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 HEALTH EFFECTS DIVISION
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, D.C. 20460

OFFICE OF
 PREVENTION, PESTICIDES AND
 TOXIC SUBSTANCES

Sept. 18, 1998

MEMORANDUM:

SUBJECT: PP#7F04886: Glyphosate, Isopropylamine Salt and Monoammonium Salt (Roundup® Ultra Herbicide EPA Reg.# 524-475) on Glyphosate-Tolerant Sugar Beets. Evaluation of Residue Data and Analytical Methodology. Chemical No. 103601; MRID No.s 443316-01 to 443316-03; DP Barcode No. D238398.

FROM: Joel Garbus, PhD., Chemist
 Chemistry and Exposure Branch 2
 Health Effects Division (7509C)

And

Thurston Morton, Chemist
 Chemistry and Exposure Branch 2
 Health Effects Division (7509C)

*Thurston Morton
 9/18/98*

THROUGH: Susan Hummel, Senior Scientist
 Chemistry and Exposure Branch 2
 Health Effects Division (7509C)

Susan Hummel

TO: Vickie Walters/James Tompkins
 Product Management Team #25
 Fungicide - Herbicide Branch (7505C)
 Registration Division

EXECUTIVE SUMMARY:

- Providing the petitioner revises the product label to specify a 30 day PHI, HED recommends for the the proposed glyphosate tolerances for the concentrated aqueous formulation plus surfactant 10 ppm for sugar beet tops and roots and 25 ppm for dried sugar beet pulp on genetically modified sugar beets.

- The proposed use of Roundup® Ultra is adequately described. The petitioner must add a comment about the 30 day plant-back interval for crops on which the use of glyphosate is not registered.

The petitioner, Monsanto Co., has petitioned the Agency for tolerances to permit residues of the herbicide glyphosate resulting from the application of the isopropylamine salt and/or the monoammonium salt of glyphosate in or on glyphosate tolerant (Roundup Ready™) sugar beets. The proposed tolerances are sugar beet tops (leaves) at 10 ppm; sugar beet roots at 10 ppm; and dried sugar beet pulp at 25 ppm.

BACKGROUND:

The IUPAC chemical name of glyphosate is [N-phosphonomethyl] glycine]. The CAS Registry number of glyphosate is 38641-94-0.

Glyphosate is a non-selective herbicide registered for use on many food and non-food crops. Roundup® Ultra is a concentrated aqueous solution which contains 41 % by weight of glyphosate in its isopropylamine salt form. Roundup® Ultra is being proposed for use on genetically modified sugar beets. These Roundup Ready™ Sugar Beets have been genetically modified to provide tolerance to the non-selective action of glyphosate.

According to 40 CFR §180.364, there are existing tolerances for the combined residues of glyphosate and its metabolite aminomethylphosphonic acid (AMPA) in/on the kidney of cattle, goats, hogs, horses, and sheep at 4.0 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.5 ppm; and liver and kidney of poultry at 0.5 ppm. There is a tolerance for glyphosate and AMPA in/on beets, sugar at 0.2 ppm.

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, 8-19-92, 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.

As the use of glyphosate tolerant beets allows for the application of greater amounts of glyphosate, the registrant has requested increased tolerances.

This petition represents the first permanent tolerance request for this chemical on Roundup Ready™ Sugar Beets.

CONCLUSIONS:

1. As noted in the Product and Residue Chemistry Chapter of the Re-registration Eligibility Decision (RED) Document (R. Perfetti, 27-SEP-1992), all product chemistry data requirements have been satisfied for the glyphosate isopropylamine (IPA) acid technical.

2. The proposed use of Roundup[®] Ultra is adequately described. The petitioner must add a comment about the 30 day plant-back interval for crops on which the use of glyphosate is not registered.

