation: HPLC OPA post-column reactor system
- Oxidative solution
- Reagents

The method used for the analysis of glyphosate residues in safflower and sunflower samples is adequate for data collection.

860.1360 Multiresidue Methods

0F06130, 0F06195, and 0F06273, DP Barcodes: D265970, D275014, and D275015, W. Donovan, 1/31/02

The Pestrak database (1990) indicates that recoveries are not likely for glyphosate under FDA Multiresidue Methods. No further data regarding multiresidue methods are required for this proposed use. This conclusion is corroborated by the 2005 update of the Pestrak database.

860.1380 Storage Stability

0F06130, 0F06195, and 0F06273, DP Barcodes: D265970, D275014, and D275015, W. Donovan, 1/31/02
DP Barcode: D166777, R. B. Perfetti, 4/2/92
MRID# 46408001, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06
MRID# 46408002, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06

The maximum total storage intervals for grass, wheat, and alfalfa/clover samples were 11, 9.2, and 15 months, respectively. The available storage stability data indicate that residues of glyphosate are stable under frozen storage conditions (-20°C): in or on plant commodities for a

period of at least 1 year, in animal commodities for at least 2 years, and in water for at least 1 year (Memo. R. Perfetti, 10/27/92). Sunflower storage stability samples exhibited average recoveries of 76 ± 2% after storage for 857 days (MRID #46408002). There is adequate data available indicating that residues of glyphosate are stable in frozen safflower and sunflower samples for the duration of the study.

860.1480 Meat, Milk, Poultry, and Eggs

DP Barcode: D256740, W. Donovan, 6/9/00
0F06130, 0F06195, and 0F06273, DP Barcodes: D265970, D275014, and D275015, W. Donovan, 1/31/02
MRID# 46408001, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06
MRID# 46408002, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06

Although safflower and sunflower meal are considered feed commodities, the current proposal to establish a tolerance for safflower and sunflower meal at 85 ppm is not expected to result in an increase in the dietary burden for cattle, poultry, and hogs. Respective dietary burdens of 210 and 220 ppm were previously estimated for dairy and beef cattle, including a contribution from alfalfa hay as the roughage component of the diet with a tolerance of 400 ppm (DP Barcode: D256740, W. Donovan, 6/9/00). No impact is expected on the dietary burdens to dairy or beef cattle, poultry or hogs since safflower and sunflower meal are minor contributors to livestock dietary burdens relative to other livestock feedstuffs.

860.1500 Crop Field Trials

MRID# 46408001, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06
MRID# 46408002, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06

Table 4. Summary of Residues from the Crop Field Trials with Glyphosate.

Commodity	Total Applic. Rate, lb ai/A (kg ai/ha)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[1]	Median (STMdR)	Mean (STMR)	Std. Dev.
Safflower	6 (6.73)	7	6	1.1	2.9	2.8	1.6	1.87	0.76
		14	2	0.89	1.1	1.0	1.0	1.0	0.15
		20	2	1.7	1.9	1.8	1.8	1.8	0.14
Sunflower	2.02 – 2.04 (2.26 – 2.29)	6	4	0.63	2.4	2.25	1.43	1.47	0.91
	1.32 – 2.54 (1.48 – 2.85)	7	10	0.07	20	18.5	4.95	6.13	7.11
	2.51 (2.81)	8	2	2.9	3.6	3.25	3.25	3.25	0.49

Safflower: IR-4 has submitted field trial data for glyphosate on safflower. Three supervised crop field trials were conducted in ND (Region 7). The study was originally conducted for registration for regional use only. A higher tolerance based on sunflower data is being proposed instead of a regional restriction. In each trial, Roundup Ultra® Herbicide was applied to preemergence safflower, with a second foliar application to the physiologically mature crop. A total of 6.0 lb a.i./A (6.7 kg a.i./hectare) of compound was applied per treated plot, approximately 109% of the proposed rate of 5.5 lb a.i./A (6.16 kg a.i./hectare). The treatment interval was 106 days in all trials. Activator 90 non-ionic surfactant was added to the spray

mixture for all applications. The number and locations of safflower field trials are not in accordance with OPPTS Guideline 860.1500.

