The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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HOWARD K. KOH, MD, MPH
COMMISSIONER

October 18, 2000

Dear Interested Party:

Enclosed is a copy of a report prepared by an eleven-person panel of nationally and internationally recognized experts on the public health effects and science of PCBs (polychlorinated biphenyls). This expert panel was convened by William D. O'Leary, Secretary of the Massachusetts Executive Office of Health and Human Services, because of continuing community concerns relative to the health effects of PCBs among Pittsfield area residents. The panel, chaired by Dr. Henry Anderson of the Wisconsin Department of Health and Family Services, first met in person in Boston in January 1999 and was charged with reviewing, assessing, and summarizing the most up-to-date published and ongoing research on PCBs and public health, with special emphasis on:

- Identifying the potential for adverse health outcomes in association with exposure to PCBs;
- The latest information on typical levels in the U.S. of PCBs in the blood and the public health significance of these levels;
- The thoroughness of information on ways humans can be exposed to PCBs (such as via air, water, soil, food).

At least eight of the eleven panel members will return to Massachusetts to attend a public meeting in the Greater Pittsfield area, tentatively scheduled for December 7, 2000, to discuss their report and answer questions from the audience.

As you know, the MDPH committed to return to the community with as many of the panel members as possible so that residents could directly ask them questions. We are very pleased that so many of the panel members will be available to attend the meeting and appreciate their willingness to do so.

Further details on the specific location and time of the public meeting in December will be provided at a later time. Copies of the report will be distributed to library repositories established for the General Electric site in the Pittsfield area. Copies will also be available on the MDPH web site and distributed to community representatives who serve on advisory committees of the MDPH, the Massachusetts Department of Environmental Protection, and the U.S. Environmental Protection Agency.

Sincerely,

Suzanne K. Condon

Suzanne K. Condon, Assistant Commissioner
Bureau of Environmental Health Assessment

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# INFORMATION BOOKLET

for the

# MEETING SUMMARY
# OF THE
# EXPERT PANEL ON THE HEALTH EFFECTS OF POLYCHLORINATED BIPHENYLS (PCBS)

with Administrative Support from

THE BUREAU OF ENVIRONMENTAL HEALTH ASSESSMENT
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
BOSTON, MASSACHUSETTS

Funding from

THE EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
BOSTON, MASSACHUSETTS

and

THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
ATLANTA, GEORGIA

October 2000

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# COMMONWEALTH OF MASSACHUSETTS
# EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

## Questions and Answers

1. **Q. Why was an expert panel convened?**

   **A.** Because of continuing concerns relative to the health effects of PCBs among Pittsfield area residents, the Secretary of the Executive Office of Health and Human Services (EOHHS) called for a review of this topic by a panel of independent experts. It was hoped that this panel would establish consensus on the available health information where possible, reflect the range of scientific opinion, and report on the current state of the science and directions of current research.

2. **Q. Who was on the expert panel?**

   **A.** The panel comprised 11 nationally and internationally recognized experts on the health effects of PCBs from a wide range of disciplines, including toxicology, epidemiology, public health, and analytical chemistry.

3. **Q. How and why were the panelists selected?**

   **A.** The Secretary of EOHHS invited the public to nominate potential panel members who had expertise in one of the following disciplines: toxicology; epidemiology; environmental exposure assessment; laboratory science; medicine (including cancer and reproductive outcomes); environmental fate and transport; and organic chemistry. The public comment period for submission of nominations ran from August 2nd to August 21st, 1998. Nearly 40 individuals were nominated representing a variety of disciplines. In selecting the final 11 panelists, the Secretary made every effort to have a panel of individuals with the diversity of technical disciplines noted above and who were nominated by a variety of publicly interested parties.

4. **Q. What topics did the panel discuss? How were these topics selected?**

   **A.** The role of the panel was to review, assess, and summarize the most up-to-date published and ongoing research on PCBs and public health, with special emphasis on:
   - The latest information on typical levels in the U.S. of PCBs in blood serum and the public health significance of these levels;
   - The adverse health outcomes associated with exposure to PCBs;
   - The thoroughness of information on ways humans can be exposed to PCBs (such as via air, water, soil, food);
   - The interactions between PCBs and other chemicals.

   EOHHS compiled a preliminary list of questions for the panel based on the experiences of



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the Massachusetts Department of Public Health (MDPH) with PCB contamination in the Housatonic River Area and throughout the Commonwealth. Furthermore, EOHHS and the chairman of the panel held a public meeting in Pittsfield on the eve of the panel meeting to solicit additional questions and comments from the public in Berkshire County.

5. Q. **What were the findings of the expert panel with respect to typical background levels of PCBs in blood serum?**

A. The panel agreed that the information on typical background serum PCB levels for non-occupationally exposed people in the Toxicological Profile for PCBs[1] (i.e., 4-8 ppb) is not current. In addition, the panel concluded that the information that now exists suggests that the range is probably lower than 4-8 ppb, but that comparisons are difficult due to differences in the age of various study populations and whether or not they eat fish. Some recent studies have found background serum PCB levels for women of reproductive age around 2 ppb, while other researchers have observed levels around 6 ppb for elderly people who do not eat much fish. The recent studies provide valuable data points that must be shared within the context of all relevant factors. For example, studies have consistently shown that serum PCB levels increase with age and are correlated to factors such as fish consumption and exposures to PCBs at work.

The varied analytical and statistical methods used by different researchers often make comparisons between studies difficult or impossible. Therefore, the panel strongly recommended that an individual's serum PCB level be evaluated by comparisons to the distribution of levels within the local and other comparable populations, considering age, fish consumption habits, and occupational exposures.

6. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the current estimates of typical background levels for non-occupationally exposed individuals?**

A. When comparing serum PCB levels between different studies, it is important to match populations with similar ages and opportunities for exposures to PCBs (e.g., occupation, fish consumption habits). Analytical and statistical methods (e.g., chromatographic and detection methods, detection limits, target congeners, treatment of non-detected samples) can also vary among studies, further complicating comparisons. Nevertheless, if the appropriate factors are considered, the serum PCB levels measured in recent studies may provide useful comparison data for the results from the Housatonic River Area.

7. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the population in the study from The Netherlands?**

A. In a recent study from The Netherlands, 415 women of reproductive age (i.e., mid-20s to mid-30s) were found to have median serum PCB levels around 2 ppb. Because of the analytical methods used in this study, this result may actually correspond to approximately 4

[1] Toxicological Profile for Polychlorinated Biphenyls, Draft for Public Comment, Agency for Toxic Substances and Disease Registry, Atlanta, Georgia, December 1998.



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ppb of total serum PCBs as measured for MDPH's Exposure Assessment Study. This could be predicted with greater certainty if some samples are analyzed by both techniques. In contrast, non-occupationally exposed residents of the Housatonic River Area between 18 and 34 years old (n=8) had median serum PCB concentrations less than 2 ppb.

8. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to people over 50 years old who do not each much fish?**

A. A recently published study reportedly found that 180 people over 50 years old who do not eat much fish (i.e., less than 6 pounds per year) had serum PCB levels around 6 ppb. The median serum PCB levels for non-occupationally exposed, older (i.e., 50 years and older, including those greater than 70) participants in MDPH's Exposure Assessment Study were 3.70 (n=19) and 5.90 (n=12) ppb for the Exposure Prevalence and Volunteer phases, respectively.

9. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the population in the Great Lakes study?**

A. A mixed-age population in the Great Lakes region who did not consume sport-caught fish had geometric mean (i.e., approximately median) serum PCB levels of 1.5 and 0.9 ppb for males (n=57) and females (n=42), respectively. For a similar population in the Housatonic River Area (i.e., non-occupationally exposed participants, 18-64 years old, who either never ate fish or ate only store-bought fish), the median serum PCB levels were 3.30 (n=10) and 1.66 (n=8) ppb in the Exposure Prevalence and Volunteer phases, respectively. Direct comparisons between these studies are hampered by the fact that the method detection limit for MDPH's Exposure Assessment Study (2 ppb) was greater than the median levels measured in the Great Lakes study.

10. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the populations in the New York breast disease studies?**

A. Two studies of women with benign breast disease in the New York area reported average concentrations of serum PCBs of 2.15 (n=173) and 4.06 (n=19) ppb. The average serum PCB concentrations for non-occupationally exposed participants in MDPH's Exposure Assessment Study were slightly higher than this range, 4.49 (n=52) and 5.77 (n=53) ppb for the Exposure Prevalence and Volunteer phases, respectively. This may be because the women in the New York studies were on average about 10 years younger than the participants in MDPH's Exposure Assessment Study. Furthermore, the method detection limit for the larger of the New York studies (0.5 ppb) was four times lower than the detection limit for MDPH's Exposure Assessment Study (2 ppb).

11. Q. **Overall, how do the serum PCB levels from residents of the Housatonic River Area compare to the populations in these recent studies?**

A. Because of the complications discussed earlier, direct comparisons between studies are difficult. However, the available data indicate that serum PCB levels for the non-



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occupationally exposed population from MDPH's Exposure Assessment Study are generally similar to the background exposure levels reported in recent studies.

12. **Q. What were the findings of the expert panel with respect to adverse health outcomes associated with PCB exposures?**

A. While the panel cited some conflicting human studies, overall the panel members agreed that the evidence is clear that PCBs are a definite carcinogen in animals. In humans, the evidence with regard to cancer is suggestive but inconclusive.

Most of the panel agreed that there appears to be some developmental effects (e.g., subtle cognitive deficits) associated with exposure to PCBs. Developmental effects observed in animal studies have also been seen in humans. However, frank neurotoxic effects such as seizure disorders have not been seen. Many agreed that the most susceptible population to these effects seems to be fetuses *in utero*.

There is some suggestive, but not conclusive, evidence from animal and human studies that exposures to PCBs can affect the immune system. Dermal effects (e.g., chloracne) have been observed in workers who were exposed to PCBs on the job.

13. **Q. What were the findings of the expert panel with respect to the public health implications of serum PCB levels near background levels?**

A. The current research suggests that prenatal exposures to fetuses at near background levels of PCBs may subtly affect the mental development of children. Immunological and hormonal effects have also been seen following prenatal exposure, in addition to the neurological effects. Recent studies in The Netherlands observed that children born to mothers with greater than 3 ppb of serum PCBs scored slightly lower on tests of cognitive abilities than children whose mothers had serum PCB levels less than 1.5 ppb. While statistically significant for the study population, the panel agreed that these effects were probably not noticeable on an individual basis. Moreover, because of the analytical methods used in this study, the serum PCB measurements represent approximately one-half the total serum PCBs and, hence, should be doubled to be comparable to the test results from MDPH's Exposure Assessment Study.

Importantly, this same study also found that children who were breast fed scored better on cognitive tests than children who were fed formula, despite additional exposures to PCBs and dioxins in breast milk. This finding reinforces the beneficial properties of breast feeding and highlights that exposures to PCBs *in utero* are likely of greatest concern.

14. **Q. Should I be concerned about the cognitive development of my children?**

A. The results of recent studies from The Netherlands raise legitimate concerns about developmental effects as a result of near background exposures to PCBs for fetuses *in utero*. However, the cognitive effects observed are slight and many panelists felt they were not biologically significant on an individual basis. Furthermore, the panel felt that other factors that affect a child's aptitude for learning (e.g., parental involvement with the child's

education, good nutrition, supportive family environment) probably play a much larger role than background PCB exposures. Nevertheless, these findings provide more justification for continuing to clean up PCB contamination to reduce opportunities for exposure as much as possible.

15. **Q. What were the findings of the expert panel with respect to exposure routes for non-occupationally exposed populations?**

A. The panel agreed that exposures to PCBs are possible through multiple routes (e.g., air, water, soil, and food), however, the vast majority of exposure typically occurs through eating food of animal origin (e.g., fish, meat, dairy).

16. **Q. How can people avoid important opportunities for exposure to PCBs?**

A. Observing fish consumption advisories and eating a healthy diet that is low in fatty foods is the most effective way to reduce overall exposures to PCBs. However, because even small exposures add incrementally to overall body burden, it is important to reduce exposures via all routes.

Because the bioavailability of PCBs in air, water, and soil is uncertain, the expert panel endorsed serum PCB tests as the best available measure of actual exposure for individuals who are concerned about their exposures to PCBs.

