MEMORANDUM

DATE: 17-MAY-1999

SUBJECT: PP# 7F04853. Sulfosate (Glyphosate-Trimesium) in or on Edible-Podded Legume Vegetables Subgroup, Succulent Shelled Pea And Bean Subgroup, and Dried Shelled Pea and Bean (Except Soybean) Subgroup. **Evaluation of Residue Data and Analytical Methods**. MRID#s 44316601 thru 44316603. Chemical 128501. Barcode D243368. Case 289001. Submission# S526513.

FROM: George F. Kramer, Ph.D.
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THROUGH: Melba Morrow, D.V.M., Branch Senior Scientist
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TO: Jim Tompkins/Tobi Colvin-Snyder
Registration Division (7505C)

The attached contractor's document has been reviewed and revised to reflect HED policy.

Executive Summary of Chemistry Deficiencies

- Revised Section B.

cc (with attachments): PP#7F4853, G. Kramer
RDI: Team (4/29/99), M. Morrow (5/17/99), S. Chun (4/29/99)
G.F. Kramer:806T:CM#2:(703)305-5079:7509C:RAB1

GLYPHOSATE-TRIMESIUM (SULFOSATE)

(DP Barcode D243368)

PP#7F04853: Petition For The Establishment Of Permanent Tolerances For Residues Of Sulfosate In/On Edible-Podded Legume Vegetables Subgroup, Succulent Shelled Pea And Bean Subgroup, And Dried Shelled Pea And Bean (Except Soybean) Subgroup

March 30, 1999

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

GLYPHOSATE-TRIMESIUM (SULFOSATE)

(DP Barcode D243368)

PP#7F04853: PETITION FOR THE ESTABLISHMENT OF PERMANENT TOLERANCES FOR RESIDUES OF SULFOSATE IN/ON EDIBLE-PODDED LEGUME VEGETABLES SUBGROUP, SUCCULENT SHELLED PEA AND BEAN SUBGROUP, AND DRIED SHELLED PEA AND BEAN (EXCEPT SOYBEAN) SUBGROUP

BACKGROUND

Glyphosate-trimesium (sulfosate), a nonselective systemic herbicide which is active against a broad range of weeds, is being developed for agricultural use in a wide range of crops. Zeneca Ag Products has submitted a petition to establish the following tolerances for sulfosate (sulfonium, trimethyl- salt with N-(phosphonomethyl) glycine (1:1)):

Edible podded legume vegetables subgroup ..... 0.50 ppm
(of which no more than 0.3 ppm is trimethylsulfonium)
Succulent shelled pea and bean subgroup ..... 0.20 ppm
(of which no more than 0.1 ppm is trimethylsulfonium)
Dried shelled pea and bean (except soybean) subgroup ..... 6.00 ppm
(of which no more than 1.5 ppm is trimethylsulfonium)

Sulfosate (the trimethylsulfonium salt of glyphosate) is a 1:1 molar salt of the N-(phosphonomethyl)glycine anion (PMG) and the trimethylsulfonium cation (TMS) and is formulated as Touchdown® (EPA Reg. No. 10182-324) and Touchdown® BTU (EPA Reg. No. 10182-429). Tolerances for sulfosate have been established for the following RACs [40 CFR §180.489(a)]: almond hulls, bananas (import only), corn commodities, grapes, the stone fruit group, the citrus fruit group, the tree nuts group, meat, milk, eggs, and soybean commodities.

The Agency has recommended for a petition (PP#7F04876) for sulfosate uses on fruiting vegetables pending revisions of the proposed labels (DP Barcode D243450, 9/28/98, J. Rowell and G. Kramer). In addition, RAB1 concluded in the same memorandum that sufficient data are available to support the proposed increase (to 8 lb ai/A/year) in the application rate of sulfosate on citrus, grapes, pome fruit group, tree nut group, soybeans, and stone fruit group. However, data available for corn are insufficient to raise the application rate of sulfosate from 4 to 8 lbs ai/A/year.

The Agency has also recommended for a petition (PP#7F04854) for preharvest use of sulfosate on soybeans pending revisions of the proposed tolerances (DP Barcode D244318, 4/23/99, G. Kramer). The following revised tolerances are required to support this use:

Soybean, seed	21 ppm
Kidney*	6.0 ppm
Meat Byproducts* (except kidney)	1.5 ppm
Meat*	1.0 ppm
Fat*	0.5 ppm
Milk	1.5 ppm

Poultry Meat Byproducts	0.1 ppm
Poultry Meat	0.05 ppm
Poultry Fat	0.05 ppm
Eggs	0.05 ppm
Soybean, hulls	45 ppm
Aspirated grain fractions	1300 ppm

* of cattle, hogs, sheep, goats, and horses

CONCLUSIONS

OPPTS 830 Series GLNs: Product Properties

1. Product chemistry data for sulfosate were previously submitted and reviewed by RD. No additional product chemistry data are required in support of this petition.

OPPTS GLN 860.1200: Proposed Uses

2. The specimen labels (Touchdown®, 6 lb/gal SC formulation, EPA Reg. No. 10182-324, and Touchdown® BTU, 5 lb/gal SC formulation, EPA Reg. No. 10182-429) adequately delineate the proposed use pattern for sulfosate on beans (all types), catjang, guar, lentils (all types), lupines (all types), peas (all types), and soybean (immature seed). However, the proposed labels must be modified to include a restriction against application of sulfosate to beans and peas grown for animal feed and a PHI for edible podded legume vegetables and succulent shelled peas and beans. **A revised Section B must be submitted.**

OPPTS GLN 860.1300: Nature of the Residue - Plants

3. No new metabolism studies were submitted with this petition. Sulfosate metabolism studies in plants have been submitted in conjunction with previous petitions. The nature of the residue is considered to be understood in grapes (DP Barcode D182279, 12/7/93, G. Otakie), corn (DP Barcode D171509, 9/30/92, F. Griffith) and soybeans (DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer). HED concluded that the parent ions are the residues of

regulatory concern for sulfosate in these crops; these data will be translated to the edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups. The parent ions are considered to be the residues of concern.

