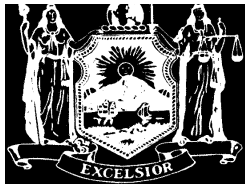

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

IOT SPITZER
orney General

DIVISION OF PUBLIC ADVOCACY
ENVIRONMENTAL PROTECTION BURE

August 4, 2006

Public Information and Records Integrity Branch
Information Resources and Services Division (7502C)
Office of Pesticide Programs
United States Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Attention: Docket OPP-2005-0174
Docket OPP-2003-0373
Comments in Support of Motion for Stay of Effectiveness of Tolerances for Sulfuryl Fluoride and Fluoride

Dear Sir or Madam:

In response to the notice published July 5, 2006 at 71 FR 38125, the Office of the New York Attorney General submits these comments in support of the Objectors' Motion dated June 1, 2006 for a stay of the effectiveness of Final Rules establishing tolerances for sulfuryl fluoride promulgated on January 23, 2004 and July 15, 2005. These Rules authorized the first food use for a chemical that was previously registered as a structural fumigant. Since sulfuryl fluoride was already registered, the manufacturer was able under the Food Quality Protection Act (FQPA) to petition the Environmental Protection Agency (EPA) for the establishment of tolerances without the lengthy and multifaceted review that accompanies new pesticide registrations.

This office has in the past commented on, and in some cases brought legal challenges to, determinations by EPA with respect to pesticide reregistration and the establishment of tolerances for several pesticides. In our view, EPA's decision to establish food residue tolerances for sulfuryl fluoride suffers from a number of serious legal, scientific and logical flaws. Taken together, these shortcomings amount to a failure to meet the basic mandates of the FQPA, in particular the requirements that EPA establish a tolerance for pesticide residue on food only if it determines that such tolerance is "safe;" and that in establishing such tolerances EPA consider the special susceptibility of infants and children. 21 U.S.C. §§ 346a(b)(2)(A)(I); 346a(b)(2)(C).

The validity and credibility of EPA's determination are seriously undermined by the agency's failure to defer its decision until it could consider two essential assessments. First, it was unreasonable to establish the tolerances at issue ahead of the March 2006 release of the National Research Council report, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* (herein "NRC report"), which EPA itself sponsored pursuant to the Safe Drinking Water Act. EPA has offered no rationale for ignoring the expert review that it requested. The agency thus deprived its decisionmaking process of the most up-to-date expert authority on the health effects of fluoride exposure, authority that actually contradicted at least two of EPA's central assumptions. For one, the NRC report concluded that the current Maximum Contaminant Level Goal (MCLG) of 4 milligrams of fluoride per liter (4 mg/L) for drinking water, on which EPA relied in setting the reference dose for the tolerance assessment, does not protect against adverse health effects and should be reduced (NRC report at 299). In addition, while the EPA assessment uses crippling skeletal fluorosis as the health effect endpoint and identifies dental fluorosis as merely a cosmetic effect (Human Health Risk Assessment dated January 18, 2006 at 4), the NRC report identified *both* dental fluorosis and skeletal effects, such as increased risk of bone fracture, as adverse health effects resulting from exposure to fluoride (NRC report at 104 and 145). Therefore, extrapolating from the conclusions of the NRC report, the tolerances established by EPA are not sufficiently protective against adverse health effects.

Second, EPA published the Final Rules establishing new tolerances for sulfuryl fluoride prior to finalizing its own Human Health Risk Assessment (HHRA), which was not released until six months later in January 2006. Although the HHRA is supposed to support the tolerance determination, the final assessment reflects a number of substantive changes from the draft released in June 2005. EPA's decision to establish new tolerances prior to finalizing the underlying health risk assessment has deprived the public of any meaningful participation in the rulemaking, and inevitably fosters the public impression that this process has been driven by the needs of the petitioner rather than by concern for the safety of the public food supply.

