APPENDIX A

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United States
Environmental Protection Agency
Office of Research and Development

Technical Workshop on Issues Associated with Considering Developmental Changes in Behavior and Anatomy When Assessing Exposure to Children

Holiday Inn on the Hill
Washington, DC
July 26–27, 2000

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APPENDIX B

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APPENDIX C

CHARGE TO THE EXPERTS

Technical Workshop on Issues Associated with Considering Developmental Changes in Behavior and Anatomy When Assessing Exposure to Children

U.S. Environmental Protection Agency
Washington, D.C.
July 26–27, 2000

Charge to Experts/Discussion Issues

This workshop is being held to discuss issues associated with how to consider important developmental changes when assessing the exposure of children to environmental contaminants. The workshop discussions will focus on broad technical issues rather than any one specific methodology. These issues were raised by Agency scientists who have been working to improve exposure and risk assessment methodologies for children in response to the President's Executive Order (Executive Order 13045) and such legislative mandates as the Food Quality Protection Act of 1996. The focus of the workshop discussions will be on defining and characterizing the important facets of child development and how best to estimate childhood exposure given the limitations in existing exposure information.

Background

The 1993 National Academy of Sciences (NAS) report "Pesticides in the Diets of Infants and Children" highlights important differences between children and adults with respect to risks posed by pesticides. Some of the principles in the NAS report provided the foundation for the Food Quality Protection Act of 1996 (FQPA) and the President's Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risk. FQPA requires the consideration of aggregate exposure to children when establishing pesticide tolerances (legal limits for residues in food). Executive Order 13045 broadens consideration of impacts on children by stating that "each Federal agency: shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks." Many of the comments the EPA received on the Proposed Guidelines for Carcinogen Risk Assessment relate to the implementation of Executive Order 13045. In response to these comments and regulatory initiatives, EPA has been investigating ways to improve Agency risk assessments for children.

An Agency workgroup convened under the auspices of the Risk Assessment Forum has been exploring children's exposure assessment issues. This workgroup has concluded that a major issue facing Agency assessors is how to consider age related changes in behavior and physiology when preparing exposure assessments for children. Children's behavior changes over time in ways that can have an important impact on exposure. Further, children's physiology changes over time in ways that

can impact both their exposures and their susceptibility to certain health effects. There are two aspects to these physiological changes. First, there are anatomical changes resulting from physical growth. Second, there are changes in pharmacokinetics and pharmacodynamics which affect the absorption, distribution, excretion and effects of environmental contaminants. The Agency is examining the pharmacokinetic/pharmacodynamic changes in children through a separate effort. The present workshop discussions will focus on how to consider age related changes in behavior and anatomy.

Discussion Issues

The broad technical issues identified for the workshop discussions can be organized into two categories: issues associated with behavioral changes in children and issues associated with anatomical changes and physical growth. Although organized in this manner to facilitate discussions, it is understood that these two categories are considerably intertwined. The issues identified under each category will be the focal point for discussions during this workshop. These issues/questions are intended to help structure and guide, not limit the workshop discussions.

In addressing these issues/questions, workshop participants are asked to consider several overarching questions:

- what is the ideal approach to preparing childhood exposure assessments that reflect changes in children's behavior and anatomy over time;
- is the existing exposure information adequate to implement the ideal approach; if not, what additional information is needed;
- what short term studies could be conducted to supply the necessary information or provide additional guidance; and
- what longer term research may be needed to achieve the ideal approach to preparing childhood exposure assessments.

Behavioral Changes During Child Development and Their Impact on Exposure to Environmental Contaminants

Childhood behavior changes over time in ways that can have an important impact on exposure to environmental contaminants. These changes are linked to physical and mental growth and can influence where children spend their time, what physical activities they engage in, and what foods they eat. Rephrased in terms of exposure factors, these changes can influence time spent in microenvironments, the frequency and duration of micro and macro level activities, and the intake rate

for water and selected foods and beverages. Recognizing the importance of these changes in behavior, exposure assessors have invariably estimated exposure for such subgroups as infants, toddlers, children, and adolescents. The ages ascribed to these groups vary and are often based on the exposure pathways and routes of concern, expert judgment, and/or the availability of exposure information. The goal of the present discussion is to examine how childhood behavior changes over time, identifying those aspects of behavior that are most important for consideration in exposure assessment. The following questions will serve as a guide for this discussion.