OPPTS GLN 860.1300: Nature of the Residue - Animals

4. If the petitioner modifies the proposed labels to prohibit use of sulfosate on beans and peas grown for animal feed, then no data pertaining to animal metabolism will be required to support this petition.

OPPTS GLN 860.1340: Residue Analytical Methods

5a. Enforcement analytical methods have previously been submitted for residues of sulfosate in/on crops. The petitioner used the previously submitted enforcement methods (Methods RR 92-042B RES and RR 93-105B RES) for data collection in the submitted field trial studies on edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups. Concurrent method recoveries demonstrated that methods RR 92-042B RES and RR 93-105B RES are adequate for data collection in/on these crop subgroups.

5b. Enforcement of the proposed tolerances requires two enforcement methods: one method for PMG and one method for TMS. The revised method RR 92-042B RES was approved by HED for the enforcement of proposed tolerances for residues of the PMG ion of sulfosate in/on crops (DP Barcode D215869, 7/6/95, G. Kramer). The revised method, RR 93-105B RES was accepted by HED for the enforcement of proposed tolerances for residues of TMS in/on crops (DP Barcode D221955, 1/22/96, G. Kramer). Both methods have been submitted to the FDA for inclusion in PAM II.

OPPTS GLN 860.1360: Multiresidue Method

6. A report on the behavior of TMS and PMG in FDA Multiresidue protocols I, II, III, and IV, has been forwarded to the FDA for review (Memo dated 10/29/90, S. Koepke).

OPPTS GLN 860.1380: Storage Stability Data

7. The RAC samples from the submitted field trials were stored frozen for a maximum of ~10 months from harvest to analysis. Previously, the petitioner demonstrated that residues of TMS and PMG are stable in soybean seed and straw for up to 2 years (CB Nos. 6814, 6815, and 6816, 5/9/91, S. Koepke); in sorghum grain for up to 4 years and in wheat grain for up to

2 years (CB Nos. 6200, 6201, and 6202, 12/21/90, S. Koepke); in orange fruit for up to 2 years (CB No. 6962, 10/10/91, S. Malik); and in grapes for up to 2 years (Memo dated 10/30/91, B. Schneider). HED is willing to translate these storage stability data to the edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups. No additional storage stability data are required to support the submitted field trials on legume vegetable subgroups.

OPPTS GLN 860.1500: Crop Field Trials

8. **Provided the Touchdown labels are modified to specify a PHI of at least 50 days**, the submitted residue data are adequate to support the proposed preemergence use on the **edible podded legume vegetables subgroup**. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 0.50 ppm (of which no more than 0.3 ppm is trimethylsulfonium) in/on snow peas and snap beans (seed with pods) harvested following the maximum proposed application rate. Residues of PMG were less than the LOQ (0.05 ppm) in/on six samples of snow peas and 12 samples of snap beans harvested 49-75 days following a single broadcast application of the 6 lb/gal SC formulation at 8 lb ai/A made prior to crop emergence (1x the maximum proposed seasonal rate). Residues of TMS were <0.05-0.088 ppm in/on six samples of snow peas and <0.05-0.251 ppm in/on 12 samples of snap beans.

9. **Provided the Touchdown labels are modified to specify a PHI of at least 70 days**, the submitted residue data are adequate to support the proposed preemergence use of sulfosate on the **succulent shelled pea and bean subgroup**. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 0.20 ppm (of which no more than 0.1 ppm is trimethylsulfonium) in/on green peas and lima beans (seed without pods) harvested following the maximum proposed application rate. Residues of PMG were less than the LOQ (0.05 ppm) in/on 12 samples each of green peas and lima beans harvested 58-157 days following a single broadcast application of the 6 lb/gal SC formulation at 8 lb ai/A made prior to crop emergence (1x the maximum proposed seasonal rate). Residues of TMS were <0.05-0.105 ppm in/on 12 samples of green peas and <0.05-0.071 ppm in/on 12 samples of lima beans.

10a. The submitted residue data for the **dried shelled pea and bean (except soybean) subgroup** are adequate. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 6.00 ppm (of which no more

than 1.5 ppm is trimethylsulfonium) in/on dry peas and beans (shelled dried seed) harvested following the maximum proposed application rate. The combined residues of PMG and TMS were 0.06-3.21 ppm (<0.05-0.85 ppm of which was TMS) in/on dry peas and <0.05-4.92 ppm (<0.05-1.06 ppm of which was TMS) in/on dry beans harvested 7 days following the last of a single broadcast application of the 6 lb/gal SC formulation at 7 lb ai/A made prior to crop emergence and a subsequent preharvest broadcast application at 1 lb ai/A (1x the maximum proposed seasonal rate).

10b. Residues of both PMG and TMS in dry beans (shelled dried seed) increased from the 0- to 10-day PTIs in the decline study. The petitioner cited decline studies previously performed with soybeans (see PP#7F04854, DP Barcode D243318, 4/23/99, G. Kramer) that demonstrated that residues of PMG and TMS did not decline or increase significantly with increasing posttreatment intervals. The increase in residues observed in the dry bean decline trial may be a result of sampling variability.

10c. If the petitioner modifies the product labels to prohibit use of sulfosate grown on animal feed, then no data pertaining to cowpea forage and hay or field pea vines and hay will be required to support this petition.

