1-27-97

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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 1/27/97

SUBJECT: Time-Limited Tolerances for Residues of **Glyphosate** in/on **Field Corn, Sorghum, and Oat Commodities.**

DP Barcode: D231386 Caswell No.: 661A
PC No.: 417300 PRAT Case #: 280708.
Class: Herbicide
PP nos: 5F4555, 6E4645, 8F3672, 8F3673

TO: Philip Errico, Acting Manager, PM Team 25
Vickie Walters, Reviewer, PM Team 25
Registration Division (7505C)

FROM: Jim Carleton, George Kramer, Barbara Madden, Catherine Eiden, Felicia Fort, Rich Griffin, Linnea Hansen, Deborah McCall and Steve Robbins
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THROUGH: Michael S. Metzger, Acting Chief
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INTRODUCTION

Monsanto Co. is petitioning for time-limited tolerances for glyphosate in/on field corn grain, fodder, and aspirated grain fractions (PP#8F3673); grain sorghum and grain sorghum fodder (PP#8F3672); oats (PP#6E4645), and corn forage (PP#5F4555) from use of Roundup® Ultra Herbicide (524-475). The proposed tolerances for residues of glyphosate are:

Field corn grain, 1.0 ppm
Field corn forage, 1.0 ppm
Field corn fodder, 100 ppm
Aspirated grain fractions, 200 ppm
Sorghum grain, 15 ppm

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Sorghum grain fodder, 40 ppm
Oat, 20 ppm

This petition is being examined with regard to the criteria set forth in the Food Quality Protection Act (FQPA). The Registrant has submitted no new toxicology or residue chemistry data with this petition, but did include a notice of finding that covers aggregate exposure and risk assessment for glyphosate based on proposed uses.

RECOMMENDATION

HED has evaluated the petitions for the establishment of time-limited tolerances for glyphosate on field corn, sorghum, and oat commidities. At this time, no additional concerns for exposure to infants and children were identified. Estimated aggregate chronic risk from combined dietary, non-dietary, and drinking water exposures for glyphosate does not exceed HED's level of concern for establishing time-limited tolerances.

Due to the absence of human health concerns as outlined above, HED can recommend in favor of granting a one year time-limited tolerance for residues of glyphosate on field corn, sorghum, and oat commodities.

RISK CHARACTERIZATION

Dietary Risk- Food: Chronic dietary exposure estimates for published permanent and time-limited glyphosate tolerances resulted in a Theoretical Maximum Residue Contribution (TMRC) that is 3% of the reference dose. There are no concerns for acute dietary exposure at this time.

Non-occupational (Residential) Risks: Glyphosate is registered for use on non-food sites including lawns, ornamental plants, and hedgerows. However, available data indicated no evidence of significant toxicity via dermal or inhalation routes, therefore this risk assessment is not required.

Dietary Risk- Water: HED does not have available data to perform a complete quantitative risk assessment for the U.S. general population's exposure to glyphosate in drinking (ground and surface) water at this time (exposure estimates based upon limited available monitoring data are presented in Attachment II). Environmental fate data for glyphosate indicates little potential for the chemical to migrate to ground water, but some potential for residues to migrate to surface waters. Glyphosate is not highly mobile and not persistent in a soil and water environment. HED will assume that drinking water risk is 10% of the total allowable chronic risk until further data are provided.

Aggregate Exposure/Risk: Based on the available data and assumptions used for dietary/water/residential exposure and risk estimates, the population groups estimated to be the most highly exposed to glyphosate are non-nursing infants <1 year old and children 1-6 years old, with a risk estimate from combined sources equalling 13% of the RfD for chronic risk.

Occupational Exposures: Data indicated no evidence of significant toxicity via the dermal or inhalation routes; therefore occupational and residential risk assessments are not required at this time.

CONCLUSIONS

Hazard Assessment for Glyphosate

1. Occupational Exposure Endpoint Selection for Glyphosate: An Ad Hoc Toxicology Endpoint Selection Committee concluded this risk assessment is not required, based on the lack of any observable effects in a 21-day dermal toxicity study at the limit dose, and the observation of no adverse effects in a developmental toxicity study in rats up to 1000 mg/kg/day and rabbits up to ≥ 175 mg/kg/day. Therefore, worker exposure risks (MOEs) will not be calculated based on available data which indicates no evidence of significant toxicity by the dermal or inhalation routes.