17. **Q. What were the findings of the expert panel with respect to interactions between PCBs and other chemicals?**

A. PCBs are thought to behave as tumor promoters in susceptible tissues. Therefore, the carcinogenic effects of PCBs are likely to be influenced by other carcinogens or toxins that may be present. It is hoped that ongoing research will reveal more about the toxicity of mixtures of PCBs and other chemicals in the future.

18. **Q. The focus in the Housatonic River Area Exposure Assessment Study was on individuals living near the river. Is there a need for the MDPH to examine the PCB serum levels of a population further away from the river?**

A: The Housatonic River Area Exposure Assessment Study was purposely aimed to select individuals with highest opportunity for exposure, therefore the focus was on individuals living near the river or engaging in a variety of activities that may increase their opportunities for exposure to PCBs (e.g., fish consumption, recreational activities near the river, gardening, construction activities, fiddlehead fern consumption). Since these people were largely found to have levels near typical background ranges, individuals living further away from the river would not be expected to have higher PCB levels.

19. **Q. Will MDPH evaluate all the adverse health outcomes that have been associated with PCB exposures?**

A. In addition to a large number of public health assessments, MDPH is conducting an analysis

of cancer incidence from 1982 to 1994 in the Housatonic River Area using data from the Massachusetts Cancer Registry. For this project, the cancers most strongly associated with PCB exposures will be evaluated (i.e., liver cancer, breast cancer, non-Hodgkin's lymphoma, Hodgkin's disease, thyroid cancer, and bladder cancer). If environmental data indicate significant opportunities for exposure to other carcinogens (e.g., PCBs and smoking as co-carcinogens), or if the literature and further discussions with appropriate experts identifies additional cancers of concern (e.g., brain, testicular, lung cancer), the list of cancers under review may be expanded. The expert panel agreed that MDPH's approach for the health assessment and other public health activities, along with the continued clean-up efforts, were adequate measures to be taken at this time.

MDPH is also conducting a pilot study assessing the relationship between environmental exposures to PCBs and DDE and new diagnoses of breast cancer.

**20. Q. What can I do if I am concerned about my exposures to PCBs?**

**A.** MDPH has established a toll free hotline to advise local area residents about any health related concerns or questions they may have. An exposure assessment questionnaire has been and will continue to be provided to all residents who wish to have their opportunities for exposure evaluated and a blood test taken. The hotline number is (800) 240-4266.

**21. Q. Where can I get additional information?**

**A.** For information on the expert panel or MDPH health studies in the Housatonic River Area, contact the Bureau of Environmental Health Assessment of MDPH at (617) 624-5757 or (800) 240-4266.

# Meeting Summary
# Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

*with Administrative Support from*

**The Bureau of Environmental Health Assessment**
**Massachusetts Department of Public Health**
**Boston, Massachusetts**

*Funding from*

**Executive Office Of Health And Human Services**
**Massachusetts Department Of Public Health**
**Boston, Massachusetts**
**and**
**Agency For Toxic Substances And Disease Registry**
**Atlanta, Georgia**

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## Preface

This meeting summary represents the results of deliberations by the Expert Panel on Health Effects of Polychlorinated Biphenyls (PCBs), which met on January 22, 1999, in Boston, Massachusetts. Administrative support was provided by the Bureau of Environmental Health Assessment of the Massachusetts Department of Public Health (MDPH). Funding for the expert panel was provided by both the MDPH and the U.S. Agency for Toxic Substances and Disease Registry. All of the comments in this meeting summary do not necessarily reflect the views of the U.S. Agency for Toxic Substances and Disease Registry.

**Members**
**Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)**

Henry Anderson, M.D. (Chair) State epidemiologist
Wisconsin Department of Health and Family Services

Lucy Anderson, Ph.D., D.A.B.T.
National Cancer Institute

Linda Birnbaum, Ph.D., D.A.B.T.
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National Health and Environmental Effects Research Laboratory

David M. Gute, Ph.D., M.P.H. former comm of Health New Bedford
Tufts University

Stephen Hamilton, Ph.D. Fairfield CT
General Electric

Joseph Jacobson, Ph.D.
Wayne State University

Loren Koller, D.V.M., Ph.D. pathologist
Oregon State University

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David Ozonoff, M.D., M.P.H.
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Deborah Rice, Ph.D.
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Susan Schantz, Ph.D.
University of Illinois Urbana-Champaign

COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

# EXECUTIVE SUMMARY

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

### Friday, January 22, 1999

The expert panel was convened to assist the Secretary of Health and Human Services in addressing health questions raised by the widespread PCB contamination in the Housatonic River Area. The general charge to the panel was to discuss the current science on several key topics related to the health effects of PCBs. It was neither intended nor possible for the panel to conduct a conclusive and comprehensive review of the voluminous literature on the health effects of PCBs. This meeting summary is a reflection of the panel exchanges on a wide range of subjects, during which a variety of views were offered, and there was general agreement on a number of topics.

The panel agreed that the information on typical background serum PCB levels for non-occupationally exposed people contained in the 1997 ATSDR Toxicological Profile is not current. The panel concluded that more recent information that now exists suggests that the range may be lower than 4-8 ppb. Some recent studies have found background serum PCB levels for women of reproductive age around 1-2 ppb, while other researchers have observed levels around 6 ppb for older people (i.e., people 50 and older including those 70 and greater) who do not eat much fish. The panel also pointed out that analytical methods need to be considered when comparing results from one study to another at these low ranges. The recent studies provide valuable data points that must be placed within the context of all relevant factors.

The panel further agreed that serum PCB levels are complex indicators that cannot be compared individually to a single background range to ascertain health risks. Rather, the results should be evaluated by comparison with the distribution of levels within local and reference populations, considering age, fish eating habits, occupational exposures, and analytical methods.



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The panel agreed that it is a positive sign that the typical serum PCB levels in non-occupationally exposed populations are lower now than they were a decade ago but there was some disagreement as to whether levels may be continuing to decrease. However, as diagnostic capabilities increase, researchers are also observing subtle developmental effects on the fetus if the mother's serum PCB levels are close to background levels. The panel stressed that these effects may not be significant on an individual level, but are of concern for the population at large.

While the panel cited some conflicting epidemiological studies, overall most of the panel members agreed that the evidence supports that PCBs are a definite carcinogen in animals, and thus a possible to probable carcinogen in humans.

Most of the panel agreed that there appear to be some developmental effects (e.g., subtle cognitive deficits) associated with exposure to PCBs. However, frank neurotoxic effects such as seizure disorders have not been seen. Most panel members agreed that the most susceptible stage of development for these effects seems to be the fetal/prenatal stage.

Individuals who are concerned about exposures to PCBs may want to have their PCB serum level measured because this is the best available indicator of actual exposure. In any case, individuals should take steps to reduce potential exposures (e.g., refrain from consumption of fish from PCB-contaminated water bodies). This would be particularly true for individuals whose serum PCB levels are found to be elevated.

While serum PCB levels are good indicators of exposure, risk of adverse health outcomes will vary. What the actual numbers mean in terms of health for an individual is dependent on a number of factors, such as age at exposure and other conditions of increased susceptibility (e.g., impacts on fetal development for women who are pregnant or are planning to become pregnant).

Panel members stressed that fish consumption advisories must be followed, including advice on cooking and preparation methods.



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**for the**

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# OF THE
# EXPERT PANEL ON THE HEALTH EFFECTS
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**with Administrative Support from**

**THE BUREAU OF ENVIRONMENTAL HEALTH ASSESSMENT**
**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH**
**BOSTON, MASSACHUSETTS**

**Funding from**

**THE EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES**
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**and**

**THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY**
**ATLANTA, GEORGIA**

**October 2000**

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# COMMONWEALTH OF MASSACHUSETTS
# EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

## Questions and Answers

1. **Q. Why was an expert panel convened?**

   **A.** Because of continuing concerns relative to the health effects of PCBs among Pittsfield area residents, the Secretary of the Executive Office of Health and Human Services (EOHHS) called for a review of this topic by a panel of independent experts. It was hoped that this panel would establish consensus on the available health information where possible, reflect the range of scientific opinion, and report on the current state of the science and directions of current research.

2. **Q. Who was on the expert panel?**

   **A.** The panel comprised 11 nationally and internationally recognized experts on the health effects of PCBs from a wide range of disciplines, including toxicology, epidemiology, public health, and analytical chemistry.

3. **Q. How and why were the panelists selected?**

   **A.** The Secretary of EOHHS invited the public to nominate potential panel members who had expertise in one of the following disciplines: toxicology; epidemiology; environmental exposure assessment; laboratory science; medicine (including cancer and reproductive outcomes); environmental fate and transport; and organic chemistry. The public comment period for submission of nominations ran from August 2nd to August 21st, 1998. Nearly 40 individuals were nominated representing a variety of disciplines. In selecting the final 11 panelists, the Secretary made every effort to have a panel of individuals with the diversity of technical disciplines noted above and who were nominated by a variety of publicly interested parties.

4. **Q. What topics did the panel discuss? How were these topics selected?**

   **A.** The role of the panel was to review, assess, and summarize the most up-to-date published and ongoing research on PCBs and public health, with special emphasis on:
   - The latest information on typical levels in the U.S. of PCBs in blood serum and the public health significance of these levels;
   - The adverse health outcomes associated with exposure to PCBs;
   - The thoroughness of information on ways humans can be exposed to PCBs (such as via air, water, soil, food);
   - The interactions between PCBs and other chemicals.

   EOHHS compiled a preliminary list of questions for the panel based on the experiences of



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the Massachusetts Department of Public Health (MDPH) with PCB contamination in the Houstonic River Area and throughout the Commonwealth. Furthermore, EOHHS and the chairman of the panel held a public meeting in Pittsfield on the eve of the panel meeting to solicit additional questions and comments from the public in Berkshire County.

5. Q. **What were the findings of the expert panel with respect to typical background levels of PCBs in blood serum?**

A. The panel agreed that the information on typical background serum PCB levels for non-occupationally exposed people in the Toxicological Profile for PCBs[1] (i.e., 4-8 ppb) is not current. In addition, the panel concluded that the information that now exists suggests that the range is probably lower than 4-8 ppb, but that comparisons are difficult due to differences in the age of various study populations and whether or not they eat fish. Some recent studies have found background serum PCB levels for women of reproductive age around 2 ppb, while other researchers have observed levels around 6 ppb for elderly people who do not eat much fish. The recent studies provide valuable data points that must be shared within the context of all relevant factors. For example, studies have consistently shown that serum PCB levels increase with age and are correlated to factors such as fish consumption and exposures to PCBs at work.

The varied analytical and statistical methods used by different researchers often make comparisons between studies difficult or impossible. Therefore, the panel strongly recommended that an individual's serum PCB level be evaluated by comparisons to the distribution of levels within the local and other comparable populations, considering age, fish consumption habits, and occupational exposures.

6. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the current estimates of typical background levels for non-occupationally exposed individuals?**

A. When comparing serum PCB levels between different studies, it is important to match populations with similar ages and opportunities for exposures to PCBs (e.g., occupation, fish consumption habits). Analytical and statistical methods (e.g., chromatographic and detection methods, detection limits, target congeners, treatment of non-detected samples) can also vary among studies, further complicating comparisons. Nevertheless, if the appropriate factors are considered, the serum PCB levels measured in recent studies may provide useful comparison data for the results from the Housatonic River Area.

7. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the population in the study from The Netherlands?**

A. In a recent study from The Netherlands, 415 women of reproductive age (i.e., mid-20s to mid-30s) were found to have median serum PCB levels around 2 ppb. Because of the analytical methods used in this study, this result may actually correspond to approximately 4

[1] Toxicological Profile for Polychlorinated Biphenyls, Draft for Public Comment, Agency for Toxic Substances and Disease Registry, Atlanta, Georgia, December 1998.



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ppb of total serum PCBs as measured for MDPH's Exposure Assessment Study. This could be predicted with greater certainty if some samples are analyzed by both techniques. In contrast, non-occupationally exposed residents of the Housatonic River Area between 18 and 34 years old (n=8) had median serum PCB concentrations less than 2 ppb.

8. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to people over 50 years old who do not each much fish?**

A. A recently published study reportedly found that 180 people over 50 years old who do not eat much fish (i.e., less than 6 pounds per year) had serum PCB levels around 6 ppb. The median serum PCB levels for non-occupationally exposed, older (i.e., 50 years and older, including those greater than 70) participants in MDPH's Exposure Assessment Study were 3.70 (n=19) and 5.90 (n=12) ppb for the Exposure Prevalence and Volunteer phases, respectively.

9. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the population in the Great Lakes study?**

A. A mixed-age population in the Great Lakes region who did not consume sport-caught fish had geometric mean (i.e., approximately median) serum PCB levels of 1.5 and 0.9 ppb for males (n=57) and females (n=42), respectively. For a similar population in the Housatonic River Area (i.e., non-occupationally exposed participants, 18-64 years old, who either never ate fish or ate only store-bought fish), the median serum PCB levels were 3.30 (n=10) and 1.66 (n=8) ppb in the Exposure Prevalence and Volunteer phases, respectively. Direct comparisons between these studies are hampered by the fact that the method detection limit for MDPH's Exposure Assessment Study (2 ppb) was greater than the median levels measured in the Great Lakes study.

10. Q. **How do the serum PCB levels from residents of the Housatonic River Area compare to the populations in the New York breast disease studies?**

A. Two studies of women with benign breast disease in the New York area reported average concentrations of serum PCBs of 2.15 (n=173) and 4.06 (n=19) ppb. The average serum PCB concentrations for non-occupationally exposed participants in MDPH's Exposure Assessment Study were slightly higher than this range, 4.49 (n=52) and 5.77 (n=53) ppb for the Exposure Prevalence and Volunteer phases, respectively. This may be because the women in the New York studies were on average about 10 years younger than the participants in MDPH's Exposure Assessment Study. Furthermore, the method detection limit for the larger of the New York studies (0.5 ppb) was four times lower than the detection limit for MDPH's Exposure Assessment Study (2 ppb).

11. Q. **Overall, how do the serum PCB levels from residents of the Housatonic River Area compare to the populations in these recent studies?**

A. Because of the complications discussed earlier, direct comparisons between studies are difficult. However, the available data indicate that serum PCB levels for the non-



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occupationally exposed population from MDPH's Exposure Assessment Study are generally similar to the background exposure levels reported in recent studies.

12. Q. **What were the findings of the expert panel with respect to adverse health outcomes associated with PCB exposures?**

A. While the panel cited some conflicting human studies, overall the panel members agreed that the evidence is clear that PCBs are a definite carcinogen in animals. In humans, the evidence with regard to cancer is suggestive but inconclusive.

Most of the panel agreed that there appears to be some developmental effects (e.g., subtle cognitive deficits) associated with exposure to PCBs. Developmental effects observed in animal studies have also been seen in humans. However, frank neurotoxic effects such as seizure disorders have not been seen. Many agreed that the most susceptible population to these effects seems to be fetuses *in utero*.

There is some suggestive, but not conclusive, evidence from animal and human studies that exposures to PCBs can affect the immune system. Dermal effects (e.g., chloracne) have been observed in workers who were exposed to PCBs on the job.

13. Q. **What were the findings of the expert panel with respect to the public health implications of serum PCB levels near background levels?**

A. The current research suggests that prenatal exposures to fetuses at near background levels of PCBs may subtly affect the mental development of children. Immunological and hormonal effects have also been seen following prenatal exposure, in addition to the neurological effects. Recent studies in The Netherlands observed that children born to mothers with greater than 3 ppb of serum PCBs scored slightly lower on tests of cognitive abilities than children whose mothers had serum PCB levels less than 1.5 ppb. While statistically significant for the study population, the panel agreed that these effects were probably not noticeable on an individual basis. Moreover, because of the analytical methods used in this study, the serum PCB measurements represent approximately one-half the total serum PCBs and, hence, should be doubled to be comparable to the test results from MDPH's Exposure Assessment Study.

Importantly, this same study also found that children who were breast fed scored better on cognitive tests than children who were fed formula, despite additional exposures to PCBs and dioxins in breast milk. This finding reinforces the beneficial properties of breast feeding and highlights that exposures to PCBs *in utero* are likely of greatest concern.

14. Q. **Should I be concerned about the cognitive development of my children?**

A. The results of recent studies from The Netherlands raise legitimate concerns about developmental effects as a result of near background exposures to PCBs for fetuses *in utero*. However, the cognitive effects observed are slight and many panelists felt they were not biologically significant on an individual basis. Furthermore, the panel felt that other factors that affect a child's aptitude for learning (e.g., parental involvement with the child's



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education, good nutrition, supportive family environment) probably play a much larger role than background PCB exposures. Nevertheless, these findings provide more justification for continuing to clean up PCB contamination to reduce opportunities for exposure as much as possible.

15. Q. **What were the findings of the expert panel with respect to exposure routes for non-occupationally exposed populations?**

A. The panel agreed that exposures to PCBs are possible through multiple routes (e.g., air, water, soil, and food), however, the vast majority of exposure typically occurs through eating food of animal origin (e.g., fish, meat, dairy).

16. Q. **How can people avoid important opportunities for exposure to PCBs?**

A. Observing fish consumption advisories and eating a healthy diet that is low in fatty foods is the most effective way to reduce overall exposures to PCBs. However, because even small exposures add incrementally to overall body burden, it is important to reduce exposures via all routes.

Because the bioavailability of PCBs in air, water, and soil is uncertain, the expert panel endorsed serum PCB tests as the best available measure of actual exposure for individuals who are concerned about their exposures to PCBs.

17. Q. **What were the findings of the expert panel with respect to interactions between PCBs and other chemicals?**

A. PCBs are thought to behave as tumor promoters in susceptible tissues. Therefore, the carcinogenic effects of PCBs are likely to be influenced by other carcinogens or toxins that may be present. It is hoped that ongoing research will reveal more about the toxicity of mixtures of PCBs and other chemicals in the future.

18. Q. **The focus in the Housatonic River Area Exposure Assessment Study was on individuals living near the river. Is there a need for the MDPH to examine the PCB serum levels of a population further away from the river?**

A: The Housatonic River Area Exposure Assessment Study was purposely aimed to select individuals with highest opportunity for exposure, therefore the focus was on individuals living near the river or engaging in a variety of activities that may increase their opportunities for exposure to PCBs (e.g., fish consumption, recreational activities near the river, gardening, construction activities, fiddlehead fern consumption). Since these people were largely found to have levels near typical background ranges, individuals living further away from the river would not be expected to have higher PCB levels.

19. Q. **Will MDPH evaluate all the adverse health outcomes that have been associated with PCB exposures?**

A. In addition to a large number of public health assessments, MDPH is conducting an analysis

of cancer incidence from 1982 to 1994 in the Housatonic River Area using data from the Massachusetts Cancer Registry. For this project, the cancers most strongly associated with PCB exposures will be evaluated (i.e., liver cancer, breast cancer, non-Hodgkin's lymphoma, Hodgkin's disease, thyroid cancer, and bladder cancer). If environmental data indicate significant opportunities for exposure to other carcinogens (e.g., PCBs and smoking as co-carcinogens), or if the literature and further discussions with appropriate experts identifies additional cancers of concern (e.g., brain, testicular, lung cancer), the list of cancers under review may be expanded. The expert panel agreed that MDPH's approach for the health assessment and other public health activities, along with the continued clean-up efforts, were adequate measures to be taken at this time.

MDPH is also conducting a pilot study assessing the relationship between environmental exposures to PCBs and DDE and new diagnoses of breast cancer.

**20. Q. What can I do if I am concerned about my exposures to PCBs?**

A. MDPH has established a toll free hotline to advise local area residents about any health related concerns or questions they may have. An exposure assessment questionnaire has been and will continue to be provided to all residents who wish to have their opportunities for exposure evaluated and a blood test taken. The hotline number is (800) 240-4266.

**21. Q. Where can I get additional information?**

A. For information on the expert panel or MDPH health studies in the Housatonic River Area, contact the Bureau of Environmental Health Assessment of MDPH at (617) 624-5757 or (800) 240-4266.



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T 1: Serum PCB Concentrations (ppb) for non-occupationally expo participants in MDPH's Housatonic River Area PCB Exposure
A ssment Study[1]

**(A) Exposure Prevalence Phase**

| Age | Fish Consumption Habits | n | Minimum | 25th % | Median | Mean | 75th % | Maximum |
|---|---|---|---|---|---|---|---|---|
| 18-34 | Never ate fish | 0 | | | | | | |
| 18-34 | Ate fish but not from the H.R.[3] | 1 | 1.74 | 1.74 | 1.74 | 1.74 | 1.74 | 1.74 |
| 18-34 | Ate fish from the H.R. | 3 | 1.35 | 1.35 | 1.88 | 2.11 | 3.09 | 3.09 |
| 18-34 | Total | 4 | 1.35 | 1.55 | 1.81 | 2.02 | 2.49 | 3.09 |
| 35-49 | Never ate fish | 3 | 1.53 | 1.53 | 2.50 | 5.21 | 11.60 | 11.60 |
| 35-49 | Ate fish but not from the H.R. | 10 | 1.00 U[2] | 1.74 | 3.36 | 3.86 | 5.09 | 8.16 |
| 35-49 | Ate fish from the H.R. | 4 | 1.00 U | 1.23 | 3.06 | 3.49 | 5.75 | 6.83 |
| 35-49 | Total | 17 | 1.00 U | 1.63 | 3.12 | 4.01 | 5.09 | 11.60 |
| 50-64 | Never ate fish | 4 | 2.04 | 2.31 | 2.87 | 3.17 | 4.04 | 4.92 |
| 50-64 | Ate fish but not from the H.R. | 11 | 2.18 | 3.43 | 3.70 | 4.19 | 5.58 | 6.31 |
| 50-64 | Ate fish from the H.R. | 4 | 2.97 | 3.45 | 4.14 | 4.41 | 5.37 | 6.40 |
| 50-64 | Total | 19 | 2.04 | 3.16 | 3.70 | 4.02 | 4.92 | 6.40 |
| 65+ | Never ate fish | 5 | 3.25 | 3.53 | 5.31 | 5.48 | 6.99 | 8.32 |
| 65+ | Ate fish but not from the H.R. | 6 | 3.78 | 4.58 | 6.79 | 7.12 | 9.31 | 11.44 |
| 65+ | Ate fish from the H.R. | 1 | 10.87 | 10.87 | 10.87 | 10.87 | 10.87 | 10.87 |
| 65+ | Total | 12 | 3.25 | 4.18 | 6.15 | 6.75 | 8.82 | 11.44 |
| 18-65+ | All participants | 52 | 1.00 U | 2.70 | 3.67 | 4.49 | 5.66 | 11.60 |

**Notes**

1. *Final Report of the Housatonic River Area Exposure Assessment Study*, Bureau of Environmental Health Assessment, Massachusetts Department of Public Health, Boston, MA, September 1997.
2. U = Not detected. The value shown is one-half the method detection limit.
3. H.R. = Housatonic River



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**Table 1 (cont.):** Serum PCB Concentrations (ppb) for non-occupationally exposed participants in MDPH's Housatonic River Area PCB Exposure Assessment Study[1]

**(B) Volunteer Phase**

| Age | Fish Consumption Habits | n | Minimum | 25th % | Median | Mean | 75th % | Maximum |
|---|---|---|---|---|---|---|---|---|
| 18-34 | Never ate fish | 0 | | | | | | |
| 18-34 | Ate fish but not from the H.R.[3] | 3 | 1.00 U[2] | 1.00 U | 1.00 U | 2.13 | 4.40 | 4.40 |
| 18-34 | Ate fish from the H.R. | 1 | 1.00 U | 1.00 U | 1.00 U | 1.00 U | 1.00 U | 1.00 U |
| 18-34 | Total | 4 | 1.00 U | 1.00 U | 1.00 U | 1.85 | 2.70 | 4.40 |
| 35-49 | Never ate fish | 4 | 1.00 U | 1.00 U | 1.00 U | 1.00 U | 1.00 U | 1.00 U |
| 35-49 | Ate fish but not from the H.R. | 13 | 1.00 U | 1.00 U | 2.84 | 3.30 | 3.24 | 10.70 |
| 35-49 | Ate fish from the H.R. | 0 | | | | | | |
| 35-49 | Total | 17 | 1.00 U | 1.00 U | 1.00 U | 2.76 | 3.13 | 10.70 |
| 50-64 | Never ate fish | 4 | 2.32 | 3.63 | 7.58 | 12.22 | 20.82 | 31.41 |
| 50-64 | Ate fish but not from the H.R. | 7 | 1.00 U | 1.00 U | 5.15 | 5.14 | 6.93 | 11.03 |
| 50-64 | Ate fish from the H.R. | 1 | 7.10 | 7.10 | 7.10 | 7.10 | 7.10 | 7.10 |
| 50-64 | Total | 12 | 1.00 U | 3.28 | 5.90 | 7.67 | 8.67 | 31.41 |
| 65+ | Never ate fish | 6 | 4.31 | 7.39 | 7.90 | 8.65 | 11.88 | 12.50 |
| 65+ | Ate fish but not from the H.R. | 13 | 3.36 | 5.09 | 7.69 | 7.40 | 9.39 | 12.00 |
| 65+ | Ate fish from the H.R. | 1 | 11.68 | 11.68 | 11.68 | 11.68 | 11.68 | 11.68 |
| 65+ | Total | 20 | 3.36 | 5.17 | 7.80 | 7.99 | 10.44 | 12.50 |
| 18-65+ | All Participants | 53 | 1.00 U | 1.00 U | 4.86 | 5.77 | 7.90 | 31.41 |

