UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
RESEARCH AND DEVELOPMENT

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Chair, Children's Health Protection Advisory Committee
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Dear Dr. Marty:

Thank you for your April 18, 2003, letter to former U.S. Environmental Protection Agency (EPA) Administrator Christine Todd Whitman regarding your concerns about chemical contaminants in human milk. The Administrator's office has asked me to respond to your letter because many of your comments relate to past or planned activities by EPA's Office of Research and Development (ORD). In preparing this response, my staff have also consulted with EPA's Office of Children's Health Protection (OCHP).

As you noted, ORD and OCHP co-sponsored the February 2002, "Technical Workshop on Human Milk Surveillance and Research on Environmental Chemicals." As a result of this workshop and other strategic research planning initiatives, ORD is engaged in several activities which directly relate to your concerns about the need for increased EPA and government wide attention to developing a better understanding of the chemical contaminants in human breast milk. As you will see below, we have also sought out partnerships with other federal agencies that closely relate to these topics.

- ORD is developing methods for the collection and analysis of human milk samples in support of anticipated future efforts that will broadly characterize children's exposures to environmental contaminants. We expect to link the breast milk sampling with critical human activity patterns to determine the key factors influencing children's exposure associated with breast-feeding.

- In 2000, the Agency's Voluntary Children's Chemical Evaluation Program proposed consideration of testing of chemicals reported in human milk. Furthermore, the recommendation of the Endocrine Disruptor Screening and Testing Advisory Committee to screen and potentially test "representative mixtures to which large segments of the

population are exposed" including human milk is under consideration by EPA's Office of Prevention, Pesticides and Toxic Substances. In addition, the Agency has supported the World Health Organization's exposure monitoring of certain persistent, lipophilic environmental chemicals as a part of their milk surveillance studies around the world.

- ORD has ongoing research grants through the Science-To-Achieve Results program that are focused on biomarkers of exposure related to chemical contaminants in human milk. EPA, together with the National Institute of Environmental Health Sciences (NIEHS), is also jointly sponsoring twelve Centers of Excellence for Children's Environmental Health and Disease Prevention Research. Three of these centers are engaged in monitoring concentrations of several environmental contaminants (e.g., polybrominated biphenyls, mercury, lead, organophosphate pesticides) in human breast milk at the community level. More information on the children's centers can be found on the Internet at http://es.epa./gov/ncer/centers.

- ORD's National Health and Environmental Effects Research Laboratory, in collaboration with the University of Texas, is monitoring the levels of 13 congeners of polybrominated biphenyl ethers (PBDE) in human breast milk. The preliminary results of the pilot study are expected to be published shortly. EPA recognizes that there is a clear need for more detailed investigation of the levels of PBDEs in human breast milk as well as of the pathways of exposure in the general U.S. population.

- ORD's National Center for Environmental Assessment prepared an interim final report on *Child-Specific Exposure Factors Handbook* (September 2002) that summarizes recommendations on breast milk intake rates (Chapter 2) derived from key published studies (website address: http://cfpub.epa.gov/ncea/cfm/efcsefh2.cfm).

- ORD is collaborating with the Centers for Disease Control and Prevention (CDC) in designing future studies under the National Health and Nutrition Examination Survey program to include breast milk sampling.

- ORD is partnering with the National Institute of Child Health and Human Development, NIEHS and CDC in designing the National Children's Study (NCS), a prospective longitudinal study of approximately 100,000 children across the United States from birth to age 18. Human milk monitoring for environmental contaminants is being considered as a part of this longitudinal cohort study. More information on the NCS can be found on the Internet at http://www.nationalchildrensstudy.gov.

The incorporation of the human milk exposure pathway into risk assessment is a standing practice in ORD where data are available to properly account for the potential contribution of the pathway. As an example, the human milk exposure pathway is incorporated into EPA's draft dioxin exposure and human health assessment as a part of an analysis of contributions to total body burden. More broadly, there is an increasing awareness in EPA that the human milk pathway needs to be examined for persistent bioaccumulating toxicants.

Your letter also mentions the need for a proactive health education campaign to accompany any human milk monitoring program. I agree that this would be a necessary endeavor. EPA's current efforts regarding milk monitoring, however, are limited to specific research activities. At this time EPA's outreach efforts are directed at identifying partners inside and outside of the federal government to both collaborate on these research efforts and to conduct related research that would address some of the other important science issues associated with chemical contaminants in human milk.

The Agency recognizes that human milk is uniquely suited for the infant and provides a superior nutrition source and that breast feeding remains the preferred choice for infant nutrition. EPA endorses the recent positions and guidance provided by the U.S. Department of Health and Human Services (2000), the U.S. Food and Drug Administration (1998), as well as that of the American Academy of Pediatrics (2001).

I trust that this response conveys the scope of our current and anticipated activities. The interests and concerns of the Children's Health Protection Advisory Committee are a valuable contribution to our research planning to protect children's health.

Sincerely yours,

Paul Gilman

Paul Gilman, Ph.D.
Assistant Administrator