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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Glyphosate on Potatoes, Corn, Sorghum, Grapes, Plums/Prunes, Sugar Beets, and Peanuts. Impact of Craven Analytical Data on Registrations.
MRID Nos. 419470-01, -02, -03, -04, -05, -06.
CB Number 8367 DP Barcode D167350

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In response to EPA's (Linda Fisher's) letter dated 2/27/91 which requested identification of all data generated at Craven Laboratories, and a subsequent letter dated 6/20/91 which requested alternative data which could support continuation of existing registrations/tolerances until replacement data could be generated, Monsanto Company has submitted information on the herbicide glyphosate. This information is contained in a letter from the Company to Ms. Patricia Bagley dated July 11, 1991, and in 6 volumes of data (MRID Nos. 419470-01, -02, -03, -04, -05, -06). This information was required because the Agency has received allegations concerning the reliability of certain residue and environmental fate studies conducted by Craven Laboratories. The Agency will not rely on Craven data for regulatory decisions before the issues surrounding the validity of the data generated at Craven Laboratories are resolved.

The commodities for which glyphosate data or discussions have been submitted are potatoes, corn, sorghum, and grapes. No data have been submitted for glyphosate on sugar beets, plums/prunes, or peanuts which also have Craven-generated residue data.

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Tolerances are established for residues of **glyphosate** and its metabolite aminomethylphosphonic acid resulting from the application of the isopropylamine salt and/or the monoammonium salt (40 CFR 180.364 (A)); for application of these two salts or the sodium sesqui salt for herbicidal and plant growth regulator purposes (40 CFR 180.364(B)); and from the use of irrigation water (40 CFR 180.364(C)). Included are tolerances for potatoes (0.2 ppm), stone fruits (including plums, 0.2 ppm), grapes (0.2 ppm), grain crops (including corn and sorghum, 0.1 ppm), forage grasses (including corn and sorghum forage, silage, and fodder, 0.2 ppm), and sugar beets (0.2 ppm). [We note that tolerances for corn and sorghum grain, forage, silage and fodder were established for commodity groupings which no longer exist. These tolerances have not been modified to reflect current crop groupings as defined in 40 CFR 180.34.] Tolerances are pending for corn grain (1 ppm), corn forage/fodder (20 ppm), sorghum grain (5 ppm), sorghum forage/fodder (20 ppm), and sorghum milling fractions (excluding grits)(25 ppm). A Registration Standard has been completed for glyphosate (Residue Chemistry Chapter, 5/31/85), as well as a Registration Standard Update (see R. Schmitt, 4/26/90).

Conclusions and Recommendations

1. Potatoes. Available non-Craven potato processing data are inadequate to support the current registrations or the pending food additive tolerances discussed in the Registration Standard Update on a permanent basis. CBRS recommends that a DCI be issued for a potato processing study in which potatoes bearing detectable, field-weathered residues are processed into potato chips, wet peel, and dry peel. It may be necessary to treat with exaggerated rates to obtain measurable residues in the raw agricultural commodity. If concentration occurs, appropriate food/feed additive tolerances must be proposed.

   Available non-Craven data are sufficient to support the use on potatoes while the potato processing study is being generated.

2. Corn (pre-Harvest application). The requested registration for this use is pending (PP#8F3673). Non-Craven U.S. field trial data are not available.

   Should Monsanto wish to finalize its petition before issues relating to Craven Laboratories are resolved, additional residue data are necessary. Field corn should be treated with glyphosate (Roundup, EPA Reg. No. 524-308) at a rate of 0.75 lbs.a.i./A plus 0.5 to 1% nonionic surfactant in 3 gallons of water per acre (ground) and in 3 gallons of water

per acre (aerial). Samples of field corn grain, forage, silage and fodder should be obtained. The residue data should include samples taken at a 7-day PHI. Samples should be analyzed for residues of parent glyphosate and its metabolite, AMPA. The registrant is referred to Subdivision O of the Pesticide Assessment Guidelines for additional information regarding conducting these studies.

Because this use is pending, no EPA action regarding Craven data on corn (pre-harvest applications) is necessary.

3. Sorghum (pre-harvest application): The requested registration for this use is pending (PP#8F3672). Non-Craven U.S. field trial data are not available.

