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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 31-JAN-2002

SUBJECT: PP#s 0F06130, 0F06195, and 0F06273. Glyphosate in/on Pasture and Rangeland Grasses, Roundup Ready® Wheat, and Nongrass Animal Feeds. **Evaluation of Residue Data and Analytical Methods.** MRID#s 450894-01, 451747-01, and 453654-01. DP Barcodes D265970, D275014, and D275015. PC Codes 103601 and 417300. PRAT Case#s 292955, 293286, and 293997. Submission#s S579658, S597322, and S597324.

FROM: William H. Donovan, Ph.D., Chemist
Registration Action Branch 1 (RAB1)
Health Effects Division (HED) (7509C)
William H. Donovan

THRU: G. Jeffrey Herndon, Branch Senior Scientist
RAB1/HED (7509C)
G. Jeffrey Herndon

TO: J. Tompkins/V. Walters, PM Team 25
Registration Division (RD) (7505C)

Monsanto Company has submitted amended registration applications for 1) postemergence use of glyphosate (product name Roundup Ultra® Herbicide; EPA Reg. No. 524-475) on pasture and rangeland grasses, along with a petition to increase the tolerance for the grass forage, fodder, and hay group as a result of the proposed amended use, 2) glyphosate (product name Roundup Ultramax® Herbicide; EPA Reg. No. 524-512) use on nongrass animal feeds, along with a petition to establish a permanent crop group tolerance on nongrass animal feeds (forage, fodder, straw, and hay) group as a result of the proposed amended uses, and 3) expanded uses of glyphosate (product name Roundup Ultra® Herbicide; EPA Reg. No. 524-475) on Roundup Ready® wheat, along with a petition to establish permanent tolerances on wheat forage and hay as a result of the proposed amended uses.

As a result of the proposed new uses, the petitioner is proposing establishment of permanent tolerances for residues of glyphosate (N-(phosphonomethyl)glycine) *per se* resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate and the ammonium salt of glyphosate in/on:

Animal feed, nongrass, group (Crop Group 18) ..... 400 ppm
Grass, forage, fodder and hay, group (Crop Group 17) ..... 300 ppm
Wheat, forage ..... 10.0 ppm
Wheat, hay ..... 10.0 ppm

This memo provides a summary of the reviews of the residue chemistry database supporting the proposed uses. Detailed reviews providing more information about the following studies are available in separate memos (in the template DER format): crop field trial data for nongrass animal feeds (45365401.der.wpd), grasses (45089401.der.wpd), and Roundup Ready wheat (45174701.der.wpd); and a wheat processing study (45174701.de1.wpd).

The supporting DER documents have been reviewed and revised to reflect current HED policy.

Executive Summary of Chemistry Deficiencies

- Revised Section B
- Revised Section F

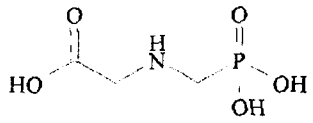
RECOMMENDATIONS

Provided Sections B and F are revised as specified under Conclusions 1a-1c, 9b, 9d, and 13, HED concludes there are no residue chemistry data requirements that would preclude the establishment of the following permanent tolerances for glyphosate (N-(phosphonomethyl)glycine) *per se* resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate and the ammonium salt of glyphosate in/on:

Animal feed, nongrass, group ..... 400 ppm
Grass, forage, fodder and hay, group ..... 300 ppm
Wheat, forage ..... 10 ppm
Wheat, hay ..... 10 ppm
Wheat, grain ..... 6.0 ppm

HED will initiate a human health risk assessment of the proposed uses of glyphosate in/on grasses, nongrass animal feeds, and wheat in a separate document.