**Notes**

1. *Final Report of the Housatonic River Area Exposure Assessment Study*, Bureau of Environmental Health Assessment, Massachusetts Department of Public Health, Boston, MA, September 1997.
2. U = Not detected. The value shown is one-half the method detection limit.
3. H.R. = Housatonic River



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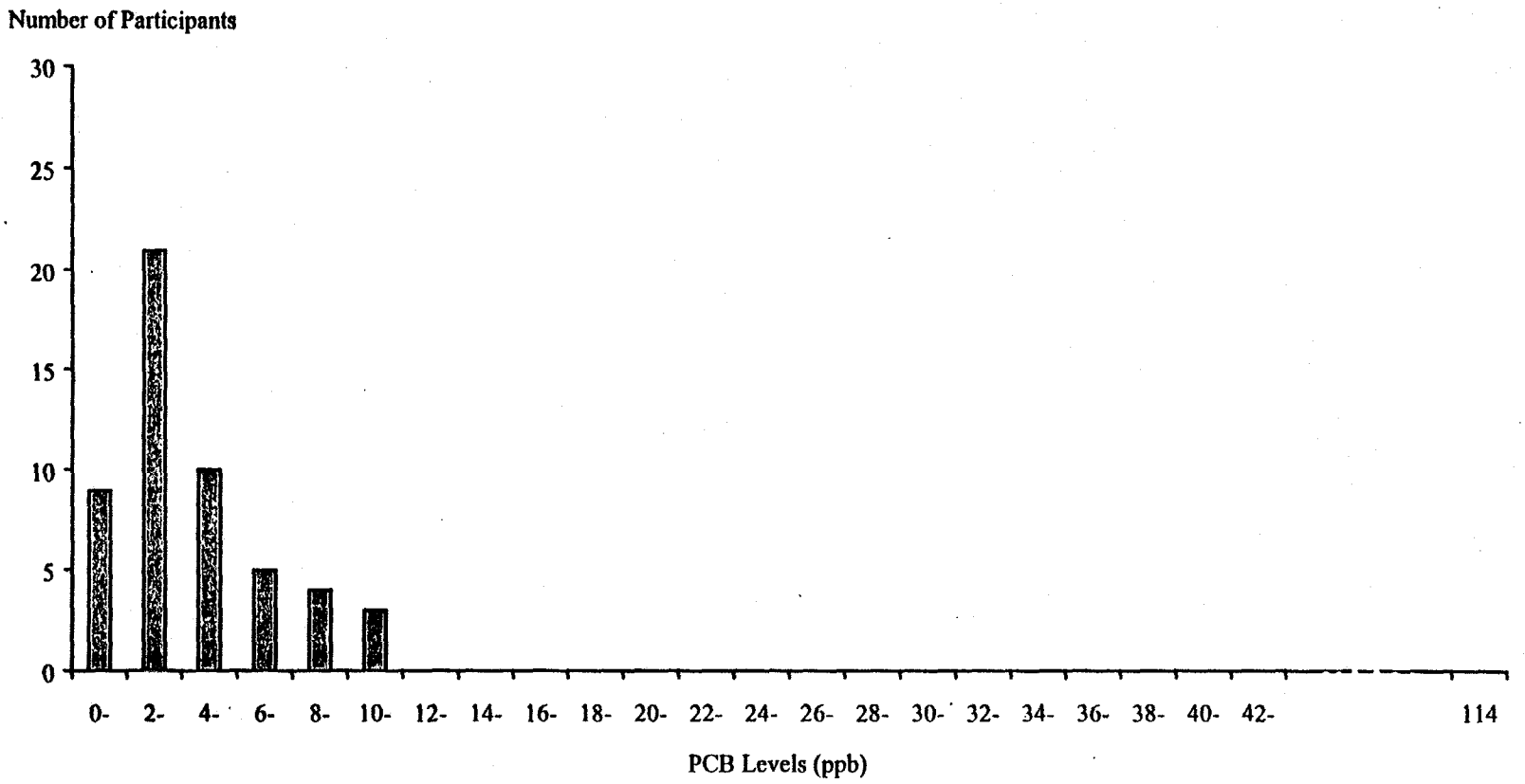


**Figure 1(A)**: Distribution of Serum PCB Concentrations - Non-Occupationally Exposed Participants in the Exposure Prevalence Phase

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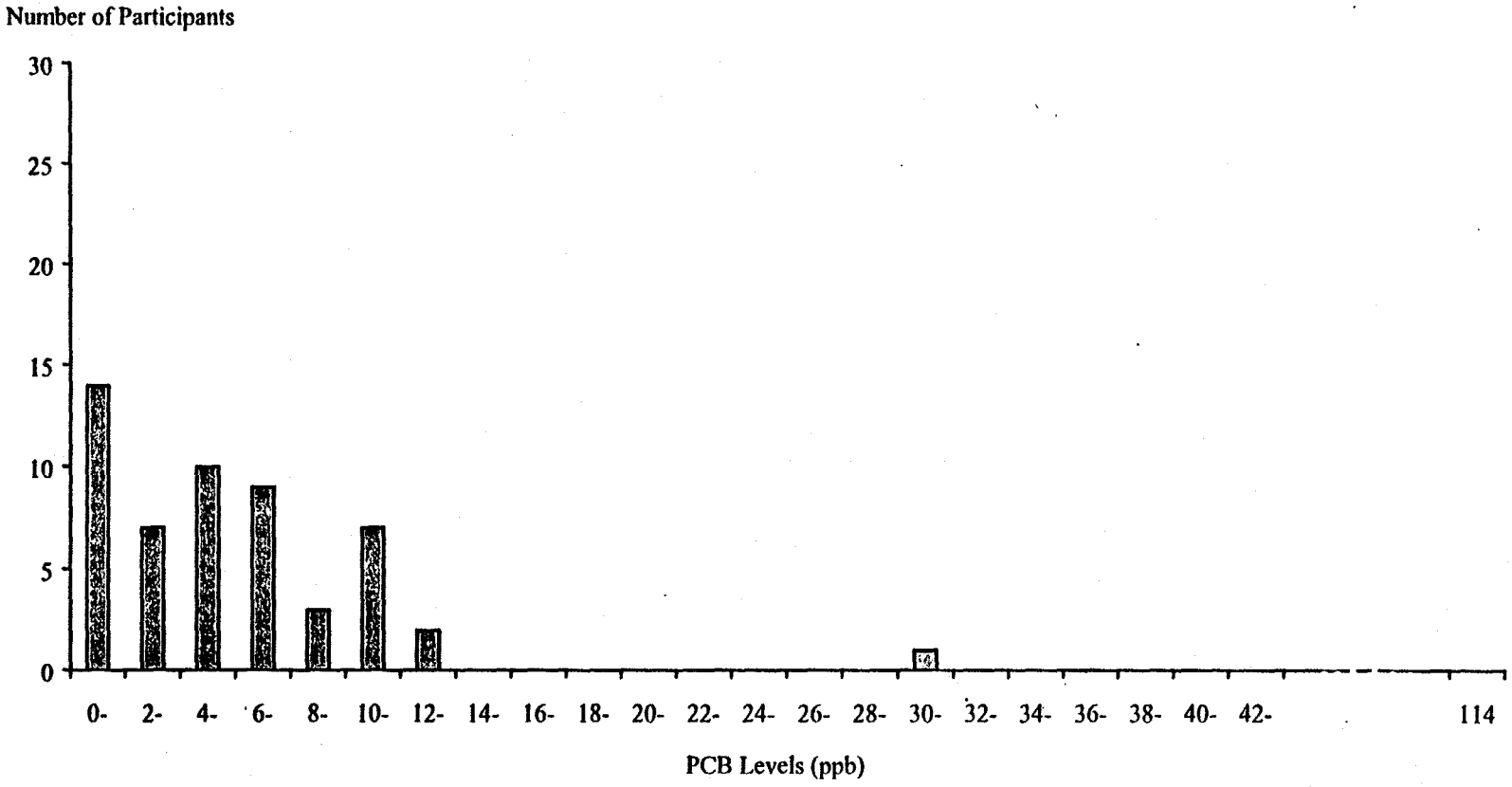


**Figure 1(B)**: Distribution of Serum PCB Concentrations - Non-Occupationally Exposed Participants in the Volunteer Phase

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**Figure 2(A):** Serum PCB Concentrations - Non-Occupationally Exposed Participants in the Exposure Prevalence Phase