Should Monsanto wish to finalize its petition before issues relating to Craven Laboratories are resolved, additional residue data are necessary. Sorghum should be treated with glyphosate (Roundup, EPA Reg. No. 524-308) at a rate of 0.75 lbs.a.i./A plus 0.5 to 1% nonionic surfactant in 3 gallons of water per acre (ground) and in 3 gallons of water per acre (aerial). Samples of sorghum grain, forage, silage, hay and fodder should be obtained. The residue data should include samples taken at a 7-day PHI. Samples should be analyzed for residues of parent glyphosate and its metabolite, AMPA. The registrant is referred to Subdivision O of the Pesticide Assessment Guidelines for additional information regarding conducting these studies.

Because this use is pending, no EPA action regarding Craven data on sorghum (pre-harvest applications) is necessary.

4. Grapes. Insufficient non-Craven data are available to support the tolerance/registration for glyphosate on grapes on either an interim or a permanent basis. Although the residue data for grapes, per se, is sufficient, residue data for processed grape commodities are not sufficient.

CBRS recommends that a DCI be issued requiring data depicting residues of glyphosate and AMPA in or on wet and dry grape pomace, raisins, raisin waste, and juice processed from grapes bearing measurable weathered residues. It may be necessary to treat with exaggerated rates to obtain measurable residues in the raw agricultural commodity. If concentration occurs, appropriate food/feed additive tolerances must be proposed.

We note that the data gap for grape processing data was identified in the Glyphosate Registration Standard (Residue Chemistry Chapter dated 5/31/85).

5. Plums. Available non-Craven data for plums and prunes are not sufficient to support the established tolerance and registrations on a permanent basis. CBRS recommends that a DCI be issued for residue field trial data on plums or fresh prunes harvested 14 days after the last of multiple applications with the 3 lb.a.e./gallon SC/L formulation (the final treatment at 3.75 lbs.a.e./A) totaling 7.95 lbs.a.e./A/season. Tests should be conducted in CA, ID, ND, and OR/WA. Additionally, the DCI should be issued for processing data for prunes derived from plums bearing measurable, weathered residues. If residues are found to concentrate in dried prunes, then an appropriate food additive tolerance must be proposed.

   Sufficient non-Craven data are available to support the tolerance/registration for glyphosate on plums on an interim basis until the data discussed above are generated.

6. Sugar beets. Insufficient non-Craven sugar beet processing data are available to support the established tolerance and registrations on a permanent basis. Although data for the rac, sugar beets, is sufficient, data for processed sugar beet commodities are not sufficient. CBRS recommends that a DCI be issued for processing data in which sugar beets bearing measurable, weathered residues are processed into dehydrated pulp, molasses, and refined sugar. Exaggerated application rates may be necessary to achieve measurable residues. If residues are found to concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

   Considering the lack of detectable residues found in field trials carried out at exaggerated rates for both sugar beets and potatoes, the long PHI associated with this use, and the tolerance level which is twice the combined limit of detection for glyphosate and AMPA, the current tolerance and registrations are adequately supported on an interim basis until the processing study can be generated.

7. Peanuts. Insufficient non-Craven residue data are available to support the growth regulator use on peanuts, either on an interim or a permanent basis. We note that tolerances for glyphosate on peanuts are included in both 40 CFR 180.364 (A) and 180.164 (B) reflecting applications made preemergence for weed control and post-emergence as a growth regulator, respectively. CBRS recommends that a DCI be issued for peanut field trial data in which peanuts are treated with the sodium sesqui salt of glyphosate (EPA Reg. No. 524-332) at a rate of 0.0375 lbs.a.i./A. If the current label restrictions are to remain, samples of peanuts, hulls and hay should be obtained at an 84-day PHI and analyzed for residues of glyphosate and AMPA. Applications should be

made in 10 gallons of water per acre. Applications should be made with an approved non-ionic surfactant at a 0.5% surfactant concentration.

Detailed Considerations

Metabolism

The metabolism of glyphosate in plants has been adequately described. The total toxic residue includes parent glyphosate and its metabolite aminomethylphosphonic acid (AMPA).

Below we discuss separately, for each commodity, the adequacy of the submitted data to support the current tolerances and registrations.