2. Dietary Endpoint Selection

   a) Acute Risk No endpoint was selected by an Ad Hoc TES Committee so this risk assessment was not required.

   b) Chronic Risk. RfD = 2 mg/kg/day. On August 27, 1992, the Reference Dose Peer Review Committee recommended the RfD for glyphosate be established at 2 mg/kg/day. The RfD was based on the maternal toxicity NOEL of 175 mg/kg/day from the rabbit developmental toxicity study (MRID 00046363) using an uncertainty factor (UF) of 100. The LOEL of 350 mg/kg/day (highest dose tested) was based on treatment-related findings of diarrhea, nasal discharge, and death (62.5% of does died by gestation day 21). Developmental toxicity was not observed at any dose tested.

   c) Cancer Risk. Glyphosate has been classified as a Group E chemical (evidence of non-carcinogenicity for humans) by the Cancer Peer Review Committee (6/26/91). The classification was based on a lack of convincing evidence of carcinogenicity in adequate studies with two animal species, rat and mouse.

d) Infants and Children

i) Developmental Studies

Rat - In the rat developmental toxicity study (MRID # 00046362), the maternal (systemic) NOEL is 1000 mg/kg/day. The maternal (systemic) LOEL of 3500 mg/kg/day was based on the following treatment-related effects: diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, decreases in total implantations/dam and inviable fetuses/dam, and death (24% of the group). The developmental (pup) NOEL is 1000 mg/kg/day. The developmental (pup) LOEL of 3500 mg/kg/day was based on treatment-related developmental effects observed only in the high-dose group of: increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights.

Rabbit - In the rabbit developmental toxicity study (MRID # 00046363), the maternal (systemic) NOEL is 175 mg/kg/day. The maternal (systemic) LOEL of 350 mg/kg/day was based on treatment-related effects that included: diarrhea, nasal discharge, and death (62.5% of does died by gestation day 21). The developmental (pup) NOEL is ≥ 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxocity). Developmental toxicity was not observed at any dose tested.

ii) Reproduction Studies

Rat - A three-generation reproduction study was conducted with Sprague-Dawley rats (MRID # 00105995), the parental NOEL/LOEL is ≥ 30 mg/kg/day (highest dose tested). The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F_{3b} pups.

Since the focal tubular dilation of the kidneys was not observed at the 1500 mg/kg/day level (HDT) in the 2-generation rat reproduction (see below), but was observed at the 30 mg/kg/day level (HDT) in the 3-generation rat reproduction study, the OPP Developmental Peer Review Committee concluded that the latter was a spurious rather than glyphosate-related effect. Therefore, the parental and reproductive (pup) NOELs are ≥30 mg/kg/day.

Rat - A two-generation reproduction study was conducted

with Sprague-Dawley rats (MRID # 41621501). Treatment-related effects observed in the high dose group included: soft stools, very frequent, in the F_0 and F_1 males and females, decreased food consumption and body weight gain of the F_0 and F_1 males and females during the growth (premating) period, and decreased body weight gain of the F_{1a}, F_{2a} and F_{2b} male and female pups during the second and third weeks of lactation. Focal tubular dilation of the kidneys, observed in the 3-generation study, was not observed at any dose level in this study. Based on the above findings, the parental and developmental (pup) NOEL's are 500 mg/kg/day and the parental and developmental (pup) LOEL's are 1500 mg/kg/day. The reproductive toxicity NOEL is ≥1500 mg/kg/day.

Occupational Exposures

Available data indicated no evidence of significant toxicity by the dermal or inhalation routes. Worker risk assessment is not required, therefore this exposure has not been assessed.

Some glyphosate end-use products (non-"homeowner" usage only) are in Toxicity Categories I and II for dermal and eye irritation, and have been associated with illnesses or injuries related to skin or eye irritation (J. Evans, OREB, 11/18/92). However, under the protective clothing requirements of the Worker Protection Standard (WPS), handlers of these products are expected to be adequately protected.

