



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

JAN 12 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: PP4F4312/4H5692: Glyphosate (Roundup Herbicide) in or on Alfalfa. Request for Increased and Additional Tolerances. Evaluation of Analytical and Residue Data. CETS #s 13474, 13475, 13476, & 13519 DP Barcode #s D201255, D201252, D201250, & D201254 MRID #430770-01

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Tolerance Petition Section III *1-10-1995*
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Monsanto Company, in a letter from Dr. Sheila A. Schuette - Manager, Regulatory Affairs - dated December 16, 1993, is requesting the establishment of tolerances for residues of the herbicide glyphosate [N-(phosphonomethyl-glycine)] and its metabolite aminomethylphosphonic acid (AMPA) resulting from the application of the isopropylamine (IPA) salt of glyphosate and/or the monoammonium salt of glyphosate in or on the agricultural commodities alfalfa, fresh (forage) at 75 ppm, alfalfa, hay at 200 ppm, alfalfa, meal at 400 ppm, and cattle, kidney at 5 ppm.



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BACKGROUND:

Glyphosate is a non-selective herbicide registered for use on many food and non-food crops as well as non-crop areas. It is also used as a plant growth regulator. Three salts of glyphosate are used as active ingredients in registered pesticide products. The isopropylamine salt, subject of this petition, is used as a herbicide to control broadleaf weeds and grasses. It is formulated as a liquid, solid or pellet/tablet, and is applied using ground or aerial equipment. The sodium salt is used as a growth regulator. The monoammonium salt, used as herbicide and growth regulator, was registered after November 1984 and is not subject to re-registration. The company code number for glyphosate is MON-2139. The EPA Registration for glyphosate is #524-445.

According to 40 CFR §180.364, there are existing tolerances for the same residues indicated above in or on several agricultural commodities, including alfalfa at 200 ppm, alfalfa, fresh & hay at 0.2 ppm, livestock (including poultry), kidney at 0.5 ppm, and livestock (including poultry), liver at 0.5 ppm.

As noted, a tolerance of 200 ppm is currently established for residues of glyphosate and AMPA in or on alfalfa. However, the Glyphosate Re-registration Eligibility Decision (RED) Document has recommended that "the existing and conflicting tolerances for alfalfa, alfalfa fresh and hay, clover, and forage legumes (except soybeans and legumes) should be deleted and that concomitant with the deletion of these tolerances, a tolerance of 100 ppm for residues in or on the non-grass animal feeds group, forage and hay, is to be established." The non-grass animal feeds group, as defined in 40 CFR §180.34 (f)(9)(xviii), includes alfalfa; bean, velvet; clover; kudzu; lespedeza; lupine; sainfoin; trefoil; vetch; vetch, crown; and vetch, milk. Alfalfa and clover are the representative commodities of this crop group. There is a tolerance for residues of glyphosate as defined above for clover at 200 ppm. The petitioner is requesting that the tolerance remain at 200 ppm for alfalfa hay to support the proposed use.

The HED Metabolism Committee has determined that AMPA does not need to be regulated and should be dropped from the tolerance expression in the future (R. Perfetti, 8-19-1992, Memorandum to the HED Metabolism Committee). Consequently, the Residue Chemistry Chapter of the RED Document explains that AMPA no longer needs to be regulated and that it will be dropped from the tolerance expression.

Food additive and feed additive tolerances are established under 40 CFR §185.3500 and §186.3500, respectively, for the combined residues of glyphosate and AMPA.

As noted, a tolerance of 0.5 ppm is currently established for residues of glyphosate and AMPA on cattle, kidney & liver.

Roundup Herbicide is proposed to be used as a pre-harvest application in alfalfa for quackgrass control.

A tolerance in alfalfa seed is not being requested with this petition.

Glyphosate is a List A chemical, Case #0718, for which a RED Document was issued in September 1993 (Cover letter dated February 16, 1994 from D. Barolo). A Registration Standard was issued in June 1986. The Glyphosate Product and Residue Chemistry Re-registration Standard Update was completed on April 26, 1990.

