

February 28, 2004

The Honorable Michael Leavitt
Administrator
U.S. Environmental Protection Agency
Office of the Administrator
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Finalization of Revisions to 40 CFR Part 158: Toxicity Testing Requirements to include developmental neurotoxicity testing

Dear Administrator Leavitt

Close to one in five American children suffer from one or more disorders of learning, behavior and development. The consequences of these developmental disorders are lifelong, often having serious consequences for both the child and his/her family, and very costly for society. The causes of most developmental disorders are unknown, while there is some evidence that incidence rates are increasing. A U.S. National Academy of Sciences report in 2000 estimated that 3% of neurobehavioural disorders are caused directly by toxic environmental exposures, and that another 25% are caused by interactions between environmental factors (defined broadly), and genetic susceptibility of individual children.

As organizations devoted to public health, the health and safety of children and the health of the environment, we urge you to promptly finalize and sign the long-delayed revisions to 40 CFR Part 158 regulations for the toxicity testing of pesticides prior to their registration or their re-registration. These revisions were first proposed in 1994 and include developmental neurotoxicity data as core requirement for pesticides to address potential toxicity to the nervous system. In November 1994, the FIFRA Scientific Advisory Panel (SAP) endorsed these revisions. Yet they were never signed or finalized.

Since 1998, EPA has been signaling its intent to finally complete the revisions, promising at one point to do so by spring 1999. The agency, to its credit, promises to make the latest revisions reflective of the newest science. For example, EPA promises to add requirements that all new pesticides be tested for toxicity to the developing nervous system, and has issued a data call-in to registrants requiring these data for classes of neurotoxic pesticides.

In 1993 the National Academy of Science reported that exposure to neurotoxic compounds, at levels believed to be safe for adults, can result in permanent loss of brain function if occurring during the prenatal and early childhood periods of brain development. In addition, it has been well established in the laboratory that developing animals are more sensitive than adults to acute neurotoxicity from cholinesterase-inhibiting chemicals, like the organophosphate and carbamate insecticides – widely used in schools, around homes and on agricultural crops. For example, pups exposed to Malathion via maternal exposure were 16 times more sensitive to cholinesterase inhibition than adult animals. Recent studies also add to the substantial body of evidence that

cholinesterase-inhibiting pesticides may adversely affect brain function, but also brain morphology during development through multiple pathways.

In 1998, EPA scientists compared the results of all developmental neurotoxicity testing submitted to EPA to date, including nine pesticides. The review suggested that for many chemicals the Agency's current core battery is less sensitive than would be a revised battery including DNT testing, for assessing many toxic effects including effects on the developing brain and nervous system. 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. The Agency's Toxicology Working Group concluded in November 1998 that "40 CFR Part 158.340 (Subpart F) should be updated as soon as possible to include the adult and developmental neurotoxicity guidelines..." In March 1998, the FIFRA Scientific Advisory panel unanimously recommended that EPA consider requiring DNT testing for all neurotoxic insecticides, with a portion of the panel urging a DNT testing requirement for all pesticides.

On May 12, 1999, the Learning Disabilities Association and other science and public interest groups wrote to the Agency urging that "EPA should move directly to include developmental neurotoxicity as part of changes to 40 CFR Part 158 requirements being submitted to OMB."

EPA is obtaining neurotoxicity data for one class of the eleven classes of registered pesticides with neurotoxic actions. However the DCI only applies to pesticides known to have neurotoxic properties, and already on the market; it fails to answer the need for developmental neurotoxicity data for new pesticides being registered, old pesticides undergoing re-registration, or during reassessments under the FQPA. Until the proposed expansion of the core data requirements to include testing for toxicity to the developing nervous system becomes policy, it is very possible that the risks from pesticide exposures to children's neurodevelopment are being underestimated.

In summary, we request that the Agency give the highest priority to finalization of its proposed revisions to 40 CFR Part 158 testing requirements. Just as importantly, these revisions should be forwarded immediately to the Office of Management and Budget for approval.

The scientific and public health imperative for greater pre-market testing of pesticides has only strengthened in recent years. A higher minimum level of testing is need to meet the public health imperative in the Food Quality Protection Act of 1996, that registered pesticides carry a "reasonable certainty" of no harm to infants and children.

Please direct any questions to Lynne Cannon at (319) 338 0438, or Barbara McElgunn at (416) 281 9676, Learning Disabilities Association of America, 4156 Library Road, Pittsburgh, PA 15234.

We look forward to your reply.

Sincerely,

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References