3. The nature of the residue in plants is adequately understood. The residue of concern is glyphosate *per se*.

4. The nature of the residue in animals is adequately understood. The residue of concern is glyphosate *per se*.

5a. Adequate analytical methods are available for residue collection and enforcement of the proposed tolerances of glyphosate in or on Roundup Ready[™] sugarbeets. These methods include GLC, HPLC with fluorometric detection, and GC/MS.

5b. The FDA Pestrak data base [Pesticide Analytical Manual (PAM) I, Appendix, dated November 6, 1990] indicates that recoveries are not likely for glyphosate under FDA Multiresidue Methods. No further data regarding multiresidue methods are required for this proposed use.

6. Available storage stability data indicates that residues of glyphosate and AMPA are stable under frozen (-20°C) storage conditions for a period of one year in/on plant commodities and for two years in animal commodities.

7. Geographical representation of residue field trial data is adequate for the proposed use on sugarbeets.

8. The Agency concludes that, based on the submitted residue data, the proposed tolerances for glyphosate residues in/on sugarbeets will not be exceeded for the proposed use. Treatment 3 utilized a final application of 2 quart/acre, which is 2X the label specified final application. Therefore residues certainly should not be greater than those of treatment 3. The maximum glyphosate residues for sugarbeet roots were 2.676 ppm and 8.637 ppm for treatments 2 and 3, respectively. The maximum glyphosate residues for sugarbeet tops were 1.749 ppm and 8.390 ppm for treatments 2 and 3, respectively. Results of the decline study showed that glyphosate residues declined in both the roots and tops with increasing preharvest intervals.

9. At harvest, glyphosate residues (Danish Field Trials) in

CONCLUSIONS:

1. As noted in the Product and Residue Chemistry Chapter of the Pre-registration Eligibility Decision (RED) Document (R. Perfetti, 27 SEP-1992), all product chemistry data requirements have been satisfied for the glyphosate isopropylamine (IPA) acid technical.
2. The proposed use of Roundup® Ultra is adequately described. The petitioner must add a comment about the 30 day plant-back interval for crops on which the use of glyphosate is not registered.
3. The nature of the residue in plants is adequately understood. The residue of concern is glyphosate *per se*.
4. The nature of the residue in animals is adequately understood. The residue of concern is glyphosate *per se*.
- 5a. Adequate analytical methods are available for residue collection and enforcement of the proposed tolerances of glyphosate in or on Roundup Ready™ sugarbeets. These methods include GLC, HPLC with fluorometric detection, and GC/MS.
- 5b. The FDA Pestrak data base [Pesticide Analytical Manual (PAM) I, Appendix, dated November 6, 1990] indicates that recoveries are not likely for glyphosate under FDA Multiresidue Methods. No further data regarding multiresidue methods are required for this proposed use.
6. Available storage stability data indicates that residues of glyphosate and AMPA are stable under frozen (-20°C) storage conditions for a period of one year in/on plant commodities and for two years in animal commodities.
7. Geographical representation of residue field trial data is adequate for the proposed use on sugarbeets.
8. The Agency concludes that, based on the submitted residue data, the proposed tolerances for glyphosate residues in/on sugarbeets will not be exceeded for the proposed use. Treatment 3 utilized a final application of 2 quart/acre, which is 2X the label specified final application. Therefore residues certainly should not be greater than those of treatment 3. The maximum glyphosate residues for sugarbeet roots were 2.676 ppm and 8.637 ppm for treatments 2 and 3, respectively. The maximum glyphosate residues for sugarbeet tops were 1.749 ppm and 8.390 ppm for treatments 2 and 3, respectively. Results of the decline study showed that glyphosate residues declined in both the roots and tops with increasing preharvest intervals.
9. At harvest, glyphosate residues (Danish Field Trials) in

samples for a total of 3.8 quart/acre with 2.7 quart/acre postemergent treatment ranged from 0.2 - 0.3 ppm for sugarbeet roots and 0.2 ppm for sugarbeet tops. Treatment of sugarbeets at a rate of 3.8 quart/acre (2.7 quart/acre postemergent) will not result in quantifiable residues in thick juice, molasses and refined sugar obtained from processing Roundup® Ultra treated sugarbeets.

