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

471AR3
012584

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

17-APR-1998

MEMORANDUM

SUBJECT: ***GLYPHOSATE*** - Report of the FQPA Safety Factor Committee.

FROM: Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)
and
Jess Rowland, Executive Secretary
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

TO: Rick Loranger, Branch Senior Scientist
Registration Action Branch 2
Health Effects Division (7509C)

PC Code: 103601

The Health Effects Division (HED) FQPA Safety Factor Committee met on April 06, 1998 to evaluate the hazard and exposure data for Glyphosate and recommend application of the FQPA Safety Factor (as required by FQPA), to ensure the protection of infants and children from exposure to this chemical. The Committee recommended that the10x FQPA safety factor be removed since the hazard and exposure assessments for Glyphosate do not indicate a concern for potential risk to infants and children.

I. HAZARD ASSESSMENT

1. Determination of Susceptibility

The Hazard Identification Assessment Review Committee (HIARC) determined that the **data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to Glyphosate.** In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity (*Summary Provided to the FQPA Safety Factor Committee by J. Rowland*, dated April 1, 1998).

2. Adequacy of Database

There are **no data gaps** for the assessment of the effects of Glyphosate following *in utero* and/or postnatal exposure. Based on the toxicity profile for Glyphosate, a developmental neurotoxicity study in rats was not required by the HIARC.

II. EXPOSURE ASSESSMENT

1. Dietary Exposure Considerations

Established tolerances for Glyphosate are listed in 40 CFR 180.364, with values ranging from a low of 0.1 ppm to a high of 200 ppm. New tolerances have been proposed for the tropical fruits durian, mangosteen, and rambutan at 0.2 ppm. The residue of concern is Glyphosate per se (N-phosphonomethyl)glycine. The HED Metabolism Committee decided that only the parent need be regulated in plant and animal commodities (*Memorandum:* R. Perfetti, dated 03/17/94). The residues are typically systemic and while uptake from soil is limited, the residues taken up are readily translocated.

The possibility of transfer of Glyphosate residues to meat and milk exists. In feeding studies, no residues of Glyphosate were found in milk or fat at any dosing level and only minimal residues were found in eggs and muscle (at the highest dose of 400 ppm). Significant residue levels were found in animal liver and kidney, however, secondary residues are not expected to exceed currently established animal tolerances.

HED DRES system was used for the chronic dietary exposure estimate for Glyphosate (B. Steinwand on 06/18/96). Using permanent and time-limited tolerances resulted in a Theoretical Maximum Residue Contribution (TMRC) equivalent to ≤ 3% of the RfD for all population subgroups. No percent crop treated or anticipated residue data were used in the analysis. This results in an overestimate of dietary exposure since the very

conservative assumptions were made that all commodities will contain Glyphosate residues and that those residues will be at the level of the tolerance.

2. Drinking Water Exposure Considerations

Drinking water exposure estimates for Glyphosate were not available at the time of this FQPA Safety Factor Committee meeting. However, monitoring data for Glyphosate in ground water were recently used in a risk assessment establishing Time Limited Tolerances for Glyphosate on field corn, sorghum, and oat commodities. In this review, the Pesticides in Ground-Water Database (PGWDB) was searched for monitoring data on Glyphosate residues in ground water. Ground water monitoring wells 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 (*Memorandum:* J. Carlton to P. Errico dated January 27, 1997).

3. Residential Exposure Considerations

There are registered residential uses for Glyphosate (outdoor non-food sites such as turf and ornamentals), however, HIARC has determined that no risk assessments are required for short-, intermediate-, or long-term dermal or inhalation exposure to Glyphosate due to the lack of toxicity observed via these routes.

III. RISK CHARACTERIZATION

1. Determination of the Factor

The Committee recommended that the **10x factor** for enhanced sensitivity to infants and children (as required by FQPA) should be **removed.**

2. Rationale for Selection of the FQPA Factor

- There was no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to Glyphosate. In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of appreciable parental toxicity.

- The use of generally high quality data, conservative models and/or assumptions in the exposure assessment provide adequate protection of infants and children.

012584

FQPA Safety Factor Committee Meeting
06-APR-1998
Chemical: Glyphosate

Name	Division/Branch
Debbie McGlo	RD / SRRD
Will Donovan	HED/RAB1
Bill Dykstra	HED/RAB2
Nancy Dodd	HED/RAB1
Olga Odiott	HED/RAB1
Daniel Rider	EFED
Ray Kent	HED
Ed Zager	HED
WJB	HED/SAB
[illegible]	HED/[illegible]
Janet Lennon	SRRD/RB-1
Brenda Tarplee	HED

13544

032248

Chemical:	**Isopropylamine glyphosate (N-(phosphono**
PC Code:	**103601**
HED File Code	**21500 FQPA**
Memo Date:	**04/17/98**
File ID:	**TX012584**
Accession Number:	**412-02-0012**

HED Records Reference Center
03/21/2002