Samples of safflower seed were analyzed for glyphosate using *Analytical Method for Glyphosate and AMPA in Raw Agricultural Commodities and their Processed Fractions*, Monsanto Document Number: RES-008-90, Version 4; February 1994. Minor modifications to the method are described in the discussion about Section 860.1340 in this document. Safflower sample extracts were analyzed using a two-column-switching HPLC equipped with an o-phthalaldehyde post-column reactor and a fluorescence detector. Samples of control safflower seed were fortified at levels ranging from 0.05 to 50 ppm. The percent recovery of glyphosate during method validation in safflower seed ranged from 84 to 100%. During sample analysis, untreated safflower seed were fortified with glyphosate at levels of 0.05, 0.99 and 2.0 ppm for concurrent recovery spikes; concurrent recovery values ranged from 80% to 106%. Untreated control safflower meal was fortified at 4.0 ppm and untreated control safflower oil was fortified at 0.05 ppm for concurrent recovery spikes; concurrent recoveries for meal and oil were 83% and 76%, respectively. A peak that may or may not be glyphosate appeared within the glyphosate retention window for control samples of seed. During method validation, different HPLC columns were used to separate the interfering peak form the glyphosate peak, but without success. The interfering peak was not observed in concurrent recovery samples.

Safflower seed was harvested at a 7-day PHI. The results from these trials show that glyphosate residues ranged from 1.1 ppm to 2.9 ppm on/in treated safflower seed when the test substance was applied at the seasonal application rate of approximately 6 lb a.i./A. A residue decline study was conducted where safflower seed samples were collected at PHI's of 7, 14, and 20 days. Average residues ranged from a high of 1.8 ppm at PHI = 20 days to a low of 1.0 ppm at PHI = 14 days. Safflower seed was stored frozen (-25°C to -11°C) for 666 to 680 days. The petitioner indicated that storage stability data were unnecessary because analyses were performed within two years of sample collection. Previous reviews were cited to corroborate that glyphosate residues remain stable in crop tissues for more than 2 years (CBRS No. 8337, DP Barcode: D166777, R. Perfetti, 4/2/92), although the cited document stated that storage stability is 2 years in animal tissues and 1 year in crop matrices. However, storage stability data were submitted with the sunflower petition showing recoveries of 76 ±2% after 857 days in frozen storage. Therefore, TRB concludes that there is sufficient storage stability data to support the safflower residue trials.

Sunflower: IR-4 has submitted field trial data for glyphosate on sunflower. Supervised crop field trials were conducted in Prosper, ND (one trial in Region 5); Minot, ND (2 trials in Region 7), Scottsbluff, NE (2 trials in Region 7), Brookings, Aurora and South Shore, SD (three trials in Region 5). In each trial, Roundup Ultra® Herbicide was to be applied to preemergence sunflower, with a second foliar application to the physiologically mature crop. No adjuvants or additives were added to the spray mixture for any of the sunflower applications. A total of 2.0 lb a.i./A (2.24 kg a.i./hectare) of compound was to be applied per treated plot, approximately 105% of the proposed label rate of 1.9 lb a.i./A (2.13 kg a.i./hectare). In two trials, the initial preemergence treatment was not applied because the plots were too wet to spray before sunflower emergence. In addition, applications in four trials were 1.22X to 1.33X higher than specified by the protocol because of calculation errors. The interval between treatments ranged

from 105 to 118 days. The number and locations of sunflower field trials are not in accordance with OPPTS Guideline 860.1500 because no trials were conducted in Region 8 as required by the Guidelines. However, the two trials conducted in Scottsbluff, NE were 60 miles from Region 8. Therefore, this deviation from Guideline requirements is not significant, and the residue trials are acceptable.

