

US EPA ARCHIVE DOCUMENT

MEMORANDUM:

SUBJECT: Glyphosate. Residue Data on Plums, Grapes and Sugar Beets. Replacement of Craven-Data by Monsanto Submission Containing Reanalyses of Stored Samples. MRID Nos. 43315701, 43315702, 43315703 and 41940701. DP Barcode D206278. CBRS No. 14165.

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Monsanto has submitted data for glyphosate residues on plums, grapes and sugar beets. These residue data are intended to replace data previously generated by Craven Laboratories for these commodities. The purpose of this review is to determine if the submitted residue data on plums, grapes and sugar beets can be used to replace Craven data.

BACKGROUND

Residue data generated by Craven Laboratories will not be relied upon to support regulatory decisions (see memo dated 10/21/91, M. Metzger, CBRS No. 8367, Barcode No. D167350 and memo dated 4/26/93, M. Metzger). Monsanto Agricultural Chemical Company was notified by a Data-Call-In (DCI) Notice dated January 24, 1994 to replace crop residue data generated by Craven Laboratories. The DCI noted the need for non-Craven data on raw agricultural commodities (r.a.c.s) as well as data on the associated processed commodities to support tolerances for glyphosate. Monsanto has submitted replacement data for review. The residue data submitted are for N-phosphonomethylglycine (glyphosate) and its degradate, aminomethylphosphonic acid (AMPA). The residue trials were conducted with glyphosate applied at 1X, 2X, 5X and 10X the recommended label rate.

These data are intended to support tolerances for glyphosate on plums, grapes and sugar beets. Currently, tolerances for all three of these commodities are set at 0.2 ppm (Reregistration Eligibility Document (RED) Glyphosate, September 1993). These tolerances are supported by existing data on an interim basis pending the submission of non-Craven residue data for plums, grapes and sugar

beets. The metabolite of glyphosate, aminomethylphosphonic acid (AMPA), has been dropped from the tolerance expression (Reregistration Eligibility Document (RED) Glyphosate, September 1993).

The residue data submitted are the results of analyses performed by Monsanto at their laboratories on samples from residue trials conducted in 1987. Therefore, the residue data submitted are from analyses of samples that were stored frozen at -18 degrees Celsius (C) for approximately five years. Because of the long storage period, storage stability data necessary to support the residue analyses have been reviewed along with the residue data.

CONCLUSIONS

1. The residue data submitted by Monsanto for plums, grapes and sugar beets from samples that were stored frozen at -18 C for approximately five to six years, show residues of glyphosate and aminomethylphosphonic acid (AMPA) to be <0.05 ppm (non-detectable) in all samples. (The lower limit of validation for the method used to analyze glyphosate and AMPA residues in crops is 0.05 ppm.) Because Monsanto found no residues of glyphosate or AMPA at or near the tolerance level resulting from exaggerated application rates up to 10X, they did not determine concentration factors for and did not analyze residues in processed fractions of grapes or sugar beets. They did, however, analyze residues in prunes from plums harvested five years earlier and kept in frozen storage. They found no evidence of glyphosate or AMPA residues in the prune samples analyzed. According to the RED for glyphosate, the data requirements for glyphosate residues in processed commodities from plums, grapes and sugar beets have been satisfied.
2. Based on storage stability data from fortified samples, glyphosate is a stable molecule under frozen storage conditions (-18 C) for at least 2.5 years. And there is a body of evidence suggesting that glyphosate residues (fortified or weathered) are stable for several years beyond this.

3. Data from 28 previous residue trials conducted in 1977 on plums (5 trials), grapes (21 trials) and sugar beets (2 trials) show combined residues of glyphosate and AMPA to be between <0.23 to <0.05 ppm (non-detectable) on these crops. These residue and analytical data were generated by Monsanto Agricultural Chemical Co. and Analytical Development Co. (Monument, CO) not by Craven Laboratories.

RECOMMENDATIONS

The submitted residue data satisfy the requirement for a replacement of Craven data as issued in the January 24, 1994 DCI Notice and support the existing tolerances for glyphosate on grapes, plums, and sugar beets of 0.2 ppm. In light of an extensive review of storage stability data and previously submitted residue trial data for glyphosate on grapes, plums and sugar beets, the residue data contained in this submission are reasonable and within the realm of expected results for glyphosate residues on these crops.