OPPTS GLN 860.1520: Processed Food/Feed

11. There are no processed commodities associated with any of the edible-podded legume vegetable, succulent shelled peas and beans, and dried shelled peas and beans subgroups; therefore, no data pertaining to this guideline are required.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

12. If the petitioner modifies the proposed labels to prohibit use of sulfosate on beans and peas grown for animal feed, then no data pertaining to meat, milk, poultry or eggs will be required to support this petition.

OPPTS GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

13. HED has previously reviewed two confined rotational crop studies for sulfosate and concluded that rotational crop restrictions were not required for uses on crops in which the total seasonal application rate does not exceed 8.0 lbs. a.i./A (DP Barcode D209543, 5/16/95, G. Kramer). No additional rotational crop data are required to support this petition.

RECOMMENDATIONS

Provided Section B is revised as specified in Conclusions 2, 8 and 9; HED concludes there are no residue chemistry data requirements that would preclude the establishment of the proposed permanent tolerances for sulfosate in/on the edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups. A human-health risk assessment will be prepared as a separate document.

Note to RD: ***RAB1 notes that the submitted Touchdown labels contain revised use directions for corn in which the application rate is increased from 4 to 8 lbs ai/A/year. However, HED has previously determined that the data available for corn are insufficient to raise the application rate of sulfosate from 4 to 8 lbs ai/A/year.***

DETAILED CONSIDERATIONS

OPPTS 830 Series GLNs: Product Properties

No new studies were submitted with this petition. Product chemistry data were reviewed by RD and found to be adequate (Memo dated 3/17/87, K. Liefer) when sulfosate was initially submitted for a nonfood use. There are no product chemistry data gaps (Letter dated 2/15/89, R. Taylor); no additional product chemistry data are required to support this petition.

OPPTS GLN 860.1200: Proposed Uses

Labels have been provided for use of sulfosate formulated as Touchdown®, 6 lb/gal SC formulation, EPA Reg. No. 10182-324, and Touchdown® BTU, 5 lb/gal SC formulation, EPA Reg. No. 10182-429. Sulfosate is proposed for multiple broadcast applications before, during, or after planting prior to crop emergence on the following vegetable crops: beans (all types), catjang, guar, lentils (all types), lupines (all types), peas (all types), and soybean (immature seed) at 0.25-4 lb ai/A/application. A PHI was not specified for edible podded legume vegetables or succulent shelled peas and beans. Preharvest applications of sulfosate formulations to dried beans (all), catjang, guar, dried lentils (all), dried lupines (all), and dried peas (all) at a maximum rate of 1 lb ai/A are also proposed. The preharvest applications to dried beans, dried lentils, and dried peas are to be made when

the crop has 30% or less grain moisture content. The maximum yearly application, no matter which treatments are made, is 8 lb ai/A. A 7-day PHI for vegetable crops is proposed following the pre-harvest application. Pre-harvest applications to vegetable crops grown for seed are prohibited.

Ground applications are to be made in 10-30 gal/A with conventional equipment or in 3-10 gal/A with low-volume equipment; applications using aerial equipment are to be made in a minimum of 3 gal/A. The use of a surfactant or wetting agent is required. Sulfosate formulations may be tank mixed with other herbicides registered for these uses.

A restricted entry interval (REI) of 4 hours has been established. Rotational crops may be planted back into treated areas 35 days after application. Grazing or harvest of treated cover crops for feed is prohibited.

Comments: The specimen labels (Touchdown®, 6 lb/gal SC formulation, EPA Reg. No. 10182-324, and Touchdown® BTU, 5 lb/gal SC formulation, EPA Reg. No. 10182-429) adequately delineate the proposed use pattern for sulfosate on beans (all types), catjang, guar, lentils (all types), lupines (all types), peas (all types), and soybean (immature seed). However, the proposed labels must be modified to include a restriction against application of sulfosate to beans and peas grown for animal feed and a PHI for edible podded legume vegetables and succulent shelled peas and beans. **A revised Section B must be submitted.**

OPPTS GLN 860.1300: Nature of the Residue - Plants

No new metabolism studies were submitted with this petition. Sulfosate metabolism studies in plants have been submitted in conjunction with previous petitions. The nature of the residue is considered to be understood in grapes (DP Barcode D182279, 12/7/93, G. Otakie), corn (DP Barcode D171509, 9/30/92, F. Griffith) and soybeans (DP Barcodes D208740, D208742, D213615, and D213612, 4/4/95, G. Kramer). HED concluded that the parent ions are the residues of regulatory concern for sulfosate in these crops; these data will be translated to the edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups. The parent ions are considered to be the residues of concern.

HED has previously determined that the tolerance expression for sulfosate must include both of the parent ions (DP Barcode D211742, 2/9/95, G. Kramer, et al.). Tolerances for sulfosate should be expressed as "residues of sulfosate (sulfonium,

trimethyl-salt with N-(phosphonomethyl)glycine (1:1)) in or on..." In situations where the levels of both ions are expected to be below the levels of quantitation (0.05 ppm), tolerances should be established as:

RAC = 0.05 ppm

In cases where quantifiable residues are expected, tolerances should be established as:

RAC (of which no more than x ppm is trimethylsulfonium) = y ppm,

where x is the maximum expected residue of TMS and y is the maximum expected total of TMS and PMG.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

If the petitioner modifies the proposed labels to prohibit use of sulfosate on beans and peas grown for animal feed, then no data pertaining to animal metabolism will be required to support this petition.

OPPTS GLN 860.1340: Residue Analytical Method - Plant Commodities

Enforcement analytical methods have previously been submitted for proposed tolerances; the petitioner used the previously submitted enforcement methods (Methods RR 92-042B RES and RR 93-105B RES) for data collection in the submitted field trial studies on edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups.

