



May 24, 2006

Stephen L. Johnson, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator Johnson:

We Local Presidents of EPA Unions representing scientists, risk managers, and related staff, are writing to express our concern that EPA could betray the public trust by violating the intention of the Food Quality Protection Act (FQPA) to protect the Nation's infants, children, and susceptible subpopulations, unless the Agency adheres to principles of scientific integrity and sound science in the pesticide tolerance reassessments it is undertaking.

There are more than 20 neurotoxic organophosphate (OP) and carbamate pesticides scheduled for final tolerance decisions by EPA no later than August 3, 2006, as required by the FQPA. During the 1990s, the Agency reached partial cancellation agreements with the registrants of certain OP pesticides, such as chlorpyrifos, methyl parathion, and diazinon, based on compelling information that these neurotoxic pesticides damage the developing nervous system of fetuses, infants and children (an effect known as "developmental neurotoxicity").

Those actions were consistent with the overarching precautionary intent of FQPA which requires that, in the absence of reliable data on toxicity or exposure, the Agency must ensure an adequate margin of safety for the health of the nation's infants, children, and susceptible subpopulations through the use of uncertainty factors in relevant analysis.

Accordingly, as EPA approaches the August 2006 statutory deadline for the determination of final tolerances for the remaining OP and carbamate pesticides, we urge the Agency to adhere to its principles of scientific integrity and employ the precautionary approach intended by the FQPA in assessing the cumulative and aggregate exposure and risk from the uses of these neurotoxicants. This approach – compliance with the FQPA and our principles of scientific integrity - is the only way to remain faithful to the public trust and ensure that our children will not be exposed to pesticides that may permanently damage their brains and nervous systems.

The partial cancellation agreements of the 1990's mostly addressed residential exposures, but did not adequately consider continued exposure through foods eaten. As risk assessors, we continue to be troubled by the Agency's failure to adequately consider exposure to neurotoxic pesticides by infants and children who commonly enter fields treated with these pesticides while accompanying their parents employed to perform post-application tasks. The children of farmworkers, living near treated fields, are also repeatedly exposed through pesticide drift onto outdoor play areas and through exposure to pesticide residues on their parents' hair, skin, and clothing.

Additionally, we are concerned that unborn fetuses may also be exposed to these neurotoxicants when pregnant women are employed to handle (mix, load, apply) these pesticides or are employed to enter treated areas to perform hand labor tasks following pesticide applications.

The Agency's own Scientific Advisory Panel (SAP) has expressed concern that the Pesticide Program's current approaches may not be sufficiently conservative, may underestimate the risks to infants and children, and do not adequately identify individuals that may be inherently sensitive to neurotoxicants. (May 25, 1999 SAP meeting)

We are confident that you share our sense of urgency about taking the necessary actions to protect the health of our Nation's children. As you are aware, in August 1999, EPA informed the public that it was issuing data call-in notices to pesticide registrants of cholinesterase-inhibiting OP pesticides and requiring submission of data on developmental neurotoxicity.

We are concerned that the Agency has not, consistent with its principles of scientific integrity and sound science, adequately summarized or drawn conclusions about the developmental neurotoxicity data received from pesticide registrants. Our colleagues within the Agency, including EPA's Inspector General (EPA IG), believe that it would be premature to conclude that there is a complete and reliable database on developmental neurotoxicity of pesticides (see Attachment) upon which to base any final tolerance reassessment decisions as required by the FQPA. Consequently, EPA's risk assessments cannot state with confidence the degree to which any exposure of a fetus, infant or child to a pesticide will or will not adversely affect their neurological development.

As you also know, in the absence of a robust body of data, FQPA requires EPA to use an additional 10-fold safety factor in its risk assessments when setting pesticide tolerances. Thus both statutory language and sound science require that the Agency continue to retain the 10-fold safety factor as a precaution when reassessing the tolerances for the remaining OP and carbamate pesticides given the existing uncertainty about developmental neurotoxicity.

Many influential proponents of agriculture have repeatedly expressed their concerns to EPA about properly coordinating with agricultural stakeholders, the U.S. Department of Agriculture (USDA), and producers when implementing FQPA. It appears that the Agency has inadvertently taken this to mean that the concerns of agriculture and the pesticide industry come before our responsibility to protect the health of our Nation's citizens. We are concerned that the

Agency has lost sight of its regulatory responsibilities in trying to reach consensus with those that it regulates, and the result is that the integrity of the science upon which Agency decisions are based has been compromised.