POTATOES

Use Directions (from Registration Standard Update, 4/26/90):

> The 3 lb/gal SC/L formulation is registered for preemergence soil broadcast application to potatoes at 0.75-3.75 lbs.a.i./A/application, not to exceed 6 lbs.a.i./A/year using conventional ground equipment. Applications with hand-held or high volume ground equipment may be made in 3-15 lbs.a.i./100 gal of spray solution except in CA where the carrier rate is limited to 6 lbs.a.i./100 gal. Treated areas may not be grazed by livestock within 8 weeks after application.

Adequate residue data generated by laboratories other than Craven are available for the rac potatoes. The processing study required by the 1985 Registration Standard was generated by Craven, and the data provided in this submission are meant to substitute for these Craven data. Two studies submitted are discussed separately below.

Glyphosate Residues in Potato Tubers Following Application of Roundup in Norway and Finland (MRID No. 419470-01)

Roundup was applied to potatoes either pre-emergent, post-emergent, or pre-harvest (separate studies) by directed spray to the weeds. Field trials were carried out in Norway and Finland. The application rates were 1, 1.1, 2 or 1.4 kg/HA (= 1.1, 1.2, 2.2 or 1.5 lbs.a.i./A). These rates correspond to 0.29X, 0.32X, 0.59X and 0.40X relative to the maximum U.S. rate of 3.75 lbs.a.i./A. Samples were obtained at normal harvest time (as mixed samples from four replication plots) and stored outside for 7 days (5-10°C), in cool storage for 1 month (3-4°C), and then frozen until analysis (unspecified temperature and time interval).

The analytical method used to determine residues of glyphosate

and AMPA was "Analytical Procedure for N-Phosphonomethyl Glycine and Aminomethylphosphonic Acid in Potatoes". Briefly, frozen potato samples are ground with dry ice and allowed to sit overnight. The ground sample is blended with chloroform and water, centrifuged, and the aqueous layer is cleaned up on an ion exchange column (Duolite A-101D). Further clean up is accomplished using charcoal treatment and column chromatography (AG 50W-X8). Following derivitization with trifluoroacetic acid, the sample are analyzed by GLC-FPD. Insufficiently labeled sample chromatograms were submitted. The reported LOD is 0.05 ppm for each component. Only average recovery values are provided: 77% for glyphosate, 82% for AMPA at unspecified fortification levels. Residues are summarized in Table 1.

Table 1: Residues of Glyphosate and AMPA in Potatoes Treated with Roundup

Application Rate (lbs ai/A)	PHI (days)	Type of Treatment	Residue (ppm)	
			Glyphosate	AMPA
1.1	112	pre-emerg	<0.05	<0.05
2.2	112		<0.05	<0.05
1.1	109	post-emerg	<0.05	<0.05
2.2	109		<0.05	<0.05
1.1	105		<0.05	<0.05
2.2	105		<0.05	<0.05
1.1	112	pre-emerg	<0.05	<0.05
2.2	112		<0.05	<0.05
1.1	105	post-emerg	<0.05	<0.05
2.2	105		<0.05	<0.05
1.1	99		<0.05	<0.05
2.2	99		<0.05	<0.05
1.5	86	-	<0.05[1]	<0.05[1]
1.5	104	-	<0.1[1]	<0.02[1]
1.2	91	-	<0.1[1]	<0.02[1]
1.5	17	pre-harvest	0.5	<0.05

[1]Potato samples were washed prior to residue analysis.

Glyphosate Residues in Starch Potatoes Following Preharvest Roundup Herbicide Treatment Holland 1982-1983 Trials (MRID No. 419470-02

Field trials were carried out in the Netherlands in which "starch potatoes" were foliarly treated with Roundup at rates of 0.78-3.14 lbs.a.i./A with PHIs of 6 or 7 days. Samples were "deepfrozen" within 3 days of harvest. Storage times were not provided. Potato samples were also processed into starch as follows:

> Starch was obtained by slurrying a 100 g of mashed potatoes in 300 ml water. Starch was separated from fibers by wet sieving through a 100 mesh screen. The supernatant liquid was decanted after 1 hour standing. Starch was then rinsed with small amount of fresh water which is decanted. Starch is dried in rotary evaporator at 40°C prior to analysis. Residue analysis is carried out on a 12.5 g subsample, slurried in water and boiled for 20 minutes. This brings the starch granules to a maximum hydration which is followed by rupture and collapse yielding granule fragments, starch aggregates and molecules.
>
> The gelatinized potato starch was then hydrolyzed by dilute acid and neutralized prior to A 101 D anion exchange resin clean up.

