



STATE OF NEW YORK  
OFFICE OF THE ATTORNEY GENERAL

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Attorney General

DIVISION OF PUBLIC ADVOCACY  
ENVIRONMENTAL PROTECTION BUREAU

December 27, 2004

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-2003-0376 Carbaryl**

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 carbaryl Interim Reregistration Eligibility Decision (IREED) 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 October 27, 2004 (69 Fed. Reg. 62,663-62,666). We believe, for the reasons set out below, that the IRED 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 carbaryl 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)(c)). 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. The FQPA also requires EPA to consider the cumulative effects of pesticides that have a common mechanism of toxicity with carbaryl and consider the endocrine disruption effects of carbaryl (FQPA, 21 U.S.C. § 346a(b)(2)(D)(v) and (viii)). EPA has not conducted a cumulative risk assessment for pesticides with a common mechanism of toxicity with carbaryl and has not assessed endocrine disruption effects. As required under the FQPA, the lack of such information and assessments are 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 carbaryl (e.g. N-methyl carbamates such as oxamyl and

aldicarb). In a discussion on page 62 of the IRED, EPA states that since this is an IRED, the assessment of cumulative risks is not required, but must be completed before the final RED. We are concerned because EPA's own assessment found that the current risks of carbaryl exposure alone, without consideration of other carbamates, are unacceptable, and that changes in label uses are necessary to reduce those risks to an acceptable level. Consideration of the cumulative risks of all carbamate pesticides is likely to result in additional public health concerns and restrictions of carbaryl use, beyond the revised label restrictions proposed in this IRED.

The discussion on page 63 of the IRED indicates that EPA acknowledges that this IRED does not fully satisfy the reassessment requirements of the existing carbaryl food residue tolerances as called for by the FQPA due to the lack of a cumulative assessment. 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 IRED determined that an FQPA safety factor of one is adequate (page 13). We strongly disagree, since the lack of a cumulative risk assessment for carbamate pesticides significantly underestimates human health risks, and in particular, the assessment of risks to infants and children consuming food containing carbaryl. The FQPA ten-fold safety factor was intended to address these uncertainties in cumulative exposures from chemicals of the same class. EPA's assessment of acute dietary risks for children 1 to 2 years old indicate that the estimated dose of carbaryl is 93% of the acute population adjusted dose (aPAD). This aPAD 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 (930%). Given the lack of an assessment of the contribution of commonly used methyl-carbamate pesticides to the total dietary risk to children, this IRED significantly underestimates the potential risks and does not propose adequate mitigation measures.

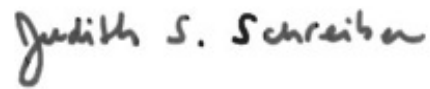
## (2) Lack of evaluation of potential endocrine disruption effects.

Carbaryl is a pesticide with potential endocrine disruption effects (Klotz,1997). EPA did not perform an evaluation of potential endocrine disruption effects of carbaryl in the IRED. The EPA acknowledges on page 84 that once EPA's Endocrine Disruptor Screening Program is developed carbaryl may be subjected to screening to characterize its endocrine effects. EPA does not have to wait to perform a preliminary assessment of carbaryl's endocrine disruption effects. The IRED should present an evaluation of the existing literature on carbaryl's potential endocrine disruption effects and characterize the likelihood of such effects occurring. No review or assessment has been presented as required by FQPA. Given that there is some evidence that carbaryl has potential endocrine effects, 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.

In summary, EPA has not fulfilled its mandate to protect children under FQPA because it has underestimated exposure and risks due to carbaryl, 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 carbaryl. Also, since carbaryl is "likely to be carcinogenic to humans" (EPA, 2004), EPA should take every step to ensure that children's exposure is reduced and that mitigation actions are protective of public health.

Should you have any questions about the submitted information, please contact us at (518) 474-9267, and we will be happy to discuss these issues with you.

Sincerely,

A handwritten signature in black ink that reads "Judith S. Schreiber". The signature is written in a cursive style with a large initial 'J'.

Judith S. Schreiber, Ph.D.  
Senior Public Health Scientist  
Environmental Protection Bureau

Karen R. Kaufmann  
Assistant Attorney General  
Environmental Protection Bureau

## REFERENCES

EPA, 2004. Environmental Protection Agency. Chemicals Evaluated for Carcinogenic Potential. Science Information Branch, Health Effects Division, Office of Pesticides Programs. Printed 12/21/04 from website.

Klotz, DM, SF Arnold, JA McLachlan. 1997. Inhibition of 17 beta-estradiol and progesterone activity in human breast and endometrial cancer cells by carbamate insecticides. Life Sci 60(17):1467-75.