

US EPA ARCHIVE DOCUMENT

Executive Summary

Glyphosate is a nonselective herbicide that is currently registered for pre- and post-emergence control of susceptible weeds in a variety of fruit, vegetable, and field crops. When applied at lower rates, glyphosate is also a plant growth regular. Glyphosate is among the most widely used pesticides by volume. The Glyphosate Reregistration Eligibility Decision (RED) was issued September 1993.

The Interregional Research Project No. 4 (IR-4) has proposed, in PP#5E6987, the establishment of permanent tolerances for residues of the herbicide glyphosate, N-(phosphonomethyl)glycine, in/on the following agricultural commodities to support new use on Indian mulberry and amended use on dry pea:

Mulberry, Indian.....	0.20 ppm
Vegetable, legume, Group 6, except soybean	8.0 ppm

In conjunction with the subject petition, IR-4 is proposing to add Indian mulberry as a labeled crop under the existing directions for use for Tropical and Subtropical Trees and Fruits, with no change in the established use pattern. For dry pea, IR-4 is proposing to amend the use pattern for the 4.5 lb ae/gal (5.5 lb a.i./gal) water soluble concentrate formulation of the isopropyl amine (IPA) salt of glyphosate to increase the application rate and reduce the PHI for preharvest harvest aid and spot treatment uses, from 0.6 lb ae/A (0.73 lb a.i./A) with a 14-day PHI to 2.25 lb ae/A (3.0 lb a.i./A) with a 7-day PHI. The use on Indian mulberry has been proposed on behalf of the Agricultural Experiment Station of HI, and the amended use on dry pea has been proposed on behalf of the Agricultural Experiment Stations of ID, ND, SD, and WA.

Tolerances are currently established for residues of glyphosate resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in/on various plant commodities at levels ranging 0.20-400 ppm [40 CFR §180.364(a)]. Tolerances at 0.20 ppm are currently established for a number of tropical fruits that are similar to Indian mulberry including biriba, ilama, imbe, pawpaw, and sugar apple. A tolerance at 5.0 ppm is currently established for legume vegetables, Group 6, except soybeans.

The nature of the residue in plants is understood based on acceptable plant metabolism studies conducted in corn, cotton, and soybeans. The residue of concern in crop commodities for purposes of tolerance enforcement and risk assessment is glyphosate *per se*.

Because the proposed use on dry peas prohibits feeding of treated vines and hay to livestock and treatment of field (feed) peas grown for livestock feed, there are no livestock feed items associated with the proposed use. Therefore, no livestock metabolism data, enforcement methods, storage stability data, or feeding studies are required to support this petition.

Acceptable enforcement analytical methodology is available for the determination of glyphosate in plant commodities. These methods include a gas liquid chromatography (GLC) method published in the Pesticide Analytical Manual (PAM) Vol. II and an high pressure liquid chromatography (HPLC) method with fluorescence detection (FLD), which has undergone

Agency method validation and was recommended for inclusion in PAM Vol. II. Under the current petition, samples of dry pea were analyzed for residues of glyphosate using an HPLC/FLD method with a limit of quantitation (LOQ) of 0.05 ppm. The method is nearly identical to the HPLC/FLD method that has been approved for enforcement purposes, and was adequately validated in conjunction with the field trial studies.

No crop field trial data have been submitted in support of the proposed use on Indian mulberry; however, acceptable crop field trial data were previously reviewed in support of similar tropical fruits. In connection with establishment of tolerances on a number of minor crops, HED previously agreed to data translations between data for sugar apple, a tropical fruit that is similar in fruit size and type to Indian mulberry, to the following tropical fruits: biriba, ilama, imbe, and pawpaw. ARIA now concludes that data translation may be translated from sugar apple to support the proposed use on Indian mulberry.

IR-4 has submitted data from five field trials on peas. In four trials, Roundup Ultra® Herbicide was applied to preemergence plants, with a second foliar application to the physiologically mature crop. The preemergence application was not made at one location because the initial planting was destroyed by disease; the broadcast foliar application was made to a second planting.

The broadcast foliar treatment was applied to mature peas 7 days prior to harvest, with a 91-day retreatment interval between treatments on plots which received a preemergence treatment. Application rates ranged 2.16-2.27 lb ae/A (2.88-3.02 lb a.i./A) for preplant applications (~0.6x the maximum established preplant/preemergence application rate) and 2.21-2.35 lb ae/A (2.95-3.13 lb a.i./A) for harvest aid applications (~1x the maximum proposed application rate) for total application rates of 4.42-4.51 lb ae/A (5.89-6.01 lb a.i./A) (~0.75x the maximum established seasonal application rate) at the sites receiving two applications and 2.21 lb ae/A (2.95 lb a.i./A) for the site receiving a single application. One test location each in WA and ND included collection of samples at 13 or 14 and 21 days after the second application to assess residue decline.

Samples of dry pea were analyzed for residues of glyphosate using an HPLC/FLD method. The validated LOQ was 0.05 ppm, and the LOD was 0.025 ppm. This method is adequate for data collection based on acceptable method validation and concurrent recovery data.

The maximum storage interval for dry pea from harvest to analysis was 221 days (7.3 months). The storage intervals and conditions of the study are supported by available data which indicate that residues of glyphosate are stable in/on plant commodities stored frozen for up to 1 year.