The sample clean up method used for potato and starch samples was referenced but not included with this submission (report MLL 30.102(1), with modifications on extraction procedures). Similarly, the analysis methods were referenced (glyphosate, o-phthalaldehyde PCRS ((1), Method C))(AMPA, Ninhydrin PCRS (Method D) or the o-phthalaldehyde procedure). The reported LODs were 0.05 ppm for each component. Reported recoveries ranged from 92-100% and 91,96% for glyphosate from potato tubers and starch respectively, and from 80-89% and 78,82% for AMPA from potato tubers and starch respectively. Sample chromatograms were provided. Standard curves were not provided.

Residues of glyphosate and AMPA found in potatoes and potato starch in these studies are shown in Table 2.

Table 2: Residues of Glyphosate and AMPA in Potato Tubers and Potato Starch - Holland Study

Application Rate (lbs.a.i./A)	PHI (days)	Tuber Residues (ppm)		Starch Residue (ppm)	
		Glyphosate	AMPA	Glyphosate	AMPA
0.78 (0.2X)	6	<0.05	<0.05		
1.56 (0.4X)		<0.05	<0.05		
2.34 (0.6X)		0.12	<0.05		

Application Rate (lbs.a.i./A)	PHI (days)	Tuber Residues (ppm)		Starch Residue (ppm)	
		Glyphosate	AMPA	Glyphosate	AMPA
0.78		0.09	<0.05		
1.56		0.08	<0.05		
2.34		0.07	<0.05		
0.78		0.11	<0.05		
1.56		<0.05	<0.05		
2.34		0.07	<0.05		
0.78		<0.05	<0.05		
1.56		<0.05	<0.05		
2.34		<0.05	<0.05		
1.56	7	<0.05	<0.05	<0.05	<0.05
2.34		0.59	<0.05	<0.05	<0.05
3.14 (0.8X)		<0.05	<0.05	<0.05	<0.05
1.56		<0.05	<0.05	<0.05	<0.05
2.34		0.21	<0.05	<0.05	<0.05

Summary: Potatoes

The data submitted are not adequate alternative data to the Craven data for processed potato products because (1) residue data for the processed potato products included in Table 2 of Subdivision O of the Pesticide Assessment Guidelines are not provided (data are provided only for potato starch), and (2) exaggerated rate data reflecting pre-emergent applications at the maximum theoretical concentration factor (if possible in light of phytotoxicity), which could be utilized in lieu of the processing data, are not available.

Monsanto states in a letter provided with these submissions that in the potato processing study previously submitted, Craven analyzed only chips and stock feeds, while the remaining fractions (granules and flakes, both showing concentration factors of 2X) were analyzed in-house; thus, data for only potato chips remain in question. (We note that at the time this processing study was submitted, processing data for wet and dry peel were not required, while data for dried potatoes were required.) Monsanto further references an exaggerated rate (2X)

field trial utilizing preemergent applications in which no detectable residue were found. The Food and Food Production Encyclopedia (Considine, D.M., Considine, G.D., 1982) indicates that approximately 21-32 lbs. of potato chips are produced from 100 lbs. of potatoes yielding a maximum concentration factor of ca. 5X. We note that the recommended food additive tolerance for potato chips reflects a 5X concentration factor. Considering this information, CBRS concludes that sufficient information is available on an interim basis to support the current registrations and tolerances for glyphosate use on potatoes. However, CBRS recommends that a DCI be issued for an additional potato processing data to replace Craven data wherein potatoes bearing measurable, weathered residues are processed into potato chips, wet peel, and dry peel.

CORN: PRE-HARVEST APPLICATION

Use Directions (from Registration Standard Residue Chemistry Chapter, 5/31/85) indicate that glyphosate may be applied to corn as follows:

0.75-3.75 lbs.a.i./A	pre-plant broadcast
0.75-3.00 lbs.a.i./A	pre-plant spot treatment at plant pre-emergent
3-15 lbs.a.i./100 gal	post plant spot treatment
0.75 lbs.a.i./A	post emergent (SLNs: OK, NM, TX)

OPP's Reference Files System (REFS) indicates that the Special Local Needs (SLN, 24C) post emergent treatments in OK, NM, and TX have been canceled. The remaining uses of the pesticide on corn are either spot treatments (prior to silking) or early season uses (8-week PHI and pre-grazing restriction).