CONCLUSIONS:

1. a. Additional pertinent Product Chemistry data requirements are still outstanding for unregistered trisodium salt technical, the 94% isopropylamine (IPA) Formulation Intermediate (FI), and the 75% IPA FI.
b. The registrant must either certify that the suppliers of beginning materials and manufacturing processes for the glyphosate technical products and manufacturing-use products (MPs) have not changed since the last comprehensive Product Chemistry or submit a complete updated Product Chemistry data package.
c. For the purposes of this petition in or on alfalfa, resolution of these Product Chemistry deficiencies (1a & 1b) can be satisfied as part of the re-registration process.
2. a. The nature of the residue of glyphosate in or on plants has been adequately delineated and is considered to be understood. For the purposes of the proposed tolerance in or on alfalfa, the residue of concern in plants is glyphosate per se.
b. The nature of the residue of glyphosate in or on animals has been adequately delineated and is considered to be understood. For the purposes of the proposed tolerance in or on alfalfa, the residue of concern in animals is glyphosate per se.
3. The proposed use of Roundup Herbicide in or on alfalfa was adequately described.
4. a. Adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in or on alfalfa. These methods include GLC and HPLC with fluorometric detection.

b. The FDA Pestrack data base [Pesticide Analytical Manual (PAM) I, Appendix, dated November 6, 1990] indicates that recoveries are not likely for glyphosate under FDA Multiresidue Methods.

5. Available storage stability data indicate that residues of glyphosate and AMPA are stable under frozen (-20 °C) storage conditions for a period of 1 year in or on plant commodities and for 2 years in animal commodities. The alfalfa samples analyzed during the course of the submitted residue study were maintained frozen for up to 10.7 months between harvest and extraction. Consequently, storage conditions used during the study are covered under available storage stability data. For the purposes of this tolerance petition of glyphosate in or on alfalfa, no additional storage stability data are needed.

6. a. The residue data obtained supports the proposed tolerances of 200 ppm and 75 ppm for alfalfa hay and alfalfa forage, respectively.

b. Alfalfa meal is pelletized alfalfa hay. The tolerance on alfalfa hay will cover any residue in meal from this use of glyphosate. Therefore, a tolerance in alfalfa meal is not necessary. A Section F deleting this tolerance should be submitted.

7. This is a 40 CFR §180.6(a)(1) with respect to secondary residues in meat, milk, and eggs.

a. The exposure analysis and the available feeding data will support a tolerance request of 4 ppm for cattle, kidney. We will translate the results to goats, hogs, sheeps, and horses. Therefore, the petitioner should submit a revised Section F proposing tolerances for cattle, goats, hogs, sheeps, and horses, kidney at 4 ppm.

b. The established tolerances for cattle, goats, hogs, sheeps, and horses, liver as well as poultry, liver and kidney, are adequate for this proposed use of glyphosate.

RECOMMENDATIONS:

CBTS can recommend for the establishment of tolerances for residues of the herbicide glyphosate [N-(phosphonomethyl-glycine)] and its metabolite aminomethylphosphonic acid (AMPA) resulting from the application of the isopropylamine (IPA) salt of glyphosate and/or the monoammonium salt of glyphosate in or on alfalfa, fresh (forage) at 75 ppm and alfalfa, hay, at 200 ppm. However, a revised Section F is needed deleting the tolerance for alfalfa, meal and proposing a tolerance of 4 ppm for kidney of cattle, goats, hogs, sheeps, and horses.

NOTE TO THE PM:

The "Good Laboratory Practice Statement" on page 4 of the submitted study reports that Good Laboratory Practice (GLP) standards "according to 40 CFR §160 were followed except for the following:

1. Weather data presented were not collected under GLP standards.
2. The stabilities of the test and reference substances in the carrier (water) were not identified in compliance with GLP standards.
3. Some raw data for the characterization of impurities in the glyphosate analytical reference standard were not collected or archived in accordance with GLP standards.
4. Data were generated using a computer system that has not been fully validated as required by GLP standards."