Aggregate Exposure (Dietary- Food, Dietary- Water & Residential)

Dietary Exposure-Food

The nature of the residue in plants and animals, enforcement methodology and residue chemistry data in support of these petitions were all previously evaluated by CBTS (PP#8F3673, PP#8F3672, PP#6E4645 and PP#5F4555).

1. The nature of the residue in plants and animals is adequately understood and consists of the parent, glyphosate. The HED Metabolism Committee has decided that only glyphosate parent is to be regulated in plant and animal commodities, and that the major metabolite, AMPA (aminomethyl phosphonic acid) is not of toxicological concern regardless of its level in food (see Metabolism Committee Memo, R. Perfetti 3/17/94; see also Attachment I).

2. Adequate enforcement methods are available for analysis of residues of glyphosate 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 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. A GC/MS method for glyphosate in crops has also been validated by ACL (Memo, G. Kramer, 3/21/95, PP#5F04555). This method has not yet been submitted for publication in PAM-II.

3. As a result of these uses, residues of glyphosate are not expected to exceed:

Corn, field, grain, 1.0 ppm
Corn, field, forage, 1.0 ppm
Corn, field, stover, 100 ppm
Aspirated grain fractions, 200 ppm
Sorghum, grain, grain, 15 ppm
Sorghum, grain, stover, 40 ppm
Oats, 20 ppm

4. Secondary residues in animal commodities are expected from this use. However, the established and proposed livestock tolerances are adequate to cover secondary residues which may result from feeding field corn and sorghum commodities with residues of glyphosate to animals. Since no U.S registration has been proposed for oats, it has been concluded that oat feed items are not likely to enter channels of trade in the U.S.

6. Acute Dietary Risk. There is no acute dietary exposure endpoint of concern for glyphosate.

7. Chronic Dietary Risk. Chronic dietary exposure estimates (DRES) for glyphosate are summarized in Attachment III (B. Steinwand, 6/18/96). Published (permanent and time-limited) glyphosate tolerances result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percents of the RfD:

U.S Population	1%
Nursing Infants	1%
Non-Nursing Infants (<1 year old)	3%
Children (1-6 years old)	3%
Children (7-12 years old)	2%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

8. Cancer Risk. Glyphosate is classified as a Group E (non-carcinogen) chemical by the HED Cancer Peer Review Committee (10/30/91). Therefore, a quantitative cancer risk assessment is not required.

9. International Harmonization. Codex MRL's for the residues of glyphosate exist on maize and the straw and fodder, dry of cereal grains at 0.1 and 100 ppm respectively. Mexican limits on maize exist at 0.1 ppm. Canadian limits on all other food crops exist at 0.1 ppm. HED suggests the petitioner consider providing all relevant studies to Codex once the U.S. tolerances are established in order that the Codex MRLs may be amended to accommodate U.S. use needs.

Dietary Exposure and Risk Estimates- Water

HED does not have available data to perform a complete quantitative risk assessment for the U.S. general population's exposure to glyphosate in drinking (ground or surface) water at this time. Environmental fate data for glyphosate indicate little potential for the chemical to migrate to ground water, but some potential for residues to migrate to surface waters. Glyphosate is not highly mobile and not persistent in a soil and water environment. HED will **assume that drinking water risks are 10% of the total allowable chronic risk** until further data are provided. Based on analysis of water monitoring data for a large number of pesticides with varying toxicities, soil mobility characteristics, environmental fate profiles, the assumption of 10% of the total acute and chronic risk allocated to drinking water is considered conservative and protective of the public health. This exposure estimate is very conservative and will need refinement with time as more environmental fate and monitoring data on glyphosate becomes available.

Non-Occupational Exposure

Glyphosate is registered for uses on non-food sites such as turf that result in non-occupational exposures. However, since there are no toxicological endpoints for non-dietary exposures, the resulting risks cannot be assessed, therefore these exposures have not been estimated.

Total Aggregate Exposure (Dietary + Water + Residential)

a) Chronic Risk: Based on the available data and assumptions used for dietary/water/residential exposure and risk estimates, the population group estimated to be the most highly exposed to glyphosate is non-nursing infants (<1 year old), with a risk estimate from combined sources equalling 13% of the RfD (dietary = 3%

+ drinking water = 10%).