10. At harvest, glyphosate residues (U.K. Field Trials) in samples for a 3.8 quart/acre (2.7 quart/acre postemergent) treatment ranged from 0.09 - 0.3 ppm for sugarbeet roots and <0.02 - 0.7 ppm for sugarbeet tops. Treatment of sugarbeets at a rate of 3.8 quart/acre (2.7 quart/acre postemergent) will not result in quantifiable residues in thick juice, molasses and refined sugar obtained from processing Roundup® Ultra treated sugarbeets.

11. The Agency expects no increase in the dietary burden of glyphosate in poultry or ruminants as a result of this use. Therefore, the Agency anticipates that the animal residues would be covered by the established tolerances.

RECOMMENDATION:

Providing the petitioner revises the product label to specify a 30 day PHI, HED recommends for the the proposed glyphosate tolerances of 10 ppm for sugar beet tops and roots and 25 ppm for dried sugar beet pulp.

The proposed use of Roundup Ultra is adequately described. The petitioner must add a comment about the 30 day plant-back interval for crops on which the use of glyphosate is not registered.

NOTE: For the commodities of human consumption that are in the DEEM database, use 1/30 of the HAFT(8.6 ppm) = 0.3 ppm. The value 1/30 represents the ratio of the residues in the RAC to that found in the processing commodities sugar and molasses.

DETAILED CONSIDERATIONS:

PRODUCT CHEMISTRY:

As noted in the Product and Residue Chemistry Chapter of the Re-registration Eligibility Decision (RED) Document (R. Perfetti, 27-SEP-1992), all product chemistry data requirements have been satisfied for the unregistered glyphosate isopropylamine (IPA) acid technical.

PROPOSED USE:

A proposed supplemental label for Roundup[®] Ultra Herbicide (EPA Reg. No. 524-475) was submitted with this petition. Roundup Ultra herbicide is intended to give non-selective control of annual weeds, perennial weeds, woody brush and trees.

Roundup Ultra contains 4 pounds of the active ingredient glyphosate isopropylamine salt per gallon of formulation. Roundup Ultra is a concentrated aqueous formulation plus a surfactant.

Application rate of 1 quart per acre (1 lb ai/acre) is being proposed. Applications are to be made with water as the liquid carrier. Ground spray volumes of 5-40 gallons per acre should be used. Aerial application is also proposed using 3-15 gallons of water per acre. Ammonium sulfate may be included in the spray mix. A maximum of four post-emergent (over the top) treatments, each at a rate of no more than 1 quart per acre can be made per sugar beet growing season. Do not apply a total of more than 2 quart per acre prior to the eight leaf stage or a total of more than 2 quarts per acre between the eight leaf stage and canopy closure. The label states that some weeds with multiple germination times may require a second application for complete control. The second application should be made after some regrowth and at least 10 days after a previous application. It was noted that a maximum annual application rate of no more than 8 quarts/acre is specified on the Roundup[®] Ultra label for all cropping situations, and would apply here.

A PHI of 30 days after treatment for harvest or feeding of sugar beets is stated on the label. The final treatment at this 30-day PHI can be no more than 1 quart/acre, while the enclosed residue study used a 2 quart/acre final treatment. The petitioner states, since residues in harvested sugar beets commodities are most strongly influenced by the last application, resulting residues from the proposed label treatments would not exceed those found in the residue study.

The proposed label has a no rotational crops restrictions. The Agency in a memo (G. Kramer, 5/94) recommended against the petitioner removing the no rotational crop restriction comment for unregistered uses of glyphosate.

Comment: The proposed use of Roundup[®] Ultra is adequately described. The petitioner must add a 30 day plant-back interval for crops on which the use of glyphosate is not registered.

NATURE OF THE RESIDUE:**Plants:**

A plant metabolism study with sugar beets (MRID #096684) was submitted 12/9/77 for review and found to be suitable. The residue to be regulated is glyphosate *per se*. (R.B. Perfetti, Product and Residue Chemistry Chapter of the RED Document, 10-27-92).