Due to these exceptions to the GLP standards, CBTS is requesting the Laboratory Data Integrity Assurance Division (LDIAD) of the Office of Compliance (OC) to conduct a laboratory inspection/study audit. A request for a laboratory inspection/study audit is being submitted to the OPP GLP RoundTable for subsequent submittal to OC.

DETAILED CONSIDERATIONS:

PRODUCT CHEMISTRY:

As noted in the Product and Residue Chemistry Chapter of the Re-registration Eligibility Decision (RED) Document (R. Perfetti, 10-27-1992), all pertinent data requirements have been satisfied for the unregistered isopropylamine (IPA) acid technical and the 62% IPA Formulation Intermediate (FI). Additional pertinent data requirements are still outstanding for unregistered trisodium salt technical, the 94% IPA FI, and the 75% IPA FI. It was also concluded in the RED Document that the registrant must either certify that the suppliers of beginning materials and manufacturing processes for the glyphosate technical products and manufacturing-use products (Mps) have not changed since the last comprehensive Product Chemistry or submit a complete updated Product Chemistry data package.

For the purposes of this petition in or on alfalfa,

resolution of these deficiencies can be satisfied as part of the re-registration process.

PROPOSED USE:

A supplemental label was submitted for review.

Roundup Herbicide is proposed as a pre-harvest use application in or on alfalfa for quackgrass control. The product is proposed to be used in declining alfalfa stands or any stand where crop destruction is acceptable.

Treated forage can be harvested and fed to livestock. Field corn, sweet corn, soybeans and other labeled crops can be planted immediately after forage harvest.

The proposed Roundup Herbicide concentrated aqueous formulation contains 41.0% glyphosate in the form of its isopropylamine salt. This formulation contains 480 grams per liter or 4 pounds per gallon of the isopropylamine salt of glyphosate (the active ingredient), which is equivalent to 356 grams per liter or 3 pounds per gallon of the free acid, glyphosate. The proposed application rate is 1 quart per Acre (equivalent to 0.75 lb acid equivalents per Acre) plus 0.5 percent ethoxylated tallowamine, a non-ionic surfactant, in 3 to 10 gallons of clean water carrier per Acre. A pre-harvest interval (PHI) of 24 hours is proposed.

Applications should be made in Spring or Fall when quackgrass is vigorously growing.

Roundup Herbicide is not to be used on alfalfa grown for seed production.

The proposed use of Roundup Herbicide in or on alfalfa was adequately described.

NATURE OF THE RESIDUE:

-Plants:

Plant metabolism studies for glyphosate were not submitted with this petition.

Studies have been performed on several plants including corn, cotton, soybeans, and wheat. Results indicate that uptake of glyphosate or AMPA from soil is limited but that residues which are taken up are readily translocated. Foliarly applied glyphosate is readily absorbed and translocated through apples, coffee, dwarf citrus, grapes, and pears. Metabolism occurs via N-methylation and ultimately yields N-methylated glycines and phosphonic acids. The ratio of glyphosate to AMPA is 9 to 1 but

can approach 1 to 1 in a few cases. Most of the residue data for crops reflect residues ranging from 0.05 to 0.15 ppm along with a non-detectable (<0.05 ppm) amount of AMPA. The terminal residue to be regulated is glyphosate per se. (R.B. Perfetti, Product and Residue Chemistry Chapter of the RED Document, 10-27-1992)

The nature of the residue of glyphosate in or on plants has been adequately delineated and is considered to be understood. For the purposes of the proposed tolerance in or on alfalfa, the residue of concern in plants is glyphosate per se.

-Animals:

Animal metabolism studies for glyphosate were not submitted with this petition.

Studies involving 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) and that the results are consistent with the metabolism studies in rats, rabbits, and cows. The terminal residues in eggs, milk, and animal tissues are glyphosate and AMPA. The terminal residue to be regulated is glyphosate per se. (R.B. Perfetti, Product and Residue Chemistry Chapter of the RED Document, 10-27-1992)

The nature of the residue of glyphosate in or on animals has been adequately delineated and is considered to be understood. For the purposes of the proposed tolerance in or on alfalfa, the residue of concern in animals is glyphosate per se.