Residue data were submitted in Glyphosate and AMPA Residues in Corn Grain Following Roundup Herbicide Preharvest Application in France, 1979-1980-1983-1984 Trials (MRID No. 419470-03). Corn was treated by "direct spray" at rates of 0.54-8.64 kg/ha (= 0.59-9.42 lbs.a.i./A). PHIs ranged from 8-64 days. Storage times and conditions between harvest and milling/chopping in the laboratory were not specified. Following milling/chopping samples were stored at -20°C for an unspecified period of time.

Two analytical methods were used to determine residues of glyphosate and AMPA. Both incorporate aqueous extraction followed by clean up on an ion exchange column. In the first method, glyphosate and AMPA are derivitized to the N-trifluoroacetylmethyl esters and analyzed by GC using an FPD. The second method utilizes an HPLC post-column reactor system based on O-phthalaldehyde reactions. The reported LODs are 0.05 ppm for each component.

Reported recoveries from corn grain for the GC method range from 60-114% for glyphosate (avg.= 77%, s.d.= 15%; fortification levels of 200-4000 ppm), and for corn straw from 34-103% (avg.= 74%, s.d.= 20%; fortification levels of 200-3000 ppm). Recoveries for AMPA from corn grain using the GC method range from 46-115% (avg.= 80%, s.d.= 21%; fortification levels of 25-200 ppm), and for corn straw range from 35-100% (avg.= 73%, s.d.= 18%; fortification levels of 100, 200 ppm). Reported recoveries for corn grain from the HPLC method range from 50-91% for glyphosate (avg.= 68%, s.d.= 9%; fortification levels of 500, 1000 ppm), and for AMPA ranged from 49-81% (avg.= 62%, s.d.= 10%; fortification levels of 50-250 ppm). Recoveries from straw were not determined for the HPLC method. We assume that the reported fortification levels are ppb rather than ppm; however, this must be confirmed by the submitter. Representative chromatograms were submitted.

Residue data are summarized in Table 3.

Table 3: Residues of Glyphosate and AMPA in Corn Grain and Straw

Sample	App. Rate (lbs.a.i./A)	PHI (days)	Uncorrected Residue, ppm ()=avg	
			Glyphosate	AMPA
corn grain	0.59	14-16	<0.05-0.4 (0.12)	<0.05
		27-32	<0.05-0.5 (0.23)	<0.05
		44	<0.05-0.3 (0.10)	<0.05
		55	<0.05-0.4 (0.13)	<0.05
	1.18	14-16	<0.05-1.2 (0.13)	<0.05
		27-32	<0.05-0.6 (0.31)	<0.05
		44	<0.05-0.6 (0.23)	<0.05
		55	<0.05-0.4 (0.17)	<0.05
	2.35	14-16	<0.05-0.5 (0.12)	<0.05
		27-32	<0.05-1.0 (0.51)	<0.05
		44	<0.05	<0.05
		55	<0.05-0.2 (0.10)	<0.05
	4.71	8-9	0.1-0.5 (0.27)	<0.05
		13-16	<0.05-0.5 (0.16)	<0.05
		18-22	<0.05-0.3 (0.14)	<0.05

Sample	App. Rate (lbs.a.i./A)	PHI (days)	Uncorrected Residue, ppm ()=avg	
			Glyphosate	AMPA
		25-32	0.2-3.8 (1.2)	<0.05-0.07 (0.05)
		39-44	<0.05-0.1 (0.06)	<0.05
		55-64	0.1-0.3 (0.18)	<0.05
	9.42	8-9	0.1-0.9 (0.27)	<0.05
		13-15	<0.05-0.2 (0.11)	<0.05
		18-22	0.3-1.7 (0.33)	<0.05
		25-29	0.3-6.5 (2.2)	<0.05-0.16 (0.07)
		39	<0.05-0.1 (0.08)	<0.05
		64	0.1-0.5 (0.35)	<0.05
corn straw	0.59	14-16	0.8-3.7 (1.92)	<0.05-0.06 (0.05)
		31-32	0.2-1.4 (0.78)	<0.05
		44	1.6-4.5 (3.4)	<0.05-0.06 (0.05)
		55	0.9-1.8 (1.3)	<0.05-0.09 (0.06)
	1.18	14-16	1.4-6.0 (3.2)	<0.05-0.05 (0.05)
		31-32	0.4-3.7 (1.45)	<0.05
		44	0.9-3.3 (2.2)	<0.05
		55	0.9-4.5 (2.1)	<0.05-0.07 (0.06)
	2.35	14-16	1.4-8.7 (4.4)	<0.05
		31-32	0.5-3.7 (1.6)	<0.05
		44	1.3-6.7 (1.4)	<0.05-0.07 (0.06)
		55	1.0-3.6 (2.2)	<0.05-0.05 (0.05)
	4.71	14-16	5.0-16.7 (9.4)	<0.05-0.1 (0.07)
		31-32	0.9-18.9 (8.3)	<0.05-0.17 (0.09)
		44	0.3-0.6 (0.4)	<0.05
		55	0.4-0.8 (0.6)	<0.05