The results from the dry pea field trials show that residues in dry pea harvested 7 days following preplant + harvest aid application at a total seasonal rate of 4.42-4.51 lb ae/A (5.89-6.01 lb a.i./A) were 0.59-3.57 ppm; residues in two samples of dry pea harvested 7 days following a single harvest aid application at 2.21 lb ae/A (2.95 lb a.i./A) were 2.20 and 6.19 ppm. Although the petitioner noted some unusual weather conditions at the ND sites, weather conditions were not reported to affect plant growth and development. The residue decline data demonstrate that residues of glyphosate either increased or did not decline significantly over the 21-day sampling

intervals. ARIA concludes that the desiccation observed in the residue decline study is inconclusive and insignificant.

The submitted dry pea field trial data are adequate to satisfy data requirements. Although preplant applications were included at four of the five trial sites, ARIA has concluded that the preplant applications would result in negligible residues; therefore, the trials reflect the proposed harvest aid use pattern at the proposed maximum rate and minimum PHI. These data will also support the proposed spot treatment use. ARIA also concludes that, given the nontoxic nature of glyphosate, its high solubility in water, and the likelihood that any salt formulation will dissociate rapidly in water, the submitted data for the IPA salt formulation of glyphosate are acceptable to support the proposed use of the K salt formulation on dry pea.

Geographic representation is adequate. As required under OPPTS 860.1500 Table 1, a total of five dry pea trials were conducted. Three trials were conducted in Zone 11, which accounts for 97% of dry pea production (OPPTS 860.1500 Table 6), and two trials were conducted in Zone 5.

Acceptable crop field trial data have been submitted reflecting the proposed harvest aid use on dry pea; these data will also support the proposed spot treatment use. The data are supported by adequate storage stability data. No processing data are required to support either of the proposed uses.

An acceptable confined rotational crop study indicated that residues of glyphosate were not detectable in crops planted 30 days after treatment; a 30-day plantback interval is established for any crop for which use of glyphosate is not registered.

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for glyphosate residues in various commodities. The Codex and U.S. tolerances are in harmony with respect to MRL/tolerance expression; both regulate the parent glyphosate only. Codex MRLs are established at 5.0 ppm in peas (dry) and 2 ppm in beans (dry). MRLs for glyphosate in various crops have been established by Codex, Canada, and Mexico. The proposed tolerance of 8.0 ppm in dry peas exceeds the existing Codex MRL of 5.0 ppm. This discrepancy is not expected to result in a trade barrier, however, because the United States accounts for only about 5% of world dry production and is not expected to be a significant exporter of this commodity.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of a revised section F, and the results of the forthcoming human health risk assessment, ARIA recommends for the establishment of tolerances under 40 CFR 180.364(a) as follows:

Mulberry, Indian.....	0.20 ppm
Pea, dry.....	8.0 ppm

Previous chemistry reviews have recommended the inclusion of a 30-day plantback interval for rotational crops. ARIA has concluded that the language in Section 8.0 of the WeatherMax® master label is sufficient for this purpose.

860.1550 Proposed Tolerances

- The proposed tolerance should be revised to reflect the correct tolerance expression: glyphosate N-(phosphonomethyl)glycine resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate.
- A new, separate tolerance should be established for “pea, dry.” The available data indicate that a tolerance of 8.0 ppm would be appropriate.
- The established tolerance for “vegetable, legume, Group 6, except soybean” should remain as established at 5.0 ppm. The commodity definition should be revised to “vegetable, legume, Group 6, except soybean and pea, dry.”

Background

Glyphosate is a nonselective herbicide that is currently registered for pre- and post-emergence control of susceptible weeds in a variety of fruit, vegetable, and field crops. Tolerances are currently established for residues of glyphosate resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in/on various plant commodities at levels ranging 0.20-400 ppm [40 CFR §180.364(a)]. The Glyphosate RED was issued September 1993.

The chemical structure and nomenclature of glyphosate is presented in Table 1. The physicochemical properties of the technical grade of glyphosate is presented in Table 2.

TABLE 1. Test Compound Nomenclature	
Compound	Chemical Structure
	$\begin{array}{c} \text{O} \qquad \qquad \text{O} \\ \parallel \qquad \qquad \parallel \\ \text{HO} \text{CCH}_2 \text{NHCH}_2 \text{P}(\text{OH})_2 \end{array}$
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 ^b	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 x 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
^a FAO Specifications and Evaluations	
^b Value obtained from International Programme on Chemical safety from data provided by Monsnato	
^c Exttoxnet	

860.1200 Directions for Use

IR-4 has provided copies of supplemental labels for "Treatment of Weeds in Tropical and Subtropical Trees and Fruits" and "Preharvest and Spot-Treatments of Weeds in Dry Peas, Lentils, and Chickpeas," as well as detailed directions for use under Section B for the Monsanto 4.5 lb ae/gal (5.5 lb a.i./gal) K salt soluble concentrate formulation of glyphosate (Roundup WeatherMax® Herbicide; EPA Reg. No. 524-537) reflecting the proposed uses of glyphosate on Indian mulberry and dry peas.

