

## **CONCLUSIONS, RESEARCH NEEDS, AND RECOMMENDATIONS OF THE EXPERT PANEL: TECHNICAL WORKSHOP ON HUMAN MILK SURVEILLANCE AND RESEARCH FOR ENVIRONMENTAL CHEMICALS IN THE UNITED STATES**

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An expert panel was convened for the Technical Workshop on Human Milk Surveillance and Research for Environmental Chemicals in the United States, held at the Milton S. Hershey Medical Center, Pennsylvania State University College of Medicine, Hershey, PA, on 15–17 February 2002. The expert panel was comprised of over 30 participants representing academia, industry, nonprofit organizations, and the federal government, with expertise in the fields of pediatrics, family medicine, nursing, lactation, breast-milk sampling, analytical chemistry, pharmacology, toxicology, epidemiology, nutrition, exposure, and health risk assessment. The following conclusions, enumeration of research needs, and recommendations represent the consensus of the expert panel.

## CONCLUSIONS

The Technical Workshop on Human Milk Surveillance and Research for Environmental Chemicals in the United States focused on methods for obtaining human milk, detecting the presence of environmental chemicals in those samples, and interpreting and communicating the information obtained during such surveillance and research. Human milk studies may be for the purposes of exposure monitoring, etiologic research or risk assessment, trends of exposures to environmental chemicals in the overall population, and influence of lactation on maternal depuration, as well as monitoring of infant exposure in the general or in select populations. Study design, including participant selection and data collection, will vary accordingly. Of crucial importance in carrying out studies of human milk is that the research process not adversely impact breast-feeding, through misinformed publicity, rumors, or beliefs. For this reason, in human milk studies the communication of information to participants is at least as important as obtaining study data from the participants themselves. The panel strongly supports the scientific and public health value of studies on environmental chemicals in human milk. However, it is even more strongly emphasized that the mere presence of an environmental chemical in human milk does not necessarily indicate that a health risk exists for breast-fed infants. The accumulated data overwhelmingly supports the positive health value of breast-feeding infants. Few, if any, adverse effects have been documented as being associated with consumption of human milk containing background levels of environmental chemicals, and none have been clinically or epidemiologically demonstrated. Only in very rare situations involving high levels of contamination have effects on infants occurred through human milk consumption (for example, hexachlorobenzene-induced pemba yara and porphyria cutanea tarda, perchloroethylene-induced jaundice, and polychlorinated biphenyl [PCB]-induced growth retardation and abnormal skin pigmentation). Within limits, human milk may contain components that either prevent intestinal absorption of xenobiotics or inactivate them. If environmental chemicals in human milk at background levels pose any risk, the nature of that risk is unclear and its magnitude unknown. In contrast, epidemiological studies

have demonstrated that human milk and the practice of breast-feeding confer significant, measurable health benefits to infants and to nursing mothers.

The panel agrees with the recommendations of the American Academy of Pediatrics (AAP, 1997) and national and international organizations (e.g., U.S. DHHS, 2000; WHA, 2001) that human milk is the optimal form of nutrition for infants because “breast-feeding of infants provide advantages with regard to general health, growth and development, while significantly decreasing risk for a large number of acute and chronic diseases” (AAP, 1997).

While the demonstrated benefits for both mother and infant associated with breast-feeding are well recognized, concerns have nonetheless been expressed over the presence of environmental chemicals in human milk in the United States and their potential adverse health effects to mothers who carry the chemical burden and to their suckling infants. Currently, it is not possible to fully address these concerns because of the paucity of information in several areas, including: (1) lack of any national monitoring program or comprehensive database on environmental chemicals found in human milk in the United States, and (2) information on the potential adverse health effects, if any, of environmental chemicals in human milk. In addition, the limited U.S. data for certain environmental chemicals are difficult to interpret because of variation in participant selection, analytical methods and quality control procedures, and reporting practices.

Therefore, the panel believes that the following research is needed to address uncertainties in our understanding of the potential risks and established benefits of different sources of infant nutrition.

### **Research Needs**

- Determination of levels of environmental chemicals (e.g., persistent organic pollutants, heavy metals, chemicals in personal care products) found in human milk and infant formula. Special attention should be given to those women who may have increased exposure and to other disproportionately exposed populations.
- Characterization of pharmacokinetics/toxicokinetics and pharmacodynamics/toxicodynamics in suckling infants to elucidate potential mechanism(s) as a basis for action of environmental chemicals at levels currently found in breast-fed and formula-fed babies.
- Identification of human biomarkers of exposure, susceptibility, and effects to predict potential health risks associated with specific environmental chemicals to breast-fed and formula-fed infants, mothers, and families.
- Development of methods to analyze the risk–benefit ratio for exposure to environmental chemicals and endogenous chemicals for breast-feeding versus formula feeding to infants and children.
- Creation of a computerized, web-accessible database for recording levels of environmental chemicals reported in human milk and infant formula in a standardized manner, with interpretation, in a manner inclusive of geographic locations.

- Utilization of standardized study guidelines, as described by this workshop, for human milk sampling, subject selection, analytical methods, and quality assurance/quality control programs through independent review and validation processes; and consideration of special ethical issues in such research including sharing of results with participants and the need to make special efforts to preserve and maintain breast-feeding.
- Development of strategies for the accurate dissemination of research findings, through education and other means, to health care providers (e.g., physicians, nurses, midwives, social workers, etc.) and the public. These strategies would need to include both the communication of the known benefits of breast-feeding as well as the potential health risks of environmental chemicals found in human milk and commercial formulas.
- Evaluation of existing animal toxicity testing protocols for their scientific basis and adequacy for protecting infants from potential exposure to environmental chemicals through human milk and formula.
- Supporting, organizing and coordinating research and service efforts provided by the federal government (e.g., the U.S. Environmental Protection Agency, Department of Health and Human Services, Consumer Product Safety Commission, U.S. Department of Agriculture), and nonfederal professional organizations (e.g., American Academy of Pediatrics, Human Milk Banking Association of North America), to ensure that infants are protected from unacceptable exposures to environmental chemicals via human milk and infant formula.

## RECOMMENDATIONS

The panel recommends that:

- The federal government, along with interested parties, should develop a collaborative national agenda that identifies the key public health questions concerning human milk, including the identification of key issues along with testable hypotheses. Following the development of this hypothesis-driven agenda, the government, in collaboration with a variety of stakeholders, should work to implement and finance a program to answer these questions. For some hypotheses, the panel recommends the establishment of a national program to monitor trends of environmental chemicals over time in human milk samples as a part of the National Health and Nutrition Examination Surveys. For other hypotheses, the panel recommends the conduct of well-designed research studies as part of the National Children's Study commissioned by the U.S. Congress under the Children's Act, 2000.
- The harmonized guidelines produced from the workshop should form the basis for these future studies.

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