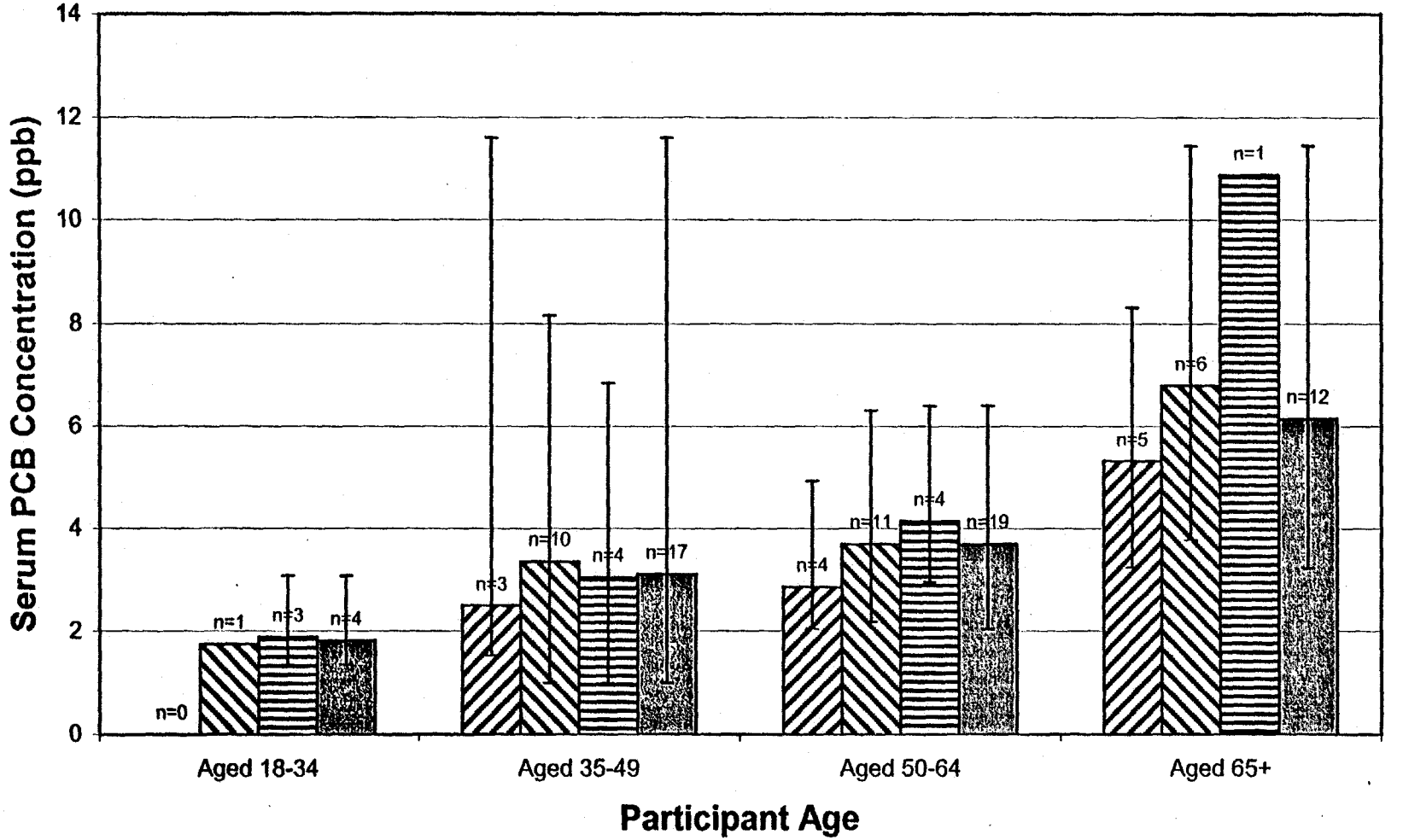


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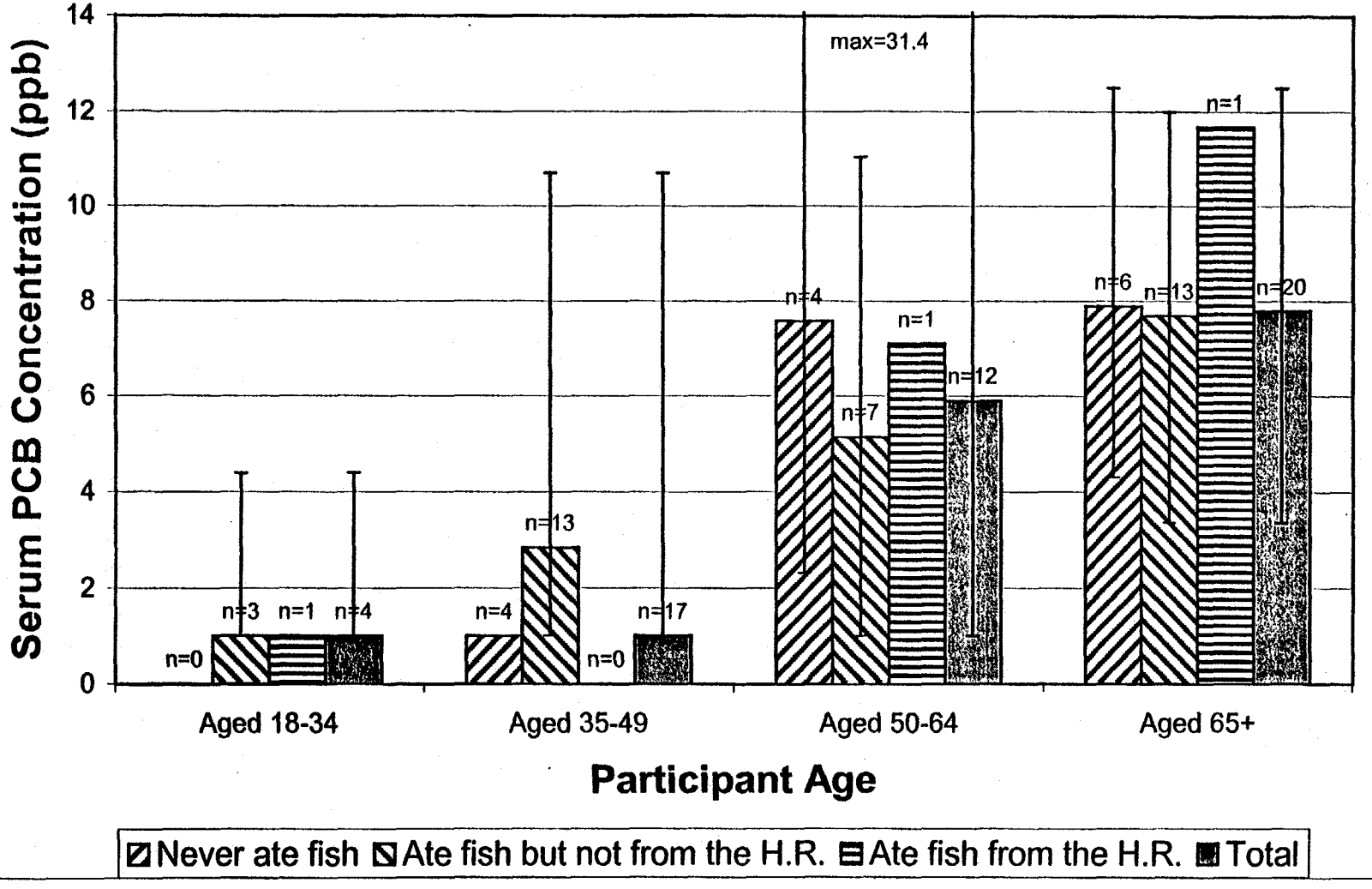
**Figure 2(B)**: Serum PCB Concentrations - Non-Occupationally Exposed Participants in the Volunteer Phase

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COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES

# MEETING SUMMARY

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

**Friday, January 22, 1999**
**9:00 AM - 4:00 PM**

## I. Opening Remarks by William O'Leary, Secretary, Executive Office of Health and Human Services

William O'Leary, Secretary of the Executive Office of Health and Human Services (EOHHS), was introduced by Suzanne Condon, Director of the MA Department of Public Health (MDPH), Bureau of Environmental Health Assessment Program. Secretary O'Leary stated that the purpose of convening the expert panel was to continue to provide information to the public about the health effects of PCB exposure and to further the national discussion on this issue.

## II. Introduction to the Experiences of MDPH with Regards to PCBs and Health Effects

Elaine Krueger, Chief of the Environmental Toxicology Unit of the Bureau of Environmental Health Assessment, provided panel members with an overview of the PCB-related public health investigations undertaken to date by the MDPH (see slides and information booklet in Attachments E and F).

A 1981 fire involving PCB transformers in Canton, Massachusetts prompted a public health investigation under which MDPH, in connection with the Centers for Disease Control (CDC), performed serum PCB level tests for ten individuals. Another investigation in Norwood in the 1980s stemmed from a Superfund Site at which soil levels of PCBs were among the highest ever found, at approximately 200,000 ppm. An exposure assessment screening survey was administered to a 10% random sample of the entire community. The highest 10% of these people (those reporting greatest opportunities for exposure) participated in serum PCB testing. Results showed elevations associated with occupational but not with recreational exposures. MDPH's



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investigation of the Greater New Bedford Harbor area began in 1982, after the fisheries there were closed in 1979 due to PCB pollution. MDPH along with the CDC conducted a pilot study that prompted a large study of serum PCB levels in New Bedford and surrounding towns. This produced a large data set from 850 subjects, including blood tests and in-depth interviews, and serves as the model for the current investigation of the Housatonic River Area. Higher serum PCB levels were noted for older individuals, fish eaters, as well as those with occupational exposures.

The Housatonic River Area activities began in 1982 when MDPH issued a fish advisory for the River where PCB levels in fish were found to average 30 and range as high as 25[illegible] ppm. Due to public concern in this area of Western Massachusetts, DPH has focused its current efforts there through an Exposure Assessment Study; a Hotline to help evaluate health concerns and resultant Hotline Follow-up Report; a Breast Cancer Pilot Study; Public Health Assessments (one for each of the ten General Electric (GE) sites in cooperation with the Agency for Toxic Substances and Disease Registry, ATSDR); and an Occupational Epidemiological Feasibility Assessment to determine whether a study can be done to respond to concerns of community members who worked in this industry. MDPH sought information from GE to carry out this feasibility study. MDPH further noted that the community has initiated its own survey and has informed us that the results will be shared with MDPH to assist in other public investigations.

***HRA-PCB Exposure Assessment Conclusions***

MDPH reported that the Exposure Prevalence Survey based upon surveys of 800 households along the river in the Housatonic River Area revealed potential avenues for PCB exposure. The results were as follows: 25% ate freshwater fish; 3% ate fish from the Housatonic River; 5% ate fiddlehead ferns; 11% canoed on the River; 4% birdwatched; 29% did vegetable gardening. Serum PCB levels were tested in 69 of the 120 individuals invited to participate. Results showed these levels to be within the background range (i.e., 4-8 ppb) for the general population as reported by ATSDR. Most subjects were in the lower range with the highest levels found in older residents who consumed fish or who had occupational exposure. In these tests, the most important variables were age and occupation. In addition, this survey and supplemental serum

PCB testing was expanded to include the whole of Berkshire County in order to receive more information from concerned individuals.

***PCB Hotline***

MDPH established a PCB Hotline in September 1997 to evaluate health concerns related to recent discoveries of contaminated residential properties. Over two hundred calls have been received to date, and approximately 160 additional persons have completed individual exposure surveys and received serum PCB tests. A health assessment report for these individuals will be drafted by MDPH. [Note: As of May 2000, more than 250 calls have been received.]

***Berkshire Breast Cancer and Environmental Exposure Pilot Study***

Environmental concerns regarding PCBs, DDT, and DDE prompted this pilot study to address feasibility issues and to assist with the design of a larger future study. The Study objective is to investigate changes in serum PCB and DDE levels over time among women with and without breast cancer. Women ranging in age from 30 to 80 have provided serial blood samples at the point of diagnosis and three separate times over a one-year period following the initial blood draw. MDPH noted that the medical community has been receptive to this Study and that 30% of the women diagnosed with breast cancer in Berkshire County have chosen to participate. The rationale behind the Study is to investigate links between PCBs, DDE and breast cancer, the effect of disease or treatment on level, and to address scientific data gaps.

***Health Assessment Process and Overview***

MDPH reported that the Health Assessment Process for each of the ten GE Sites includes: comprehensive site information, gathering of community concerns, contaminants of concern, exposure pathways, public health implications, and to form conclusions and provide recommendations. The Health Assessment Process could have multiple outcomes and requires a systematic and multi-faceted approach that can lead to following activities: health education, health advisories, health surveillance, toxicological profiles, exposure/disease registries, research, health studies, medical care, and testing.

*GE Site - Public Health Assessments*

MDPH reported that twelve reports will result from the Public Health Assessments being undertaken at this time, including the Hotline Assessment, Cancer Assessment, and ten GE sites: Newell St. Area 1, Newell St. Area 2, East St. Area 1, East St. Area 2, Unkamet Brook Area, Hill 78 Area, Lyman St., Allendale School Property, Housatonic River/Silver Lake, and, The former Oxbows. It was noted that the GE plant employed 20,000 people when in operation and continues to operate its Plastics Division Headquarters.

*Purpose and Charge of the Expert Panel*

MDPH stated that the expert panel was convened in response to public concern about the many questions raised through the GE site investigations. The purpose of the panel is to clarify health information, reflect a range of scientific opinion, discuss the current science on key topics, identify data gaps and limitations, inform MDPH as to the extent of the statements to be made regarding these issues, and to set a foundation for future health assessment work. The charge to the panel is to suggest typical background serum PCB levels and their public health significance, to provide information about adverse health outcomes associated with exposure to PCBs, to assess the importance of various exposure pathways, and to evaluate the interactions of PCBs with other chemicals (see panel mission in Attachment C).

## III. Summary of Comments Received at the Public Meeting in Pittsfield on January 21, 1999

The panel chairman reviewed comments and questions received from the public at the public meeting in Pittsfield on January 21, 1999. He reported that the community is concerned about the unknowns surrounding PCB levels and their health effects and hopes that this panel can shed some light on these issues. In addition, the community questions if any more can or should be done to address health concerns based on new scientific findings. The community seeks a general consensus of the panel regarding the nature and extent of harmful effects of PCBs. The chairman provided the panel with a list of specific questions asked at the public meeting, each of



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which will be addressed under the relevant topic, below (see public comments/questions in Attachment D).

## IV. Review of Panel's Mission and Discussion of Procedural Issues

The primary mission of this expert panel as stated by MDPH is to provide EOHHS with an updated review of the literature to date, summarize research that is currently underway, and identify data gaps or limitations of research previously conducted such that appropriate next steps can be outlined (see panel mission in Attachment C). The panel agreed that mission would not be exhaustively performed in the short time the group was convened, but that these three items would be brought to the table to the extent that panel members were knowledgeable about those items. The panel also agreed that they would not comment on regulations or clean-up levels.

It was noted that some community members wished to attend today's session. Some panel members expressed that they would have had no problem with this. However, MDPH explained that in order to keep the group small and to promote free scientific dialogue among panel members, attendees were limited to the expert panel and key officials from MDPH. Representatives from ATSDR, the U.S. Environmental Protection Agency (EPA), and the Massachusetts Department of Environmental Protection (MDEP), were originally asked to attend only the first part of the panel meeting, but during the course of the meeting it was clear that the panel would benefit by having agency representatives on hand to answer questions from panel members during the afternoon session as well.

It was stressed that a summary of the panel deliberations would be provided as part of a report to be presented at a future public meeting. Expert panel members were invited to attend that public meeting.