1. Does it make sense to think about childhood behavioral development as a series of discrete events which lend themselves to characterization using age group categories or "bins?" Alternatively, should exposure assessors be thinking in terms of a continuum of behavioral development that contributes to an exposure function over all ages? If so, how would one pursue this later approach? When existing information is not adequate to construct an exposure function that reflects continuous behavioral development, a consistent, default approach using age group "bins" may be needed. In such cases, what "bins" serve as a reasonable surrogate for the continuous function? How would one characterize the uncertainties that arise from the use of such "bins?"

2. What are the most important developmental milestones in children's behavior? For each milestone, what is the range of ages during which the behaviors are typically observed? How much variability is there among children with respect to the age of onset and the age of abandonment (if applicable) for these behaviors? Are the observed changes in behavior associated with these milestones likely to affect children's exposure to environmental contaminants? If so, how?

3. For those behaviors that are likely to have an important impact on exposure, is there existing exposure information that is representative of the behavior? Comment on the existing information including some indication of accessibility and quality. If such information is not available, is there exposure information that could serve as a reasonable surrogate? Comment on this information including some indication of accessibility and quality.

4. For those behaviors that are represented in existing exposure information, compare the age groups identified for the developmental milestone in question 2 with the age groups in the existing exposure information. Were the age groups reported in the exposure information based on consideration of child developmental milestones, are they an artifact of study/survey design and/or responses, or are they based on the expert judgment of the study investigator?

5. For those behaviors where the age groups reported in the exposure information are not

aligned with the age groups defined by the developmental milestone, what is the best approach to representing the appropriate age groups in an exposure assessment? The issue of alignment is compounded when attempting to aggregate exposure across multiple routes (e.g., dermal, inhalation, and ingestion). For example, exposure information may be available to characterize children's inhalation exposure at a particular stage of development while such information may be lacking to characterize exposure by the dermal and ingestion routes. Under these circumstances, what is the best approach to characterizing childhood aggregate exposure?

Anatomical Changes and Physical Growth During Child Development and Their Impact on Exposure To Environmental Contaminants

As stated in the background, children's physiology changes over time in ways that can impact both their exposures to environmental contaminants and their susceptibility to certain health effects. These physiological changes include anatomical changes resulting from physical growth. The focus of the present discussion will be on the anatomical changes that relate directly to commonly used exposure factors information (e.g., body weight, skin surface area, skin permeability, gut absorption, and inhalation rate). The following questions will help to guide this discussion.

1. Does it make sense to think about childhood anatomical development as a series of discrete events which lend themselves to characterization using age group categories or "bins?" Alternatively, should exposure assessors be thinking in terms of a continuum of anatomical development that contributes to an exposure function over all ages? If so, how would one pursue this later approach? When existing information is not adequate to construct an exposure function that reflects continuous anatomical development, a consistent, default approach using age group "bins" may be needed. In such cases, what "bins" serve as a reasonable surrogate for the continuous function? How would one characterize the uncertainties that arise from the use of such "bins?"

2. What are the most important developmental milestones for anatomical changes related to physical growth in children? For each milestone, what is the range of ages during which the characteristics are typically observed? How much variability is there among children with respect to the age of onset for the characteristics? Are the observed characteristics associated with these milestones likely to affect children's exposure to

environmental contaminants? If so, how?

3. For those anatomical characteristics that are likely to have an important impact on exposure, is there existing exposure information that is representative of the characteristics? Comment on the existing information including some indication of accessibility and quality. If such information is not available, is there exposure information that could serve as a reasonable surrogate? Comment on this information including some indication of accessibility and quality.

4. For those characteristics that are represented in existing exposure information, compare the age groups identified for the developmental milestone in question 2 with the age groups in the existing exposure information. Were the age groups reported in the exposure information based on consideration of child developmental milestones, are they an artifact of study/survey design and/or responses, or are they based on the expert judgment of the study investigator?