DETAILED CONSIDERATIONS

Storage Stability Data

Because the samples analyzed for this submission were held in frozen storage for 48 to 63 months prior to analysis, storage stability data for glyphosate and AMPA were reviewed. Monsanto provided a storage stability study on glyphosate and AMPA in five different crops (corn, sorghum straw, clover, tomato and soybean forage) using fortified samples placed in frozen storage at -18 C.

The samples were analyzed over a period of 0 to 31 months. Zero-time sample analyses were provided. Residues of glyphosate did not degrade or degraded only very slowly over time (depending on the crop matrix) under the conditions of storage. Remaining glyphosate residues were between 105 and 72% of the initial fortification level on the various crops at the end of 31 months' time. Residues of AMPA fluctuated between 50 and 99% of the initial fortification level depending on the matrix (crop) during this same time period.

To further analyze and clarify this point, simple linear regression analyses were performed on the fortified sample residue data for glyphosate on several crops. The results show that the variation in the percent recovery values for the crops tested cannot be explained fully by a relationship with time. It is likely that instrument, analytical and operator errors may be causing the variation in the percent recoveries for glyphosate residues over time. The data indicate that glyphosate residues in these frozen fortified samples are either stable or degrading slowly within 31 months' time. Extrapolations to the 60 month time point indicate that even after five years, glyphosate is stable or degradation is occurring very slowly.

The equation for the regression line describing percent recovery versus months in storage for clover is:

Recovery(%) = 98.01 + 0.0277 x (Month). Extrapolating to the 5 year or 60 months point in time, the percent recovery would be 99.67.

The equation for the regression line describing percent recovery versus months in storage for tomatoes is:

Recovery(%) = 99.06 + 0.1252 x (Month). Extrapolating to the 5 year or 60 months point in time, the percent recovery would be 106.57.

The equation for the regression line describing percent recovery versus months in storage for corn is:

Recovery(%) = 102.69 - 0.6233 x (Month). Extrapolating to the 5 year or 60 months point in time, the percent recovery would be 65.29.

Based on this range of recoveries expected over a five year period (106% to 65%) and back-calculating from the replacement residue data submitted by Monsanto to determine residues present initially on the plums, grapes and sugar beets, the concentration of glyphosate in or on plums, grapes and sugar beets would still be <0.05 ppm at the zero time point.

Monsanto also provided a storage stability study on "weathered" residue samples for glyphosate and AMPA in the same five commodities as tested in the study using fortified samples and for two crops not used in the fortified storage stability study. Six of the 7 crops tested contained glyphosate residues after 5 to 6 years of frozen storage. These weathered samples were analyzed during varying time intervals after harvest. Because there are no zero-time analyses for any of the weathered residue samples used for analysis, there is no way to determine what percentage of the original residue present at harvest remains at any given time interval.

Although, there is no definitive study tracking the decline or stability of glyphosate and AMPA residues (weathered or fortified) in crops over a five year (0 to 60 months) period, there is a body of evidence that glyphosate residues (fortified or weathered) persist for several years on several crops under frozen conditions.

Weathered residues of AMPA were very low in the samples held in frozen storage for 2.5 to 5 years. To compensate for this, Monsanto provided residue analyses of glyphosate and AMPA residues on two crops beginning their analysis of weathered residues between the first and second month after harvest and continuing until approximately 2 years after harvest. Results from this data show AMPA residues remaining between 96 and 72% at the end of two years' time on alfalfa seed and potatoes, respectively. However, the stability of AMPA residues present on crops is not of concern, as AMPA has been dropped from the tolerance expression.

Residue Trial Data

Residue trial data previously submitted by Monsanto and summarized in the Residue Chemistry Chapter for Glyphosate's Registration Standard (5/31/85) were reviewed and compared against the results of the current submission by Monsanto regarding glyphosate residues on grapes, sugar beets and plums. The results of the review show that combined residues of glyphosate and AMPA were determined to be: between 0.1 and <0.05 ppm (non-detectable) in or on grapes, <0.1 ppm in or on sugar beets, and <0.16 to <0.23 ppm in or on plums. Application rates used varied from 1.1X to 3X the maximum label rates recommended for the crops. These trials were conducted in 1976 to 1977. These data are non-Craven data.

A comparison of the 1976/1977 data to the 1987 data submitted by Monsanto for glyphosate and AMPA residues on grapes, plums and sugar beets show the results to be similar. In both sets of data the combined residues were frequently <0.05 ppm (non-detectable) on these crops. AMPA residues were <0.05 ppm (non-detectable) in all three crops. Glyphosate residues were <0.05 ppm for sugar beets and grapes.

cc: RF,SF, C. Eiden, Glyphosate Reg. Std. File, Circ.
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