For Indian mulberry, IR-4 is proposing to simply add Indian mulberry as a labeled crop under the existing directions for use for Tropical and Subtropical Trees and Fruits, with no change in the established use pattern.

The 4.5 lb ae/gal (5.5 lb a.i./gal) K salt formulation is currently registered for a number of uses on dry peas, including preplant, preemergence, preharvest post-emergence, post-harvest, and spot treatment applications; similar use patterns are registered for dry beans. Under the current petition, IR-4 is proposing use of glyphosate as a preplant burn-down and harvest aid. When the proposed use pattern is compared to the registered use pattern for dry pea, the proposed use directions reflect an increase in the harvest aid and spot treatment application rates and a decrease in the PHI for those treatments. Although the submitted crop field trial data reflect preplant + harvest aid applications, no changes were proposed to the registered preplant application directions.

The currently registered uses proposed are presented in Table 3, and the proposed uses under PP#5E6987 relevant to Indian mulberry and dry peas are presented in Table 4.

Table 3. Summary of Registered Directions for Use of Glyphosate on Tropical and Subtropical Trees and Fruits, Legume Vegetables (Succulent or Dried), Dry Peas, and Dry Beans.						
Applic. Timing; Type; and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ae/A)/ (lb a.i./A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ae/A)/ (lb a.i./A)	PHI (days)	Use Directions and Limitations
Tropical and Subtropical Trees and Fruits including ambarella, atemoya, avocado, banana, Barbados cherry (acerola), biriba, blimbe, breadfruit, cacao (cocoa) bean, canistel, carambola (starfruit), cherimoya, coffee, custard apple, dates, durian, feijoa, figs, governor's plum, guava, ilama, imbe, imbu, jaboticaba, jackfruit, longan, lychee, mamey apple, mango, magosteen, marmaladebox (genip), mountain papaya, papaya, pawpaw, plantain, persimmon, pomegranate, pulasan, rambutan, rose apple, sapodilla, sapote (black, mamey, white), Spanish lime, soursop, star apple, sugar apple, Surinam cherry, tamarind, tea, ti (roots and leaves), wax jambu						
Preplant (site preparation) broadcast spray Post-emergence/ Established: directed sprays, spot treatment Ground	4.5 lb ae/gal (5.5 lb a.i./gal) K salt [524-537] (Master label accepted 4/11/02)	3.7/4.5	NS (not specified)	7.9/9.6 (combined total of all treatments)	14/28 in coffee	An application for site preparation may be made prior to planting or transplanting. In addition, applications may be made to established plantings in middles (between rows of trees or vines), strips (within rows of trees or vines), and for general weed control or perennial grass suppression and cut stump. Applications are to be made in spray volumes of 3-40 gal/A using ground equipment including selective equipment (shielded sprayers or wiper treatment).
Legume vegetables (succulent or dried) including: Bean (<i>Lupinus</i> : includes grain lupin, sweet lupin, white lupin, and white sweet lupin), Bean (<i>Phaseolus</i> : includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean), Bean (<i>Vigna</i> : includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean), Broad bean (fava), Chickpea (garbanzo), Guar, Jackbean, Lablab bean, Lentil, Pea (<i>Pisum</i> : includes dwarf pea, edible-podded pea, English pea, field pea, garden pea, green pea, snowpea, sugar snap pea), Pigeon pea, Soybean (immature seed), Sword bean.						
Preplant/ Preemergence/ At-planting/ Postemergence/ Post-harvest Ground or aerial	4.5 lb ae/gal (5.5 lb a.i./gal) K salt [524-537] (Master label accepted 4/11/02)	3.7/4.5	NS (not specified)	6.0/7.3 (combined total of all treatments)	14	Applications may be made chemical fallow, preplant fallow beds, preplant, preemergence, prior to transplanting vegetables, at planting, postemergence in row middles using selective ground equipment (hooded/shielded sprayers or wiper treatment), and postharvest. Applications are to be made in spray volumes of 3-40 gal/A using ground equipment and 3-15 gal/A using aerial equipment. In crops with vines, hooded sprayer, shielded sprayer, and wiper applications to row middles should be made prior to vine development.