GLYPHOSATE



INTRODUCTION

On February 7, 2001, glyphosate was granted reduced risk status for use on glyphosate-tolerant wheat (Letter, M. Johnson, 16-FEB-2001). Accordingly, the wheat petition (PP# 0F06195) has qualified for expedited review under the Reduced Risk Pesticide Initiative. In addition, the grass petition (PP# 0F06130) has also been granted reduced risk status. In support of the grass, Roundup Ready® wheat, and nongrass animal feeds petitions, the following label modifications were proposed:

Pasture and Rangeland Grasses
Monsanto Company submitted a revision of the master label for the 3 lb ae/gal isopropylamine salt soluble concentrate/liquid (SC/L) formulation of glyphosate (Roundup® Ultra Herbicide; EPA Reg. No. 524-475) adding postemergent broadcast application to any grass in the Graminease family except sugarcane, corn, and cereal grains, and including Bahiagrass, bermudagrass, bluegrass, brome, fescue, orchardgrass, ryegrass, timothy, and wheatgrass. In addition, the established spot treatment and wiper application uses, and preplant, preemergence, and pasture renovation uses were modified as noted below. A combined maximum seasonal rate resulting from all treatments is established at 6 lb ae/A.

For postemergence use, the product is proposed for multiple broadcast applications at 0.28-1.5 lb ae/A to grasses, with a maximum seasonal application rate of 2.25 lb ae/A; neither a minimum retreatment interval nor a PHI is specified. Applications may be made in 3-40 gal/A using ground equipment or in 3-15 gal/A using aerial equipment. Use of ammonium sulfate is not recommended when spraying rangeland grasses. On the revised label, the petitioner has revised the crop title from "Pastures" to "Grass in Pastures and Rangelands".

For spot treatment and wiper application, the use pattern has been modified as follows: for application rates >2.25 lb ae/A, no more than one-tenth of any acre should be treated at one time; and for application rates ≤2.25 lb ae/A, the entire field or any portion of it may be treated using these methods. Applications may be made in the same area at 30-day intervals. Domestic livestock must be removed prior to application, and a 7-day pregrazing/preharvest interval is proposed. Previously (label date 1/13/99), the use directions reflected the more restrictive use

pattern now specified for application rates >2.25 lb ae/A and the PGI/PHI was established at 14 days.

For preplant, preemergence, and pasture renovation uses, the use pattern has been modified to specify a 0-day PGI/PHI for application rates ≤2.25 lb ae/A and a PGI/PHI of 56 days for application rates >2.25 lb ae/A. In addition, if applications total >2.25 lb ae/A, domestic livestock must be removed prior to application. The previously registered use directions reflected the more restrictive use pattern now specified for application rates >2.25 lb ae/A.

Roundup Ready Wheat
Monsanto Company submitted supplemental labeling for the 3 lb ae/gal isopropylamine salt soluble concentrate/liquid (SC/L) formulation of glyphosate (Roundup® Ultra Herbicide; EPA Reg. No. 524-475) allowing broadcast preplant or preemergence, broadcast postemergence over-the-top and/or broadcast preharvest application to wheat with the Roundup Ready® gene. The petitioner noted that because Roundup Ready® wheat will initially be available only as selected spring wheat varieties, use is restricted to those states which represent the major spring wheat growing regions of the U.S.

The supplemental labeling restricts application of the 3 lb ae/gal SC/L formulation to Roundup Ready® wheat in the following states: ID, IL, IN, IA, KS, KY, MN, MO, MT, NE, ND, OH, OR, SD, WA, WI, and WY.

> For preplant or preemergence use, an unspecified number of preplant or preemergence applications are proposed at an unspecified individual application rate for a maximum combined application rate from all preplant or preemergence applications of 3.75 lb ae/A/season.
>
> For postemergence over-the-top application, the product is proposed for up to two applications at 0.75 lb ae/A/application, made at emergence through the fifth-leaf stage of development, with a 10-day retreatment interval. The label proposes 7-, 30-, and 55-day PHIs for forage, hay, and grain, respectively following over-the-top applications.
>
> For preharvest applications, the product is proposed for a single application at 0.75 lb ae/A made at the hard dough stage of grain (≤30% grain moisture), provided no more than 0.375 lb ae/A has been applied previously over-the-top.

A 7-day PHI for grain is proposed for preharvest use, and wheat stubble or straw may be grazed or fed immediately after harvest. Applications may be made in 5-20 gal/A (10-20 gal/A for preharvest applications) using ground equipment or in 3-15 gal/A using aerial equipment; applications made by aerial equipment are not to exceed 0.75 lb ae/A. The label contains the following statement regarding rotational crops: "There are no rotational crop restrictions following application of this glyphosate product."

