STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

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DIVISION OF PUBLIC ADVOCACY
ENVIRONMENTAL PROTECTION BUREAU

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Public Information and Records Integrity Branch
Information Resources and Services Division (7502C)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Attn: Docket control number OPP-2004-0347 Fluazifop-P-butyl

Dear Sir or Madam:

On behalf of the Office of the Attorney General of the State of New York, we submit these comments on the draft Tolerance Reassessment Decision (TRED) Fluazifop-P-butyl which includes the human health, environmental fate and effects risk assessments and other related documents. These comments are pursuant to the Federal Register notice of January 26, 2005 (70 Fed. Reg. 16, 3702-3704). We believe, for the reasons set out below, that the draft TRED is inadequate to fulfill EPA's obligations under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act (FQPA) to assure that Fluazifop-P-butyl tolerance levels in food are protective of public health and are safe for infants and children.

The FQPA imposes a legal mandate to apply an additional ten-fold safety factor when determining food tolerances to account for the susceptibility of infants and children (FQPA, 21 U.S.C. § 346a(b)(2)©). This factor can only be reduced or eliminated when, on the basis of reliable data, such (lesser) margin will be safe for infants and children. Id. The FQPA also requires EPA to consider, *inter alia*: (a) the cumulative effects of pesticides that have a common mechanism of toxicity with Fluazifop-P-butyl; and (b) the endocrine disruption effects of Fluazifop-P-butyl (FQPA, 21 U.S.C. § 346a (b)(2)(C)(II)). EPA has not conducted a cumulative risk assessment for pesticides with a common mechanism of toxicity with Fluazifop-P-butyl and has not fully assessed endocrine disruption effects. As required under the FQPA, the lack of such information and assessments is the very reason to apply the full ten-fold safety factor for the protection of infants and children.

(1) Lack of Cumulative Risk Assessment.

EPA did not conduct a cumulative risk assessment for pesticides that may have a common mechanism of toxicity with Fluazifop-P-butyl (e.g. aryloxyphenoxy propionate herbicides such as Diclofop, Fenoxaprop, Haloxyfop and Quizalafop). The EPA Diclofop Reassessment Decision of September 2000 indicates that this chemical has similar target organ and developmental effects as Fluazafop-P-butyl. EPA notes that a common mechanism of toxicity finding has not been made for Fluazafop-P-butyl and that for purposes of this TRED, EPA assumed that it does not have a common mechanism of toxicity with other substances (page 72). In this case, since EPA has toxicological databases for both Fluazifop-P-butyl and Diclofop, a credible cumulative assessment could, and should, be performed. EPA does not state that the risk assessment for Fluazifop-P-butyl will be reassessed when a cumulative assessment is developed.. After a cumulative assessment is performed, Fluazifop-P-butyl and other pesticides with a common mechanism of toxicity must be reassessed.

The lack of a cumulative risk assessment requires that EPA apply a ten-fold FQPA safety factor in the assessment of total dietary food risks. The TRED determined that an FQPA safety factor of one is adequate (page 19). We strongly disagree, since the lack of a cumulative risk assessment for aryloxyphenoxy propionate herbicides significantly underestimates human health risks, and in particular, the assessment of risks to infants and children consuming food containing them. The FQPA ten-fold safety factor is intended to address these uncertainties in cumulative exposures from chemicals of the same class.

(2) Lack of Evaluation of Potential Endocrine Disruption Effects.

There is some evidence presented in the TRED that indicates that Fluazifop-P-butyl is a chemical with potential endocrine disruption effects. EPA states (page 56) that *in vitro* studies did not indicate any endocrine disruption effects. However, they also note that changes in reproductive organs of the male and female were found in intermediate and long-term testing in the rat and hamster. EPA suggests that these may be due to endocrine mediated effects, yet failed to perform a full evaluation of potential endocrine disruption effects of Fluazifop-P-butyl in the TRED. The EPA acknowledges on page 56 that once EPA's Endocrine Disruptor Screening Program is developed Fluazifop-P-butyl may be subjected to screening to characterize its endocrine effects. There are test results in this TRED that raise the possibility of endocrine effects from this chemical. Given the uncertainties, EPA is required by FQPA to apply the ten-fold safety factor to account for uncertainties in this health end-point. Consequently, EPA's reduction of the tenfold safety factor is not justified.

(3) Underestimated Chronic Population Risk

EPA's assessment of chronic dietary risks for infants (< 1 year old) indicates that the estimated dose of Fluazifop-P-butyl is 94.7% of the chronic population adjusted dose (cPAD). The most significant contributors to infant dose were water, carrot babyfood, and spinach babyfood. This cPAD was based on an FQPA safety factor of 1X. If a ten-fold FQPA safety factor were applied, as required, the "risk cup" would be overfilled (947%). Without this modification, this TRED significantly underestimates potential population risks, does not propose adequate mitigation measures, and is inconsistent with the requirements of FQPA.

Fluazifop-P-butyl is used on many food crops including carrots, soybeans, onions, sweet potatoes and yams. These are important agricultural products in New York State. Fluazifop-P-butyl is used on foods eaten by children and adults, and is used on turf grasses. We are concerned that EPA has not fulfilled its mandate to protect children under FQPA because it has underestimated exposure and risks due to Fluazifop-P-butyl, and has failed to use the required ten-fold safety factor for children's health protection. By underestimating risks, EPA has not evaluated mitigation measures needed to adequately control the childhood exposures to Fluazifop-P-butyl.

Should you have any questions about the submitted information, please contact us at (518) 486-4550, and we will be happy to discuss these issues with you.

Sincerely,

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Environmental Protection Bureau

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