Comment: The nature of the residue in plants is adequately understood. The residue of concern is glyphosate *per se*.

Animal Metabolism:

Animal metabolism studies (MRID #40532001 to 40532004) were submitted 2/23/88 for review and found to be suitable. The residue to be regulated is glyphosate *per se*. (R.B. Perfetti, Product and Residue Chemistry Chapter of the RED Document, 10-27-92).

Comment: The nature of the residue in animals is adequately understood. The residue of concern is glyphosate *per se*.

ANALYTICAL METHODOLOGY:

Adequate enforcement methods are available for analysis of residues in/on plant commodities. These methods include GLC (Method I in PAM II) and HPLC with fluorometric detection (W. Dykstra & W. Donovan, 6-23-98).

The analytical method begins with the extraction of glyphosate and AMPA with dilute hydrochloric acid. The extract is then eluted through a resin in the Fe(III) form, which retains glyphosate and AMPA by chelation. The retained iron salts are then removed from the resin by elution with 6 N HCl. The isolated iron salts are 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, to remove the HCl, the samples are redissolved in water and analyzed by HPLC with fluorometric detection.

Samples were fortified with glyphosate and AMPA, extracted, and analyzed concurrently with the field samples. Recoveries from sugarbeet root samples fortified over the range of 0.05 - 40 ppm averaged 97.7 % for glyphosate and ranged from 62.3 - 141.3 %. The recoveries of AMPA from the same samples averaged 92.4 % and ranged from 59.7 - 127.4 %. Recoveries from sugarbeet top samples fortified over the range of 0.05 - 25 ppm averaged 92.9 % and ranged from 62.3 - 120.3 %. Recoveries of AMPA from the same

samples averaged 89.4 % and ranged from 60.1 - 113.3 %.

Comment: Adequate analytical methods are available for residue collection and enforcement of the proposed tolerances of glyphosate in or on Roundup Ready™ sugarbeets. These methods include GLC, HPLC with fluorometric detection, and GC/MS.

Multiresidue Testing:

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.

Comment: The FDA Pestrak data base [Pesticide Analytical Manual (PAM) I, Appendix, dated November 6, 1990] indicates that recoveries are not likely for glyphosate under FDA Multiresidue Methods. No further data regarding multiresidue methods are required for this proposed use.

Storage Stability:

Residue storage stability studies (MRID #414220022 and 41947006) were submitted in 1990 & 1991 and found to be suitable. As noted in the Product and Residue Chemistry Chapter of the RED Document (R. Perfetti, 10-27-92), storage stability data indicates that residues of glyphosate and AMPA are stable under frozen (-20°C) storage conditions for a period of one year in/on plant commodities and for two years in animal commodities.

The sugarbeet root samples were stored frozen for 86-284 days prior to extraction. The sugarbeet top samples were stored frozen for 136-208 days prior to extraction.

Storage conditions used for this study were covered adequately under the available storage stability data.

Comment: Available storage stability data indicates that residues of glyphosate and AMPA are stable under frozen (-20°C) storage conditions for a period of one year in/on plant commodities and for two years in animal commodities.

Magnitude of the Residue in/on Sugar Beets and Sugar Beet RACs:

The petitioner has submitted residue data from twelve field trials of the application of glyphosate.

MRID 443316-01
 Title: Magnitude of Glyphosate Residues in Glyphosate-Tolerant
 Sugarbeet Raw Agricultural Commodities
 Author: M. McCann, M. Bleeke

Date: July, 1997
 Site: Monsanto Co., St. Louis, MO

Twelve studies were conducted during 1996 in the United States. Application was post-emergence broadcast spray to sugar beets at the required growth stage. Roundup Ultra formulation was diluted with water and applied with a hand-held or tractor sprayer at the rate of 10-20 gal/acre of diluted product.