Nongrass Animal Feeds
Monsanto Company submitted supplemental labeling for the 3.7 lb ae/gal isopropylamine salt soluble concentrate/liquid (SC/L) formulation of glyphosate (Roundup® Ultramax Herbicide;

EPA Reg. No. 524-512) allowing broadcast preharvest application to alfalfa and clover and other forage legumes, including kudzu, lespedeza, lupin, sainfoin, trefoil, velvet bean, vetch, crown vetch, and milk vetch.

The product is proposed for a single broadcast application at 1.5 lb ae/A for alfalfa or 1.16 lb ae/A for clover and other forage legumes. Use is limited to declining crop stands or any stand where crop destruction is acceptable. Use for crop grown for seed is prohibited. A 1.5-day PHI is proposed for alfalfa, and a 3-day PHI is proposed for clover.

Although the 3 lb/gal SC/L formulation of glyphosate (EPA Reg. No. 524-475) was used in the submitted field trials, the petitioner submitted supplemental labeling for the 3.7 lb ae/gal SC/L formulation (EPA Reg. No. 524-512). The petitioner stated that the new labeling is intended to allow all forage legumes to be treated in the same manner as alfalfa. Both labels support preplant, preemergence, and at-planting, and renovation (3.7 lb ae/gal only) applications to alfalfa, clover, and other forage legumes, and permit spot treatment or wiper application of glyphosate to alfalfa, clover and other forage legumes (3 lb ae/gal) or to alfalfa and clover only (3.7 lb ae/gal). The preharvest use directions which appear on the submitted label for alfalfa have already been approved on supplemental labels dated 10/5/2000 and 5/10/2001 for the 3 lb ae/gal and 3.7 lb ae/gal formulations, respectively. The preharvest use on clover and other forage legumes represents the only significant proposed change to the current labeling; the preharvest use pattern for alfalfa is presented for informational purposes.

On the submitted labeling, spot treatment and wiper applications have been expanded to include the other forage legumes in addition to alfalfa and clover. This is a house-keeping change for which no data are required; the proposed use already appears on the label for the 3 lb ae/gal SC/L formulation.

RECOMMENDATIONS

Provided Sections B and F are revised as specified under Conclusions 1a-1c, 9b, 9d, and 13, HED concludes there are no residue chemistry data requirements that would preclude the establishment of the following permanent tolerances for glyphosate (N-(phosphonomethyl)glycine) *per se* resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate and the ammonium salt of glyphosate in/on:

Animal feed, nongrass, group	**400 ppm**
Grass, forage, fodder and hay, group	**300 ppm**
Wheat, forage	**10 ppm**
Wheat, hay	**10 ppm**
Wheat, grain	**6.0 ppm**

HED will initiate a human health risk assessment of the proposed uses of glyphosate in/on grasses, nongrass animal feeds, and wheat in a separate document.

CONCLUSIONS

OPPTS GLN 860.1200: Proposed Uses

1a. The proposed use directions for grasses are not adequate. The petitioner should submit a revised Section B specifying a 0-day PGI and PHI for the proposed postemergence use on grass forage, and include a 30-day plant back restriction for rotational crops.

1b. The proposed use directions for nongrass animal feeds are not adequate. The petitioner should submit a revised Section B specifying a 30-day plant back restriction for rotational crops.

1c. The proposed use directions for Roundup Ready® wheat are not adequate. The petitioner should submit a revised Section B stating that the maximum combined application rate is 4.875 lb ae/A/season when more than one type of application (preemergence, postemergence, or preharvest) is made, and include a 30-day plant back restriction for rotational crops. Specifically, the maximum use pattern for Roundup Ready® wheat consists of the following: 160 ounces (oz) of Roundup Ultra® as preplant/preemergence applications + 16 oz postemergence over-the-top application + 32 oz preharvest application = 208 oz total.

