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Toxic Chemicals & Health: Kids' Health: In Depth: Comments Developmental Neurotoxicity Data Gaps and the Children's 10X Safety Factor

May 12, 1999

This is a letter submitted to the U.S. Environmental Protection Agency by the following groups: the Learning Disabilities Association of America, Consumers Union, the Natural Resources Defense Council, the Science and Environmental Health Network, Physicians for Social Responsibility, and the U.S. Public Interest Research Group.

May 12, 1999

The Honorable Carol Browner
Administrator, Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Developmental Neurotoxicity Data Gaps and the Children's 10X Safety Factor

Dear Administrator Browner:

As organizations devoted to public health, the health and safety of children and the environment, we are deeply concerned that EPA intends to depart from the additional tenfold safety factor for the vast majority of pesticides used on food. As you know, this children's safety factor was prescribed under the Food Quality Protection Act of 1996 (FQPA) to take into account potential pre -- and post -- natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children. We are especially dismayed about EPA's treatment of the 39 organophosphate insecticides (OPs) used or found on foods. OPs are designed specifically to act on the nervous system, yet EPA lacks data from developmental neurotoxicity (DNT) testing -- using EPA's validated protocol -- for all but one. Without these data, of critical importance to the actions of these pesticides, EPA cannot assure the public that pesticides exposures will not compromise human brain development.

EPA indicates it will retain the children's 10X safety factor for just five of the 28 OPs for which the Agency has released preliminary risk assessments. Organophosphates kill pests by disrupting the brain and nervous system. It is well established that developing animals are more sensitive than adults in a laboratory setting to acute toxicity from cholinesterase -- inhibiting chemicals, like the OP and carbamate insecticides.^[1] Recent studies add to significant evidence that cholinesterase -- inhibiting chemicals may adversely affect brain development in young animals through multiple pathways.^[2] For organophosphates, however, EPA only requires neurotoxicity tests performed in adult animals. EPA has had an extensively validated Developmental Neurotoxicity Test Guideline (OPPTS 870.6300) since 1991, but it is not a "core" or required test for pesticides. EPA

has received a complete DNT test, using its validated protocol, for just one of the 39 OPs used or found on foods or in homes.

EPA's intention to drop the child's safety factor for most OPs, despite the failure to test these chemicals for toxicity to the developing brain and nervous system, disregards recommendations by both EPA scientists and outside scientists, as well as strong scientific evidence that EPA's current core tests for pesticides are inadequate to assess developmental neurotoxicity. You convened an internal EPA Task Force on February 25, 1998 to address the FQPA requirements, and in part to address the lack of DNT data for pesticides. In December, the Toxicology Work Group of your Task Force gave to the SAP a draft recommendation that EPA's core data requirements for pesticides should include developmental neurotoxicity testing for all "conventional chemical" food use pesticides. The Toxicology Working Group also found that "the need for a developmental neurotoxicity study was [previously] based on criteria or triggers. More recent information suggests that these triggers may not be inclusive enough to signal all chemicals that have the potential to produce developmental neurotoxicity."ⁱⁱⁱ On this basis, presumably, three senior EPA administrators signed a October 1998 memorandum stating that EPA "intends to propose extension of its core data requirement to include developmental neurotoxicity testing."^{iv} EPA staff now indicate, however, that the addition of DNT testing to core requirements might only apply to **new** pesticides, and this has us concerned.

The National Research Council also recommended in 1993 that developmental neurotoxicity data be included in pesticide evaluations.^v And in March 1998, the FIFRA Scientific Advisory Panel reported, "One point of consensus is that the developing human, especially its nervous system, is vulnerable to a variety of toxicants, both pesticides and non -- pesticides, and is certainly deserving of our best efforts to afford it protection with the intent of the 1996 FQPA."

Although 350 pesticides are registered for use on food alone, companies have submitted developmental neurotoxicity test results for just nine pesticides, as well as for three solvents. In December 1998, EPA's Dr. Susan Makris, presented to the SAP the results of a study reviewing testing for these 12 chemicals. The study suggests that for many chemicals the Agency's core or required tests will be less sensitive than the DNT protocol for assessing many toxic effects, including a pesticide's effect on the developing brain and nervous system.^{vi} It is apparent therefore that EPA's current test protocols are not sufficient to protect against a pesticide's possible effect on brain development in humans.

EPA's assertion that the lack of relevant developmental neurotoxicity data for nearly every OP somehow provides the scientific basis for removing the additional tenfold safety factor is even more astounding since the scientific record on other developmental neurotoxins -- including PCBs, mercury and lead -- clearly shows that *even with DNT data*, far more than a tenfold safety factor is needed to adequately protect the human population from the serious harm of developmental neurotoxins.^{vii} In the absence of DNT data, therefore, an additional tenfold safety factor is not arbitrary and unnecessary. Rather, it is much -- needed and clearly supported by a sizable body of science.

