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November 30, 2004

The Honorable Michael Leavitt
Administrator
Environmental Protection Agency
Washington, DC 20460

Dear Mr. Leavitt:

We are writing to inquire about the Longitudinal Field Measurement Study of Infant and Toddler's Aggregate Exposure to Pesticides and Persistent Pollutants the Agency planned to initiate this fall with the Centers for Disease Control, the Duval County Florida Health Department and the American Chemistry Council. We are encouraged by the recent decision to postpone this study. The Agency's intention of directing a study focused on children of such a young age to chemical exposures raises a number of questions and concerns.

Dr. Farland's November 8 memorandum to EPA employees states the study design has been reviewed by four Institutional Review Boards (IRBs) for technical merit and ethical protections. Please provide us with documents from these four reviews including the charge to the committees and the final reports of the IRBs. The memorandum also indicated EPA's intention to submit the study review to a new committee whose membership will be drawn from three existing EPA advisory boards.[1] All of these committees are advisory committees under the Federal Advisory Committee Act (FACA).

1) Will the review committee also be an advisory committee governed by FACA? We believe it should be to ensure transparency in the deliberations on this project.

We have several questions about the information EPA will provide to participants in the study during the recruitment process and during the course of the study. The November 8, 2004 Fact Sheet prepared by the Office of Research and Development[2] contains information that appears inconsistent with the Study Design.[3] The original study design requires selecting a majority of families for monitoring who have "high" pesticide use and who will receive exposures at a level to ensure that, "a high proportion of both environmental and biological samples have measurable

[1] The Science Advisory Board, the Science Advisory Panel authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Children's Health Protection Advisory Committee.
[2] FACT SHEET, A Children's Environmental Exposure Research Study – CHEERS, National Exposure Research Laboratory, Office of Research and Development, November 8, 2004, 10p.

levels of pesticides."[4] The Fact Sheet, however, states that: "Participants who are found to have high pesticide exposures or who are inappropriately using pesticides will be contacted immediately and educated in the proper and safe use of pesticides." It appears that "high" levels of use and exposure are required to obtain useful samples for analysis. The analytical needs of this study appear to conflict with the Agency's stated goals of ensuring a minimal risk to study participants. We would like clarification of the Agency's definitions of "high" for both use and exposure to the products in this study:

2) How does the Agency define "high" use of pesticides in cases where the participant's use of pesticides is in accordance with the product label instructions?
3) How does the Agency define "high" exposure to pesticides in cases where the exposure does not exceed the dose levels used for exposure risk assessments?
4) Does the Agency intend to retain the original eligibility criteria for the study and select participants determined to have "high" pesticide use?

Additionally, we have questions regarding the information the Agency intends to supply to potential participants regarding the risk of pesticide use and exposure. Question 9 of your "Question and Answers" for potential recruits to the study: "Is there a risk to my family?" is answered by: "No. You and your child will not experience any risks from participating in this study."

For sometime now the public health community has argued that children are a subpopulation of special vulnerability to chemical exposure, implying that low exposures are preferable to high ones. Yet this study is selecting and monitoring infants and toddlers living in homes that EPA identifies as having higher than average exposure levels. It is true that participant families will incur no **additional** risk because they are participating in the study. However, we feel these families should be reminded that all levels of pesticide use involve some risk, their family's use of pesticides has been identified as higher than average, and infants and toddlers are considered to be especially vulnerable to chemical exposure.

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[3] National Exposure Research Laboratory, "Longitudinal Field Measurement Study of Infant and Toddler's Aggregate Exposure to Pesticides and Persistent Pollutants: Peer Reviewed Study Design," September 30, 2002.
[4] Ibid. Section 3.2.1: Eligibility Criteria, page 16. Page 16 states: "A high frequency of detection is important, for example, to evaluate the factors that affect exposure. Therefore, the study will be performed in residences expected to have high pesticide use based on pesticide frequency and patterns of use as reported by the participants and results of a screening visit to the potential participant's home."

The Fact Sheet indicates the Agency intends to educate the participants on the proper use of pesticides and to correct any misuse of pesticides identified during the course of the study. The Fact Sheet did not indicate whether the Agency intends to inform participants that their pesticide use is higher than average and may pose a risk to them.

5) What general information regarding the risks of pesticide exposure to infants and children will be supplied to the participants in the study?
6) Will participants be informed of their pesticide use level (high, medium, or low) relative to that of other participants and to average pesticide usage for their region?

We also have several questions relating to the presentation of information resulting from the testing of metabolites in urine samples. The Fact Sheet indicates that metabolites will be compared to Dose Levels used for exposure risk assessments for organophosphate and pyrethroid pesticides. It is unclear from the study design and the Fact Sheet how the dose levels relate to the measurements of metabolites in urine and how this information would translate into a potential for future harm to health. Our knowledge of the linkage between metabolites in urine and specific health outcomes is limited. In contrast, studies of a substance such as lead would permit researchers to relate levels present in the home, levels present in the blood, and the potential for specific health outcomes.

7) Does EPA's information permit researchers to determine a potential health risk associated with the presence of a particular level of chemical metabolite/s detected in the child's urine sample?
8) How will information about environmental and biological exposure measures be presented and interpreted to the families in the study?
9) Does EPA anticipate that any of the chemicals monitored in this study are among those that accumulate in human tissues?
10) Are the biological sampling methods used in this study capable of detecting accumulation of chemicals in body tissue? If so, has EPA defined a level where impairment of health would be expected?

We appreciate the difficulty of obtaining information through scientific study of realistic human exposures to chemicals. We also understand EPA's desire to have its regulatory decisions rest upon good information. However, human health – especially the future health of infants and toddlers – should not be sacrificed to obtain a data set or to provide marginal improvement to our risk assessment techniques. At a minimum, participants in a study such as this should be fully informed of all potential risks and made aware of the limitations of our knowledge about the relationships between human health and chemical exposures.

We look forward to receiving the requested materials and responses to our questions. We thank you for your attention to our concerns.

Sincerely,

BART GORDON Ranking Member Committee on Science	EDDIE BERNICE JOHNSON Ranking Member, Subcommittee on Basic Research	MARK UDALL Ranking Member, Subcommittee Environment, Technology and and Standards