Residues of glyphosate in sunflower were quantitated using *Analytical Method for Glyphosate and AMPA in Raw Agricultural Commodities and their Processed Fractions*, Monsanto Document Number: RES-008-90, Version 4; February 1994. Minor modifications to the method are described in the discussion about Section 860.1340 in this document. Sunflower sample extracts were analyzed using a two-column-switching HPLC equipped with an o-phthalaldehyde post-column reactor and a fluorescence detector. Samples of control sunflower were fortified at levels ranging from 0.05 to 25.0 ppm. The percent recovery of glyphosate during method validation in sunflower seed ranged from 74 to 99%. During sample analysis, untreated sunflower seed was fortified with glyphosate at levels of 0.05, 0.1, 0.5, 1.0 and 10.0 ppm for concurrent recovery spikes; concurrent recovery values ranged from 72% to 113%. Untreated control sunflower meal and oil were fortified at 0.05 ppm for concurrent recovery spikes; the concurrent recovery was 93% in sunflower meal and 85% in sunflower refined oil. The method is adequate for data collection.

Sunflower seed was harvested at a 6 to 8-day PHI. The proposed PHI is 7 days, and these deviations are considered to be insignificant. The results from these trials show that glyphosate residues ranged from 0.07 to 20 ppm on/in treated sunflower seed when the test substance was applied at a seasonal application rate of 1.32 to 2.54 lb a.i./A with a 6 to 8-day PHI. The first and second applications in the trial yielding the maximum residue value were applied at 1.32X and 1.22X of the target protocol application rate. Sunflower seed was stored frozen (-25°C to -8°C) for a maximum of 855 days. After storage for 857 days, average recovery was 76 ± 2%. There is sufficient storage stability data available to support the residue chemistry data.

The residue field trial studies for safflower and sunflower were adequate in number and geographic location, conducted in accordance with the proposed uses, and supported by appropriate storage stability data. There are adequate analytical methods available for tolerance enforcement. The analytical method used for data gathering is acceptable for that purpose. The residue chemistry data support the proposed tolerance for the residues of glyphosate at 85.0 ppm on/in safflower and sunflower.

The MRL Spreadsheet (PMRA PRO2005-04, 9/28/05; Attachment 1) was used to estimate recommended glyphosate tolerances in safflower and sunflower. Based on the available data, TRB will extend the sunflower data to cover safflower even though it has a higher use rate. The petitioner proposed a tolerance of 25 ppm for safflower and sunflower. The spreadsheet indicates a much higher recommended tolerance than that being proposed. Therefore, TRB recommends for the requested glyphosate tolerance of 85 ppm on safflower and sunflower.

860.1520 Processed Food and Feed

MRID# 46408001, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06
MRID# 46408002, PP# 4E6878, DP Barcode: D321667, J. R. Tomerlin, 1/31/06

Safflower (MRID #46408001) was treated with one preemergence application and one foliar application (at crop physiological maturity) of Roundup Ultra® herbicide (the test substance). The total amount applied was approximately 5.9 lb a.i./A (6.61 kg a.i./hectare), approximately 107% of the proposed label rate of 5.5 lb a.i./A (6.16 kg a.i./hectare) for WeatherMAX®.

Sunflower (MRID #46408002) was treated with one preemergence application and one foliar application (at crop physiological maturity) of Roundup Ultra® herbicide (the test substance). The total amount applied in the processing trial was approximately 2.05 lb a.i./A (2.13 kg a.i./hectare), approximately 108% of the proposed label rate of 1.9 lb a.i./A (2.3 kg a.i./hectare) for WeatherMAX®.