These data are meant to substitute for Craven data submitted with PP#8F3673 in which revised tolerances for corn grain, fodder, and forage are requested as well as a revised use pattern. However,

the Agency is utilizing non-U.S. residue data only as supplemental supporting data when determining the adequacy of non-Craven data to support tolerances and registrations. Since high residues are found resulting from this use, the submitted data have several deficiencies, and since no U.S. data are available, we conclude that the available non-Craven data do not support the pending registrations and proposed tolerances.

Because this use is a pending action, no EPA action is necessary. However, if Monsanto wishes to complete action on the petition before issues of Craven data have been resolved, additional data are necessary. Field corn should be treated with glyphosate (Roundup, EPA Reg. No. 524-308) at a rate of 0.75 lbs.a.i./A plus 0.5 to 1% nonionic surfactant in 3 gallons of water per acre (ground) and in 3 gallons of water per acre (aerial). Samples of field corn grain, forage, silage and fodder should be obtained. The residue data should include samples taken at a 7-day PHI. Samples should be analyzed for residues of parent glyphosate and its metabolite, AMPA. The registrant is referred to Subdivision O of the Pesticide Assessment Guidelines for additional information regarding conducting these studies.

SORGHUM: PRE-HARVEST APPLICATION

Use Directions (from Registration Standard Residue Chemistry Chapter, 5/31/85) indicate that glyphosate may be applied to sorghum as follows:

- 0.78-3.75 lbs.a.i./A — pre-plant/pre-emergence
- post-emergence spot treatments
- 0.75 lbs.a.i./A — post-harvest aerial (OK. NM, TX)
- Wiper application — KS, MO, NE, NM, OK, TX (PHI = 14 days)

All of the SLN registration listed above have been canceled. The wiper application registrations were canceled because of the possibility of over-tolerance residues at the 14-day PHI.

The most recently accepted Roundup label (dated 12/4/90) shows the following additional use:

- Wiper applications — (PHI = 40 days)

Two studies have been provided with this submission to substitute for Craven data on sorghum: Glyphosate Residues in Sorghum Grain and Forage Following Preharvest Application of Roundup Herbicide in Australia (MRID No. 419470-04), and Glyphosate Residues in Processed Fractions of Wheat, Barley and Oats Following Preharvest Treatment with Roundup Herbicide. European Field Trials. (MRID No. 419470-05). The data submitted are meant to

substitute for Craven data submitted with PP#8F3672. The use requested in this petition is one not currently on the glyphosate label. Sorghum is to be treated pre-harvest at 1 qt./A with a 7-day PHI. As discussed in the case of corn above, the Agency is utilizing non-U.S. residue data only as supplemental supporting data when determining the adequacy of non-Craven data to support tolerances and registrations. Since high residues are found resulting from this use, and since no U.S. data are available, we conclude that the available non-Craven data do not support the pending registrations and proposed tolerances. We will not review this study in detail at this time.

Because this use is a pending action, no EPA action is necessary. However, if Monsanto wishes to complete action on the petition before issues of Craven data have been resolved, additional data are necessary. Sorghum should be treated with glyphosate (Roundup, EPA Reg. No. 524-308) at a rate of 0.75 lbs.a.i./A plus 0.5 to 1% nonionic surfactant in 3 gallons of water per acre (ground) and in 3 gallons of water per acre (aerial). Samples of sorghum grain, forage, silage, hay and fodder should be obtained. The residue data should include samples taken at a 7-day PHI. Samples should be analyzed for residues of parent glyphosate and its metabolite, AMPA. The registrant is referred to Subdivision O of the Pesticide Assessment Guidelines for additional information regarding conducting these studies.

