



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

DEC 15 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Dietary Exposure Analysis for Glyphosate in
Support of the Reregistration Eligibility Document

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THROUGH: James P. Kariya, Chief *Kariya* *W. B. Bunn*
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Action Requested

Provide a Dietary Risk Evaluation System analysis to estimate the worst case chronic dietary exposure and risk from glyphosate food uses that are either published, pending, or being supported through reregistration.

Discussion

1. Toxicological Endpoint: The Dietary Risk Evaluation System (DRES) chronic analysis used a Reference Dose (RfD) of 2 mg/kg body weight/day, based on a No Observed Effect Level (NOEL) of 175 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was taken from a developmental toxicity study in rabbits which demonstrated increased incidence of soft stool, diarrhea, nasal discharge, and death as effects (G. Ghali memo to J. Kariya, 12/8/92, personal communication w/ G. Ghali, 12/8/92). The Reference Dose was determined by the HED RfD Peer Review Committee on August 27, 1992.

Glyphosate has been classified as a Group E human carcinogen by the HED Carcinogenicity Peer Review Committee (Second Peer Review of Glyphosate, W. Dykstra and G. Ghali, 10/30/91).

2. Residue Information: Food uses evaluated in this analysis are the published and/or recommended tolerances being supported in the reregistration of glyphosate, as listed in Table B of the Residue Chemistry Chapter of the Reregistration Eligibility Document (RED) (R.B. Perfetti, 10/27/92). Published tolerances for glyphosate are listed in 40 CFR 180.364, 185.3500, and 186.3500. Pending tolerances for glyphosate in/on field corn and

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the kidney and liver of cattle, goats, hogs, horses, poultry, and sheep are included in the DRES analysis as well. These tolerances are to expire three years after the date of issuance of the Federal Register notice for this petition (F.D. Griffith, Jr. memo dated 7/13/90).

Feed items listed in Table B were not included in the DRES analysis, and any proposed increases, decreases, or revocations in tolerances for feed items (e.g. alfalfa, soybean hay, forage grasses) are reflected in the DRES analysis only through changes in the tolerances for meat and poultry. Glyphosate residues do not transfer to fat and therefore are not present in milk and eggs (personal communication, J. Smith, R.B. Perfetti, 11/30/92).

This DRES analysis portrays a "worst case" scenario; it includes commodities for which tolerances have been recommended for reregistration, even though registrants have not yet petitioned for such tolerances; tolerances for which revocation has been recommended but which have not yet been revoked; and tolerances pending registration. The recommended tolerances in Table B were the residue levels used in the analysis except where an existing tolerance in the file (published or pending) was greater than the residue level recommended in Table B. For instance, the existing tolerance of 0.2 ppm for kiwifruit was used in the analysis instead of the tolerance of 0.1 ppm recommended for reregistration.

In the DRES glyphosate file, if a pending or recommended tolerance for a raw agricultural commodity (RAC) was greater than the existing published tolerance, the information about the published tolerance was preserved by entering multiple listings for that commodity. For instance, in the file under "mung beans (sprouts)" there are two entries; one at 0.2 ppm which reflects the published tolerance for "seed and pod vegetables" in CFR 180.364 and the other at 4.8 ppm, reflecting the difference between the tolerance recommended as part of reregistration of 5 ppm and the existing tolerance (the sum of these two entries is equal to the recommended tolerance of 5 ppm). This was done for the commodities in the legume vegetables crop group (formerly the seed and pod vegetables crop group), the pending tolerance on field corn, and the secondary residues in the kidney and liver of cattle, goats, hogs, horses, and sheep.

There are several glyphosate tolerances existing on crop groups which are being supported through reregistration. It should be noted that in some cases the crop groups in DRES do not match the crop groups listed in 40 CFR 180.34; many of the commodities listed as being members of crop groups in the CFR do not have consumption reported in the 1977-78 USDA Nationwide Food Consumption Survey (NFCs) from which DRES consumption estimates are derived, and do not appear in DRES (e.g., arrugula or chrysanthemum, which are members of the "leafy vegetables (except Brassica) group" in the CFR). To the extent that these commodities are not included in the DRES analysis but are capable of having glyphosate residues on them and being consumed, underestimation of exposure is possible. However, most of the commodities in the CFR crop groups but not in DRES are food items normally considered as having low consumption.