Table 3. Summary of Registered Directions for Use of Glyphosate on Tropical and Subtropical Trees and Fruits, Legume Vegetables (Succulent or Dried), Dry Peas, and Dry Beans.						
Applic. Timing; Type; and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ae/A)/ (lb a.i./A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ae/A)/ (lb a.i./A)	PHI (days)	Use Directions and Limitations
Dry peas, lentils, and chick peas						
Broadcast foliar Ground or aerial	4.5 lb ae/gal (5.5 lb a.ai/gal) K salt [524-537] (Supplemental labeling accepted 5/20/04, 8/26/04, and 9/8/04)	0.6/0.73	1	0.6/0.73	14	Use limited to CO, ID, IA, MN, MT, NE, ND, OR, SD, WA, and WI. Application is to be made over-the-top prior to the harvest of dry peas, lentils, and chickpeas. Apply at the hard dough stage of the legume seed (30% grain moisture or less) in spray volumes of 3-20 gal/A. Do not combine preharvest spray with a spot treatment on same crop area. Feeding treated vines and hay to livestock is prohibited. Treatment of field (feed) peas grown for livestock feed is prohibited.
Spot treatment Ground	4.5 lb ae/gal (5.5 lb a.ai/gal) K salt [524-537] (Supplemental labeling accepted 5/20/04, 8/26/04, and 9/8/04)	0.6/0.73	1	0.6/0.73	14	Use limited to CO, ID, IA, MN, MT, NE, ND, OR, SD, WA, and WI. Application is to be made in spray volumes of 10-20 gal/A using ground equipment or as a 2% solution using a handheld sprayer. Application should be made at or beyond the bud stage of growth. Do not combine spot treatments with a preharvest broadcast spray in on same crop area. The crop receiving spray in treated areas will be killed. Feeding treated vines and hay to livestock is prohibited. Treatment of field (feed) peas grown for livestock feed is prohibited.
Dry beans						
Broadcast foliar Ground or aerial	4.5 lb ae/gal (5.5 lb a.ai/gal) K salt [524-537] (Supplemental labeling accepted 5/20/04, 8/26/04, and 9/8/04)	0.8/0.9	1	0.8/0.9	7	Application is to be made over-the-top prior to the harvest of dry beans. Apply at the hard dough stage of the legume seed (30% grain moisture or less) in spray volumes of 3-20 gal/A. Do not combine preharvest spray with a spot treatment on same crop area. Feeding treated vines and hay to livestock is prohibited. Treatment of cowpeas is prohibited.

Table 3. Summary of Registered Directions for Use of Glyphosate on Tropical and Subtropical Trees and Fruits, Legume Vegetables (Succulent or Dried), Dry Peas, and Dry Beans.

Applic. Timing; Type; and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ae/A)/ (lb a.i./A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ae/A)/ (lb a.i./A)	PHI (days)	Use Directions and Limitations
Spot treatment Ground	4.5 lb ae/gal (5.5 lb a.i./gal) K salt [524-537] (Supplemental labeling accepted 5/20/04 and 9/8/04)	0.8/0.9	1	0.8/0.9	7	Application is to be made in spray volumes of 10-20 gal/A using ground equipment or as a 2% solution using a handheld sprayer. Application should be made at or beyond the bud stage of growth. Do not combine spot treatments with a preharvest broadcast spray in on same crop area. The crop receiving spray in treated areas will be killed. Feeding treated vines and hay to livestock is prohibited. Treatment of cowpeas is prohibited.

Table 4. Summary of Proposed Directions for Use of Glyphosate.

Applic. Timing; Type; and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ae/A)/ (lb a.i./A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ae/A)/ (lb a.i./A)	PHI (days)	Use Directions and Limitations
Indian mulberry						
Preplant (site preparation) broadcast spray Post-emergence/ Established: directed sprays, spot treatment Ground	4.5 lb ae/gal (5.5 lb a.i./gal) K salt [524-537]	3.7/4.5	NS (not specified)	7.9/9.6 (combined total of all treatments)	14	An application for site preparation may be made prior to planting or transplanting. In addition, applications may be made to established plantings in middles (between rows of trees or vines), strips (within rows of trees or vines), and for general weed control or perennial grass suppression and cut stump. Applications are to be made in spray volumes of 3-40 gal/A using ground equipment including selective equipment (shielded sprayers or wiper treatment).

Table 4. Summary of Proposed Directions for Use of Glyphosate.						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ae/A) (lb a.i./A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ae/A) (lb a.i./A)	PHI (days)	Use Directions and Limitations
Pea, dry						
Broadcast foliar Ground or aerial	4.5 lb ae/gal (5.5 lb a.i./gal) K salt [524-537]	2.25/2.75	1	2.25/2.75 (implied)	7	Application is to be made over-the-top prior to the harvest of dry peas. Apply to physiologically mature peas (hard dough stage of the legume seed; 30% grain moisture or less) in spray volumes of 3-40 gal/A for ground equipment and 3-15 gal/A for aerial equipment. Do not combine preharvest spray with a spot treatment on same crop area. Feeding treated vines and hay to livestock is prohibited. Treatment of field (feed) peas grown for livestock feed is prohibited.
Spot treatment Ground	4.5 lb ae/gal (5.5 lb a.i./gal) K salt [524-537]	2.25/2.75	1	2.25/2.75 (implied)	7	Application is to be made in spray volumes of 10-20 gal/A using ground equipment or as a 2% solution using a handheld sprayer. Applications should be made at or beyond the bud stage of growth. Do not combine spot treatments with a preharvest broadcast spray on same crop area. The crop receiving spray in treated areas will be killed. Feeding treated vines and hay to livestock is prohibited. Treatment of field (feed) peas grown for livestock feed is prohibited.

Under the use directions for tree, vine, and shrub crops, which include tropical and subtropical trees and fruits, the master label includes the following instructions: Avoid contact with foliage or green bark of trunk, branches, suckers, fruit or other parts of trees, canes, and vines; avoid applications when recent pruning wounds or other mechanical injury has occurred.

Conclusions. The proposed use directions are adequate to allow evaluation of the available crop field trial data for dry pea relative to the proposed use. In addition, sufficient information was submitted for the proposed use on Indian mulberry for HED to confirm that the petitioner is not proposing a change to the registered use on tropical plants and fruits.