Cumulative Effects

Glyphosate is structurally similar to other phosphono amino acids like glufosinate ammonium, fosamine ammonium, and sulfosate. Further, other pesticides may have common toxicity endpoints with glyphosate.

However, the Agency has not made a determination whether glyphosate and any other pesticide have a common mode of toxicity and require cumulative risk assessment. For the purposes of this tolerance and registration application, the Agency has considered only risks from glyphosate. If required, cumulative risks will be assessed as part of Reregistration and tolerance reassessment, and when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

Determination of Safety for Infants and Children

The toxicological database for evaluating pre- and post-natal toxicity for glyphosate is considered to be complete at this time. In the rabbit, no developmental toxicity was observed at doses where significant maternal toxicity was noted (death and clinical signs at 350 mg/kg/day, highest dose tested). In the rat developmental toxicity study, maternal (systemic) toxicity was noted at 3500 mg/kg/day dose level (HDT) as diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, decreases in total implantations/dam and inviable fetuses/dam, and death (24% of the group). The developmental (pup) NOEL is 1000 mg/kg/day. The developmental (pup) toxicity was exhibited only in the high dose as increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights. However, these developmental effects were assumed to be due to the extreme maternal toxicity. No effects on reproductive parameters were observed.

In the rat 2-generation reproduction study, parental toxicity was observed at 1500 mg/kg/day as soft stools, decreased food consumption and body weight gain. The developmental (pup) toxicity was also only exhibited at 1500 mg/kg/day as decreased body weight gain of the F_{1a}, F_{2a} and F_{2b} male and female pups during the second and third weeks of lactation.

Based on the available toxicity data, HED does not have concerns regarding special sensitivities for infants and children exposed to residues of glyphosate in the diet and concludes that establishment of these time-limited tolerances should not pose an unacceptable risk to infants and children. Thus, the addition of an additional uncertainty factor will not be required.

ATTACHMENTS

I. Magnitude of the Residue - Crop Field Trials
II. Exposure and Risk Estimates from Water
III. DRES analysis for glyphosate

cc: PP#8F3673, J. Carleton (HED/OREB), G. Kramer (HED/CBTS)
RDI: Team (1/23/97), M.S. Metzger (1/27/97)

Attachment I: Magnitude of the Residue - Crop Field Trials

Magnitude of the Residue - Crop Field Trials

The following summary of residue field trial data are reproduced from previous CBTS reviews as noted below. No new residue data were presented with this revised petition.

Corn grain and fodder (W. Cutchin, 3/21/96, PP#8F03673, D216229 and D216230, CBTS No. 15700, and 15701)

The results of twelve corn residue studies were submitted. Eleven studies were conducted in Region V - Michigan, Iowa, Missouri, Illinois, Wisconsin, Indiana, Ohio, Kentucky, Minnesota, Nebraska, and South Dakota and one study in Region VI-Texas.

For each of the residue studies, there was a control plot and treated plot. Roundup® Herbicide was applied to the treated plot to mature corn plants by ground equipment at the maximum rate of 3 qt (2.25 lb ai)/A. Grain and fodder were harvested six to eight days after application. The results of the analysis indicate that residues of glyphosate on corn grain ranged from ND to 0.54 ppm averaging 0.08 ppm. The corn fodder samples had 3.7 to 92 ppm glyphosate residues averaging 35 ppm.

Processing Studies

Samples of field corn from the Iowa and Illinois studies were milled to produce corn processed commodities. The highest concentration factor was 672 on grain screenings from Illinois. The requested tolerance for aspirated grain fractions is based on the highest average field trial (HAFT) grain residue found, 0.54 ppm, multiplied by the highest concentration factor found on grain dust, 395. A tolerance on milled byproducts would be calculated from the highest average grain residue, 0.54 ppm, multiplied by the average concentration factor found on dry milled commodities, 1.12 ((1.71 + 0.52)/2), found on flour. The result of this calculation, 0.6 ppm (0.54 ppm * 1.12), is lower than the requested tolerance on the corn grain, therefore no tolerance is required for milled byproducts.