Application Rates of Roundup[®] Ultra to Glyphosate-tolerant Sugar Beets

Trt. No.	Sugarbeet Genotype	Preemergent Application lb ai/acre	2-4 Leaf stage Appl. lb ai/acre	6-8 Leaf stage Appl. lb ai/acre	12-14 Leaf stage Appl. lb ai/acre	Late Season Postemerg. Application lb ai/acre
1	77	0	0	0	0	
2	77	5	1	1	1	
3	77	4	1	0	1	2

Across all the sites, the PHI for Treatment 2 ranged from 52-99 days, and the PHI for Treatment 3 ranged from 22-69 days. The residues of the study are included in the following tables.

Residues of Glyphosate in Sugarbeet Roots Resulting From Treatment 2.

Site	PHI (Days)	Glyphosate (ppm)
Clay Co. Minnesota	59	0.687
Polk Co. Minnesota	58	0.060
Renville Co. Minnesota	56	1.032
Saginaw Co. Michigan	70	0.053
Richland Co. North Dakota	59	2.672
Scottsbluff Co. Nebraska	59	0.056
Hockley Co. Texas	59	0.420
Weld Co. Colorado	63	0.238
Stanislaus Co. California	61	0.457
Stanislaus Co. California	62	0.412
Power Co. Idaho	60	0.207
Twin Falls Co. Idaho	58	0.142

Residues of Glyphosate in Sugarbeet Roots Resulting From Treatment 3.

Site	PHI (Days)	Glyphosate (ppm)
Clay Co. Minnesota	28	8.637
Polk Co. Minnesota	31	8.541
Renville Co. Minnesota	28	6.848
Saginaw Co. Michigan	31	6.545
Richland Co. North Dakota	29	7.046
Scottsbluff Co. Nebraska	29	4.828
Hockley Co. Texas	29	7.711
Weld Co. Colorado	31	3.252
Stanislaus Co California	31	6.835
Stanislaus Co. California	32	7.452
Power Co. Idaho	29	3.261
Twin Falls Co. Idaho	30	8.078

Residues of Glyphosate in Sugarbeet Tops Resulting From Treatment
2.

Site	PHI (Days)	Glyphosate (ppm)
Clay Co. Minnesota	59	0.490
Polk Co. Minnesota	58	0.127
Renville Co. Minnesota	56	0.662
Saginaw Co. Michigan	70	0.051
Richland Co. North Dakota	59	1.749
Scottsbluff Co. Nebraska	59	0.049
Hockley Co. Texas	59	0.345
Weld Co. Colorado	63	0.130
Stanislaus Co. California	61	0.386
Stanislaus Co. California	62	0.223
Power Co. Idaho	60	0.105
Twin Falls Co. Idaho	58	0.156

Residues of Glyphosate in Sugarbeet Tops Resulting From Treatment
3.

Site	PHI (Days)	Glyphosate (ppm)
Clay Co. Minnesota	28	3.645
Polk Co. Minnesota	31	5.551
Renville Co. Minnesota	28	4.175
Saginaw Co. Michigan	31	4.276
Richland Co. North Dakota	29	4.650
Scottsbluff Co. Nebraska	29	1.753
Hockley Co. Texas	29	3.888
Weld Co. Colorado	31	2.176
Stanislaus Co. California	31	6.767
Stanislaus Co. California	32	8.390
Power Co. Idaho	29	2.015
Twin Falls Co. Idaho	30	3.862

The petitioner also performed residue decline studies for glyphosate in sugarbeets. Results are included in the following tables.

Decline Residues of Glyphosate in Sugarbeet Roots Resulting from Treatment 2.

Site	PHI (days)	Glyphosate (ppm)
Saginaw Co. Michigan	70	0.053
	95	0.000
Richland Co. North Dakota	52	2.384
	59	2.672
	66	2.067
	73	1.456
	80	1.938
Scottsbluff Co. Nebraska	59	0.056
	98	0.025
Hockley Co. Texas	59	0.420
	92	0.206
Stanislaus Co. California	61	0.457
	99	0.233
Stanislaus Co. California	62	0.412
	99	0.231

Decline Residues of Glyphosate in Sugarbeet Roots Resulting from Treatment 3.

