Policy on Evaluating

Health Risks to Children

POLICY

It is the policy of the U.S. Environmental Protection Agency (EPA) to consider the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination.

BACKGROUND

When it comes to their health and development, children are not little adults. This maxim has long been understood in the medical community. Documentation of the similarities and differences between children and adults is an integral part of assessing the effects and efficacy of drugs, for example. The National Academy of Sciences has pointed out on more than one occasion[2,3] that the maxim should hold true with respect to exposure to environmental pollutants, as well.

Children may be more or less sensitive than adults when confronted with an equivalent level of exposure to an environmental pollutant. In many cases, their responses are substantially different - qualitatively and quantitatively - from those exhibited by adults. These age-related variations in susceptibility are due to many factors, including differences in pharmacokinetics, pharmacodynamics, body composition, and maturity of biochemical and physiological functions (for example, metabolic rates and pathways).

In addition, there are often age-related differences in types and levels of exposure. For example, it is known that infants and children differ from adults both qualitatively and quantitatively in their exposures to pesticides in foods. Children eat more food and drink more water per unit of body weight, and the variety of the food they consume is more limited than adults. Children also breathe more rapidly than adults and can inhale more of an air pollutant per pound of body weight than adults. Children's skin and other body tissues may absorb some harmful substances more easily. Children's bodies are not yet fully developed, so exposure to toxic substances may affect their growth and development. Infants' immune systems are not as strong as those of healthy adults, so they are less able to fight off emerging microbial threats such as Cryptosporidium in drinking water.

The Agency is particularly concerned about safeguarding the health of infants and children, who are among the nation's most fragile and vulnerable populations. Therefore, it is important that there be a clear articulation of policy in this regard.

IMPLEMENTATION

The policy already is currently being followed in many Programs and regions. The entire Agency will expand implementation activities during the Fall of 1995 as part of the overall implementation of the Administrator's policy on risk characterization. Other related activities and sources of information include the presentation of relevant

data in the revised draft Exposure Factors Handbook, and current EPA solicitations of grant proposals for independent studies on risk to children from exposure to a wide range of substances. EPA's 1991 Guidelines for Developmental Toxicity Risk Assessment are also relevant.

This policy is not retroactive; it will apply only to those assessments started or revised on or after November 1, 1995. Any questions relating to the policy and its implementation should be referred to Dr. Dorothy Patton, Executive Director of the Agency's Science Policy Council. She can be reached at 202-260-6600.

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(1) This document is a statement of Agency policy and does not constitute a rule. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States.

(2) National Research Council. 1993. Pesticides in the Diets of Infants and Children. National Academy of Sciences Press, Washington, DC.

(3) National Research Council. 1994. Science and Judgment in Risk Assessment. National Academy of Sciences Press, Washington, DC.