OPPTS GLN 860.1300: Nature of the Residue - Plants

2. 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 which is taken up is readily translocated. Foliarly applied glyphosate is readily absorbed and translocated throughout the trees of 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. Perfetti, 27-OCT-1992). In a meeting of the HED Metabolism Committee held 19-AUG-1992, the Committee determined that AMPA need not be regulated and should be dropped from the tolerance expression (Memo, R. Perfetti, 19-OCT-1992). Furthermore, in a meeting of the HED Metabolism Committee held 17-MAR-1994, the 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. Perfetti, 17-MAR-1994). Thus, the terminal residue to be regulated in plants is glyphosate *per se*.

OPPTS GLN 860.1300: Nature of the Residue - Livestock

3. The qualitative nature of the residue 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 animal tissues are glyphosate and its metabolite AMPA; there was no evidence of further metabolism (Memo, R. Perfetti, 27-OCT-1992). The conclusions of the HED Metabolism Committee on 19-AUG-1992 and 17-MAR-1994 apply to plant and livestock commodities. Thus, the terminal residue to be regulated in livestock is glyphosate *per se*.

OPPTS GLN 860.1340: Residue Analytical Method - Plants and Livestock

4. 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, 27-OCT-1992). A GC/MS method for glyphosate in crops has also been validated by EPA's Analytical Chemistry Laboratory (ACL) (PP#5F04555, G. Kramer, 21-MAR-1995).

5. Adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in/on the nongrass animal feed crop group; the grass forage, fodder, and hay crop group; wheat forage and hay; and livestock commodities.

OPPTS GLN 860.1360: Multiresidue Method

6. The Pestrak database (1990) indicate that recoveries are not likely for glyphosate under FDA Multiresidue Methods. No further data regarding multiresidue methods are required for this proposed use.

OPPTS GLN 860.1380: Storage Stability Data

7. 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, 27-OCT-1992). No additional storage stability data are needed, as the storage intervals for samples from the field trials are adequately supported by available storage stability data.

OPPTS GLN 860.1500: Crop Field Trials

Pasture and Rangeland Grasses

8a. In thirteen trials (MRID 45089401) conducted in CA (1 trial), FL (1), IA (1), LA (1), NC (1), ND (1), NE (1), NY(1), TX (2), UT (1), WA (1), and WI (1), glyphosate residues were 94-286 ppm and 6.5-270 ppm in/on grass forage and hay, respectively, harvested 0 days (forage) or 3 days (hay; plus 1-4 days drying time) following a single broadcast application of the 3 lb ae/gal SC/L formulation and treated at ~2.25 lb ae/A, equivalent to 1x the proposed rate. The highest average field trial (HAFT) values for glyphosate residues were 267 and 259 ppm in/on grass forage and hay, respectively.

8b. The submitted grass field trials conducted at ~1x indicate that residues of glyphosate ranged 8.1-251 ppm and 8.3-230 ppm in/on grass forage harvested 2-3 and 6-7 days, respectively, and 30-210 ppm in/on grass hay harvested 7 days (plus 1-4 days drying time) following a single broadcast application of the 3 lb ae/gal SC/L formulation at ~2.25 lb ae/A (1x the proposed rate). The submitted grass field trials conducted at ~0.5x indicate that residues of glyphosate ranged 37.0-168 ppm and 4.86-106 ppm in/on grass forage harvested 0 and 2/3 days, respectively, and 13.2-144 ppm in/on grass hay harvested 3 days (plus 1-4 days drying time) following a single broadcast application of the 3 lb ae/gal SC/L formulation at ~1.125 lb ae/A (0.5x the proposed rate).

8c. The crop field trials for glyphosate on grass forage and hay are classified acceptable and satisfy the guideline requirement for crop field trials. The proposed tolerance level of 300 ppm is adequate to cover residues of glyphosate *per se* in/on the grass, forage, fodder and hay, group (Crop Group 17).