Site	PHI (days)	Glyphosate (ppm)
Saginaw Co. Michigan	31	6.545
	56	5.996
Richland Co. North Dakota	22	8.055
	29	7.046
	36	5.323
	43	5.007
	50	6.389
Scottsbluff Co. Nebraska	29	4.828
	68	2.922
Hockley Co. Texas	29	7.711
	62	3.863
Stanislaus Co. California	31	6.835
	69	4.720
Stanislaus Co. California	32	7.452
	69	2.452

Decline Residues of Glyphosate in Sugarbeet Tops Resulting from Treatment 2.

Site	PHI (days)	Glyphosate (ppm)
Saginaw Co. Michigan	70	0.051
	95	0.034
Richland Co. North Dakota	52	1.846
	59	1.749
	66	1.406
	73	0.815
	80	1.421
Scottsbluff Co. Nebraska	59	0.049
	98	0.028
Hockley Co. Texas	59	0.345
	92	0.234
Stanislaus Co. California	61	0.386
	99	0.109
Stanislaus Co. California	62	0.228
	99	0.120

Decline Residues of Glyphosate in Sugarbeet Tops Resulting from Treatment 3.

Site	PHI (days)	Glyphosate (ppm)
Saginaw Co. Michigan	31	4.276
	56	3.205
Richland Co. North Dakota	22	5.238
	29	4.650
	36	3.952
	43	3.391
	50	4.389
Scottsbluff Co. Nebraska	29	1.753
	68	1.367
Hockley Co. Texas	29	3.888
	62	3.199
Stanislaus Co. California	31	6.737
	69	2.365
Stanislaus Co. California	32	8.390
	69	3.427

Comment: The Agency concludes that, based on the submitted residue data, the proposed tolerances for glyphosate residues in/on sugarbeets will not be exceeded for the proposed use of the concentrated aqueous formulation of the isopropylamine salt plus a surfactant. Treatment 3 utilized a final application of 2 quart/acre, which is 2X the label specified final application. Therefore actual residues should not be greater than those of treatment 3. The maximum glyphosate residues for sugarbeet roots were 2.676 ppm and 8.637 ppm for treatments 2 and 3, respectively. The maximum glyphosate residues for sugarbeet tops were 1.749 ppm and 8.390 ppm for treatments 2 and 3, respectively. Results of the decline study showed that glyphosate

residues declined in both the roots and tops with increasing preharvest intervals.

The Agency concludes that the geographical representation of residue field trials is adequate for the proposed use on sugar beets and meets current GLN 860.1500 requirements.

Processed Commodities:

The petitioner supplied two studies supporting the residues of glyphosate and AMPA in sugarbeets and processed sugarbeet commodities.

MRID 443316-02

Title: Residues of glyphosate and AMPA in beet containing the Roundup Ready[™] gene, following multiple applications with MON52276 herbicide. Danish field trial, 1995.

Author: A. Hontis

Date: May 8, 1996

Site: Zealand, Denmark

The processing was performed to obtain the following fractions of the sugarbeet: pulp, press water, raw juice, thin juice, thick juice, raw sugar molasses and refined sugar. A lab-scale processing technology similar to the industrial processing of sugarbeets was used.

Residual glyphosate (ppm) in beet, following a multiple treatment with glyphosate

Matrix	Days after treatment	Variety 77 glyphosate (ppm) ²	Variety 77 glyphosate (ppm) ¹	Variety A5/15 glyphosate (ppm) ²	Variety A5/15 glyphosate (ppm) ¹
Plant	prior to last application	1.4	<0.05	1.0	<0.05
Plant	0	22	20	32	21
Top	21	1.3	1.6	1.1	1.3
Top	42	0.4	0.7	0.5	0.5
Top	63	0.3	0.5	0.2	0.3
Top	116	0.2	0.2	0.1	0.5
Root	21	1.3	1.5	1.1	1.5
Root	42	0.3	0.6	0.5	0.6
Root	63	0.3	0.4	0.3	0.3
Root	116	0.2	0.3	0.2	0.3