Residues of glyphosate in safflower processed commodities were quantitated using *Analytical Method for Glyphosate and AMPA in Raw Agricultural Commodities and their Processed Fractions*, Monsanto Document Number: RES-008-90, Version 4; February 1994. Safflower sample extracts were analyzed using a two-column-switching HPLC equipped with an o-phthalaldehyde post-column reactor and a fluorescence detector. The LOQ was 0.05 ppm; a LOD was not reported. Samples of control safflower seed were processed into defatted meal and refined oil. During sample analysis, untreated safflower seed were fortified with glyphosate at levels of 0.05, 0.99 and 2.0 ppm for concurrent recovery spikes; concurrent recovery values ranged from 80% to 106%. Untreated control safflower meal was fortified at 4.0 ppm and untreated control safflower oil was fortified at 0.05 ppm for concurrent recovery spikes; concurrent recoveries for meal and oil were 83% and 76%, respectively. During sample analysis, untreated sunflower seed was fortified with glyphosate at levels of 0.05, 0.1, 0.5, 1.0 and 10.0 ppm for concurrent recovery spikes; concurrent recovery values ranged from 72% to 113% in sunflower seed. Untreated control sunflower meal and oil were fortified at 0.05 ppm for concurrent recovery spikes; concurrent recovery was 93% in sunflower meal and 85% in sunflower refined oil. The method is adequate for data collection.

Safflower seed was harvested at a 7-day PHI and processed into meal and refined oil. The results from this trial show that glyphosate residues in the processing study were 2.5 ppm in safflower seed, 3.0 ppm in safflower meal, and <0.05 ppm in safflower refined oil. The concentration factors for glyphosate in safflower meal (1.2x) and oil (0.02x) are considered to be insignificant.

Sunflower seed was harvested at a 7-day PHI and processed into meal and refined oil. The results from this trial show that glyphosate residues in the processing study were 0.12 ppm in sunflower seed, 0.053 ppm in sunflower meal, and <0.05 ppm in sunflower refined oil. The concentration factors for glyphosate in sunflower meal (0.44x) and oil (0.42x) are considered to be insignificant.

The procedures in both the safflower and sunflower processing studies imitated common commercial practice. However, commercial processing plants operate continuously, whereas the processing studies processed the commodities in batches rather than continuously because of sample size and the requirement to monitor the process. The processed food/feed studies are classified as acceptable and satisfy the guideline requirement for a processing study. Tolerances will not need to be established to cover residues of glyphosate in safflower or sunflower

processed commodities because residues in meal and refined oil of safflower and sunflower did not concentrate significantly and will be covered by the proposed tolerances of 85 ppm for safflower and sunflower.

860.1650 Submittal of Analytical Reference Standards

Personal communication, email from C. J. Stafford to W. Cutchin and J. R. Tomerlin dated 2/22/06

Analytical reference standards are on file with the Agency.

860.1850 & 1900 Confined and Field Accumulation in Rotational Crops

MRID#s 41543201 and 41543202, A. Abramovitch, 10/14/92
0F06130, 0F06195, and 0F06273, DP Barcodes: D265970, D275014, and D275015, W Donovan, 1/31/02
DP Barcode: D200041, G. Kramer, 5/12/94

An acceptable confined rotational crop study was previously reviewed (Memo; MRIDs 41543201 and 41543202, A. Abramovitch, 10/14/92) which indicated that residues of glyphosate were not detectable in crops planted 30 days after treatment. The current label for glyphosate WeatherMAX® only addresses rotational crops in relation to use of WeatherMAX® on corn with the Roundup Ready® gene. However, in an HED review of Monsanto's proposal to remove a 30-day plantback restriction for crops on which use of glyphosate is not registered, HED concluded that the petitioner would be required to demonstrate that significant glyphosate residues would not be present in rotational crops planted 0 days after soil treatment, and recommended against the label amendment. No rotational crop data have been submitted in support of a 0-day plantback interval (PBI) for rotational crops; therefore, the registrant should reinstate the 30-day PBI for crops on which use of glyphosate is not registered (DP Barcode: D200041, 5/12/94, G. Kramer). This position was reiterated in a subsequent review (D625970, W. Donovan, 1/31/02).