In addition to these serious procedural flaws, EPA's determination is substantively factually unsupported and contrary to law. The tolerances fail to meet the requirements or intent of the FQPA to establish tolerances that protect the health of infants and children. The analysis that accompanies the publication of the tolerances in the Federal Register reveals that EPA utilized a total allowable exposure of 8 mg/day for *all* population subgroups. Because an infant may weigh less than one-tenth of what an adult may weigh, this use of one absolute exposure level could result in at least ten times the allowable exposure by body weight for children as compared to adults. HHRA at 5. Yet, under the FQPA and principles of sound science, children's exposures should be *lower* per unit of body weight, given their developing body systems.

In addition, contrary to the principle underlying the requirements of the FQPA, the tolerance assessment at issue wrongly assumes that there is no special susceptibility of infants and children to the adverse health effects of fluoride exposure. By ignoring dental enamel fluorosis as a health effect, EPA fails to take into account the occurrence of this condition while the teeth are being formed, from birth to age 8. NRC report at 298. With respect to skeletal

fluorosis, EPA reaches the wholly illogical conclusion that, because that effect takes ten years of exposure to manifest itself, young children need no special protection from fluoride exposure. HHRA at 19. This conclusion flies in the face of the obvious need to protect children from *developing* adverse health effects.

Similarly unsupportable is EPA's waiver of the requirement for a developmental neurotoxicity study (first publicized in January 2006 as Appendix 1 to the HHRA), given NRC's finding that a neurotoxic effect is suggested by some studies and requires further investigation. NRC report at 187. Tellingly, the Federal Register notice announcing the newly-established tolerances in July 2005 stated that a developmental neurotoxicity study would be required as a condition of registration, 70 FR 40903, even though the waiver decision had been made in April 2004.

Other shortcomings of the tolerance assessment include the following:

$ Failure to adequately assess aggregate and cumulative exposures to fluoride. The established food residue tolerances in conjunction with other fluoride sources (such as drinking water and toothpaste) can result in exposure greater than the current reference dose of 8 mg/day merely, for example, by ingesting more than two liters of water. Aggregate and cumulative exposures have been drastically underestimated for subsets of the population under varying circumstances. For instance, individuals who consume larger volumes of water than the estimated 2 L/day, which would likely include athletes, outdoor workers and those with diabetes insipidus, will accumulate more fluoride and reach critical concentrations of fluoride in their bones, compared to the average drinker. NRC report at 298. It is estimated that in individuals with high water intake levels, drinking water would contribute 92% to 98% of their total fluoride exposure, at 4 mg/L, and 86% to 92% at 2 mg/L. Id. Water intake is only part of the total dietary exposure to fluoride, while other non-dietary exposures to fluoride must also be considered.

$ Failure to set protective tolerances. The remarkably high tolerance for dried or powdered eggs – 900 ppm – results, EPA explains, from the propensity of this compound to accumulate in foods of high fat and protein content, HHRA at 21, producing a high amount of residue under normal fumigation practices. Yet the FQPA requires tolerances to be set at levels "safe" for human health, not safe for existing industry practices. Tolerances are also too high for commodities common to many foods that the general population, including children, ingests, such as wheat flour at 125 ppm. As pointed out in the Objectors' motion, if a 25 kilogram child were to eat 4 slices of bread (about 100 grams of wheat) that contained wheat flour fumigated at the allowable tolerance, the child would be ingesting about 12 milligrams of fluoride (0.5 mg/kg-body weight)(motion at 21-22), immediately exceeding the reference dose of 8 mg/day by 50%.

$ Lack of monitoring data to adequately characterize fluoride levels in food and feed may lead to underestimated exposures. Based on communication between this office and EPA staff, there appears to be no available monitoring data for sulfuryl fluoride in

commodities. EPA should conduct more extensive monitoring to determine residue levels in commodities, rather than relying solely on the residue data submitted by the manufacturer.

In sum, because we believe the Objectors' motion has merit, this office supports their request that the tolerances at issue be stayed. Thank you for the opportunity to submit these comments. Please feel free to contact Karen Kaufmann at (518) 486-4550 if further information is required.

Sincerely,

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