Treatment 2: 1.1 quart/acre pre-emergence
 0.9 quart/acre at growth stage 2-4 true leaves
 0.9 quart/acre at growth stage 6-8 true leaves
 0.9 quart/acre at growth stage 12-14 true leaves

Treatment 3: 1.1 quart/acre pre-emergence
 1.3 quart/acre at growth stage 2-4 true leaves
 0 quart/acre at growth stage 6-8 true leaves
 1.3 quart/acre at growth stage 12-14 true leaves

n.d. means a value below detection limit (0.02 ppm)

<0.05 means a value below the quantification limit (0.05 ppm)

Processing Fractions 116 days after treatment	Residual glyphosate Treatment 3 (ppm)
Pulp*	0.2
Press water	0.2
Raw juice	0.3
Lime sludge	n.d.
Thin juice	n.d.
Thick juice	n.d.
Molasses	n.d.
Raw sugar	n.d.
Refined sugar	n.d.

n.d. means a value below detection limit (0.02 ppm)

*This study analyzed pressed pulp which experimentally consists of 27 % dry matter. EPA guidance defines dried pulp as the commodity of interest in the US. Residue Chemistry Guidelines OPPTS860.1000 states that dried pulp contains 88 % dry matter. Therefore, 0.2 ppm glyphosate residue in pressed pulp would convert to 0.8 ppm $[(0.88/0.27)*0.248]$.

Comment: At harvest, glyphosate residues (Danish Field Trials) in samples for a 3.8 quart/acre (2.7 quart/acre postemergent) treatment ranged from 0.2 - 0.3 ppm for sugarbeet roots and 0.2 ppm for sugarbeet tops. Treatment of sugarbeets at a rate of 3.8 quart/acre (2.7 quart/acre postemergent) will not result in detectable residues in thick juice, molasses and refined sugar obtained from processing Roundup® Ultra treated sugarbeets. Therefore, no separate tolerances for these commodities are necessary.

MRID 443316-03

Title: Residues of glyphosate and AMPA in beet containing the Roundup Ready[™] gene, following multiple applications with MON52276 herbicide. U.K. field trials, 1995.

Author: A. Hontis

Date: May 8, 1996

Site: East Anglia, U.K.

The processing was performed to obtain the following fractions of the sugarbeet: pulp, press water, raw juice, thin juice, thick juice, raw sugar molasses and refined sugar. A lab scale processing technology similar to the industrial processing of sugarbeets was used.

Residual glyphosate (ppm) in beet, following a multiple treatment with glyphosate

Matrix	Days after treatment	Variety 77 glyphosate (ppm) ²	Variety 77 glyphosate (ppm) ¹	Variety A5/15 glyphosate (ppm) ²	Variety A5/15 glyphosate (ppm) ¹
Stalham Plant	prior to last application	0.3	0.07	0.3	0.1
Plant	0	12	32	19	30
Top	21	0.4	0.6	0.4	0.7
Top	45	0.2	0.4	0.1	0.1
Top	64	0.2	0.2	0.06	0.06
Top	112	0.06	0.1	n.d.	n.d.
Kings Lynn Top	89	0.2	0.7	n.a.	n.a.
Stalham Root	21	0.6	0.9	0.7	0.6
Root	45	0.2	0.4	0.2	0.2
Root	64	0.2	0.4	0.2	0.2
Root	112	0.2	0.3	0.1	0.09
Kings Lynn Root	89	0.2	0.2	n.a.	n.a.

