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MEMORANDUM

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

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and
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THROUGH: Ed Zager, Chairman
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The Health Effects Division (HED) FQPA Safety Factor Committee (FQPA SFC) met on August 24, 1998 to evaluate the hazard and exposure data for Azoxystrobin 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 should be removed for this pesticide.

I. HAZARD ASSESSMENT

1. Determination of Susceptibility

On November 7, 1996, the toxicology data base for Fludioxonil was reviewed by the HED RfD/Peer Review Committee. The Toxicology Endpoint Selection (TES) Committee met on November 12, 1996 to establish hazard endpoints for Azoxystrobin. It was determined that the available studies **indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to Azoxystrobin.** In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, any observed toxicity to the offspring occurred at equivalent or higher doses than did toxicity to parental animals (P. Hurley to FQPA SFC, Aug.17, 1998).

2. Adequacy of Toxicity Database

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

II. EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

1. Dietary Exposure Considerations

Azoxystrobin is a systemic fungicide classified as a Reduced Risk Pesticide. Permanent tolerances are currently established for residues of Azoxystrobin in/on bananas, grapes, peaches, peanuts, pecans, and tomatoes at levels ranging from 0.01 ppm to 1.0 ppm (40 CFR §180.507). Temporary tolerances have also been granted for several commodities (including meat, milk, poultry, and eggs resulting from use on rice and peanut hay). The parent, Azoxystrobin, and its Z-isomer are regulated. There are no established or proposed Codex MRLs.

Azoxystrobin is used on foods which are highly consumed by infants and children, including bananas and peaches (1993 NAS report, Pesticides in the Diets of Infants and Children). No monitoring data or percent crop treated (%CT) information are currently available for Azoxystrobin. Field trial studies, however, have been conducted in several commodities. The maximum residue value found in banana field studies was 0.27 ppm. The maximum residue value found in peach field studies was 0.74 ppm.

The HED Dietary Exposure Evaluation Model (DEEM) will be used to assess the risk from chronic dietary exposure to Azoxystrobin in food. The analysis will most likely be unrefined (using no %CT information or anticipated residues), making the conservative assumption that all commodities contain residues of Azoxystrobin at the level of the established or proposed tolerance. This results in an overestimate of dietary exposure. No acute dietary risk assessment is required since an appropriate endpoint for this exposure was not identified.

2. Drinking Water Exposure Considerations

The environmental fate data base for Azoxystrobin is complete. The environmental fate data indicate that Azoxystrobin is moderately persistent in aerobic and anaerobic soils. However the magnitude of its partitioning coefficients should limit its leaching potential into ground water. Also, since Azoxystrobin is mostly foliar applied (to treat fungus on leaves) foliar interception and subsequent photodegradation on foliage could substantially reduce the amount of this chemical reaching the soil and therefore available for leaching and runoff. Transformation products of Azoxystrobin exhibit a much lower soil/binding affinity than the parent compound, and thus possess greater potential to leach through soils.

No targeted monitoring data are available for Azoxystrobin. Therefore, the drinking water exposure assessment uses modeling estimates for both surface and ground water. Estimated Environmental Concentrations (EECs) have been calculated for ground and surface water based on the current EFED first level screening models, SCI-GROW and PRZM/EXAMS respectively.

3. Residential Exposure Considerations

There are currently no registered residential uses for Azoxystrobin.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

1. Recommendation of the Factor

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

2. Rationale for Selection of the FQPA Factor

The Committee recommended that the 10x Safety Factor should be removed. since: 1) the toxicology data base is complete; 2) the developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; 3) unrefined chronic dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure; 4) modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and 5) there are currently no registered residential uses for Azoxystrobin.

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