ARIA notes that the dry pea field trials submitted in support of the current petition reflect use of the 3 lb ae/gal (4 lb a.i./gal) isopropyl amine salt (IPA) formulation of glyphosate (Roundup Ultra®; EPA Reg. No. 524-475). According to the master label for this product, it is registered for uses similar or identical to those for the 4.5 lb ae/gal (5.5 lb a.i./gal) K salt formulation,

depending on the crop. Given the nontoxic nature of glyphosate, its high solubility in water, and the likelihood that any salt formulation will dissociate rapidly in water, ARIA concludes that data for the IPA salt formulation are acceptable to support use of the K salt formulation.

The submitted dry pea field trials reflect preplant application according to the registered use pattern followed by harvest aid application according to the proposed use pattern. The submitted data reflecting harvest aid use will support the proposed spot treatment use pattern.

860.1300 Nature of the Residue – Plants

PP# 2E04118 (formerly 2H05650), DP Num: 242628, 245591, T. Bloem, 11/30/98

PP#s 0F06130, 0F06195 and 0F06273, DP Num: 280831, W. H. Donovan, W.G. Dykstra and J. T. Swackhammer, 2/20/02

5F04555, DP Num: 217539 and 217541, 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).

No plant metabolism studies were submitted with the subject petition. The Residue Chemistry Chapter of the Glyphosate RED dated 10/27/92 concluded that the qualitative nature of the residue in plants is adequately understood based on acceptable metabolism studies conducted on corn, cotton, soybeans, and wheat. HED has determined that glyphosate *per se* is the residue to be regulated in plant commodities.

Metabolism studies submitted for genetically engineered glyphosate-tolerant canola (D242628 and D245591, 11/30/98, T. Bloem) and glyphosate-tolerant corn (D217539 and D217541, 3/14/96, G. Kramer) have indicated that metabolism in glyphosate-tolerant plants is essentially the same as that in normal plants.

860.1300 Nature of the Residue – Livestock

There are no livestock feed items associated with the proposed uses; therefore, data requirements for livestock metabolism data are not relevant to this tolerance petition.

860.1340 Residue Analytical Methods

0F06130, 0F06195, and 0F06273, DP Num: 265970, 275014, and 275015, W. Donovan, 1/31/02
5F04555, DP Num: 217539 and 217541, G. Kramer, 3/14/96
Memorandum, R. B. Perfetti, 10/27/92
MRID# 46642901, PP# 5E6987, DP Num: 322410, J. R. Tomerlin, 8/9/06

Enforcement Analytical Methods. According to the Residue Chemistry Chapter of the RED, adequate enforcement methods are available for determination of glyphosate in/on plant commodities. These methods include a GLC method (Method I of PAM Vol. II; limit of detection = 0.05 ppm) and an HPLC/FLD method. Use of the GLC method has been discouraged due to lengthiness of the procedure. The HPLC/FLD method has undergone successful Agency method validation and was recommended for inclusion in PAM Vol. II; the limit of detection is 0.05 ppm. 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.

Data Collection Method. Samples from the dry pea crop field trial study were analyzed using a method entitled "Laboratory Analytical Procedure for Glyphosate in Dry Pea using HPLC Post Column Derivatization with Fluorescence Detection" (LAP No. ORR-98-011.01). This method is essentially identical to the HPLC/FLD method approved for enforcement.

Samples were extracted with chloroform/0.1 N HCl, and then centrifuged. The aqueous phase was collected, adjusted to pH 2, and centrifuged, then applied to a chromatographic column packed with Chelex[®] 100 resin in the Fe(III) form. Chelated glyphosate residues were eluted with 6 N HCl, and the eluate was applied to an anion exchange column. Glyphosate residues, in the free acid form, were eluted with 6 N HCl, and the resulting eluate was concentrated to dryness by rotary evaporation and redissolved in water, then filtered and applied to an HPLC system equipped with a cation-exchange column, a post-column derivatization system, and a fluorescence detector. The validated LOQ was 0.05 ppm (lowest level of method validation), and the limit of detection (LOD) was 0.025 ppm.

Method recovery samples were analyzed concurrently with experimental samples. An unfortified and at least two fortified control samples were analyzed concurrently with each sample set. A 10 ppm fortified control sample was added to the last four sample sets to extend the validation range. Concurrent recoveries for glyphosate ranged from 85% to 118% (mean=99%, n=10).

Conclusions. The submitted data collection method is adequate for determination of residues of glyphosate in/on dry pea. The approved HPLC/FLD enforcement method for plant commodities will be adequate for enforcing the tolerance for glyphosate residues in/on dry pea.

860.1360 Multiresidue Methods

0F06130, 0F06195, and 0F06273, DP Num: 265970, 275014, and 275015, W. Donovan, 1/31/02

The FDA PESTDATA database (dated 6/2005) does not have an entry for glyphosate. The 1990 PESTRAK database indicated that recoveries are not likely for glyphosate under FDA Multiresidue Methods. No further data regarding multiresidue methods are required for this proposed use.