Corn Forage (G. Kramer, PP#5F04555, 3/14/96, D217539 and D217541, CBTS No. 15913 and 15914)

A total of 22 field residue trials were conducted in 1994 in 16 different states, which together accounted for 92% of the U.S. grain corn acreage in 1992 (*Agricultural Statistics*, 1993). Three different treatment regimens were employed in separate plots at each site. The spray volume was 11-22 gal/A. The interval between the early and late postemergence applications

ranged from 13-38 days. Forage samples were harvested from each treated plot 25-98 days after the final postemergence application. Fodder and grain samples were harvested from each treated plot 76-153 days after the final postemergence application or 6-8 days after the preharvest application. Samples were analyzed for glyphosate and AMPA using the HPLC-fluorometric method previously reviewed by CBTS (Memo, R. Cook 1/29/91). Analysis of the treated samples showed that the maximum glyphosate residue in corn forage was 0.82 ppm, in corn fodder was 41.2 ppm, and in corn grain was 0.36 ppm.

Sorghum (S. Willett, 4/17/96, PP#8F03672, D207119 and D207121, CBTS No. 14303 and 14304)

Roundup^{R} herbicide (41% ai) was applied using ground equipment as a single preharvest treatment at eight locations in Arkansas (1), Kansas (2), Missouri (1), Nebraska (1) Oklahoma (1), South Dakota (1), and Texas (1) in 1992. The application rates were 0.74 (Texas only) to 0.75 (0.5X) lb ai acid equivalents/acre, and 1.48 (Texas only) to 1.50 (1X) lb ae/acre, and the spray volume ranged from 10 to 20 gal/acre. Six to eight days after application of glyphosate, grain and fodder samples were harvested from control, 0.5 X, and 1X plots, and stored frozen until analyzed. Results showed that residues ranged from 1.4 to 13.5 ppm in sorghum grain, 2.9 to 33.1 ppm in sorghum fodder, and 3.1 to 37.0 ppm in sorghum hay.

Oats (S. Willett, 5/8/96, PP#6E4645, D223639, CBTS No. 16948)

Monsanto submitted residue data from trials conducted from 1993 to 1994 in Canada (MRID Nos. 43927401, 43927402), and from 1978 to 1986 in Europe (43870201, 43870202 and 43870203). All of the data have been previously reviewed by the Pest Management Regulatory Agency of Canada in support of Canadian or Codex MRL's and determined to be acceptable. Table 1 summarizes the residue data as reviewed by PMRA.[1]

[1]EPA/OPP and the Pest Management Regulatory Agency of Canada (PMRA) recently announced that it would share pesticide data reviews. See EPA Press Advisory dated Monday April 22, 1996.

TABLE 2. SUMMARY OF GLYPHOSATE RESIDUES IN OATS (INTERNATIONAL TRIALS)

Country	Rate (kg ae/ha)	# of Sites	PHI (days)	Glyphosate Residues (ppm)	Median Glyphosate (ppm)
Canada	0.9	7	7-14	3.9-6.2	3.6
Canada[1]	1.8 (2X)	1		13-16	15
Norway	1.0	4	7-15	1.0-3.1	2.2
Finland	1.08	4	7-14	2.8-13	10
Europe[2]	1.44	20	5-15	1.0-10	4.7
Germany	1.8	7	5-14	4.3-17	8.3

CBTS concludes that the residue data adequately support the requested tolerance of 20 ppm for residues of glyphosate on imported oats.[4] Additional residue data may be required in the event that a U.S. registration for use of glyphosate on oats is sought.

Processing Study Data

Oats may be processed to produce flour and groats/rolled oats. Therefore the petitioner has submitted processing study data.

Oat grain from a field trial conducted in 1981 in the U.K. (MRID No. 43870204) was processed to groats and hulls. Glyphosate residue levels in oat grain from 0.5X, 1X and 2X the European label rate [4L Roundup (1.44 kg ae)/ha] and harvested 7 days after treatment ranged from 0.8 to 11.3 ppm. Analyses of the corresponding groat samples indicated no concentration as a result of processing. Residues concentrated an average of 2.6X in oat hulls. However oat hulls are not considered to be a separate human food or animal feed item (see Residue Chemistry Guidelines, Table I, OPPTS 860.1000), and so no tolerance is needed for oat hulls. Glyphosate residue levels were not reported for oat flour in this study. However, the petitioner has referenced a wheat milling study to be used as a surrogate which has been previously reviewed by CBTS. That study indicates that glyphosate residues do not concentrate as a result of processing to flour (see 1/29/91 memo of R. Cook, PP No. 0F3865).