Roundup Ready Wheat

9a. In twenty-two field trials (MRID 45174701) conducted in the U.S. in MN (1 trial), MT (2), ND (2), and WA (1), and in Canada in AB (5 trials), MB (4), and SK (7), glyphosate residues were 0.028-9.14, <0.05-6.00, 0.014-5.62, and 0.019-71.8 ppm in/on Roundup Ready® wheat forage, hay, grain, and straw, respectively, harvested a minimum of 7 days (forage), 34 days (hay), and 6 days (grain and straw) following the final application of the 3 lb ae/gal SC/L formulation and treated at ~4.48 lb ae/A, equivalent to 1x the maximum proposed rate. The HAFT values for glyphosate residues were 8.78, 5.75, 4.71, and 71.5 ppm in/on wheat forage, hay, grain, and straw, respectively. The petitioner conducted four additional U.S. field trials in ND (1 trial), SD (2) and OR (1), for which results were not reported; one of the SD sites had been intended to serve as a residue decline trial site. In the ND and SD trials, samples were harvested but not analyzed because the field sites were infected with *Fusarium*. In the OR trial, several deviations occurred in the timing of applications and sampling stages that did not represent normal agronomic practices; thus, the trial was aborted before any grain or straw samples were harvested. Monsanto stated that Roundup Ready® wheat will initially be available only as selected spring wheat varieties, and that therefore, residue sites were selected in the major spring wheat growing regions of the U.S. and Canada. According to the petitioner, this

information was presented to R. Perfetti of HED in a meeting on November 18, 1998 (no record of the meeting was included by the petitioner, and none was available for review). The petitioner stated that, based on the information presented, Dr. Perfetti concurred that the two available lines of Roundup Ready® wheat could be alternately planted among the selected sites in the study, and that a combination of 10 sites in the northern U.S. and 14 sites in Canada would provide sufficient data to support use of glyphosate over Roundup Ready® wheat in the major spring wheat growing regions of the U.S.

9b. Although the number and geographical distribution of the wheat field trials does not conform to the recommendations listed in OPPTS 860.1500, in view of the reduced risk status of this petition, the apparent agreement between Monsanto and HED with regards to the number and location of field trials, and the limitation of the use to spring wheat growing areas of the U.S., HED is willing to classify the submitted field trial data as acceptable to satisfy the guideline requirement for field trials. However, HED emphasizes that the present determination applies to this action only and that for any expanded use to include winter wheat, further field trial data will be required to represent the regions in which winter wheat is typically grown. Based on the available data, HED concludes that residues of glyphosate in/on wheat straw will not exceed the established tolerance of 100 ppm for "grain, cereal, stover, and straw" group following application to Roundup Ready® wheat according to the proposed use patterns. Further, the data support increasing existing tolerance levels for wheat forage and hay to 10 ppm. However, the maximum glyphosate residue level in wheat grain, 5.6 ppm, exceeds the established tolerance level of 5.0 ppm. Accordingly, a tolerance level of 6.0 ppm is recommended to cover residues of glyphosate *per se* in wheat grain. **The petitioner should submit a revised Section F.**

9c. The results from the residue decline study in wheat conducted in Canada (MB) indicated that residues of glyphosate appear to decline in wheat grain harvested following the preharvest application used in Treatment 6. Residues were 0.425-0.477 ppm in wheat grain at the 7-day sampling interval (proposed PHI), increased to 0.462-0.530 ppm at 10 days, and declined thereafter. Results were also reported for wheat grain collected 57-93 days following the pre-boot postemergence application used in Treatment 5; at these intervals, residue levels were relatively stable. Based on the submitted study, the proposed PHI of 7 days for forage appears to be adequate.

9d. Insufficient data were submitted to support removal of the restriction against the use of additives (nonionic surfactant and ammonium sulfate) from the label. Treatment 5 provided data representative of the proposed use pattern including additives for wheat forage only. These data indicate an increase in average glyphosate residue levels of approximately 20% above what is obtained without additive use. Prior to removal of the additive restriction, additional data would be required reflecting use of additives in applications made according to the respective maximum proposed use patterns for wheat hay, grain, and straw. **Thus, the current label restriction against the use of additives is appropriate and should be retained for wheat uses.**

9e. Two lines (25372 and 25397) of Roundup Ready® wheat were used in the submitted studies, both being genetically modified to express the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that confers tolerance to glyphosate through a modified target site for glyphosate action. No discernible difference in glyphosate residue levels could be attributed to the wheat strain tested.