5. For those anatomical characteristics where the age groups reported in the exposure information are not aligned with the age groups defined by the developmental milestone, what is the best approach to representing the appropriate age groups in an exposure assessment? The issue of alignment is compounded when attempting to aggregate exposure across multiple routes (e.g., dermal, inhalation, and ingestion). For example, exposure information may be available to characterize children's inhalation exposure at a particular stage of development while such information may be lacking to characterize exposure by the dermal and ingestion routes. Under these circumstances, what is the best approach to characterizing childhood aggregate exposure?

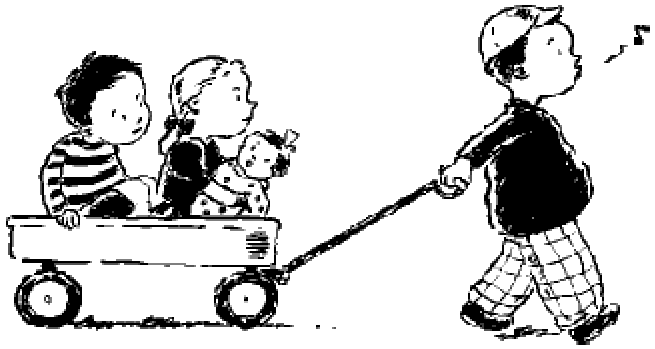
APPENDIX D

AGENDA

United States
Environmental Protection Agency
Office of Science Policy

Technical Workshop on Issues Associated with Considering Developmental Changes in Behavior and Anatomy When Assessing Exposure to Children

Holiday Inn on The Hill
Washington, DC
July 26–27, 2000



Agenda

Workshop Chair: Kimberly Thompson, Harvard Center for Risk Analysis

W E D N E S D A Y , J U L Y 2 6 , 2 0 0 0

8:00AM **Registration**

8:30AM **Welcome & Introductions** . . . . . *Jan Connery*
Eastern Research Group, Inc.,
Lexington, MA

8:45AM **Background** . . . . . *William Wood*
Risk Assessment Forum (RAF),
U.S. Environmental Protection Agency (U.S. EPA),
Washington, DC

9:15AM **EPA Perspective on Childhood Exposure Assessment: Current Practices and Future Needs** . . . . . *Michael Firestone*
Office of Children's Health Protection,
U.S. EPA,
Washington, DC

10:00AM B R E A K

10:15AM **Exposure Assessments for Children, an Overview** . . . . . *Elaine Hubal*
National Exposure Research Laboratory (NERL),
U.S. EPA,
Research Triangle Park, NC

(over)

W E D N E S D A Y , J U L Y 2 6 , 2 0 0 0 (continued)

10:45AM **Changes in Children's Exposure as a Function of Age and the Relevance of Age Definitions for Exposure and Risk Assessment** . . . . . *Kimberly Thompson*
Workshop Chair,
Harvard Center for Risk Analysis,
Boston, MA

11:45AM **Observer Comments**

12:15PM L U N C H

1:15PM **Charge to Experts** . . . . . *Kimberly Thompson*

1:30PM **Discussion Sessions**

- **#** Behavior-Related Exposure Factors - Katherine Shea, Discussion Leader
- **#** Physiologically-Based Exposure Factors - William Weil, Discussion Leader

4:30PM **Discussion Session Reports and Wrap-Up**

5:00PM A D J O U R N

T H U R S D A Y , J U L Y 2 7 , 2 0 0 0

8:00AM **Discussion Sessions**

- **#** Behavior-Related Exposure Factors - Katherine Shea, Discussion Leader
- **#** Physiologically-Based Exposure Factors - William Weil, Discussion Leader

NOON L U N C H

DISCUSSION GROUP PRESENTATIONS

1:00PM **Behavior-Related Exposure Factors**

2:00PM **Physiologically-Based Exposure Factors**

3:00PM **Observer Comments**

3:30PM B R E A K

3:45PM **Open Discussion/Next Steps/Wrap-Up**

4:30PM A D J O U R N