Method validation and successful PMV by ACL of Method RR 92-042B (originally submitted with PP#3F04238 and PP#4F04343), for the determination of PMG, and Method RR 93-105B (originally submitted with PP#1F03950), for the determination of TMS, have been completed. The methods were revised to incorporate revisions required by the Agency, and the revised methods (RR92-042B RES and RR 93-105B RES) were approved by the Agency for the enforcement of tolerances for residues of the PMG and TMS ions of sulfosate in/on crops (DP Barcodes D215869, 7/6/95, G. Kramer and D219447, D219460, and D221687, 1/23/96, G. Kramer). The methods have been submitted to the FDA for inclusion in PAM II (DP Barcodes D248046 and D248047, 8/17/98, G. Kramer).

Concurrent method recoveries were generated in conjunction with the submitted field trials. Untreated samples of snow peas (seed with pod), snap beans (seed with pod), green peas (seed without

pod), lima beans (seed without pod), dry beans (shelled dried seed), and dry peas (shelled dried seed) were fortified with PMG and TMS at 0.05-20 ppm and analyzed concurrently with the treated samples using GC methods RR 92-042B RES and RR 93-105B RES. The recoveries of the fortified samples are reported in Table 1. The concurrent method recoveries demonstrate that methods RR 92-042B RES and RR 93-105B RES are adequate for data collection in/on edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups.

Table 1.Concurrent method recoveries of sulfosate (PMG and TMS) from fortified untreated samples of legume vegetable commodities.

Commodity	PMG		TMS	
	Fortification Range, ppm	% Recovery [a]	Fortification Range, ppm	% Recovery [a]
Snow peas (seed with pod)	0.05, 1	88-110 (4); **95**	0.05, 0.15	89, 94; **92**
Snap beans (seed with pod)	0.05-1	85-120 (5); **101**	0.1, 0.5	83, 84; **84**
Green peas (seed without pod)	0.05-1.6	82-99 (3); **91**	0.05-0.15	92-112 (3); **102**
Lima beans (seed without pod)	0.05, 5	91, 107; **99**	0.1, 0.3	105, 108; **107**
Dry peas (dried seed without pod)	0.05-10	84-113 (4); **95**	0.05, 15	97, 102; **100**
Dry beans (dried seed without pod)	0.05-20	75-112 (4); **89**	0.05-5	84-105 (4); **93**

[a] Each recovery value represents one sample unless otherwise indicated in parentheses. Average recoveries are listed in **bold**.

OPPTS GLN 860.1340: Residue Analytical Methods - Animal Commodities

If the petitioner modifies the proposed labels to prohibit use of sulfosate on beans and peas grown for animal feed, then no residue analytical methods for animal commodities will be required to support this petition.

OPPTS GLN 860.1360: Multiresidue Method

The report on the behavior of TMS and PMG in FDA protocols I, II, III and IV, has been forwarded to the FDA for review (Memo dated 10/29/90, S. Koepke).

OPPTS GLN 860.1380: Storage Stability Data

No storage stability data were submitted with this petition. The RAC samples from the submitted field trials were frozen (≤-10 C) within 4 hours of harvest. Samples were transported frozen to Zeneca Ag Products, Western Research Center (Richmond, CA) where they were stored frozen (-18 C) until analysis. Total storage intervals from harvest to analysis were: 107-308 days (~4-12 months) for edible-podded beans and peas; 86-227 days (~3-8 months) for succulent shelled beans and peas; and 102-256 days (~3-8 months) for dried beans and peas.

Previously, the petitioner demonstrated that residues of TMS and PMG are stable in soybean seed and straw for up to 2 years (CB Nos. 6814, 6815, and 6816, 5/9/91, S. Koepke); in sorghum grain for up to 4 years and in wheat grain for up to 2 years (CB Nos. 6200, 6201, and 6202, 12/21/90, S. Koepke); in orange fruit for up to 2 years (CB No. 6962, 10/10/91, S. Malik); and in grapes for up to 2 years (Memo dated 10/30/91, B. Schneider). HED is willing to translate these storage stability data to the edible-podded legume vegetables, succulent shelled pea and bean, and dried shelled pea and bean (except soybean) subgroups. No additional storage stability data are required to support the submitted field trials on legume vegetable subgroups.

OPPTS GLN 860.1500: Crop Field Trials

Legume Vegetables

Edible-podded legume vegetables subgroup

Zeneca submitted a single volume of snow pea and snap bean field trial data to support the establishment of proposed tolerances for residues of sulfosate (PMG and TMS) in/on edible-podded legume vegetables subgroup at 0.50 ppm (of which no more than 0.3 ppm is trimethylsulfonium). The citation is listed below.

> 44316601 Iwata, Y. (1997) Glyphosate Trimesium: Magnitude of the Residue Study on Edible-Podded Legume Vegetables from Trials Conducted in the United States: Lab Project Number: GLYP-96-MR-05: RR97-019B: 70-MD-96-771. Unpublished study prepared by Zeneca Ag Products. 56 p.

A total of nine field residue trials were conducted in 1996 on snow peas and snap beans (representative crops of the edible-podded legume vegetable subgroup 6-A). Three trials were conducted in Regions 2 (MD), 5 (WI), and 11 (WA) on snow peas; and six trials were conducted in Regions 1 (NY), 2 (NC), 3 (FL), 5 (MI and WI), and 11 (OR) on snap beans. Mature snow peas or

snap beans (seed with pod) were harvested 49-75 days following a single broadcast application of the 6 lb/gal SC formulation (EPA Reg. No. 10182-324) at 8 lb ai/A made prior to crop emergence. Application was made using ground equipment (CO_2-pressurized hand-held boom or tractor-mounted broadcast boom) in 2.90-20 gal/A water with 1% volume of nonionic surfactant. Samples were collected by hand, bagged, and frozen (≤-10 C) within one hour of harvest. Samples were transported frozen to Zeneca Ag Products, Western Research Center (Richmond, CA) where they were stored frozen (-18 C) until analysis.