Nongrass Animal Feeds

10a. In ten field trials (MRID 45365401) conducted in AL (1 trial), CA (1), LA (1), MO (1), ND (2), NY (1), TX (2), and WI (1), glyphosate residues were 30.6-68.8 and 85.3-295.5 ppm in clover forage and hay, respectively, harvested 3 days following one application of the 3 lb ae/gal SC/L formulation and treated at 1.125 lb ae/A, equivalent to 1x the proposed rate. The HAFT values for glyphosate residues were 65.7 and 295.1 ppm in/on clover forage and hay, respectively. Glyphosate residues were 48-228 ppm in/on clover forage and 102-726 ppm in/on clover hay harvested 3-4 days, and 71-410 ppm in/on clover forage and 116-841 ppm in/on clover hay harvested 6-7 days following a single broadcast application at 2.25 lb ae/A (2x).

10b. In ten field trials (MRID 45365401) conducted in CA (1 trial), IA (2), MN (1), ND (1), NE (1), NY (1), UT (1), WA (1), and WI (1), glyphosate residues were 37-317 ppm in/on alfalfa forage and 54-526 ppm in/on alfalfa hay harvested 3-4 days, and 77-454 ppm in/on alfalfa forage and 104-545 ppm in/on alfalfa hay harvested 7 days following a single broadcast application of the 3 lb ae/gal SC/L formulation and treated at ~2.25 lb ae/A, 1.5x the proposed rate for alfalfa. The petitioner indicated that the data for alfalfa and clover treated at 2.25 lb ae/A are not relevant to the present tolerance proposal and registration amendment, and are presented for informational purposes.

10c. Although no data reflecting application of glyphosate to alfalfa according to the proposed use pattern were submitted with this action, the petitioner cited the results of another alfalfa field trial study (MRID 43077001) in support of the group tolerance for nongrass animal feeds. In this study, residues of glyphosate were 48-158 ppm in/on alfalfa forage and 44-377 ppm in/on alfalfa hay harvested from 20 field trials 1 day following a single application of a 3 lb ae/gal SC/L formulation at ~1.5 lb ae/A, equivalent to ~1x the proposed rate; hay samples were field dried for 3-6 days prior to sample collection. The HAFT values for glyphosate residues were 152.7 and 340.7 ppm in/on alfalfa forage and hay, respectively. These data were presented in an Agency review of PP#4F4312/4H5692 for preharvest use of glyphosate on alfalfa (DP Barcodes 201250, D201252, D201254, and D201255, 1/11/95, M. Rodriguez), and were recently found to be acceptable in connection with PP#9F05096 for increasing the preharvest use rate of glyphosate on alfalfa (DP Barcodes D256740 and D246741, 6/9/00, W. Donovan).

10d. The crop field trials for nongrass animal feeds (alfalfa and clover) are classified acceptable and satisfy the guideline requirement for crop field trials. Thus, a tolerance level of 400 ppm is recommended to cover residues of glyphosate *per se* in/on the animal feed, nongrass, group (Crop Group 18).

<u>OPPTS GLN 860.1520: Processed Food/Feed</u>

11a. In the wheat processed food/feed study (MRID 45174701), the 3 lb ae/gal SC/L formulation was applied to Roundup Ready® spring wheat three times (including one preemergence and two postemergence applications) at 3.79 lb ae/A (preemergence) and 0.75-0.76 lb ae/A/application (postemergence) for a total application rate of 5.30 lb ae/A (1.1x the maximum proposed seasonal rate for grain). The wheat grain was processed into flour, bran, middlings, shorts, germ, and aspirated grain fractions. Following treatment of wheat at 1.1x the maximum proposed seasonal rate for grain, detectable residues of glyphosate were observed at 4.13 ppm in wheat grain. The wheat was processed according to simulated commercial procedures into flour, bran, middlings, shorts, germ, and aspirated grain fractions. Analysis of the processed wheat fractions indicated that residues of glyphosate did not concentrate significantly in wheat flour, bran, middlings, shorts, and germ (concentration factors (CFs) of 0.93x, 1.33x, 0.89x, 1.02x, and 0.71x, respectively), but did concentrate up to 5.83x in wheat aspirated grain fractions.

