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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

27-AUG-1998

MEMORANDUM

SUBJECT: *CARBARYL* - 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: Whang Phang, Branch Senior Scientist
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The Health Effects Division (HED) FQPA Safety Factor Committee met on August 17, 1998 to evaluate the hazard and exposure data for Carbaryl and recommend application of the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996), to ensure the protection of infants and children from exposure to this pesticide. The Committee recommended that the 10-fold safety factor for increased susceptibility of infants and children be retained for this pesticide.

I. HAZARD ASSESSMENT

1. Determination of Susceptibility

The Hazard Identification Assessment Review Committee (HIARC) concluded that a determination of increased susceptibility for infants and children cannot be made due to critical data gaps in the toxicology data requirements. The developmental toxicity studies in rats and rabbits, as well as the 2-generation reproduction study in rats that were submitted to the Agency are unacceptable and do not meet the standard Subdivision F Guideline requirements. Therefore, an assessment of increased susceptibility could not be made for Carbaryl (*HED Doc. No. 012731*).

The Agency, however, has reviewed and accepted a developmental neurotoxicity study in rats. Although the data does not show increased susceptibility at this time, additional data are required for a final determination. The required additional data includes morphometric analyses of offspring brain measurements at the two lower doses (for complete information on the developmental neurotoxicity study for Carbaryl, refer to the HIARC report; *HED Doc. No. 012731*).

2. Adequacy of Toxicity Database

Data gaps exist for the following standard Subdivision F Guideline requirements for a food-use chemical by 40 CFR Part 158: 1) developmental toxicity study in the rat; 2) developmental toxicity study in the rabbit; and 3) two-generation reproduction study in the rat (*HED Doc. No. 012731*).

Over the past 20 years, there has been much debate about Carbaryl's potential as a developmental toxicant and whether the developmental/reproduction data base is adequate. Approximately 24 studies have been conducted in varied species, including the mouse, rat, gerbil, hamster, guinea pig, rabbit, dog, swine, sheep, and monkey. All of the studies were from the open literature. The results differed with some studies showing no reproductive or fetotoxic effects (monkey, rabbit and one guinea pig study) and some showing maternal toxicity but no developmental effects (two mouse, one guinea pig and three rat studies). Others had equivocal results due to study design and/or performance and still others showed developmental effects at doses causing maternal toxicity (one rabbit and one guinea pig study). These studies have undergone multiple internal and external reviews. Based on these internal and external reviews, the HIARC concluded that these studies are not considered to be adequate or acceptable for making regulatory decisions, specifically for determining susceptibility (for complete information on these studies, refer to the HIARC report; *HED Doc. No. 012731*).

II. EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

1. Dietary Exposure Considerations

Carbaryl is a broad spectrum insecticide registered for use on many food crops and residential uses. Permanent tolerances are established for residues of Carbaryl in/on many agricultural commodities ranging from 0.1 to 100 ppm (40CFR§80.169). Transfer of residues to meat and milk is possible and tolerances for these commodities are established. Codex MRLs have been established for numerous commodities including fruits, grains, forage/fodder, and livestock commodities.

Carbaryl is used on many foods which are highly consumed by infants and children, including bananas, citrus fruits, peaches, beans, carrots, milk, meats, cereal grains and soybeans (1993 NAS report, Pesticides in the Diets of Infants and Children). Residues of Carbaryl, however, are primarily surface residues and are, therefore, likely to be significantly removed from raw fruits and vegetables during normal preparation such as washing and peeling.

A variety of residue data sources are available for Carbaryl, including field trial data, Pesticide Data Program (PDP) monitoring data, and FDA surveillance data. Information on percent of crop treated (%CT) has been requested from the Biological and Economic Analysis Division (BEAD) for this pesticide.

PDP monitoring data (1996) indicate quantifiable residues of Carbaryl (well below tolerance level) in approximately 7% of the samples tested (342 samples with detections in a total of 4832 samples) including apples, apple juice, grapes, green beans, oranges, peaches, spinach, and sweet peas. There were no detections in carrots, sweet potatoes, and tomatoes. The rate of detection was highest for apple juice (32%) but the maximum concentration detected was 0.1 ppm.