860.1380 Storage Stability

0F06130, 0F06195, and 0F06273, DP Num: 265970, 275014, and 275015, W. Donovan, 1/31/02
DP Num 66777, R. B. Perfetti, 4/2/92
MRID# 46642901, PP# 5E6987, DP Num: 322410, J. R. Tomerlin, 8/9/06

Adequate storage stability data are available indicating that residues of glyphosate are stable under frozen (-20 °C) storage conditions in plant commodities for 1 year (Residue Chemistry Chapter of the RED). Additional storage stability data submitted in response to reregistration requirements (D166777, 4/2/92, R. Perfetti) indicated that residues of glyphosate are stable under frozen storage in/on corn grain and soybean forage for 24 months and in/on sorghum straw, clover, and tomatoes for 31 months.

The maximum storage interval for dry pea from harvest to analysis was 221 days (7.3 months).

Conclusions. The available storage stability data are adequate to support the sample storage intervals and conditions of the submitted dry pea field trial study.

860.1400 Water, Fish, and Irrigated Crops

The proposed uses are not relevant to this guideline topic.

860.1460 Food Handling

The proposed uses are not relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

There are no livestock feed items associated with the proposed uses; therefore, data requirements for magnitude of the residue data in meat, milk, poultry, and eggs are not relevant to this tolerance petition.

860.1500 Crop Field Trials

MRID# 46642901, PP# 5E6987, DP Num: 322410, J. R. Tomerlin, 8/9/06

Indian mulberry

No crop field trial data have been submitted in support of the proposed use on Indian mulberry; however, acceptable crop field trial data were previously reviewed in support of similar tropical fruits. In connection with establishment of tolerances on a number of minor crops, HED previously agreed (D262424, W. Donovan, 1/18/00) to data translations between selected crops with similar use rates and PHIs. Under this decision, HED permitted translation of available data for sugar apple, a tropical fruit that is similar in fruit size and type to Indian mulberry, to the following tropical fruits: biriba, ilama, imbe, and pawpaw. ARIA now concludes that data translation may be translated from sugar apple to support the proposed use on Indian mulberry.

Dry pea

IR-4 has submitted field trial data for glyphosate on dry pea. A total of five field trials were conducted in Regions 5 (ND; 2 trials) and 11 (WA; 3 trials) during the 1998 growing season.

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.

At four of the trial sites (WA sites and 1 ND site), two applications of the 3 lb ae/gal (4 lb a.i./gal) IPA formulation were made as a preplant soil application 3 days prior to planting and as a broadcast foliar application to mature peas 7 days prior to harvest, with a 91-day retreatment interval. Because plants at the fifth trial site were lost due to powdery mildew, a new trial was started, and plants at this site received only the harvest aid application. Application rates ranged 2.16-2.27 lb ae/A (2.88-3.02 lb a.i./A) for preplant applications (~0.6x the maximum established preplant/preemergence application rate) and 2.21-2.35 lb ae/A (2.95-3.13 lb a.i./A) for harvest aid applications (~1x the maximum proposed application rate) for total application rates of 4.42-4.51 lb ae/A (5.89-6.01 lb a.i./A) (~0.75x the maximum established seasonal application rate) at the sites receiving two applications and 2.21 lb ae/A (2.95 lb a.i./A) for the site receiving a single application. A nonionic surfactant was added to the spray mixture for all applications. In addition, one test location each in WA and ND included collection of samples at 13 or 14 and 21 days after the second application to assess residue decline.

Because glyphosate adsorbs strongly to the soil, the preplant application would be expected to result in negligible residues; therefore, ARIA concludes that the trial in which no preplant application was made may be considered representative of the requested use. Although the total application rates used in the trials reflect only 0.75x the maximum established seasonal rate to dry pea, the use patterns of the submitted trials reflect the proposed use, which is a higher harvest aid application rate with a lower PHI.

Samples of dry pea were analyzed for residues of glyphosate using an HPLC/FLD method. The validated LOQ was 0.05 ppm, and the LOD was 0.025 ppm. This method is adequate for data collection based on acceptable method validation and concurrent recovery data.

The maximum storage interval for dry pea from harvest to analysis was 221 days (7.3 months). The storage intervals and conditions of the study are supported by available data which indicate that residues of glyphosate are stable in/on plant commodities stored frozen for up to 1 year.

The results from the dry pea field trials are presented in Table 5 and show that residues in dry pea harvested 7 days following preplant + harvest aid application at a total seasonal rate of 4.42-4.51 lb ae/A (5.89-6.01 lb a.i./A) were 0.59-3.57 ppm; residues in two samples of dry pea harvested 7 days following a single harvest aid application at 2.21 lb ae/A (2.95 lb a.i./A) were 2.20 and 6.19 ppm. ARIA notes that residues in samples from the ND trial sites greatly exceeded residues in samples from the WA sites. Residues ranged 0.66-0.81 ppm in samples from the WA sites, while residues at the ND sites ranged 2.20-6.19 ppm. Although the petitioner noted some unusual weather conditions at the ND sites, weather conditions were not reported to affect plant growth and development.