11b. The processed food/feed study is classified as acceptable and satisfies the guideline requirement for a processing study. Tolerances will not need to be established to cover residues of glyphosate in wheat processed commodities because residues in wheat flour, bran, middlings, shorts, and germ did not concentrate significantly and will be covered by the existing tolerance of 20 ppm for wheat, milling fractions (except flour), and residues in wheat aspirated grain fractions will be covered by the 50 ppm aspirated grain fraction tolerance recommended in a recent review (D265963, W. Donovan, 09-NOV-2000): HAFT X CF = 4.71 ppm X 5.83 = 27.5 ppm.

OPPTS GLN 860.1480: Residues in Meat, Milk, Poultry and Eggs

12. Although grass forage and hay are considered significant feed commodities, the current proposal to establish a crop group tolerance for grass forage, fodder, and hay at 300 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 recently 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 Barcodes D256740, 6/9/00, W. Donovan). No impact is expected on the dietary burden to poultry or hogs since grass forage and hay are not feed items for these livestock.

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

13. An acceptable confined rotational crop study was previously reviewed (Memo, A. Abramovitch, 10/14/92; MRIDs 41543201 and 41543202) which indicated that residues of glyphosate were not detectable in crops planted 30 days after treatment. The current label for glyphosate contains the following statement regarding rotational crops: "There are no rotational crop restrictions following application of this glyphosate product." 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 (DP Barcode D200041, 5/12/94, G. Kramer) 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.**

International Considerations

14a. Codex and Mexican maximum residue limits (MRLs) are established for residues of glyphosate (glifosato) *per se* and Canadian MRLs are established for combined residues of glyphosate and AMPA in a variety of raw agricultural, processed, and animal commodities. Currently a relevant Codex MRL for hay or fodder (dry) of grasses is established at 50 ppm. No Canadian MRLs are established for any grass commodity. A Mexican MRL is established for pasture at 0.2 ppm. Because of the higher residue levels resulting from the proposed use pattern, harmonization of U.S. grass tolerances with existing Codex or Mexican MRLs is not possible.

14b. For wheat related commodities, relevant Codex MRLs exist for: wheat grain at 5 ppm; unprocessed wheat bran at 20 ppm; wheat flour at 0.5 ppm; wheat wholemeal at 5 ppm; and straw and fodder (dry) of cereal grains at 100 ppm. Canadian MRLs are established for: wheat at 5 ppm and wheat milling fractions (excluding flour) at 15 ppm. A Mexican MRL is established for wheat at 5 ppm. The recommended tolerance level of 6.0 ppm for wheat grain slightly exceeds the Codex and Mexican MRLs, but by maintaining the wheat, milling fractions (excluding flour) tolerance at 20 ppm, harmony with international tolerances for wheat processed fractions can be maintained.

14c. There are currently no Codex or Canadian MRLs established for glyphosate for any nongrass animal feed items. A Mexican MRL is established for alfalfa at 200 ppm. Harmonization with this level is not possible due to the higher residue levels found in the submitted field trial studies.

Attachment List
1. International Residue Limit Status Sheet for grasses.
2. International Residue Limit Status Sheet for wheat.
3. International Residue Limit Status Sheet for nongrass animal feeds.

cc (with Attachment): W. Donovan
RDI: RAB1 Chemists (24-JAN-2002)
W.H. Donovan:806R:CM#2:(703)305-7330:7509C:RAB1

AGENCY MEMORANDA CITED IN THIS REVIEW

DP Barcode:	D166777
Subject:	Response to the Glyphosate Reregistration Standard: Storage Stability Data
From:	R. Perfetti
To:	W. Burnam and L. Rossi
Date:	4/2/92
MRIDs:	41940701

DP Barcode:	D200041
Subject:	ID#000524-445. Label Amendment for Roundup (Glyphosate). Case 002698.
From:	G. Kramer
To:	R. Taylor
Date:	5/12/94
MRIDs:	None

DP Barcodes:	D217539 and D217541
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(s):	43712701 and 43712702