Samples (seed and pod) were analyzed for residues of PMG and TMS using Methods RR 92-042B RES and RR 93-105B RES, respectively. The method limit of quantitation (LOQ) was 0.05 ppm for both PMG and TMS. Apparent residues of PMG and TMS were each less than the LOQ (<0.05 ppm) in/on three untreated samples of snow peas (seed with pod) and six untreated samples of snap beans (seed with pod). A summary of the residues of PMG and TMS in the treated samples is listed in Table 2.

Table 2. Residues of PMG and TMS in **snow peas and snap beans** harvested 49-75 days following a single broadcast application of the 6 lb/gal SC formulation at 8 lb ai/A (1x the maximum proposed seasonal rate) made prior to crop emergence.

Commodity	EPA Region (Trial Location)	PTI, days	Residues, ppm		
			PMG	TMS	Total [a]
Snow peas (seed with pod)	Region 2 (Sudlersville, MD)	74	<0.05, <0.05	0.087, 0.088	<0.137, <0.138
	Region 5 (Baraboo, WI)	57	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 11 (Moses Lake, WA)	71	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
Snap beans (seed with pod)	Region 1 (Williamson, NY)	53	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 2 (Whitakers, NC)	49	<0.05, <0.05	0.15, 0.251 [b]	<0.20, <0.301
	Region 3 (Oviedo, FL)	56	<0.05, <0.05	0.094, 0.111	<0.144, <0.161
	Region 5 (Conklin, MI)	53	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 5 (Baraboo, WI)	64	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 11 (Ontario, OR)	75	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
Average [c]			**0.025**	**0.060**	**0.085**

[a] Total residues of PMG and TMS were determined according to the HED tolerance expression; if both ions were less than the LOQ then the total was reported as <0.05 ppm (LOQ).
[b] Highest residue value from duplicate analyses (0.227, 0.251 ppm).
[c] Values less than the LOQ then the total was calculated as <0.025 ppm (1/2 LOQ)

Geographic representation is adequate to support the proposed uses for sulfosate on edible podded legume vegetables subgroup. The submitted field trials were conducted in Regions 2 (1 trial), 5 (1 trial), and 11 (1 trial) on snow peas, and Regions 1 (1 trial), 2 (1 trial), 3 (1 trial), and 5 (2 trial), and 11 (1 trial) for green beans. The number of trials conducted for each commodity is adequate to support a tolerance for crop subgroup 6-A (OPPTS 860.1500, Table 3). According to the current guidance (OPPTS 860.1500, Table 6) Regions 2, 5, and 11 account for 75% of the U.S. succulent pea (garden) production and Regions 1, 2, 3, 5, and 11 account for 94% of the U.S. snap bean production.

Study summary: **Provided the Touchdown labels are modified to specify a PHI of at least 50 days**, the submitted residue data are adequate to support the proposed preemergence use on the edible podded legume vegetables subgroup. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 0.50 ppm (of which no more than 0.3 ppm is trimethylsulfonium) in/on snow peas and snap beans (seed with pods) harvested following the maximum proposed application rate. Residues of PMG were less than the LOQ (0.05 ppm) in/on six samples of snow peas and 12 samples of snap beans harvested 49-75 days following a single broadcast application of the 6 lb/gal SC formulation at 8 lb ai/A made prior to crop emergence (1x the maximum proposed seasonal rate). Residues of TMS were <0.05-0.088 ppm in/on six samples of snow peas and <0.05-0.251 ppm in/on 12 samples of snap beans.

Succulent shelled peas and beans subgroup

Zeneca submitted a single volume of green pea and lima bean field trial data to support the establishment of proposed tolerances for residues of sulfosate (PMG and TMS) in/on succulent shelled peas and beans subgroup at 0.20 ppm (of which no more than 0.1 ppm is trimethylsulfonium). The citation is listed below.

44316602 Iwata, Y. (1997) Glyphosate Trimesium: Magnitude of the Residue Study on Succulent Shelled Peas and Beans from Trials Conducted in the United States: Lab Project Number: GLYP-96-MR-06: RR97-018B: 57-NY-96-801. Unpublished study prepared by Zeneca Ag Products. 59 p.

A total of 12 field residue trials were conducted in 1996 in green peas and lima beans (representative crops of the succulent shelled pea and bean subgroup 6-B). Six trials were conducted in Regions 1 (NY), 5 [MN and WI(2)], 11 (WA), and 12 (OR) on green peas, and six trials were conducted in Regions 2 (MD, NC, SC), 5 (IL), 10 (CA), and 11 (WA) on lima beans. Mature green peas and lima beans were harvested 58-157 days following a single broadcast application of the 6 lb/gal SC formulation (EPA Reg. No. 10182-324) at 8 lb ai/A made prior to crop emergence. Application was made using ground equipment (CO_2-pressurized hand-held boom or tractor-mounted broadcast boom) in 3-20 gal/A water with 1% volume of nonionic surfactant; the OR trial did not include the nonionic surfactant. Samples were collected by hand, bagged, and frozen (<-10 C) with in 2.5 hours of harvest. Samples were transported frozen to Zeneca Ag Products, Western Research Center (Richmond, CA) where they were stored frozen (-18 C) until analysis.