ANALYTICAL METHODOLOGY:

Adequate enforcement methods are available for analysis of residues of glyphosate and AMPA in or on plant 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 being discouraged due to lengthiness of the experimental procedure. The HPLC method has undergone successful Agency validation and was recommended for inclusion in *PAM II*; the limit of detection is 0.0005 ppm.

The method used in the submitted study consisted of the extraction of glyphosate and AMPA residues from the plant residues with dilute hydrochloric acid. The extract solution was eluted through a resin in the Fe(III) form, which retained glyphosate and AMPA by chelation. The iron salts were removed by elution with 6 N HCl. The isolated glyphosate and AMPA iron salts were then applied to a strong anion exchange resin and eluted with 6 N HCl to remove the iron and obtain the free acids of glyphosate and AMPA. After concentration to dryness, the

samples were redissolved in water and analyzed by HPLC with fluorometric detection.

The method used in the submitted study was validated for glyphosate and AMPA concentrations over a range of 5 to 250 ppm in alfalfa forage and field-dried hay. Glyphosate recoveries from fortified alfalfa forage samples ranged from 68% to 107%. AMPA recoveries ranged from 65% to 107%. For fortified alfalfa field-dried hay, glyphosate recoveries ranged from 66% to 101%. AMPA recoveries ranged from 64% to 101%.

For the processing part of the study, glyphosate and AMPA recoveries from alfalfa field-dried hay samples, alfalfa bin-dried hay sample (fortified), two alfalfa milled hay samples (fortified), and two alfalfa meal pellet samples (fortified) were also calculated and reported by the petitioner.

For enforcement of tolerances in or on animal commodities, an HPLC method with fluorescence detector is available; the reported limits of detection are 0.01 ppm for glyphosate and 0.012 ppm for AMPA. (R.B. Perfetti, Product and Residue Chemistry Chapter of the RED Document, 10-27-1992)

Adequate analytical methods are available for residue data collection and enforcement of the proposed tolerances of glyphosate in or on alfalfa.

The FDA Pesttrack data base [Pesticide Analytical Manual (PAM) I, Appendix, dated November 6, 1990] indicates that recoveries are not likely for glyphosate under FDA Multiresidue Methods.

STORAGE STABILITY DATA:

As noted in the Product and Residue Chemistry Chapter of the RED Document (R. Perfetti, 10-27-1992), available storage stability data indicate that residues of glyphosate and AMPA are stable under frozen (-20 °C) storage conditions for a period of 1 year in or on plant commodities and for 2 years in animal commodities.

The alfalfa samples analyzed during the course of the submitted residue study were maintained frozen for up to 10.7 months between harvest and extraction. For the alfalfa meal (treated as a processed commodity by the petitioner), some samples were stored frozen for up 13 months.

Consequently, storage conditions used during the study are covered under available storage stability data.

Therefore, for the purposes of this petition of glyphosate

in or on alfalfa, no additional storage stability data are needed.

RESIDUE DATA:

A. Magnitude of the Residue in Plants:

The following study was submitted for review:

M.E. Oppenhuizen. November 1993. *Magnitude of Glyphosate Residues Following Preharvest Use in Alfalfa*. Study performed by Monsanto Company, St. Louis, MO (Field Management Contractor was Stewart Agricultural Research Services, Inc., Macon, MO) and submitted by Monsanto Company, St. Louis, MO. Laboratory Project ID#MSL-12953 (MRID #430770-01)

(Reviewer's Notes: a. This study was performed and submitted for review prior to the issuance of Table II (1994). In such table, the following applies. Forage and hay are listed as raw agricultural commodities (racs) for alfalfa. Residue data on alfalfa silage are optional. b. As noted in the Background Section of this review, the HED Metabolism Committee has determined that AMPA does not need to be regulated. Therefore, although the petitioner submitted data for this metabolite, it is not reported in detail in this review.).