The residue decline data demonstrate that residues of glyphosate either increased or did not decline significantly over the 21-day sampling intervals. In samples from the WA trial, residues increased from 0.66-0.73 ppm at the 7-day PHI to 0.98-1.08 ppm at the 13-day PHI and 1.02-1.17 ppm at the 21-day PHI. In samples from the ND trial, residues decreased from 3.27-3.57 ppm at the 7-day PHI to 2.90-3.05 ppm at the 14-day PHI; however, residues from samples at the 21-day PHI were 2.84 and 3.74 ppm. The petitioner did not address the residue decline study results other than to note that they were inconclusive. ARIA concludes that the desiccation observed in the residue decline study is inconclusive and insignificant.

Conclusions. The submitted dry pea field trial data are adequate to satisfy data requirements. Although preplant applications were included at four of the five trial sites, ARIA has concluded that the preplant applications would result in negligible residues; therefore, the trials reflect the proposed harvest aid use pattern at the proposed maximum rate and PHI. These data will also support the proposed spot treatment use. ARIA also concludes that, given the nontoxic nature of glyphosate, its high solubility in water, and the likelihood that any salt formulation will dissociate rapidly in water, the submitted data for the IPA salt formulation of glyphosate are acceptable to support the proposed use of the K salt formulation on dry pea.

Geographic representation is adequate. As required under OPPTS 860.1500 Table 1, a total of five dry pea trials were conducted. Three trials were conducted in Zone 11, which accounts for 97% of dry pea production (OPPTS 860.1500 Table 6), and two trials were conducted in Zone 5. Because ND and SD were two of the states requesting the proposed use, the location of two trials in Region 5 is appropriate.

A summary is presented in Table 5.

Table 5. Summary of Residue Data from Crop Field Trials with										
Crop matrix	Application		PHI (days)	Residue Levels (ppm)						
	Timing	Rate (lb ae/A)/ (lb a.i./A)		n	Min.	Max.	HAFT ¹	Median	Mean	Std. Dev.
Dry pea (proposed use = 2.25 lb ae/A, 7-day PHI)										
Dry pea	Preplant	2.16-2.27/ 2.88-3.03	7	10	0.59	6.12	4.16	0.80	1.95	1.85
	Harvest aid	2.21-2.35/ 2.95-3.13								
	Total	2.21-4.51 ² / 2.95-6.01								
Dry pea	Preplant	3.0; 2.88	13-14	4	0.98	3.05	2.98	1.99	2.00	1.13
	Harvest aid	2.97; 3.13								
	Total	5.97-6.01								
Dry pea	Preplant	3.0; 2.88	21	4	1.02	3.74	3.29	2.0	2.19	1.32
	Harvest aid	2.97; 3.13								
	Total	5.97-6.01								

¹ HAFT = Highest average field trial result.

² The total is not simply added "by column." The trial with the 2.16 lb ae/gal preplant treatment (not the 2.27 lb ae/gal preplant treatment) was linked to a harvest aid rate of 2.35 lb ae/gal, for a total of 4.51 lb ae/gal.

The MRL Spreadsheet (PMRA PRO2005-04, 9/28/05; Attachment 1) was used to estimate recommended glyphosate tolerances in dry peas. The petitioner proposed a tolerance of 8.0 ppm for Vegetable, legume, Group 6, except soybean. However, the submitted residue field trial data are adequate to support a revised tolerance only for dried peas, not Group 6 in its entirety. The MRL spreadsheet supports a revised tolerance of 8.0 ppm for dried peas. Therefore, pending submission of a section F and the results of the forthcoming human health risk assessment, ARIA recommends for the requested glyphosate tolerance of 8.0 ppm, but only on peas, dry.

860.1520 Processed Food and Feed

The Agency does not require residue data for any processed commodities associated with Indian mulberry or dry pea; therefore, data requirements for processed food and feed are not relevant to this tolerance petition.

860.1650 Submittal of Analytical Reference Standards

An analytical standard for glyphosate is currently available in the National Pesticide Standards Repository (personal communication with Dallas Wright 3/7/06).

860.1850 and 860.1900 Confined and Field Accumulation in Rotational Crops

MRID#s 41543201 and 41543202, A. Abramovitch, 10/14/92
0F06130, 0F06195, and 0F06273, DP Num: 265970, 275014, and 275015, W. Donovan, 1/31/02
DP Num: 200041, 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 30-day plantback interval listed on the current label for glyphosate WeatherMAX® is adequate.

860.1550 Proposed Tolerances

The Agency has determined that the nature of the residue in plants and animals is adequately understood and that the tolerance expression includes glyphosate *per se*.

Tolerances are currently established for residues of glyphosate resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, the ammonium salt of glyphosate, and the potassium salt of glyphosate in/on various plant commodities at levels ranging from 0.20-400 ppm [40 CFR §180.364(a)]. Tolerances at 0.20 ppm are currently established for a number of tropical fruits that are similar to Indian mulberry including biriba, ilama, imbe, pawpaw, and sugar apple. A tolerance at 5.0 ppm is currently established for legume vegetables, Group 6, except soybeans.

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for glyphosate residues in various commodities. The Codex and U.S. tolerances are in harmony with respect to MRL/tolerance expression; both regulate the parent glyphosate only. Codex, Mexican and Canadian MRLs are summarized in Attachment 2. The proposed tolerance of 8.0 ppm in dry peas exceeds the existing Codex MRL of 5.0 ppm. This discrepancy is not expected to result in a trade barrier, however, because the United States accounts for only about 5% of world dry production and is not expected to be a significant exporter of this commodity (Agricultural Marketing Policy Center, Briefing No. 57, "Dry Pea", V. H. Smith and J. Jimmerson, November 2005 (revised)).