GRAPES

No new data were provided with this submission reflecting residues of glyphosate on grapes or grape processed commodities. In response to a data gap for grape processing data identified in the Registration Standard, Craven Laboratories analyzed grape samples from a field trial study submitted in 1988 (MRID No. 407853-03). In this study, grapes were treated at an exaggerated rate of 37.5 lbs.a.i./A (=10X) with no detectable residues found. Based on the lack of detectable residues at this exaggerated application rate (which exceeds the maximum theoretical concentration factor), a processing study was not performed, and it was concluded in the Registration Standard Update that a grape processing study would not be required. The available residue data for grapes, per se, are adequate, but grape processing data are unavailable, and this data requirement was to be met by the exaggerated rate study in which samples were analyzed by Craven.

Other exaggerated rate data are discussed in the Registration Standard in which grapes were treated at 16 or 24 lbs.a.i./A (2 or 3 applications at 8 lbs.a.i./A, 14-65 day intervals, 42-day PHI, = 2X or 3X the maximum seasonal application rate). In these studies, residues were not all non-detectable in grape samples but ranged from <0.05 - 0.1 ppm glyphosate and <0.05 ppm AMPA.

An additional study was discussed in the Registration Standard in which grapes were treated with three applications at 8 lbs.a.i./A/application (= 24 lbs.a.i./A/season = 3X). Residues of glyphosate and AMPA in 4 raisin samples were non-detectable (<0.05 ppm).

Because detectable residues were found in grape samples treated at a 2X rate, and additional processing data are not available, we conclude that insufficient non-Craven data are available to support the tolerance for glyphosate on grapes on an interim basis.

CBRS recommends that a DCI be issued requiring data depicting residues of glyphosate and AMPA in or on wet and dry grape pomace, raisins, raisin waste, and juice processed from grapes bearing measurable weathered residues. It may be necessary to treat with exaggerated rates to obtain measurable residues in the raw agricultural commodity. If concentration occurs, appropriate food/feed additive tolerances must be proposed.

We note that the data gap for grape processing data was identified in the Glyphosate Registration Standard (Residue Chemistry Chapter dated 5/31/85).

PLUMS

Monsanto presents no Craven-alternate data for plums with this submission. In response to a data gap for plum field trial and processing (prune residues) data identified in the Registration Standard, Craven Laboratories analyzed plum samples from a field trial study submitted in 1988 (MRID No. 407853-01). Residues of glyphosate and AMPA were all non-detectable (<0.05 ppm) in 16 plum samples treated at 3.75-37.5 lbs.a.i./A (1-10X the maximum registered rate, 14-day PHI). Based on the lack of detectable residues at the exaggerated application rates (which exceed the maximum theoretical concentration factor), a processing study was not performed, and it was concluded in the Registration Standard Update that a plum processing study would not be required.

Residue data for plums were discussed in the Registration Standard (Residue Chemistry Chapter) in which plums were treated with three applications totaling 9 lbs.a.i./A (= 1.1X, Canadian data, 17 day PHI). Residues in 4 plum samples ranged from <0.16-<0.23 ppm. One fresh prune sample from a CA test yielded non-detectable residues of glyphosate and AMPA (<0.05 ppm) 31 days after the last of 3 directed spray applications totaling 12 lbs.a.i./A (1.5X). The residue in a single prune sample processed from a plum with combined residues of <0.18 ppm was <0.19 ppm.

Insufficient non-Craven data are available to support the established tolerance and registration for glyphosate on plums on

a permanent basis. CBRS recommends that a DCI be issued for residue field trial data on plums or fresh prunes harvested 14 days after the last of multiple applications with the 3 lb.a.e./gallon SC/L formulation (the final treatment at 3.75 lbs.a.e./A) totaling 7.95 lbs.a.i./A/season. Tests should be conducted in CA, ID, ND, and OR/WA. Additionally, the DCI should be issued for processing data for prunes derived from plums bearing measurable, weathered residues. If residues are found to concentrate in dried prunes, then an appropriate food additive tolerance must be proposed.

Sufficient non-Craven data are available to support the tolerance for glyphosate on plums on an interim basis until the data discussed above can be generated.