Roundup Herbicide was applied during the 1992 growing season as a single, pre-harvest treatment with a PHI of 1 day in twenty established alfalfa plots throughout sixteen states. Eight of the trials were conducted in the Spring in the states of IA, MN, MT, NY, ND, PA, SD, and WI. Twelve Fall residue trials were conducted in the states of CA, CO, IA, ID, IL, MI, MN, NE, OK, SD, WA, and WI. All the alfalfa plots had been established during or prior to 1991. Three test plots were established at each test site: one untreated and a separate treated test plot for each application rate. At each site, Roundup Herbicide was applied to separate test plots at application rates ranging from 0.68 lb ae/A in NE to 1.54 lb ae/A in IA, representing 1X and 2X, respectively. The formulated Roundup Herbicide contained 41.2% (w/w) glyphosate isopropylamine salt (30.5% as acid equivalent). The typical crop stage at application time ranged from 2% to 50% bloom, averaging 10% bloom.

After cutting, a portion of the alfalfa forage at each test plot was collected and frozen for subsequent analysis. The remaining alfalfa was allowed to dry in the field for 3 to 6 days in order to produce hay. The alfalfa field-dried hay was then harvested and stored frozen for subsequent analysis or processing. Immediately before analysis, the samples were thawed, subsampled in duplicate, and analyzed for residues. Single subsamples of the untreated control were analyzed.

The analysis method has been previously described in the Analytical Methodology Section of this review.

Residue levels in ppm found in alfalfa forage are summarized below:

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
California	1	0.75	53.96
			66.14
		1.50	72.85
			96.69
Colorado	1	0.75	33.56
			33.19
		1.50	113.65
			101.10
Idaho	1	0.76	48.12
			35.62
		1.51	123.33
			121.24
Illinois	1	0.76	65.02
			66.45
		1.52	104.62
			122.63
Iowa -Danville, Site A	1	0.77	38.91
			36.06
		1.54	77.23
			75.75
Iowa -Danville, Site B	1	0.76	53.10
			54.71
		1.52	157.63
			147.67

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
Michigan	1	0.75	52.12
			56.16
		1.50	91.47
			48.77
Minnesota -Site A	1	0.75	36.71
			34.16
		1.50	63.62
			53.35
Minnesota -Site B	1	0.75	19.70
			26.42
		1.50	91.88
			106.58
Montana	1	0.75	24.29
			23.15
		1.49	55.86
			52.08
Nebraska	1	0.68	36.42
			35.87
		1.36	59.44
			48.01
New York	1	0.75	30.55
			28.44
		1.50	64.23
			68.00
North Dakota	1	0.75	20.80
			21.30
		1.50	54.55
			54.81

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
Oklahoma	1	0.75	44.24
			51.39
		1.50	101.36
			95.31
Pennsylvania	1	0.75	35.05
			36.56
		1.51	75.07
			72.01
South Dakota -Site A	1	0.75	30.00
			31.33
		1.50	61.20
			60.32
South Dakota -Site B	1	0.74	24.98
			20.71
		1.49	68.59
			84.11
Washington	1	0.76	26.28
			28.06
		1.51	53.85
			59.76
Wisconsin -Delevan, Site A	1	0.75	22.53
			24.48
		1.50	69.89
			58.68
Wisconsin -Delevan, Site B	1	0.75	44.46
			40.13
		1.49	87.47
			99.79

The results of the forage analyses demonstrated that glyphosate residues in alfalfa treated at the 1X rate ranged from 19.70 ppm at the Minnesota (B) site to 66.45 ppm at the Illinois site. Glyphosate residues in the alfalfa forage treated at the 2X rate ranged from 48.01 ppm at the Nebraska site to 157.63 ppm at the Iowa (Danville, B) site.