## V. Expert Panel Deliberations

The expert panel was convened to assist the Secretary of Health and Human Services in addressing health questions raised by the widespread PCB contamination in the Housatonic River Area. The general charge to the panel was to discuss the current science on several key topics

related to the health effects of PCBs. It was neither intended nor possible for the panel to conduct a conclusive and comprehensive review of the voluminous literature on the health effects of PCBs. This meeting summary is a reflection of the panel exchanges on a wide range of subjects, during which a variety of views were offered, and there was general agreement on a number of topics.

The expert panel discussion was centered on five questions from EOHHS (see panel mission in Attachment C). In addition, based upon questions and comments received from public meetings in the Housatonic River Area, the discussion was broadened.

> **EOHHS Question 1**: The ATSDR Toxicological Profile reports that typical background levels for serum PCBs for non-occupationally exposed individuals in the U.S. population is 4-8 ppb (ATSDR Toxicological Profile on PCBs, 1997). Is there new information about this reported background range?

Regarding the range of 4-8 ppb cited above, the panel agreed that this range is higher than the findings of some more recent studies. However, much of the recent data are not yet published and, hence, are not available to determine the current background range. The range of 4-8 ppb cited in the ATSDR 1997 document is based upon blood samples drawn in the 1980's. However, there are a variety of studies published that indicate there is variability in background ranges. Background ranges can vary depending upon a number of important factors (e.g., fish consumption rates, demographic characteristics for the population in question, age, dietary habits, and laboratory analytical methods). Some studies have cited background ranges lower than 4-8, i.e., 1-2 ppb (Stewart et al. 1999; Hanrahan et al. 1999; Anderson et al. 1998a), while others have cited background levels in non-occupationally exposed populations in the 5-6 ppb range (Laden et al. 1999; Schantz et al. 1996).

One panel member cited data from studies done in the 1990's which provide good evidence that the typical background range for serum PCB levels among non-occupationally exposed/non-

contaminated fish eaters has decreased since the 1980's. For example, a Great Lakes study found a range of 0.4-2.9 ppb (Anderson et al. 1998b); a study on Long Island found a mean of 2.15 ppb (Stellman et al. 1998); and a Scandinavian study found levels of 1-2 ppb (Rylander et al. 1998).

One panel member shared results of a recent study comparing serum levels of 180 people over the age of fifty with regard to fish consumption. Consumers of fish in an amount equal to or greater than 26 lbs. per year had serum levels of 16 ppb while non-fish consumers, e.g., eating less than 6 lbs. per year, had levels of 6 ppb (Schantz et al. 1996). Regarding fish consumption, the panel stressed that communities must comply with fish consumption advisories.

One panel member expressed the opinion that background levels may be lower now than in the early to mid 1930's, but there is disagreement as to whether levels may be continuing to decrease. Based upon recent data, the range of mean levels appears to be 0.5 to 3 or 4 ppb among all ages, with older people who do not consume much fish averaging about 6 ppb.

One panel member provided recent publications at the meeting, and other panel members provided additional publications after the meeting, which were forwarded to all panel members and are included in a bibliography with this meeting summary (see list in Attachment G). Some of the conclusions drawn from all of these publications include:

- For many populations, current background levels of serum PCBs are lower than 4-8 ppb.
- Fish consumers have higher PCB serum levels than non-fish consumers do.
- Age is a major factor for elevated body burdens of PCBs.
- A 2 ppb mean range or lower has been reported among reproductive aged persons; however, the distribution of serum PCB levels within this age group is necessary for interpretation of these results.

The panel agreed that the age of subjects must be taken into consideration when discussing ranges of background levels.

In response to a question from the public at the January 21, 1999 meeting in Pittsfield, the panel briefly discussed whether there are regional differences in the signature of PCB congeners in serum samples. One panelist stated that there does not appear to be any variation within the United States. However, no national survey for PCBs in serum at low detection levels has been done.

It was noted that while the NHANES III (National Health and Nutrition Examination Survey) is a population-based survey, blood samples collected for special environmental toxicants are not representative; furthermore, the samples are not yet analyzed. However, specimens collected for NHANES IV for PCB analysis will be representative of the U.S. population 12 and over; analysis began in 1999 by the CDC.

One panel member emphasized that variation in laboratory analytical methods affects mean levels reported for PCB levels in serum samples, particularly at lower ranges.

The panel discussed how different analytical methods and statistical methods can affect estimates of background serum PCB levels. For example, recently reported PCB levels are generally based on high-resolution (capillary column) gas chromatography/electron capture, while a few have been based on mass spectrometric detection. The MDPH data are based on megabore columns, which give resolution in between capillary columns and packed columns but is probably closer to the latter. Laboratory comparisons of the two chromatographic techniques indicate that the newer high-resolution methods yield PCB levels of similar or lower levels than the packed column methods. Thus, the use of higher resolution chromatographic methods (which give individual congener data) may result in lower measured total PCB levels than packed column methods when measuring the same serum extract.

Different statistical treatments of non-detected peaks representing PCB congeners influence the calculation of individual and mean PCB levels. For example, assigning a concentration value of zero for non-detectable peaks would lead to lower levels of PCBs than assigning those peaks a concentration equal to one half of the detection level. One panelist stated that a reasonable

detection limit is 2 ppb for total PCBs, but this depends on the size of the serum sample and the analytical method used. For packed column gas chromatography, levels below 2 ppb are difficult to accurately and precisely quantify. It was noted that for individual congeners, the detection limit is about 0.2 ppb for each congener, but depending on the technique used to determine the lower detection limit, the detection limit may be as low as 0.05 ppb per peak. Regarding which testing methodology is best, it was noted that every study is done on a case-by-case basis applying the best tools to the given circumstances to answer a specific question. For example, for health studies, individual congener data may help link a given health outcome or biological response to PCB exposures; whereas for exposure assessment purposes, packed column methods can ascertain differences in the degree of exposure.

It was noted that the mean serum PCB level in the Housatonic River Area is 4.5 ppb (4.49 ppb) with a detection limit of 2 ppb (MDPH, 1997). MDPH stated that the serum PCB levels of many people in this area were around or below the detection limit. Some suggested the MDPH should represent data differently than with mean or median serum levels as these statistics do not adequately represent the full range and variability within the population. (Based on this suggestion, additional analyses illustrating PCB serum levels by age range were generated. These results are reviewed at the end of Attachment F).

In addition, regarding the range seen in the Housatonic River Area, a panel member suggested that the range may not be accurate since the sample group is not random but self-selected. MDPH noted that the sample group was selected from a random survey of households along the river. It was suggested that a comparison be done with a control population that does not live near the river.

The panel was informed by MDPH that the serum samples from people in the Housatonic River Area contain a mixture of PCB congeners resembling Aroclor[1] 1260. The panel chairman had been asked by the public at the January 21, 1999 meeting if this indicated that these people had been exposed to this PCB Aroclor. The panel agreed that the particular Aroclor that is the source

of the contamination probably cannot be identified from serum samples because the PCB composition is altered by chemical reactions in the environment and the human body.

Even though it is not always necessary, the panel agreed that testing samples for a large number of individual congeners[2] using the best current technology may assist in deciphering exposures and health risks in the future. One panel member pointed out that, although consideration of the study objectives is important in choosing analytical technology, preserving serum samples or extracts for more detailed analysis, if useful at a later date, may be more cost-effective. Regarding testing for different congeners and metabolites in a cost-effective manner, one panel member cited the need to get broad permission from test subjects and the Institutional Review Board to test for many different constituents and to bank one-half of the serum samples for future testing.

In summary, the panel agreed that the information on typical background serum PCB levels for non-occupationally exposed people in the 1997 ATSDR Toxicological Profile does not reflect all of the current information. The panel concluded that more recent information that now exists indicates that the range may be lower than 4-8 ppb. Some recent studies have found background serum PCB levels for women of reproductive age around 2 ppb, while other researchers have observed levels around 6 ppb for older people (i.e., people 50 and older, including those 70 and older) who do not eat much fish. The recent studies provide valuable data points that must be placed within the context of all relevant factors.

The panel further agreed that serum PCB levels are complex indicators that cannot be compared individually to a single background range to ascertain health risks. Rather, the results should be evaluated by comparison with the distribution of levels within local and reference populations, with age, fish eating habits, occupational exposures, and laboratory analytical methods taken into account.

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[1] Aroclors are commercial polychorinated biphenyls (PCBs) mixtures which were produced in the United States before 1977 (ATSDR Toxicological Profile for PCBs, 1997).
[2] There are 209 possible congeners for PCBs (ATSDR Toxicological Profile for PCBs, 1997).



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**EOHHS Question 2**: What is the public health significance of serum PCB levels within the range of or greater than typical background levels (i.e., 4-8 ppb) but less than 20 ppb (the 95$^{th}$ percentile in the U.S. population)?

The panel agreed that, based upon its conclusions regarding the previous question, the typical background levels cited in this question are not current. Panel members suggested that this should be updated to consider all available data on serum levels in populations, i.e., age, occupation, fish consumption, analytical methodology, and, if possible, background ranges for different age groups. Some panel members agreed that there is emerging scientific evidence that exposure to PCBs at levels common for the general population but lower than occupational exposures, may pose some risk or probability of subtle effects. Studies in monkeys have shown behavioral effects at very low exposure levels. Monkeys with blood levels of about 1.5-3.0 ppb for a very short time postnatally were impaired in a variety of tasks (e.g., spatial delayed alteration tasks) compared to monkeys with levels less than 0.5 ppb (Rice, 1999). One panel member referred to the study of workers, which showed no effects with high exposure levels while monkeys at low levels did show effects and suggested that monkeys may be more sensitive to PCB exposures than humans (Gillis and Price, 1996). However, the occupationally exposed population has not been studied in terms of second generation effects, including subtle differences in cognitive abilities. Furthermore, workplace exposures are to a different mixture of PCB congeners than environmental exposures. Thus, while of interest, health studies with workers may not be completely relevant to environmental exposures for the public.

Most of the panel agreed that small differences in cognitive abilities (e.g., a decrease of a few points in I.Q. level), while probably real, may not be meaningful on an individual basis but could be significant on a population-wide basis. Moreover, a group mean of a few IQ points may reflect a much more substantial decrease for those individuals who may be particularly vulnerable to the exposure. It was recognized that diagnostic techniques have improved, allowing for better measurement of those subtle changes, and in this dynamic field of study, more research needs to be done and results disseminated. One panel member stated the need for continued discussion among researchers to improve consistency of measurement in studying cognitive development.



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It was noted that while serum PCB levels are a good indicator of exposure, risk of adverse health outcomes will vary. What the actual numbers mean in terms of health for an individual is dependent on a number of factors, such as age at exposure and other conditions of increased susceptibility (e.g., impacts on fetal development for women who are pregnant or are planning to become pregnant).

The panel addressed the relationship between serum PCB levels and adverse health effects in more detail as they answered the remaining questions.

> **EOHHS Question 3**: Do PCBs cause adverse health outcomes? If so, what effects and is information available on conditions of exposure and estimated dose levels at which these effects are produced? If data gaps exist for human studies, what does the preponderance of animal studies indicate for these effects?

This meeting summary is a reflection of the panel exchanges on a wide range of subjects, during which a variety of views were offered, and there was general agreement on a number of topics. It was neither intended nor possible for the panel to conduct a conclusive and comprehensive review of the voluminous literature on the health effects of PCBs.

***Reproductive and Developmental Effects***

The panel agreed that there is no conclusive evidence at this time that PCBs interfere with sperm count or reproduction. However, while there are very little data at this time, most of the panel agreed that there appears to be some developmental effects (e.g., subtle cognitive deficits) associated with exposure to PCBs. The panel discussed two important current studies that support the likelihood that that there are some effects from exposure at low levels (i.e., approximately background ranges). A study in The Netherlands regarding exposure to PCBs and dioxins studied subjects from 11 days to 42 months of age found subtle but real effects on



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immunological and cognitive deficits in children of women with serum levels above 3 ppb utilizing a congener-based analytical methodology (Lanting et al. 1998a; Patandin et al. 1999a, 1999b). This study further found impaired neurological function at 11 days of age (Huisman et al, 1995). The Oswego study supported these findings (Stewart et al., 2000).