Samples (seed without pod) were analyzed for residues of PMG and TMS using Methods RR 92-042B RES and RR 93-105B RES, respectively. The method LOQ was 0.05 ppm for both PMG and TMS. Apparent residues of PMG and TMS were each less than the LOQ (<0.05 ppm) in/on six untreated samples each of green peas and lima beans (seed without pod). A summary of the residues of PMG and TMS in the treated samples is listed in Table 3.

Table 3.Residues of PMG and TMS in **green peas and lima beans** harvested 58-157 days following a single broadcast application of the 6 lb/gal SC formulation at 8 lb ai/A (1x the maximum proposed seasonal rate) made prior to crop emergence.

Commodity	EPA Region (Trial Location)	PTI, days	Residues, ppm		
			PMG	TMS	Total [a]
Peas, green (seed without pod)	Region 1 (North Rose, NY)	70	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 5 (Sanborn, MN)	58	<0.05, <0.05	0.051, 0.051	<0.101, <0.101
	Region 5 (Baraboo, WI)	70	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 5 (Delavan, WI)	62	<0.05, <0.05	<0.05, 0.063	<0.05, <0.113
	Region 11 (Walla Walla, WA)	73	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 12 (Hillsboro, OR)	69	<0.05, <0.05	0.07 [b], 0.105 [c]	<0.12, <0.155
Beans, lima (seed without	Region 2 (Sudlersville, MD)	89	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05

Commodity	EPA Region (Trial Location)	PTI, days	Residues, ppm		
			PMG	TMS	Total [a]
	Region 2 (Whitakers, NC)	81	<0.05, <0.05	0.065, 0.071	<0.115, <0.121
	Region 2 (Elko, SC)	98	<0.05, <0.05	<0.05, 0.059	<0.05, <0.109
	Region 5 (Champaign, IL)	99	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 10 (Visalia, CA)	108	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
	Region 11 (Moses Lake, WA)	157	<0.05, <0.05	<0.05, <0.05	<0.05, <0.05
Average [d]			**0.025**	**0.039**	**0.064**

[a] Total residues of PMG and TMS were determined according to the HED tolerance expression; if both ions were less than the LOQ then the total was reported as <0.05 ppm (LOQ).
[b] Highest residue value from duplicate analyses (0.069, 0.07 ppm).
[c] Highest residue value from triplicate analyses (0.072, 0.075, 0.105 ppm).
[d] For values less than the LOQ, the total was calculated with <0.025 ppm (1/2 LOQ).

Geographic representation is adequate to support the proposed uses for sulfosate on the succulent shelled pea and bean subgroup. The submitted field trials were conducted in Regions 1 (1 trial), 5 (3 trials), 11 (1 trial), and 12 (1 trial) on green peas, and Regions 2 (3 trials), 5 (1 trial), 10 (1 trial), and 11 (1 trial) for lima beans. The number of conducted field trials is adequate to support a tolerance for crop subgroup 6-B (OPPTS 860.1500, Table 3). According to the current guidance (OPPTS 860.1500, Table 6) Regions 1, 5, 11, and 12 account for 85% of U.S. green pea production and Regions 2, 5, 10, and 11 account for 97% of the U.S. green lima bean production.

Study summary: **Provided the Touchdown labels are modified to specify a PHI of at least 70 days**, the submitted residue data are adequate to support the proposed preemergence use of sulfosate on the succulent shelled pea and bean subgroup. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 0.20 ppm (of which no more than 0.1 ppm is trimethylsulfonium) in/on green peas and lima beans (seed without pods) harvested following the maximum proposed application rate. Residues of PMG were less than the LOQ (0.05 ppm) in/on 12 samples each of green peas and lima beans harvested 58-157 days following a single broadcast application of the 6 lb/gal SC formulation at 8 lb ai/A made prior to crop emergence (1x the maximum proposed seasonal rate). Residues of TMS were <0.05-0.105 ppm in/on 12 samples of green peas and <0.05-0.071

ppm in/on 12 samples of lima beans. We note that the highest observed TMS residue of 0.105 ppm was found during triplicate analyses of the same sample; the average of the triplicate analyses was 0.084 ppm.

Dried shelled peas and beans (except soybeans) subgroup

Zeneca submitted a single volume of dry bean and dry pea field trial data to support the establishment of proposed tolerances for residues of sulfosate (PMG and TMS) in/on dried shelled peas and beans (except soybeans) subgroup at 6.0 ppm (of which no more than 1.5 ppm is trimethylsulfonium). The citation is listed below.

> 44316603 Iwata, Y. (1997) Glyphosate Trimesium: Magnitude of the Residue Study on Dried Shelled Peas and Beans from Trials Conducted in the United States: Lab Project Number: GLYP-96-MR-04: RR97-015B: 15-ID-96-751. Unpublished study prepared by Zeneca Ag Products. 68 p.

A total of 14 field residue trials were conducted in 1996 in dry beans and dry peas (representative crops of the dried shelled peas and beans subgroup 6-C). Trials were conducted in Region 11 [ID(2), OR, and WA(2)] on dry peas and in Regions 5 [MI(2), ND(2)], 7 (NE), 8 (CO), 9 (CO), 10 (CA) and 11 (ID) on dry beans. The registrant noted that the MI trials were conducted at the same location; however, different spray volumes were used in each trial (3.5 gal/A and 23 gal/A). Mature dry peas and beans were harvested 7 days following the last of a single broadcast application of the 6 lb/gal SC formulation (EPA Reg. No. 10182-324) at 7 lb ai/A made prior to crop emergence and a subsequent preharvest broadcast application at 1 lb ai/A. Additional samples were collected at 0-, 3-, and 10-day PTIs in one dry bean trial to demonstrate residue decline. Applications were made in 3.5-23 gal/A water with 1% volume of nonionic surfactant; the equipment used for application was not specified. Samples (shelled dried seeds) were collected by hand or mechanically, bagged, and frozen within 1.5 hours of harvest. Samples were transported frozen to Zeneca Ag Products, Western Research Center (Richmond, CA) where they were stored frozen (-18 C) until analysis.