Residue levels in ppm found in alfalfa field-dried hay are summarized below:

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
California	4	0.75	177.13
			152.72
		1.50	247.32
			265.61
Colorado	5	0.75	115.85
			138.53
		1.50	304.65
			376.75
Idaho	3	0.76	159.51
			167.93
		1.51	283.24
			277.71
Illinois	4	0.76	114.70
			105.37
		1.52	223.68
			191.86
Iowa -Danville, Site A	3	0.77	79.61
			73.34
		1.54	193.25
			184.90
Iowa -Danville, Site B	4	0.76	118.51
			122.10
		1.52	200.95
			189.99

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
Michigan	4	0.75	189.93
			185.13
		1.50	335.40
			Result not available
Minnesota -Hills, Site A	3	0.75	42.14
			38.69
		1.50	87.38
			78.56
Minnesota -Beaver Creek, Site B	4	0.75	46.03
			55.93
		1.50	145.33
			117.56
Montana	4	0.75	44.69
			44.38
		1.49	93.47
			100.45
Nebraska	4	0.68	21.73
			81.46
		1.36	159.44
			214.66
New York	4	0.75	99.28
			103.78
		1.50	189.72
			218.89
North Dakota	4	0.75	17.88
			18.23
		1.50	44.21
			45.81

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
Oklahoma	3	0.75	100.81
			81.05
	1.50		217.65
			210.81
Pennsylvania	4	0.75	82.82
			83.61
	1.51		195.24
			195.88
South Dakota -Site A	5	0.75	60.88
			63.25
	1.50		154.02
			142.72
South Dakota -Site B	4	0.74	70.18
			75.04
	1.49		66.02
			168.05
Washington	3	0.76	108.27
			98.43
	1.51		227.51
			211.16
Wisconsin -Delevan, Site A	4	0.75	20.56
			20.78
	1.50		99.97
			94.63
Wisconsin -Delevan, Site B	6	0.75	118.97
			127.29
	1.49		238.11
			276.47

The results of the field-dried hay analyses showed that glyphosate residues in alfalfa treated at the 1X rate ranged from 17.88 ppm at the North Dakota site to 189.93 ppm at the Michigan site. Glyphosate field-dried hay residues in alfalfa treated at the 2X rate ranged from 44.21 ppm at the North Dakota site to 376.75 ppm at the Colorado site.

The residue data obtained supports the proposed tolerances of 200 ppm and 75 ppm for alfalfa hay and alfalfa forage, respectively.

B. Magnitude of the Residue in Processing:

(Reviewer's Note: This study was performed and submitted for review prior to the issuance of Table II (1994). In such table, no processed commodities are listed under alfalfa. Previous to this edition, Table II listed alfalfa meal as an alfalfa processed commodity. At present, alfalfa meal is considered a feed commodity and no residue data has to be submitted for review.)

Samples for processing were taken from the South Dakota and Wisconsin sites, which had Spring applications. At the sites used for the processing, the cut alfalfa was allowed to field dry in order to produce alfalfa-dried hay. The drying process took 4 days in South Dakota and 3 days in Wisconsin. The South Dakota alfalfa was dried in a barn and the Wisconsin alfalfa was dried in the fields. At sampling, the alfalfa hay was collected and stored frozen until analysis. Due to a high moisture content, an additional drying step not normally required commercially had to be performed on the hay. Using a laboratory bin air dryer in order to process hay into meal pellets, the moisture content was reduced to a range of 11% to 14%. The bin-dried alfalfa was then cut and one portion was milled and another portion was shredded and pressed into alfalfa meal pellets. The pellets were further dried to a moisture content ranging from 7% to 9.5% and stored frozen. Field-dried hay, bin-dried hay, shredded hay, and meal pellets were all analyzed for residues. Milled hay, although not commercially available, was analyzed. Results demonstrated that glyphosate and AMPA residues in alfalfa hay increased in the samples that had been further dried in the bin air dryer, as well as the shredded hay and meal pellets.

The method used for analysis has been described in the Analytical Methodology Section of this review.

Residue levels in ppm found in alfalfa meal are summarized below:

Location	PHI (days)	Application Rate (lb ae/a)	Glyphosate Residues Found (ppm)
South Dakota -Site A	5	0.75	94.420
			81.936
		1.50	182.495
			221.232
Wisconsin -Delevan, Site A	4	0.75	59.303
			52.488
		1.50	158.852
			166.152

Alfalfa meal is pelletized alfalfa hay. The tolerance on alfalfa hay will cover any residue in meal from this use of glyphosate. Therefore, a tolerance in alfalfa meal is not necessary. A revised Section F deleting this tolerance should be submitted.