DP Barcodes:	D242628 and D245591
Subject:	PP# 2E04118 (formerly 2H05650) - Glyphosate residues in/on glyphosate tolerant canola seed and canola meal. Amendment of 24-August-1998.
From:	T. Bloem
To:	J. Tompkins/V. Walters
Date:	11/30/98
MRID(s):	43807203, 44528801, and 44528802

DP Barcodes:	D256740 and D256741
Subject:	PP# 9F05096. Review of Proposal to Increase the Glyphosate Pre-harvest Use Application Rate on Alfalfa Hay and Forage.
From:	W. Donovan
To:	J. Tompkins/V. Walters
Date:	6/9/00
MRID(s):	None

ATTACHMENT 1

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: N-(phosphonomethyl)glycine	Common Name: Glyphosate	☐ Proposed tolerance X Reevaluated tolerance ☐ Other	Date: 09/28/01

Codex Status (Maximum Residue Limits)	U. S. Tolerances
☐ No Codex proposal step 6 or above ☐ No Codex proposal step 6 or above for the crops requested	Petition Number: 0F06130 DP Barcode: D265790 Other Identifier:
Residue definition (step 8/CXL): Glyphosate	Reviewer/Branch: T. Lang, Dynamac
	Residue definition: Glyphosate (N-phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, and the ammonium salt of glyphosate.

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
Hay or fodder (dry) of grasses	50	Grass, forage, fodder, and hay group	300
Straw and fodder (dry) of cereal grains	100		

Limits for Canada	Limits for Mexico
☐ No Limits X No Limits for the crops requested	☐ No Limits ☐ 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)
		pasture	0.2

Notes/Special Instructions:
S. Funk, 10/02/2001. List of Codex MRLs and MRLs for Mexico is partial, those most closely related to the tolerances given.

Rev. 1998

ATTACHMENT 2

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: N-(phosphonomethyl)glycine	Common Name: Glyphosate	X Proposed tolerance X Reevaluated tolerance □ Other	Date: 09/28/01

Codex Status (Maximum Residue Limits)	U. S. Tolerances
□ No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested	Petition Number: PP#0F06195, 0F06273, 0F06130 DP Barcode: D275014, D275015, D265790 Other Identifier:
Residue definition (step 8/CXL): Glyphosate	Reviewer/Branch: T. Lang, Dynamac
	Residue definition: Glyphosate (N-phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, and the ammonium salt of glyphosate.

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
Straw and fodder (dry) of cereal grains	100	Wheat forage	10
Wheat	5	Wheat hay	10
Wheat bran, Unprocessed	20		
Wheat flour	0.5		
Wheat wholemeal	5		

Limits for Canada	Limits for Mexico
□ No Limits □ No Limits for the crops requested	□ No Limits □ 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)
barley and wheat milling fractions, excl flour	15	wheat	5
barley, oats	10	oats	20
peas, wheat	5	barley	20
		sorghum	15
		corn	1

Notes/Special Instructions:
S. Funk, 10/02/2001. List of Codex MRLs and MRLs for Mexico is partial, those most closely related to the tolerances given.

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: N-(phosphonomethyl)glycine	Common Name: Glyphosate	X Proposed tolerance X Reevaluated tolerance □ Other	Date: 09/28/01

Codex Status (Maximum Residue Limits)	U. S. Tolerances
□ No Codex proposal step 6 or above X No Codex proposal step 6 or above for the crops requested	Petition Number: PP#0F06195, 0F06273, 0F06130 DP Barcode: D275014, D275015, D265790 Other Identifier:
Residue definition (step 8/CXL): Glyphosate	Reviewer/Branch: T. Lang, Dynamac
	Residue definition: Glyphosate (N-phosphonomethyl)glycine) resulting from the application of glyphosate, the isopropylamine salt of glyphosate, the ethanolamine salt of glyphosate, and the ammonium salt of glyphosate.

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Animal feeds, non-grass group	400

Limits for Canada	Limits for Mexico
□ No Limits X No Limits for the crops requested	□ No Limits □ 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)
		alfalfa	200

Notes/Special Instructions:
S. Funk, 10/02/2001. List of Codex MRLs and MRLs for Mexico is partial, those most closely related to the tolerances given.