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In general, there are more instances where a commodity is present in a CFR crop group and not in the DRES equivalent group than the other way around, but there are a few instances where a commodity is considered as belonging to a crop group in DRES but not in CFR 180.34. For the purpose of this analysis, members of crop groups in DRES were included only if they were also present in the equivalent crop group in the CFR (e.g., "watercress", which is a member of the "leafy vegetables (excl. Brassica)" crop group in DRES, but is not a member of the equivalent group in the CFR, was not included in the analysis). It should also be noted that the commodities "dill" and "okra", which are presently in the DRES file by virtue of belonging to the old "seed and pod vegetable" group (for which a tolerance of 0.1 ppm exists in 40 CFR 180.364), do not belong to the "legume vegetables" crop group which is recommended to replace the seed and pod vegetable group in the CFR, and would need individual tolerances if glyphosate use was to continue on those sites.

Though the existing tolerance of "mamey sapote" (*Calocarpum sapota*) is being supported through reregistration, it is incorrectly reported in Table B of the Residue Chemistry Chapter of the RED that the correct commodity definition to apply this tolerance to is "sapote". The fruit referred to in the market place as "sapote" is usually "white sapote" (*Casimiroa edulis*) (B. Schneider note to S. Schaible dated 12/1/92), which no longer is registered for use on the glyphosate label, and is recommended for tolerance revocation in Table B. Mamey sapote and sapote are not the same fruit. In addition, the DRES file had previously mapped the tolerance of mamey sapote to the DRES commodity "maney (mammee apple)", which is also incorrect according to B. Schneider's note. There is presently no DRES commodity listing for mamey sapote and this tolerance was left out of the analysis for lack of consumption information to apply the residue to. Other food commodities having glyphosate tolerances but not represented in DRES are canistel, jackfruit, and jaboticaba (revocation recommended for these three); atemoya, sapodilla, and tamarind.

The DRES commodities "horseradish" and "wine and sherry" were added to the glyphosate file for this analysis; the first directly through the published tolerance for horseradish and the second indirectly through the published tolerance on grapes. Incorrect tolerances for cane sugar, passion fruit, lychee, mamey, and longan fruit (in the DRES file prior to this analysis) were corrected to reflect the proper tolerances of the CFR (cane sugar from 0.2 ppm to 2.0 ppm, the rest from 0.01 ppm to 0.2 ppm).

A summary of the residue information used in this analysis is attached as Table 1.

3. Exposure Analysis: The DRES chronic analysis used tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 DRES population subgroups. These exposures were then compared to the RfD for glyphosate to get estimates of chronic dietary risk. A summary of the TMRCs and

their representations as percentages of the RfD are attached as Table 2.

The TMRC for the overall U.S. population from food uses of glyphosate is 0.027746 mg/kg bwt/day, which represents 1.4% of the Reference Dose. Around half of this exposure comes from the recommended tolerance on wheat. None of the subgroups has an exposure that exceeds 5% of the RfD; the subgroup most highly exposed, non-nursing infants less than one year old, has an exposure of 0.060115 mg/kg bwt/day, or 3% of the RfD.

This analysis was meant to be a "worst case" scenario of risk. The inclusion of recommended tolerances for reregistration as well as tolerances recommended for revocation; the use of the highest existing, pending, or recommended residue value for each commodity; and the assumptions of tolerance level residues and 100 percent of crop treated for every commodity result in overestimation of exposure and risk values for glyphosate (though there is also underestimation due to the lack of consumption information for some of the commodities in the CFR to which glyphosate is expected to be applied). None the less, given the risk values arrived at by this analysis, it seems that the chronic dietary risk posed by this pesticide on these food uses is minimal.

Attachments

cc: DRES, CBRS, Tox 1, Caswell # 661A

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