Monsanto has not requested import tolerances for oat forage, oat

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[1]These residue data were generated at a site in Oakville Manitoba. The plot was shorter and wider than the other sites, and required two passes with the sprayer. This possibly resulted in considerable overlap resulting in a 2X rate and higher residue values. The Canadian MRL is 10 ppm (see attachment 1).

[2]See also PP No. 2E4118, MRID No. 43827802.

[4]Draft internal guidance on data requirements for import tolerances suggests that data review of pesticides with existing U.S. tolerances and adequate toxicity studies should be minimal, and that CODEX tolerances should be adopted if possible. See 11/93 CBTS working paper.

hay or oat straw since these commodities are used typically as on-farm animal feed items, and it is extremely unlikely that these commodities would enter channels of trade in the U.S..

CBTS concurs with Monsanto's position that tolerances are not needed for oat forage, oat hay or oat straw.

Meat, Milk, Poultry, and Eggs (W. Cutchin, 3/21/96, PP#8F03673, D216229 and D216230, CBTS No. 15700, and 15701)

Feeding studies have been conducted in which cattle, swine, and poultry 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 residues were found in milk or fat at any dosing level. Only minimal residues were found in eggs and muscle at 400 ppm. Significant residue levels were found in animal liver and kidney at the 120 and 400 ppm levels (PP#6F3380/ FAP6H5502, DEB#s: 4285 and 4286, 1/30/89).

Based on the above feeding study, secondary residues from these new uses are not expected to exceed currently established animal tolerances.

Attachment II: Exposure and Risk Estimates From Water

CONCLUSIONS

Glyphosate residues can migrate to ground water and surface water as evinced from the monitoring study data available to date and presented here. However, based on the available monitoring data for drinking water sources monitored for glyphosate residues, HED does not, at this time, have a concern regarding the impacts of glyphosate residues on drinking water with respect to human health. Even at the maximum level detected in ground water reported here, glyphosate residues do not pose a human health hazard. This maximum concentration used to calculate risk is not considered typical or representative of residues of glyphosate in drinking water. Data are unavailable to assess the environmental fate (persistence and mobility) of glyphosate's main degradate (AMPA).

USE PATTERN

Glyphosate is a nonselective herbicide used in the control of perennial, deep-rooted grasses and broadleaf weeds, as well as woody brush on a wide variety of crops and non-crop areas. This use pattern may impact ground water and surface water, and ultimately drinking water. Therefore, an assessment of the risks posed to human health from the potential impact of the use of glyphosate on drinking water is required. Data are available to assess the environmental fate of glyphosate. Glufosinate, fosamine, and sulfosate are pesticides structurally related to glyphosate.

1. Exposure Estimates: Ground Water

HED has estimated the exposure and risk associated with the highest glyphosate residues detected in ground water. These calculations indicate that even at high concentrations in ground water, glyphosate residues do not pose a human health hazard.

For the purposes of these exposure estimates, a few assumptions have been made and are given below:

Water consumption is defined as all water obtained from the household tap that is consumed either directly as a beverage or used to prepare foods (such as mixing water with a can of soup) and beverages (such as diluting frozen juice concentrate). For the adult exposure calculation, the average adult body weight is assumed to be 70 kg, and it is assumed that the average adult consumes 2 liters of water (L)/day. For the children's exposure, the average body weight is assumed to be 10 kg and the average water consumption is assumed to be 1 liter per day.

The other assumption inherent in this calculation is that water from the same source containing the same contaminant level (the maximum monitored concentration available from the sources cited) is consumed throughout a 70-year lifetime. The second of these assumptions is extremely conservative, since most members of the U.S. population move at some time during their lifetime and do not live in the same area or drink from the same water source for a 70-year lifetime.