Treatment 2: 1.1 quart/acre pre-emergence
 0.9 quart/acre at growth stage 2-4 true leaves
 0.9 quart/acre at growth stage 6-8 true leaves
 0.9 quart/acre at growth stage 12-14 true leaves

Treatment 3: 1.1 quart/acre pre-emergence
 1.3 quart/acre at growth stage 2-4 true leaves
 0 quart/acre at growth stage 6-8 true leaves
 1.3 quart/acre at growth stage 12-14 true leaves

n.d. means a value below detection limit (0.02 ppm)
 n.a. not available

Processing Fractions 112 days after treatment	Residual glyphosate Treatment 3 (ppm)
Pulp*	0.2
Press water	0.2
Raw juice	0.1
Lime sludge	n.d.
Thin juice	n.d.
Thick juice	n.d.
Molasses	n.d.
Raw sugar	n.d.
Refined sugar	n.d.

n.d. means a value below detection limit (0.02 ppm)

*This study analyzed pressed pulp which experimentally consists of 27 % dry matter. EPA guidance defines dried pulp as the commodity of interest in the US. Residue Chemistry Guidelines OPPTS860.1000 states that dried pulp contains 88 % dry matter. Therefore, 0.2 ppm glyphosate residue in pressed pulp would convert to 0.5 ppm $[(0.88/0.27)*0.15]$.

Comment: At harvest, glyphosate residues (U.K. Field Trials) in samples for a 3.8 quart/acre (2.7 quart/acre postemergent) treatment ranged from 0.09 - 0.3 ppm for sugarbeet roots and <0.02 - 0.7 ppm for sugarbeet tops. Treatment of sugarbeets at a rate of 3.8 quart/acre (2.7 quart/acre postemergent) will not result in detectable residues in thick juice, molasses and refined sugar obtained from processing Roundup® Ultra treated sugarbeets. Therefore, no separate tolerances for these commodities are necessary.

Rotational Crops:

The proposed amended label reads "There are no rotational crop restrictions following applications of this product". In a

memo (G. Kramer, 5/94) the Agency recommended that the registrant should retain the 30 day plant-back interval for crops which the use of glyphosate is not registered.

Comment: The registrant must therefore reinstate this 30 day plant-back interval for crops where the use of glyphosate is unregistered.

MEAT, MILK, POULTRY AND EGGS:

A plausible livestock exposure analysis is as follows:

Feed Item	Proposed tolerance (ppm)	% Dry Matter	% in diet dairy cattle	Exposure in dairy cattle (ppm) ¹	% in diet beef cattle	Exposure in beef cattle (ppm) ²
sugar beet tops	10	23	10	4.3	20	8.7
sugar beet dried pulp	25	88	20	5.7	20	5.7
alfalfa hay	200	40	40	89.9	40	89.9
soybean hulls	100	90	15	16.3	20	22.2
soybean meal	20	92	15	3.2	na	na
sugar beet molasses	na	75	10	na	10	

: **Total exposure** = 119.4 ppm

: **Total exposure** = 126.5 ppm

Feeding studies with glyphosate were not submitted for review with this petition. Feeding studies for glyphosate were discussed in previous petitions (PP6F3380/6H5502 Memo by W. Chin, 1/89). Swine, cattle, and chickens were dosed at a feeding level of 120 ppm of glyphosate and AMPA. No quantifiable (<0.05 ppm) residues were observed in fat or muscle of animals. Residues were not found in eggs or milk at this level. Kidney residues for the 120 ppm feeding level were cattle, 1.0 ppm; swine, 2.88 ppm; and poultry, 1.23 ppm. Liver residues for the 120 ppm feeding level were cattle, 0.07 ppm; swine, 0.33 ppm; and poultry, 0.3 ppm. As noted in the Product and Residue Chemistry Chapter of the Re-registration Eligibility Decision (RED) Document (R. Perfetti, 27-SEP-1992), Meat, Milk, Poultry, and Eggs requirement has been satisfied.

Comment: The Agency expects no increase in tissue residues of

poultry or ruminants as a result of this use. Therefore, the Agency anticipates that the current animal commodity tolerances are acceptable.

cc: Chem F. Clinton F. Morton

REI:Tea + P SVH:9/18/98

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