860.1550 Proposed Tolerances

The tolerance expression as stated in 40 CFR 180.364 is glyphosate (N-(phosphonomethyl)glycine). As described in the section 860.1500 – Nature of the Residue, Plants, AMPA is no longer of toxicological significance and is not included in the tolerance expression. There are currently no Codex, Canadian, or Mexican Maximum Residue Limits for residues of glyphosate on safflower or sunflower, therefore there are no international harmonization issues associated with this action (Attachment 2).

Table 5. Tolerance Summary for glyphosate (N-(phosphonomethyl)glycine)

Commodity	Established/Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Safflower	None	85	Covers residues in processed commodities
Sunflower	None	85	Covers residues in processed commodities

ATTACHMENT 1

MRL SPREADSHEET OUTPUT

Regulator:	EPA
Chemical:	Glyphosate
Crop:	Safflower
PHI:	7 Days
App. Rate:	6
Submitter:	IR-4
	Residues
	1.300
	1.100
	2.900
	2.700
	1.400
	1.800

	Regulator:	EPA	
	Chemical:	Glyphosate	
	Crop:	Safflower	
	PHI:	7 Days	
	App. Rate:	6	
	Submitter:	IR-4	
	n:	6	
	min:	1.10	
	max:	2.90	
	median;	1.60	
	average:	1.87	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	3.5	4.0	4.5
	(5.0)	(6.0)	(--)
EU Method I Log Normal	3.5	**4.5**	6.0
	(8.0)	(14)	(--)
EU Method II Distribution-Free		6.0	
California Method μ + 3σ		**4.5**	
UPLMedian95th		**19**	
Approximate Shapiro-Francia Normality Test Statistic		0.9294	
	p-value > 0.05 : Do not reject lognormality assumption		

Regulator:	EPA
Chemical:	Glyphosate
Crop:	Sunflower
PHI:	7 Days
App. Rate:	2
Submitter:	IR-4
	Residues
	0.070
	0.150
	7.600
	5.100
	4.800
	5.900
	2.900
	3.600
	17.000
	20.000
	2.400
	2.100
	0.630
	0.750
	0.330
	0.360

	Regulator:	EPA	
	Chemical:	Glyphosate	
	Crop:	Sunflower	
	PHI:	7 Days	
	App. Rate:	6/2	
	Submitter:	IR-4	
	n:	16	
	min:	0.07	
	max:	20.00	
	median;	2.65	
	average:	4.61	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	15	19	25
	(20)	(30)	(--)
EU Method I Log Normal	30	85	310
	(120)	(570)	(--)
EU Method II Distribution-Free		12	
California Method $\mu + 3\sigma$		**25**	
UPLMedian95th		**18**	
Approximate Shapiro-Francia Normality Test Statistic		0.9632	
	p-value > 0.05 : Do not reject lognormality assumption		

ATTACHMENT 2

INTERNATIONAL RESIDUE LIMIT STATUS SHEET

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: N-(phosphonomethyl) glycine	Common Name: Glyphosate	9 Proposed tolerance 9 Reevaluated tolerance 9 Other	Date:

Codex Status (Maximum Residue Limits)	U. S. Tolerances
9 No Codex proposal step 6 or above 9 No Codex proposal step 6 or above for the crops requested	Petition Number: 4E6878 DP Barcode: D321667 Other Identifier:
Residue definition (step 8/CXL): glyphosate	Reviewer/Branch: J. R. Tomerlin/RD-FB (ARIA Team)
	Residue definition: Glyphosate – N-(phosphonomethyl) glycine

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
Sunflower seed	7.		

Limits for Canada	Limits for Mexico
9 No Limits Ξ No Limits for the crops requested	9 No Limits Ξ No Limits for the crops requested
Residue definition: glyphosate plus AMPA	Residue definition: glyphosate

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions:
S.Funk, 04/17/2006.

Rev 1998

13544

R127159

Chemical: Glyphosate

PC Code:
417300

HED File Code: 12000 Exposure Reviews
Memo Date: 5/8/2006
File ID: DPD321666
Accession #: 412-06-0194

HED Records Reference Center
7/27/2006