Finally, EPA's eagerness to depart from the child's 10X safety factor for OP insecticides is suspect in light of human data showing that pesticide exposures already contribute to neurodevelopmental problems in children. For example, one study has linked pesticide exposures among Mexican children in an agrarian region to "decreases in stamina, gross and fine eye -- hand coordination, 30 -- minute memory, and the ability to draw a person."^{viii}

Given the scientific support for a requirement that all pesticides be assessed for toxicity to the developing brain and nervous system, including recommendations from the National Academy of Sciences and your own internal Task Force, the absence of DNT testing for almost every OP constitutes a clear data gap in assessing these pesticides for child's safety. EPA's intention to drop the 10X for most OPs therefore disregards the intent and

spirit of the FQPA, which states: "Ö.an additional tenfold margin of safety for the chemical residue, and for other sources of exposure **shall** [our emphasis] be applied for infants and children to take into account potential pre -- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." The absence of DNT data -- particularly for organophosphates and other insecticides specifically designed to be neurotoxic -- requires the retention of the mandated additional 10 -- fold safety factor.

In summary, we urge the following:

- EPA should move directly to include developmental neurotoxicity as part of changes to 40 CFR Part 158 requirements being submitted to OMB. EPA had indicated these revisions were to be submitted to OMB in November 1998, but to our knowledge have not been. We are especially concerned since EPA's previous revisions to 40 CFR part 158 pesticide testing requirements, published in September 1994, have yet to go to OMB nearly five years later.[\[ix\]](#)
- Since 40 CFR part 158 requirements may only be applied to new pesticides, the Agency should move immediately to also require chemical -- specific data on developmental neurotoxicity for pesticides currently found in drinking water sources, or used on food crops, topically, in hospitals, schools, homes or other residences, and other uses likely to result in children's exposures.
- EPA must retain the additional FQPA 10-fold safety factor while waiting for DNT results, and while these chemicals remain in use, to assure that EPA's regulatory decisions are protective of children.

Some pesticides have been registered for use in homes and on food for thirty or even forty years. EPA has had a good, validated DNT test protocol for eight years. Further delay in initiating DNT testing, or while waiting for a better test protocol, could result in considerable, and preventable, harm to children. Even if developmental neurotoxicity testing on new and old pesticides were to commence immediately, we have serious concerns that EPA might not receive DNT test results for several years while children's exposures to these pesticide would continue. EPA must retain the FQPA 10X safety factor, therefore, while awaiting the results of DNT testing. This is exactly the situation for which the FQPA's public health protections were put in place.

We look forward to your reply. Please direct any inquiries to Barbara McElgunn, R.N., at the Learning Disabilities Association of America or David Wallinga, M.D., at the Natural Resources Defense Council.

Sincerely,

Harrison Sylvester President Learning Disabilities Association of America	Gene Karpinski Executive Director U.S. Public Interest Research Group
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David Wallinga, M.D. Senior Scientist Natural Resources Defense Council	Robert K. Musil, Ph.D. Executive Director Physicians for Social Responsibility
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Edward Groth III, Ph.D. Director, Technical Policy and Public Service Consumers Union	Ted Schettler, M.D., M.P.H. Science Director Science and Environmental Health Network
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- iv. USEPA, Update and Implementation Plans for the Child Safety Factor of the Food Quality Protection Act, Memorandum from Lynn Goldman, OPPTS, Henry Longest II, ORD and Ramona Trovato, OCHP to EPA Administrator, October 14, 1998.
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- vi. Makris, S., Raffaele, K., Sette, W., Seed, J., A retrospective analysis of twelve developmental neurotoxicity studies submitted to the USEPA Office of Prevention, Pesticides and Toxic Substances (OPPTS), Presented to the Science Advisory Panel, December 8-9, 1998.
- vii. See Rice, D.C., Evangelista de Duffard, A. M., Duffard, R., Iregren, A., Satoh, H., Watanabe, C., Lessons for Neurotoxicity from Selected Model Compounds: SGOMSEC Joint Report, *Environ Health Perspect* 104(Suppl2): 205-215 (1996). The authors concluded:

The ability of animal studies to predict intake levels at which human health would be protected is less encouraging. It is clear from comparison of the human and rodent data that results from rodent studies often vastly underestimated intakes at which neurotoxicity was observed in humans. For PCBs, the difference in the estimated acceptable intake between humans and rodent developmental data is 3 to 4 orders of magnitude, while for methyl mercury the difference is two orders of magnitude or greater for most studies. For lead, deficits were revealed on activity and simple learning tests at doses that would also result in allowable intakes much higher than those at which cognitive impairment has been demonstrated for children. One conclusion that may be drawn from this analysis is that current methods of calculating acceptable intakes based on animal data, exemplified for sake of discussion by current practices in the United States, are insufficient to protect the human population against behavioral toxicity.
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