A study of children cited from Michigan found that while there was no connection with severe mental retardation at levels of greater than 3 ppb but less than 10 ppb, the test scores of a minority proportion of children at these levels had test scores in the range at which a child would be more likely to have difficulties performing in the normal classroom setting (Jacobson and Jacobson, 1996). The Dutch study reported a dose-effect from less than 1.5 ppb to greater than 3 ppb (Patandin 1999a, 1999b; Lanting 1998a). In addition, the Dutch study found that exposed breastfed children did better overall than their non-breastfed counterparts (Huisman et al.1995).

At the January 21, 1999 meeting in Pittsfield, some members of the public expressed concern that learning disorders may be related to PCB exposures. Hence, the panel briefly discussed this topic. The Michigan study specifically evaluated the prevalence of attention deficit disorder (ADD) in relation to prenatal exposures to PCBs, but did not find a correlation (J. Jacobson, personal communication).

The panel agreed that the key message is to minimize exposure to women of childbearing age and to children so that their serum PCB levels will be low when they approach childbearing age. Exposures to PCBs do not necessarily mean that adverse health effects will develop. The effects of exposure are questions of probability. The susceptibility of children to these effects varies on an individual basis. Learning problems that are observed should be dealt with in the same manner as impediments caused by any other condition or exposure (e.g., fetal alcohol syndrome, poor nutrition). The panel stressed that health effects observed on a population-wide basis may not be seen on an individual level.



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*Cancer*

One panel member stated that there appears to be a significant correlation of non-Hodgkin's lymphoma and serum levels of 3.8-10.3 ppb (Rothman et al. 1997). However, another study on the human mortality of occupationally exposed persons found that non-Hodgkin's lymphoma was not seen in subjects with high levels (Kimbrough et al. 1999). In this study of the largest occupational cohort ever investigated (7075), no increase in mortality due to lymphomas or lung cancer was seen. However, no actual measurements of PCB exposure were available for this study. Exposure classification was based on job description. A morbidity study of this population is currently underway at the Mt. Sinai Medical Center.

The Kimbrough study also found no indication of increase in brain cancer or malignant melanoma. However, a study by Sinks et al. did find a non-significant increase in brain cancer (Sinks et al. 1992). It was noted that all published work (including laboratory and human studies) does show a higher incidence of some tumors.

One panel member cited a study in rats, which showed that high serum levels had a suppressive effect on mammary tumors (Mayes et al. 1998). This same study also statistically showed an inverted U curve, supporting the notion that at high serum levels, PCBs can exhibit cancer suppressive effects (Mayes et al. 1998). However, high serum levels were associated with a decrease in body weight. Mammary tumors in rats are correlated with body weight. Therefore, the lower the weight, the lower the tumor incidence. A decrease in some tumors at high dose may also be a signal of generalized toxicity.

In Japan a study showed significant increases in the incidence of liver cancer associated with exposure to PCBs (Fischbein, 1985). A study by Schecter et al. (1985) found some evidence of elevated liver enzymes with PCB exposure in humans (e.g., elevated levels of SGPT, gamma GTP, SGOT, and SGPT) and animal studies of tumor promotion in rats and mice show elevated liver enzymes and tumors (i.e., in liver for rats and in liver and lung for mice) at levels of between 5 and 20 ppb (Drajnev et al., 1994; Deml et al., 1987; Anderson et al., 1994; Anderson et al., 1991). Findings of liver effects occurring at these low levels have not been reported in

other studies (Mayes et al. 1998; ATSDR 1997). However, the Mayes study did not involve tumor promotion, only administration of PCBs by themselves. Also, serum levels of PCBs were not measured in that study.

While the panel cited some conflicting studies, overall most panel members agreed that the evidence supports that PCBs are a definite carcinogen in animals and a possible to probable carcinogen in humans. Some panelists cited studies that have associated PCB exposure to an increased incidence of digestive tract cancers (biliary, liver, kidney, gall bladder), brain cancer, malignant melanoma and lung cancer (Loomis et al. 1997; Gustavsson et al. 1997). However, some panel members noted that a dose-response relationship was not seen in these studies. One "hypothesis-generating" study (Rothman et al., 1997) did find that the incidence of non-Hodgkins lymphoma was correlated with increasing serum PCB levels.

Thus, in animal experiments, PCBs have been shown to be promoters of tumors initiated by genotoxic chemicals. People exposed to genotoxicants may be especially susceptible to the tumor-promotive effects of PCBs. Therefore, one panel member suggested that smoking data and other lifestyle considerations should be viewed along with the PCB exposure levels. For example, kidneys are producers of oxygen free radicals, which promote conditions ripe for tumor growth. A healthy lifestyle including consumption of fruits, vegetables and vitamin supplements has been shown to destroy the free radicals and reduce cancer risk by as much as one-half.

A member of the audience at the public meeting in Pittsfield, Massachusetts on January 21, 1999 asked whether bladder cancer, liver cancer, breast cancer, and non-Hodgkin's lymphoma are the most important types of cancer to evaluate relative to PCB exposures. The panel discussed this issue briefly and found evaluation of these cancer types in relation to PCB exposures to be a reasonable course of action. One panel member strongly suggested that, in addition to those cancers already being evaluated, MDPH also include lung cancer, since PCBs can be considered co-carcinogens with smoking, and cancers that have been increasing without evident cause, e.g., brain and testes. The rationale for this suggestion is that, for most cancers, the greatest impact of



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PCBs is likely to be as tumor promoters. Hence, there may be increasing risk, due to occupational and lifestyle exposures to genotoxic agents.

*Neurotoxic Effects*

Most panel members generally agreed that neurotoxic effects are associated with PCB exposure, as discussed in the Developmental Effects discussion. However, frank and acute neurotoxic effects such as seizure disorders have not been seen. Many agreed that the most susceptible population to neurotoxic effects seems to be the fetal/prenatal exposure stage. There is conflicting evidence with regard to effects from the timing of PCB exposure in relation to neonatal stage of development. Most of the human data demonstrates that the prenatal period is the critical time. Some of the effects in rodents may occur in the early postnatal period, but these developmental stages occur prenatally in humans. There are clear postnatal effects in monkeys (Rice study), and monkeys are more mature than humans at birth. Breast-feeding is clearly beneficial despite possible concurrent PCB exposure via this route.

*Immunological Effects*

Regarding immunological effects associated with PCB exposure, data on experimental animals (rodents and monkeys) had indicated that these subjects are developing higher rates of otitis (i.e., inflammation of the ear), chicken pox and a suppressed vaccination take-rate. The ATSDR MRL is based on monkey immunotoxicity data (Tryphonas et al. 1991a). There was disagreement among the panel, however, as to whether the immune system endpoints seen in animals would not be expected in humans or whether these animal studies do provide plausibility for human correlation. One panelist noted that the immunological effects have been seen in the Dutch study, the Inuit studies, and the Taiwanese studies. It is important to note that few of the responses which have been examined in experimental animals have been looked at in people.

While it was stated that PCBs are not directly genotoxic, toxic effects on lymphocytes have been seen. In the study of the Dutch population, subtle changes in the lymphocyte complex were measured at ages 18 months and 42 months (Patandin et al. 1999a, 1999b; Patandin 1999c;



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Lanting et al. 1998a; Weisglas-Kuperus et al. 1995). Most panel members agreed, that the Dutch study is suggestive regarding these effects, and other studies should make attempts to replicate these findings.

Further, it was stated that the large body of literature of experimental data on primates and non-primates does indicate potential for adverse affects on humans. For example, in a study of minks, adverse effects of exposure were found to include an increased incidence of disease, developmental delays, and reproductive effects (Heaton et al., 1995; Harding et al., 1999). In addition, one panel member cited a study in Slovakia, which indicates possible thyroid and associated autoimmune effects (Langer et al. 1998).

***Other Effects***

The panel discussed the association between PCB exposure and the incidence of chloracne. Chloracne has been associated with exposure to dioxin-like substances, which are always present in PCB mixtures and at higher levels if the PCBs have been heated above threshold temperatures (i.e. approximately 200° C) for conversion (Nakagawa et al., 1977; Brown et al., 1988). The absence of chloracne does not mean that that there was no exposure. In one study, 190 occupationally exposed subjects with high PCB serum levels, up to several thousand ppb with a mean of over 400 ppb, were followed over time and chloracne was not found (Lawton et al., 1985). In this case, the manufacturing plant utilized Aroclor 1254 and then transitioned to a lower Aroclor.

Regarding the psychological effects due to stress on children due to living in an environmentally contaminated area, panel members agreed that educational programs should be provided to these children. It was noted that the National Environmental Health Education Committee is developing an environmental health curriculum, which may assist the community with this issue. The discussion on this topic was prompted by a question from the public at the January 21, 1999 meeting in Pittsfield.



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Another question from the public was whether PCBs are endocrine disrupters. The panel briefly discussed the issue of endocrine disruption and concluded that this is a mode of action, rather than an endpoint. Some of the health effects discussed earlier are probably mediated through the endocrine system. However, the specific mode of action is not yet fully understood. One panel member mentioned that there is some effect on the auditory system that appears to be mediated by effects on thyroid hormone (Crofton and Rice 1999; Goldey et al. 1995; Goldey and Crofton 1998). Effects on thyroid hormones could be a factor in cognitive development (Koopman-Esseboom et al. 1994; Morse et al. 1993; Morse et al. 1996).

Overall, most panel members agreed that whatever the mode of action, PCBs seem to affect multiple organ systems. In addition, PCBs are a probable carcinogenic promoter, lending mechanistic plausibility to the promotion of tumors at low chronic levels. Further, because of the long half-life of PCBs (i.e., ranging from 1 to 10 years), there appears to be no quick way to reduce their body burdens.

**EOHHS Question 4**: Have the following exposure routes to PCBs been thoroughly or sufficiently examined for non-occupationally exposed populations?

The panel recognized that the concern about this issue stems from the clean-up activities and noted that air, water, soil, and food are exposure routes which have been examined by the World Heath Organization to develop safe levels of exposures. Overall, the panel agreed that exposures to PCBs through air and soil are minimal and that more than 90% of PCB exposure can be attributed to the food that people eat. While it may be true in general that most exposure to PCBs is through food, that may not be the case at a Superfund site. This is particularly true for young children, whose hand-to-mouth behavior results in substantial ingestion of soil. Overall, since the area population's PCB levels are similar to background serum levels, the concern should be for incremental exposure to PCBs, particularly for sensitive groups.

Individuals who are concerned about exposures to PCBs may want to have their serum PCB level measured because this is the best available indicator of actual exposure. In any case, individuals



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should take steps to reduce potential exposures (e.g., refrain from consumption of fish from PCB contaminated water bodies). This would be particularly true for individuals whose serum PCB levels are found to be elevated. On a larger scale, society must reduce contamination of the food supply through improved environmental management. This discussion was prompted by a question from the public at the January 21, 1999 meeting regarding the validity of serum PCB testing for estimating the body burden of PCBs.

The panel agreed that the cleanup of PCBs (e.g. cessation of manufacture and unregulated disposal, and other clean-up activities) is an important and effective public health measure, as evidenced by the decrease in serum background levels over the past decade.

*Air*

MDPH stated that citizens have expressed concern regarding the indoor environment as well as ambient air quality. A panel member stated that airborne PCBs tend to be the lower chlorinated congeners.

*Water*

Regarding the community concern over houses in the floodplain whose basements flood, panel members agreed that home evacuation was not called for, however, the areas should be cleaned up. Following cleanup, the level of exposure through this route is likely to be insignificant.

The panel agreed that the recreational use of water is generally acceptable, however, direct contact with highly contaminated sediments is not advised. In addition, dermal absorption is fairly limited and takes a long time. According to one panel member, engineering data of sediments has been mapped and those areas of the river with high PCB concentrations differ from areas used for recreational activities. Another panel member considered this too much of a generalization and thought that residents should be able to view the mapped data themselves in order to evaluate the situation.

*Soil*

Concern has been expressed in the community relating to soils surrounding homes and dust samples in homes. It was noted that the clean-up level for residential soils is 2 ppm, the same as that in fish. While children do consume some quantity of soil, the focus of studies has been on adults. Panel members agreed that PCBs may or may not be bioavailable in soils depending upon many factors. Therefore, soil levels will not necessarily be indicative of blood serum levels. Overall, exposures to PCBs can only be determined through individual blood tests. Again, the significance of PCBs is the serum blood level over time.

***Food, Including Breastmilk***

Most panel members agreed that the primary exposure route of the population to PCBs is through the food chain and that the consumption of animal products is the primary source of PCB contamination due to biomagnification.