The HED Dietary Risk Evaluation System (DRES) was used in 1990 to assess the risk from chronic dietary exposure to Carbaryl in food. The analysis was refined using anticipated residues which results in a more realistic estimate of dietary exposure. This analysis will be updated for the HED RED Chapter using monitoring data and/or available %CT information whenever possible. The acute dietary risk assessment has not yet been conducted.

2. Drinking Water Exposure Considerations

The environmental fate data base for Carbaryl is mostly complete. Some submitted studies, however, do not meet Agency data requirements. Fate data indicate that Carbaryl has slight to moderate leaching potential, however, aerobic aquatic metabolism half-life was measured at approximately 5 days indicating an overall low potential for water contamination.

Some field monitoring data are available for Carbaryl and are currently under review by EFED.

The drinking water exposure assessment for Carbaryl had not been completed at the time of this meeting (use data had not yet been received). It is expected that modeling estimates will be used for both surface and ground water in exposure assessments. Estimated Environmental Concentrations (EECs) will be calculated for ground and surface water based on the current EFED first level screening models such as SCI-GROW and GENECC respectively.

3. Residential Exposure Considerations

Carbaryl is currently registered for many residential uses including: treatment of pets and pet quarters; lawn and turf treatments; and indoor and outdoor household uses. Carbaryl is formulated as bait, spray, dust, paste, and granular. There is concern for post-application exposure to infants and children in treated areas, including incidental hand-to-mouth ingestion of the pesticide.

The residential exposure assessment for Carbaryl had not been completed at the time of this meeting. However, chemical-specific data are available for some homeowner scenarios and will likely be used along with the DRAFT Standard Operating Procedures (SOPs) for Residential Exposure Assessments to assess residential and/or post-application exposure to Carbaryl.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

1. Determination of the Factor

The Committee recommended that the **10x factor** for increased susceptibility of infants and children (as required by FQPA) should be retained.

2. Rationale for Selection of the FQPA Factor

The Committee recommended that the 10x Safety Factor should be retained because:

- ▶ There are critical data gaps in the toxicology data base for: 1) the developmental toxicity study in rats; 2) the developmental toxicity study in rabbits; and 3) the two-generation reproduction study in rats.
- ▶ A determination of increased susceptibility for infants and children could not be made due to critical data gaps in the toxicology data base.
- ▶ Considering the above toxicological data gaps, there is concern for the potential exposure to infants and children from the use of Carbaryl on foods (fruits, grains, vegetables) and from post-application exposure from uses in and around the home (pets, lawns, household).

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3. Identification of Population Subgroup

Acute Dietary: The Committee determined that the FQPA Safety Factor should be **retained (10x)** for acute dietary risk assessment for **All Populations which include Infants and Children** since the endpoint is based on alterations in the FOB parameters after a single dose in the developmental neurotoxicity study in rats; and there are critical data gaps in the toxicology data base for the prenatal developmental toxicity studies in rats and rabbits.

Chronic Dietary The Committee determined that the FQPA Safety Factor should be **retained (10x)** for chronic dietary risk assessment for **All Populations which include Infants and Children** since the endpoint is based on plasma cholinesterase inhibition in the chronic toxicity study in dogs; and there are critical data gaps in the toxicology data base for the 2-generation reproduction study in rats.

Residential Exposure: The Committee determined that the FQPA Safety Factor should be **retained (10x)** for residential dermal exposure risk assessment for **All Populations which include Infants and Children** since the potential for exposure (dermal, inhalation, and/or incidental oral ingestion) to infants and children exists during or following the use of Carbaryl in and around homes. Endpoints for short-, intermediate-, and long-term residential exposure are based on the acute and chronic reference doses (see above); and there are critical data gaps in the toxicology data base.

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FQPA Safety Factor Committee Meeting

17AUG1998

Chemical: Carbaryl

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