Under the subject petition, IR-4 is proposing the establishment of tolerances for residues of the herbicide glyphosate N-(phosphonomethyl)glycine in/or on Indian mulberry and legume vegetables, Group 6, except soybean. However, the submitted data support a tolerance of 8.0 ppm only on peas, dry, not Group 6, except soybean in its entirety.

No additional data are required to support the proposed tolerance of 0.20 ppm on Indian mulberry.

The available dry pea field trial data are acceptable, and will support a tolerance of 8.0 ppm only in dried peas. A summary of the established/proposed and recommended tolerances is shown in Table 6.

Commodity	Established/Proposed Tolerance (ppm)	Recommended Tolerance (ppm)
Mulberry, Indian	0.20	0.20
Vegetable, legume, Group 6, except soybean and pea, dry	none	5.0
Pea, dry	none	8.0
Vegetable, legume, Group 6, except soybean	8.0	none

References


- DP Num: 166777
 Subject: Monsanto Agricultural Chemical Corp.: Response to the Glyphosate Reregistration Standard: Storage Stability Data (CBRS # 8337).
 From: R. Perfetti
 To: W. Burnam and L. Rossi
 Date: 4/2/92
 MRID: 41940701
- DP Num: 41543201 and 41543202
 Subject: Review of Confined Rotational Crop Data for Glyphosate.
 From: A. Abramovitch
 To:
 Date: 10/14/92
 MRID: 41543201 and 41543202
- DP Num: 217539 and 217541
 Subject: PP#5F04555. Glyphosate in or on Corn Forage. Evaluation of Residue Data and Analytical Methods.
 From: G. Kramer
 To: R. Taylor, V. Walters
 Date: 3/14/96
 MRID: 43712701 and 43712702
- DP Num: 242628 and 245591
 Subject: PP#2D04118 (formerly 2H05650) -- Glyphosate residues in/on glyphosate tolerant canola seed and canola meal. Amendment of 24-August-1998.
 From: D. Miller
 To: T. Bloem
 Date: 11/30/98
 MRID: 43807203, 44528801, and 44528802

DP Num: 262424
Subject: Glyphosate on Various Commodities. IR-4 Proposal for Tolerance Translations
for a Variety of Minor Crops.
From: W. Donovan
To: H. Jamerson/R. Forrest
Date: 1/18/00
MRID: None

ATTACHMENT 1**MRL SPREADSHEET OUTPUT**

Regulator: EPA
Chemical: Glyphosate
Crop: Legumes
PHI: 7 days
App. Rate: Various
Submitter: IR-4

Residues	LN(Residues)	Z- scores
0.660	-0.42	-1.00
0.730	-0.31	-0.66
0.590	-0.53	-1.55
0.810	-0.21	0.12
0.740	-0.30	-0.38
0.800	-0.22	-0.12
3.570	1.27	1.00
3.270	1.18	0.66
6.120	1.81	1.55
2.195	0.79	0.38

	Regulator:	EPA	
	Chemical:	Glyphosate	
	Crop:	Legumes	
	PHI:	7 days	
	App. Rate:	Various	
	Submitter:	IR-4	
	n:	10	
	min:	0.59	
	max:	6.12	
	median:	0.81	
	average:	1.95	
			99.9th Percentile
	95th Percentile	99th Percentile	
EU Method I Normal	5.0 (8.0)	7.0 (10)	8.0 (--)
EU Method I Log Normal	6.0 (17)	11 (45)	20 (--)
EU Method II Distribution-Free	7.0		
California Method $\mu + 3\sigma$			
UPLMedian95th	7.0		
Approximate Shapiro-Francia Normality Test Statistic	0.8393 0.05 >= p-value > 0.01 : Reject lognormality assumption		

ATTACHMENT 2

INTERNATIONAL RESIDUE LIMIT STATUS SHEET

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: N-(phosphonomethyl) glycine	Common Name: Glyphosate	<input type="checkbox"/> Proposed tolerance <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date:
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
<input type="checkbox"/> No Codex proposal step 6 or above <input type="checkbox"/> No Codex proposal step 6 or above for the crops requested		Petition Number: 5E6987 DP Num: D322410 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)
Beans (dry)	2		
Peas (dry)	5		
Soya bean (dry)	20		
Kiwi	0.1 (*)		
Limits for Canada		Limits for Mexico	
<input type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested		<input type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested	
Residue definition: N-(phosphonomethyl) glycine, including the metabolite aminomethylphosphonic acid		Residue definition: glifosato	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
Peas	5	Mango	0.2
Beans, lentils	4	Papaya	0.2
		Avocado	0.2
		Guava	0.2
		Beans	0.2
Notes/Special Instructions: S.Funk, 08/24/2006.			



13544

R132758

Chemical: Glyphosate

PC Code:
417300

HED File Code: 11000 Chemistry Reviews

Memo Date: 9/26/2006

File ID: DPD322410

Accession #: 412-07-0024

HED Records Reference Center
11/9/2006