OTHER CONSIDERATIONS:

Meat, Milk, Poultry and Eggs:

(Reviewer's Note: Table II (1994) lists forage, hay, meal, and silage as feed items under alfalfa feed commodities. Residue data are not needed for alfalfa meal and is optional for alfalfa silage. Residue data (tolerances) for alfalfa hay and alfalfa forage can cover residues in alfalfa meal and alfalfa silage, respectively, for livestock feeding calculations.)

Feeding studies with glyphosate were not submitted for review with this petition.

Feeding studies with glyphosate have been discussed in previous petitions. PP6F3380/6H5502, (Memorandum by W.T. Chin dated January 30, 1989, DEB #s 4285 & 4286, MRID # 405320-03) discusses feeding studies in which animals were dosed with a (9:1) mixture of glyphosate and AMPA at 0, 40, 120, and 400 ppm for 28 days and then slaughtered. No quantifiable (<0.05 ppm) residues were observed in fat or muscle of animals dosed at the 40 and 120 ppm level. Residues were not found in eggs at these levels, and were not found in milk at any level. Average residue levels obtained from cattle, swine and poultry kidney after dosing at the 40 ppm level were 0.26 ppm, 0.37 ppm, and 0.38 ppm,

respectively. Residues in liver at the 40 ppm level were 0.06 ppm, <0.05 ppm, and 0.07 ppm in cattle, swine, and poultry, respectively. Kidney residues reported from the 120 ppm and 400 ppm feeding levels were cattle, 1.0 and 4.1 ppm; swine, 2.88 and 8.77 ppm; and poultry 1.23 and 4.87 ppm, respectively. Liver residues reported at the 120 ppm and 400 ppm feeding levels were cattle, 0.07 and 0.41 ppm; swine, 0.33 and 1.14 ppm; and poultry, 0.3 and 1.16 ppm, respectively. Residues up to 0.1 ppm were reported in eggs at the 400 ppm feeding level.

A plausible exposure analysis is as follows.

For ruminants (cattle, dairy):

Feed Item	Tolerance (ppm)	% in Diet	% Dry Matter	Exposure ¹ (ppm)
Soybean hulls	100	7.5	90	8.3
Corn Silage ²	0.1	40	40	0.4
Alfalfa hay	200	40	89	89.89
Soybean meal	20	7.5	92	1.6

1 Total exposure = 99.9 ppm, calculated as $\Sigma[(\text{Tol})(\% \text{Diet}) + (\% \text{DM})]$.

2 Included under grain crops (except wheat).

For poultry (as fed basis):

Feed Item	Tolerance (ppm)	% in Diet	Exposure ¹ (ppm)
Alfalfa meal	200	10	20
Soybean meal	20	30	6
Soybean hulls	100	20	20
Corn grain ²	0.1	40	0.04

1 Total exposure = 46.04 ppm, calculated as $\Sigma[(\text{Tol})(\% \text{Diet}/100)]$.

2 Included under grain crops (except wheat).

This is a 40 CFR §180.6(a)(1) with respect to secondary residues in meat, milk, and eggs.

The exposure analysis and the available feeding data will support a tolerance request of 4 ppm for cattle, kidney. We will translate the results to goats, hogs, sheeps, and horses.

Therefore, the petitioner should submit a revised Section F proposing tolerances for cattle, goats, hogs, sheeps, and horses, kidney at 4 ppm. The established tolerances for cattle, goats, hogs, sheeps, and horses, liver as well as poultry, liver and kidney, are adequate for this proposed use of glyphosate.

cc: MIRodríguez, PP#4F4312/4H5692, Reading File, Circulation.

RDI: PVerico (1-10-1995); MFlood (12-22-1994); RALoranger (12-22-1994)
MIRodríguez: Draft (8-30-1994), Edited (1-10-1995).
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