Our colleagues in the Pesticide Program feel besieged by political pressure exerted by Agency officials perceived to be too closely aligned with the pesticide industry and former EPA officials now representing the pesticide and agricultural community; and by the USDA through their Office of Pest Management Policy. Equally alarming is the belief among managers in the Pesticide and Toxics Programs that regulatory decisions should only be made after reaching full consensus with the regulated pesticide and chemicals industry.

In the rush to meet the August 2006 FQPA statutory deadline, many steps in the risk assessment and risk management process are being abbreviated or eliminated in violation of the principles of scientific integrity and objectivity by which we as public servants are bound. Congress specifically asked EPA to take reasonable action to reduce the risk of pesticides for infants and children where existing uses posed a concern. We should honor the charge from Congress to protect the public health, unencumbered by political influences; therefore, at this time, we do not believe that the Agency should make any final tolerance reassessment decisions.

We therefore request the following:

1. Where data are insufficient for decision-making, that you make decisions based on the Precautionary Principle and add appropriate uncertainty factors to protect human health in conformity with the FQPA and our principles of scientific integrity.

2. Where developmental neurotoxicity studies are absent, it is imperative that the Agency continue to retain the 10-fold safety factor - if not increase it - as a precaution, when making final reregistration decisions for OP and carbamate pesticides.

3. That EPA issue an interim reregistration decision mandating that maximum protections - engineering controls for handlers and longer re-entry intervals for postapplication labor- be put into place for agricultural uses of these pesticides; where this is not feasible, cancel these registrations, as EPA promised before. EPA issued PR Notice 2000-9 in 2000 to this effect (Worker Risk Mitigation for Organophosphate Pesticides: http://www.epa.gov/PR_Notices/pr2000-9.pdf), but then never carried through on this: (<http://www.epa.gov/pesticides/factsheets/opworkers.htm>)

In its response to comments on this PR notice, EPA stated that the Agency will seek cancellation of uses if available risk mitigation measures, such as engineering controls and extended REI's, do not provide an adequate margin of safety and the risks outweigh the benefits: (http://www.epa.gov/PR_Notices/draftprworker-response.htm)

Six years is an unacceptably long wait. It is time to act now, and act responsibly.

4. That you take steps to ensure that the Agency consider non-pesticide chemicals - industrial

Attachment 1

Examples of support for the conclusion that EPA cannot yet ensure that fetuses, infants and children will not suffer developmental neurotoxicity from exposure to neurotoxic pesticides:

(1) The January 10, 2006 Office of Inspector General Report, "Opportunities to Improve Data Quality and Children's Health through the Food Quality Protection Act" (see <http://www.epa.gov/oigearth/reports/2006/20060110-2006-P-00009.pdf>). It states that:

EPA's required pesticide testing does not include sufficient evaluation of behavior, learning or memory in developing animals.

EPA has no standard evaluation procedure for interpreting results from DNT tests.

EPA has not yet summarized or drawn conclusions about DNT which it has collected for pesticides.

(2) Not all scientists are in agreement with EPA that developmental effects of the OP pesticide chlorpyrifos occur only at doses above those which cause cholinesterase inhibition, or even that they occur exclusively through the mechanism of cholinesterase inhibition. (see for example: Cholinergic systems in brain development and disruption by neurotoxicants: nicotine, environmental tobacco smoke, organophosphates, *Toxicol. Pharmacol.* 198: 132-151 (2004); Guidelines for developmental neurotoxicity and their impact on organophosphate pesticides: a personal view from an academic perspective, *Neurotoxicology* 25(4): 631-640 (2004).

(3) EPA has data demonstrating that the immature are more sensitive to the OP pesticide malathion than adults (see for example Developmental Neurotoxicity Study in Rats, August 22, 2002. Memorandum. MRID 45646401; and Special Study, Effects on Cholinesterase Inhibition in Adult & Juvenile CD Rats, Companion Study to Developmental Neurotoxicity Study 870.6300., Tox Review No. 0050550, MRID No. 45566201).

(4) EPA has also received, but has not released for review by the SAP or external parties, data suggestive of direct effects of malathion on brain structure concurrent with cholinesterase inhibition and changes in behavior (personal communication, Dr. Brian Dementi; see also paragraphs #8, 9, 11, 12, 13, and 17 of the June 20, 2005 letter to you from Dr. Dementi in which he advised you of these concerns).

(5) More data are accumulating indicating differential sensitivity to other OP pesticides greater than the 10-fold safety factor required by FQPA (see for example Paraoxonase

polymorphisms,
haplotypes and enzyme activity in Latino mothers and newborns, *Pharmacogenetics and Genomics* 16: 183-190 (2006).