Samples (dried seed without pod) were analyzed for residues of PMG and TMS using Methods RR 92-042B RES and RR 93-105B RES, respectively. The method LOQ was 0.05 ppm for both PMG and TMS. Apparent residues of PMG and TMS were each less than the LOQ (<0.05 ppm) in/on five untreated samples of dry peas (dried seed without pod) and nine untreated samples of dry beans (dried seed without pod). A summary of the residues of PMG and TMS in the treated samples is listed in Table 5.

Table 5. Residues of PMG and TMS in **dry peas and dry beans** harvested 7 days following a single broadcast application of the 6 lb/gal SC formulation at 7 lb ai/A made prior to crop emergence and a subsequent pre-harvest broadcast application at 1 lb ai/A (1x the maximum proposed seasonal rate).

Commodity	EPA Region (Trial Location)	PTI, days	Residues, ppm		
			PMG	TMS	Total [a]
Peas, dry (dried seed without pod)	Region 11 (Genesee, ID)	7	1.57, 2.36 [b]	0.58, 0.85	2.15, 3.21
	Region 11 (Moscow, ID)	7	1.74 [b], 2.20	0.84, 0.75	2.58, 2.95
	Region 11 (Hermiston, OR)	7	<0.05, 0.08	0.07, 0.09	<0.12, 0.17
	Region 11 (Ephrata, WA)	7	<0.05, <0.05	0.08, 0.09 [b]	<0.13, <0.14
	Region 11 (Walla Walla, WA)	7	0.07, 0.08	<0.05, 0.05	<0.12, 0.13
Beans, dry (dried seed without pod)	Region 5 (Conklin, MI)	7	<0.05, 0.24	<0.05, 0.09	<0.05, 0.33
	Region 5 (Conklin, MI)	7	<0.05, <0.05	0.07, 0.13	<0.12, 0.13
	Region 5 (Cogswell, ND)	7	0.16, 0.16	0.34, 0.38	0.50, 0.54
	Region 5 (Northwood, ND)	7	0.10, 0.21	0.13, 0.22	0.23, 0.43
	Region 7 (Madrid, NE)	7	2.42, 4.13	1.04, 0.79 [b]	3.46, 4.92
	Region 8 (Johnstown, CO)	7	0.95, 1.15 [b]	1.06, 0.92	2.01, 2.07
	Region 9 (Cory, CO)	7	0.37, 0.43	0.13, 0.11	0.50, 0.54
	Region 10 (Visalia, CA)	0	0.06	0.08	0.14
		3	0.07	0.06	0.13
		7	0.21, 0.25 [b]	0.21, 0.25	0.42, 0.50
		10	0.66	0.57	1.23
	Region 11 (Jerome, ID)	7	0.20, 0.43	0.14, 0.21	0.34, 0.64
Average [c]			**0.70**	**0.35**	**1.05**

[a] Total residues of PMG and TMS were determined according to the HED tolerance expression; if both ions were less than the LOQ then the total was reported as <0.05 ppm (LOQ).

[b] Highest residue value of duplicate analyses.

[c] For values less than the LOQ, the total was calculated with <0.025 ppm (1/2 LOQ).

Geographic representation is adequate to support the proposed uses for sulfosate on the dried shelled pea and bean (except

soybean) subgroup. The submitted field trials were conducted in Region 11 (5 trials) on dry peas, and Regions 5 (4 trials), 7 (1 trial), 8 (1 trial), 9 (1 trial), 10 (1 trial), and 11 (1 trial) for dry beans. The number of field trials is adequate to support a tolerance on crop subgroup 6-C (OPPTS 860.1500, Table 3). According to the current guidance (OPPTS 860.1500, Table 6) Region 11 accounts for 97% of the U.S. dry pea production and Regions 5, 7, 8, 9, 10, and 11 account for 97% of the U.S. dried bean production.

Study summary: The submitted residue data for the dried shelled pea and bean (except soybean) subgroup are adequate. The submitted data indicate that combined residues of PMG and TMS will not exceed the proposed tolerance of 6.00 ppm (of which no more than 1.5 ppm is trimethylsulfonium) in/on dry peas and beans (shelled dried seed) harvested following the maximum proposed application rate. The combined residues of PMG and TMS were 0.06-3.21 ppm (<0.05-0.85 ppm of which was TMS) in/on dry peas and <0.05-4.92 ppm (<0.05-1.06 ppm of which was TMS) in/on dry beans harvested 7 days following the last of a single broadcast application of the 6 lb/gal SC formulation at 7 lb ai/A made prior to crop emergence and a subsequent preharvest broadcast application at 1 lb ai/A (1x the maximum proposed seasonal rate).

Residues of both PMG and TMS in dry beans (shelled dried seed) increased from the 0- to 10-day PTIs in the decline study. The petitioner cited decline studies previously performed with soybeans (see PP#7F04854, DP Barcode D243318, currently under review) that demonstrated that residues of PMG and TMS did not decline or increase significantly with increasing posttreatment intervals. The increase in residues observed in the dry bean decline trial may be a result of sampling variability.

If the petitioner modifies the product labels to prohibit use of sulfosate grown on animal feed, then no data pertaining to cowpea forage and hay or field pea vines and hay will be required to support this petition.