Exposure is calculated using the following formula for adults:

Exposure = (chemical concentration in ug/L in consumed water) * (10^{-3} mg/ug) ÷ (70 kg body weight) * (2 L water consumed/day)

For children, the exposure is calculated using the following formula:

Exposure = (chemical concentration in ug/L in consumed water) * (10^{-3} mg/ug) ÷ (10 kg body weight) * (1 L water consumed/day)

Adult Exposure

Glyphosate Exposure (drinking water wells @ maximum concentration detected) = (150 ug/L) * (10^{-3} mg/ug) ÷ (70 kg body weight) * (2L/day) = 4.3 X 10^{-3} mg/kg/day.

Children's Exposure

Glyphosate Exposure (drinking water wells @ maximum concentration detected) = (150 ug/L) * (10^{-3} mg/ug) ÷ (10 kg body weight) * (1L/day) = 1.5 X 10^{-2} mg/kg/day.

2. Estimated Risk: Ground Water

HED calculates a percentage of the RfD to estimate the risk for drinking water using the following formula:

%RfD = Exposure (mg/kg/day) ÷ RfD (mg/kg/day) x 100

The chronic dietary risk is calculated using the RfD of 2 mg/kg/day, established from the rabbit developmental study.

Adult %RfD (drinking water wells @ maximum concentration detected) = (4.3 X 10^{-3} mg/kg/day ÷ 2) x 100 = 0.215 %RfD

Children's %RfD (drinking water wells @ maximum concentration detected) = (1.5 X 10^{-2} mg/kg/day ÷ 2) x 100 = 0.75 %RfD

1. Environmental Fate Profile

The EFGWB One-Liner database was searched for information on the environmental fate of glyphosate. The HED Metabolism Committee has determined that the residue of concern for glyphosate is the parent molecule. An environmental fate profile for glyphosate is given below:

	Glyphosate
Solubility:	1.2 x 10^4 ppm @ 20°C
Hydrolysis:	stable (pH = 3)
	stable (pH = 6)
	stable (pH = 9)

Photolysis (water) t½: stable (pHs = 5,7,9)
Photolysis (soil) t½: 90 days
Soil t½ (aerobic): < 1-3 days
Aquatic t½ (aerobic): 7 days
Aquatic (anaerobic) t½: 1-7 weeks
Mobility: Kd = 22-90 ml/gm (slightly mobile in soils)
Field dissipation t½: range 1-several months
Aquatic dissipation: residues of glyphosate decreased rapidly from water, but persisted in pond sediments.

2. Monitoring Data: Ground Water and Surface Water

The "Pesticides in Ground Water Database" was searched for monitoring data on glyphosate residues in ground water. Information on residues of glyphosate in surface waters were not readily available within HED for this review and have not been included in this assessment.

Ground water monitoring wells (representative of drinking water) were sampled in CA (116 wells sampled from 1984-1988), MO (40 wells sampled in 1986), TX (31 wells sampled in 1988), and VA (60 wells sampled in 1987). All samples from the CA and MO wells had non-detectable residues. One sample from the TX well samples contained 150 ppb glyphosate residues, and 6 samples from the VA wells had detectable residues of glyphosate ranging from 0.004 to 0.009 ppb.

HEALTH CRITERIA

The lifetime health advisory, MCL and MCLG for glyphosate are the same and given as 700 ppb in the U.S. EPA Office of Drinking Water's "Drinking Water Health Advisory: Pesticides".

AGGREGATE RISK

For the purposes of calculating the aggregate risk from glyphosate uses, the potential risk estimated for residues of

glyphosate in drinking water as a percentage of RfD are given below:

% RfD is calculated as Exposure Estimate in Water (mg/kg/day) ÷ RfD (mg/kg/day) x 100.

The percentage of RfD is calculated for the exposure estimate for glyphosate residues in ground water for adults and children. The RfD for glyphosate is 2 mg/kg/day.

% RfD (Adults) = 4.3×10^{-3} mg/kg/day ÷ 2 mg/kg/day x 100 = <1%

% RfD (Children) = 1.5×10^{-2} mg/kg/day ÷ 2 mg/kg/day x 100 = <1%