SUGAR BEETS

Monsanto presents no Craven-alternate data for sugar beets with this submission. In response to a data gap for sugar beet processing data identified in the Registration Standard, Craven Laboratories analyzed sugar beet (rac) samples from a field trial study submitted in 1988 (MRID No. 407853-04). Residues of glyphosate and AMPA were all non-detectable (<0.05 ppm) in 16 sugar beet samples treated at 3.75-37.5 lbs.a.i./A (1-10X the maximum registered rate, PHI = 172 or 237 days). Based on the lack of detectable residues at the exaggerated application rates, a processing study was not performed, and it was concluded in the Registration Standard Update that a sugar beet processing study would not be required. Non-Craven sugar beet processing data are not available. The available residue data for sugar beets, per se, were considered adequate in the Registration Standard, but sugar beet processing data are unavailable, and this data requirement was to be met by the exaggerated rate study in which samples were analyzed by Craven.

Sugar beet field trial data were presented in the Residue Chemistry Chapter of the Registration Standard in which sugar beets were treated with a single application at 8 lbs.a.e./A (= 1.33X the maximum seasonal application rate). No detectable residues (<0.05 ppm) of glyphosate or AMPA were found in 4 samples harvested 110-162 days following application.

As discussed earlier, exaggerated rate residue data are also available for potatoes, another member of the root and tuber vegetables crop group, showing no detectable residues (<0.05 ppm) of glyphosate or AMPA resulting from the identical use (same timing and exaggerated application rate).

Insufficient non-Craven sugar beet processing data are available to support the established tolerance and registrations on a permanent basis. CBRS recommends that a DCI be issued for processing data in which sugar beets bearing weathered,

measurable residues are processed into dehydrated pulp, molasses, and refined sugar. Exaggerated application rates may be necessary to achieve measurable residues. If residues are found to concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

Considering the lack of detectable residues found in field trials carried out at exaggerated rates for both sugar beets and potatoes, the long PHI associated with this use, and the tolerance level which is twice the combined limit of detection for glyphosate and AMPA, the current tolerance and registrations are adequately supported on an interim basis until the processing study can be generated.

PEANUTS

Monsanto presents no Craven alternate data for use of glyphosate on peanuts as a growth regulator. Monsanto submitted residue data for peanuts, analyses performed by Craven Laboratories, with PP#8F3665 (MRID Nos. 407507-00, -02) reflecting applications of glyphosate (EPA Reg. No. 524-332) to peanuts at rates of 0.0375 and 0.075 lbs.a.i./A (= 1X and 2X rates, lbs. sodium sesqui salt per acre, registered PHI = 84 days). CB concluded that residues would not exceed the established tolerances for combined residues of glyphosate and AMPA in peanuts (tolerance = 0.1 ppm), hulls (0.5 ppm), and hay (0.5 ppm) at the 1X rate, but would likely exceed these tolerances at a higher rate based on the 2X data (see R. Cook, 11/22/88). Residue data for peanut forage were not obtained; therefore, a forage feeding/grazing restriction is included on the label).

Additional residue data reflecting preemergence applications and wiper applications of the isopropylamine salt were discussed in the Residue Chemistry Chapter of the Registration Standard and in conjunction with PP#5F3157/FAP#5H5446 respectively. Non-Craven data reflecting the growth regulator use or a similar use are not available.

Insufficient non-Craven residue data are available to support the growth regulator use on peanuts, either on an interim or a permanent basis. We note that tolerances for glyphosate on peanuts are included in both 40 CFR 180.364 (A) and 180.164 (B) reflecting applications made preemergence for weed control and post-emergence as a growth regulator respectively. CBRS recommends that a DCI be issued for peanut field trial data in which peanuts are treated with the sodium sesqui salt of glyphosate (EPA Reg. No. 524-332) at a rate of 0.0375 lbs.a.i./A. If the current label restrictions are to remain, samples of peanuts, hulls and hay should be obtained at an 84-day PHI and analyzed for residues of glyphosate and AMPA. Applications should be made using ground equipment in 10 gallons of water per

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acre. Applications should be made with an approved non-ionic surfactant at a 0.5% surfactant concentration.

cc: M. Metzger (CBRS), M. Flood (CBTS), Glyphosate SF, Glyphosate Reg. Std. File, RF, Circu (7), C. Furlow (PIB/FOD, H7506C)
RDI:W.Hazel:WH:10/17/91:DE:10/18/91:EZ:10/21/91
H7509C:CBRS:M.Metzger:MM:Rm810f:CM#2:10/21/91