OPPTS GLN 860.1520: Processed Food/Feed

There are no processed commodities associated with any of the edible-podded legume vegetable, succulent shelled peas and beans, and dried shelled peas and beans subgroups; therefore, no data pertaining to this guideline are required.

OPPTS GLN 860.1480: Meat, Milk, Poultry, Eggs

If the petitioner modifies the proposed labels to prohibit use of sulfosate on beans and peas grown for animal feed, then no data pertaining to meat, milk, poultry or eggs will be required to support this petition.

OPPTS GLN 860.1850/1900: Confined/Field Accumulation in Rotational Crops

HED has previously reviewed two confined rotational crop studies for sulfosate and concluded that rotational crop restrictions were not required for uses on crops in which the total seasonal application rate does not exceed 8.0 lbs. a.i./A (DP Barcode D209543, 5/16/95, G. Kramer). No additional rotational crop data are required to support this petition.

EPA MEMORANDA CITED IN THIS REVIEW

CB No.:	None
Subject:	Multiresidue Test Information for Updating PAM I.
From:	S. Koepke
To:	L. Sawyer, FDA
Dated:	10/25/90
MRID(s):	None

CB No.:	6200, 6201, and 6202
Subject:	PP#9F3796 Sulfosate (Touchdown) in or on corn grain, forage, and fodder. Evaluation of analytical methods and residue data.
From:	S. Koepke
To:	R. Taylor/C. Giles and Toxicology Branch II
Dated:	12/27/90
MRID(s):	41209909-41209919, 41235904, and 41236005

CB No.:	6814, 6815, 6816
Subject:	PP#03860 Sulfosate (Touchdown) in or on soybean seed, forage, and hay. Evaluation of analytical methods and residue data.
From:	S. Koepke
To:	R. Taylor/C. Giles and Toxicology Branch II
Dated:	4/29/91
MRID(s):	41462102-41462106 and 41209919

CB No.: 15072
DP Barcode: D211742
Subject: February 7, 1995 Meeting with Tox concerning residues of regulatory concern for glyphosate-trimesium (formerly known as sulfosate).
From: G. Kramer, R. Loranger, P. Errico, P. Hurley, W. Dykstra, and R. Gardner
To: Chemistry Branch Files
Dated: 2/9/95
MRID(s): None

CB No.: 15282
DP Barcode: D213279
Subject: PP#s 9F03796, 0F03860, 3F04238, and 4F04343. Glyphosate-trimesium (formerly known as Sulfosate) in or on corn, soybeans, citrus fruit, stone fruit, and the nut crop group (except almonds). Results of Petition Method Validation (PMV)
From: G. Kramer
To: R. Taylor
Dated: 3/21/95
MRID(s): 42848702 and 43165802

CB No.: 14617, 14618, 15346, and 15347
DP Barcode: D208740, D208742, D213615, and D213612
Subject: PP# 0F03860. Glyphosate-trimesium (formerly known as Sulfosate) in or on Soybean RACs. Amendments of 10/3/94 and 3/20/95.
From: G. Kramer
To: R. Taylor and J. Smith
Dated: 4/4/95
MRID(s): 43397001-43397003, 43589500, and 43419801

CB No.: 14729
DP Barcode: D209543
Subject: ID# 010182-00324. Label Amendment for Glyphosate-trimesium (Touchdown Herbicide).
From: G. Kramer
To: R. Taylor and J. Smith
Dated: 5/16/95
MRID(s): 43450901 and 43450902

CB No.: 15649
DP Barcode: D215869
Subject: PP#s 9F03796, 0F03860, 3F04238, and 4F04343. Glyphosate-trimesium (formerly known as Sulfosate) in or on corn, soybeans, stone fruit, and the nut crop group (except almonds). Amendment of 5/1/95.
From: G. Kramer
To: R. Taylor
Dated: 7/6/95
MRID(s): 43631301

CB No.: 16276
DP Barcode: D219866
Subject: PP#s 9F03796, 0F03860, 3F04238, 0F3890, 1H03950, and 4F04343. Glyphosate-trimesium (formerly known as Sulfosate) in or on corn, soybeans, citrus fruit, grapes, stone fruit, and the nut crop group (except almonds). Results of Petition Method Validation (PMV).
From: G. Kramer
To: R. Taylor
Dated: 10/17/95
MRID(s): 43273604

CB No.: 16674
DP Barcode: D221955
Subject: PP# 1F03950/FAP# 1H05606. Glyphosate-Trimesium in or on Grapes. Amendment of 11/29/95.
From: G. Kramer
To: R. Taylor and K. Whitby
Dated: 1/22/96
MRID(s): 43864801

DP Barcode: D248046
Subject: Analytical method (PMG ion) for inclusion in PAM Vol II.
From: G. Kramer
To: M. Clower
Dated: 8/17/98
MRID(s): 43631301

DP Barcode: D248047
Subject: Analytical method (TMS ion) for inclusion in PAM Vol II.
From: G. Kramer
To: M. Clower
Dated: 8/17/98
MRID(s): 43864801

DP Barcode: D243450
Subject: PP# 7F04876. Sulfosate (i.e. Touchdown) in/on Fruiting Vegetables (Except Cucurbits). Evaluation of Residue Data and Analytical Methods.
From: J. Rowell and G. Kramer
To: J. Tompkins/T. Colvin-Snyder
Dated: 9/28/98
MRID(s): 44326501-44326503

DP Barcode: D243318
Subject: PP# 7F04854. **Sulfosate (Glyphosate-Trimesium) in or on Soybean and Animal RACs. Evaluation of Residue Data and Analytical Methods**.
From: G. Kramer
To: J. Tompkins/T. Colvin-Snyder
Dated: 4/23/99
MRID(s): 44313901-44313903