Panel members stressed that fish consumption advisories must be followed, including advice on cooking and preparation methods. Further, sportfish consumers tend to have higher serum PCB levels as freshwater fish tend to have higher levels of PCBs. It was noted that MDPH surveys estimate that a low percentage (i.e., approximately 3%) of the community currently reports ever having consumed fish from the Housatonic River itself. This indicates that this community is aware and heeding the fish consumption advisories.

The Dutch and Oswego studies found that effects of the PCB exposure were attributable to prenatal exposures (Stewart et al., 2000; Huisman et al., 1995; Darvill et al., in press). The level of PCBs in women of childbearing age is very important as the *in utero* exposure is a critical time. One panel member commented that while breast-feeding children always do better (probably due to more optimal intellectual stimulation by nursing mothers), it is not clear that breast-feeding actually diminishes the impact of a prenatal PCB exposure. Although much larger quantities of PCBs are transmitted postnatally to the nursing infant, (compared with transplacental exposure), there is virtually no evidence of deleterious effects on the central nervous system from this route of exposure. By contrast, there are measurable effects on



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intellectual function associated with much lower levels of transplacental PCB exposure, highlighting the increased vulnerability of the fetus to these contaminants.

Panel members agreed that testing the blood serum levels in children would not be useful clinically or otherwise.

> **EOHHS Question 5**: When evaluating environmental exposure to PCBs, what contaminant interactions should be considered in evaluating the potential for health effects?

The panel reiterated that PCBs are tumor promoters and therefore, interactions between PCBs and other chemicals are likely. This effect can be additive, multiplicative or protective. According to one panel member, there is fairly good evidence that interactions between PCBs and other chemicals tend to be additive at environmental exposure levels. Other interactions between organo-metals and PCBs are being studied, finding that non-additive interactions tend to be synergistic (Bemis et al., 1999). A recent study of DDT and dioxin shows no interaction (Loeffler et al., 1999). However, in this study interactions were examined at only one concentration. One panel member noted the caveat that experimental animal data used in these studies is at PCB concentrations 100 times or higher than the levels that would be found in environmental conditions. However, again, these studies are at very high concentrations. Overall, the panel agrees that there is no clear answer to the question of interactions. It was noted that PCBs are a mixture to begin with and what is now in our bodies is not the same as the chemical mixture originally released to the environment. Some panel members believed that weathered mixtures are more toxic than the original mixtures. However, other panel members felt that the answer to this was not yet clear, because there have been very few animal studies that have used weathered mixtures, and because the type of toxic effect being evaluated and the type of weathering need to be considered in making such a determination.



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## VI. Concluding Remarks

The expert panel was convened to assist the Secretary of Health and Human Services in addressing health questions raised by the widespread PCB contamination in the Housatonic River Area. The general charge to the panel was to discuss the current science on several key topics related to the health effects of PCBs. It was neither intended nor possible for the panel to conduct a conclusive and comprehensive review of the voluminous literature on the health effects of PCBs. This meeting summary is a reflection of the panel exchanges on a wide range of subjects, during which a variety of views were offered, and there was general agreement on a number of topics.

The panel agreed that it is a positive sign that the typical serum PCB levels in non-occupationally exposed populations may be lower now than they were a decade ago, but there was some disagreement as to whether levels may be continuing to decrease. However, as diagnostic capabilities increase, researchers are also observing subtle developmental effects on the fetus if the mother's serum PCB levels are close to background levels. The panel stressed that these effects may not be significant on an individual level, but are of concern for the population at large.

One panel member noted that the Housatonic River Area population has a mean serum PCB level close to the national levels, and that it would be beneficial to examine the frequency distribution of serum PCB levels broken out by age, as this could potentially lead to different conclusions with regard to this particular community.[3] The panel did not recommend additional follow-up studies. PCB concentrations in the area are close to background levels.

The panel further agreed that the MDPH Health Assessment Plan currently underway along with the continued cleanup efforts are adequate measures to be taken at this time.

[3] The MDPH conducted supplemental analyses to address differences in Housatonic River Area exposure prevalence and volunteer populations (see Expert Panel Questions and Answers).



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## MEETING ATTENDEES

| Name | Affiliation |
|---|---|
| **Expert Panelists** | |
| Henry A. Anderson, M.D., Panel Chair | Wisconsin Div. of Public Health |
| Lucy Anderson, Ph.D., D.A.B.T. | National Cancer Institute |
| Linda Birnbaum, Ph.D., D.A.B.T. | US EPA (NHEERL) |
| David M. Gute, Ph.D., M.P.H. | Tufts University |
| Stephen B. Hamilton, Ph.D. | General Electric Company |
| Joseph Jacobson, Ph.D. | Wayne State University |
| Loren Koller, D.V.M., Ph.D. | Oregon State University |
| Larry Needham, Ph.D | Centers for Disease Control |
| David Ozonoff, M.D., M.P.H. | Boston University SPH |
| Deborah Rice, Ph.D. | Health Canada (Note: Now US EPA) |
| Susan Schantz, Ph.D. | Univ. of Illinois Urbana-Champaign |



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ATTACHMENT A

# Commonwealth of Massachusetts
# Executive Office of Health and Human Services

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

Friday, January 22, 1999

The Omni Parker House Hotel
Boston, Massachusetts

## AGENDA

| | |
|---|---|
| 8:00 – 9:00 | Breakfast in the conference room |
| 9:00 – 9:05 | Opening remarks by William O'Leary, Secretary<br>Executive Office of Health and Human Services |
| 9:05 – 9:30 | Introduction to the experiences of the Massachusetts Department of Public Health (MDPH) with regards to PCBs and health effects<br>(Elaine Krueger, MDPH) |
| 9:30 – 10:00 | Opportunity for the panel to ask questions of MDPH and other agencies |
| 10:00 – 10:30 | Summary of comments received at the public meeting in Pittsfield on January 21, 1999<br>(Dr. Henry Anderson, Panel Chair) |
| 10:30 – 11:30 | Review of the panel's mission and discussion of procedural issues<br>(Led by Dr. Henry Anderson, Panel Chair) |
| 11:30 – 12:15 | Lunch in the conference room |
| 12:15 – 4:00 | Panel deliberations<br>(Led by Dr. Henry Anderson, Panel Chair) |
| 4:00 | Adjourn |

ATTACHMENT B

# Commonwealth of Massachusetts
# Executive Office of Health and Human Services

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

| Panelists | Areas of Expertise |
|---|---|
| **Chairman**<br>Henry Anderson, M.D.<br>Wisconsin Department of Health and Family Services | Medicine/Public Health |
| Lucy Anderson, Ph.D., D.A.B.T.<br>National Cancer Institute | Toxicology/Carcinogenicity |
| Linda Birnbaum, Ph.D., D.A.B.T.<br>U.S. Environmental Protection Agency<br>National Health and Environmental Effects Research Lab. | Toxicology/Carcinogenicity |
| David M. Gute, Ph.D., M.P.H.<br>Tufts University | Environmental and Occupational Epidemiology |
| Stephen Hamilton, Ph.D.<br>General Electric Company | Health and environmental effects of PCBs |
| Joseph Jacobson, Ph.D.<br>Wayne State University | Health effects from *in utero* exposures to PCBs |
| Loren Koller, D.V.M., Ph.D.<br>Oregon State University | Developmental and immune system toxicology |
| Larry Needham, Ph.D.<br>Centers for Disease Control and Prevention | Analytical laboratory techniques |
| David Ozonoff, M.D., M.P.H.<br>Boston University | Epidemiology/Medicine |
| Deborah Rice, Ph.D.<br>Formerly: Health Canada<br>Starting in January:<br>U.S. Environmental Protection Agency<br>National Center for Environmental Assessment | Neurotoxicology |
| Susan Schantz, Ph.D.<br>University of Illinois Urbana-Champaign | Health effects of PCBs for the elderly |

ATTACHMENT C

# Commonwealth of Massachusetts
# Executive Office of Health and Human Services

## Expert Panel on the Health Effects of Polychlorinated Biphenyls (PCBs)

### Mission

The primary mission of this expert panel will be as follows:

1. Provide EOHHS with an updated review of the literature to date

2. Summarize research that is currently underway.

3. Identify current data gaps or limitations of research previously conducted such that appropriate next steps can be outlined.

Specific questions that the panel members will address include the following:

1. ATSDR has stated that typical background levels for serum PCBs for nonoccupationally exposed individuals in the U.S. population is 4-8 ppb (ATSDR Toxicological Profile on PCBs, 1997). Is there new information about this reported background range?

2. What is the public health significance of serum PCB levels within the range of or greater than typical background levels (i.e., 4-8 ppb) but less than 20 ppb (the 95th percentile in the U.S. population)?

3. Do PCBs cause adverse health outcomes?

    a. reproductive/developmental effects
    b. cancer
    c. neurotoxic effects
    d. immunological effects

    If so, what effects and is information available on conditions of exposure and estimated dose levels at which these effects are produced? If data gaps exist for human studies, what does the preponderance of animal studies indicate for these effects?

4. Have the following exposure routes to PCBs been thoroughly or sufficiently examined for nonoccupationally exposed populations?

    a. air
    b. water
    c. soil
    d. food, including breast milk

5. When evaluating environmental exposure to PCBs, what contaminant interactions should be considered in evaluating the potential for health effects?

ATTACHMENT D

## Comments/Questions Received at the Public Meeting in Pittsfield

## January 21, 1999

- What are the types of PCBs (e.g., congeners) that would be found in serum due to background exposures?
- Can PCB speciation in serum provide information on whether a person is exposed to background levels or to a direct source?
- How valid are serum PCB levels as a predictor of body burden of PCBs?

- Are bladder cancer, liver cancer, breast cancer, and non-Hodgkins lymphoma the most important types of cancer to evaluate relative to PCB exposures?
- Are PCBs endocrine disrupters?
- Are learning disabilities (e.g., ADD, PDD, autism) or other diseases (elephantitis, multiple sclerosis) caused by PCB exposures?
- Are there psychological effects on children from growing up around environmental contamination?

- Can the panel evaluate exposures to PCB vapors in ambient and indoor air?
- Can the panel evaluate exposures to PCBs in indoor dust (e.g., if there is basement flooding from the Housatonic River or if home is built on contaminated soil/fill)?
- Is it safe to have any soil with greater than 2 ppm of PCBs on a residential property?

ATTACHMENT E

## PCB Related Public Health Investigations

Massachusetts
Department of Public Health
January 1989

## MA Public Health Investigations

- Canton
- Greater New Bedford
- Norwood
- Housatonic River Area

## Housatonic River Area Activities

- Exposure Assessment Study
- Hotline Follow-up Report
- Breast Cancer Pilot Study
- Public Health Assessments
- Occupational Feasibility Assessment



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## HRA - PCB Exposure Assessment Conclusions

- Serum PCB levels - background range
- Higher levels - older residents with fish or occupational exposure
- Age - most important variable; occupationally exposed higher levels
- Exposure opportunities - multiple pathways

## PCB Hotline

- Identification of contaminated residential properties
- Hotline established - September 1997
- Over 200 calls to date
- Individual exposure survey
- Approx 160 people have had blood tests
- Health assessment report

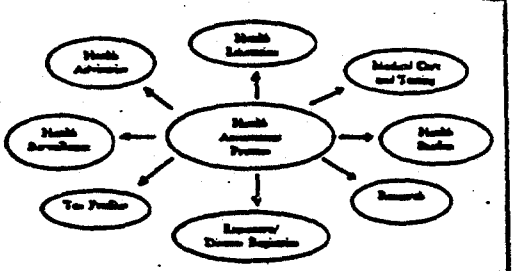
## Berkshire Breast Cancer and Environmental Exposure Pilot Study

- Objective:
- Changes in level PCB/DDE over time
- Rationale:
- Links between PCBs/DDE & breast cancer
- Scientific data gaps
- Affect of disease or treatments on level
- Environmental Concerns: PCBs, DDT/DDE

## Health Assessment Process

- Site information
- Community concerns
- Contaminants of concern
- Exposure pathways
- Public health implications
- Conclusions and recommendations

## Health Assessment Overview



## GE Site - Public Health Assessments

- Newell St Area 1
- Newell St Area 2
- East St Area 1
- East St Area 2
- Unkamet Brook Area
- Hotline Assessment
- Cancer Assessment
- Hill 78 Area
- Lyman Street
- Allendale School Property
- Housatonic River/ Silver Lake
- The Former Oxbows



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## PCB Public Health Investigations

Key Observations from MDPH Studies:

- Occupational History
- Fish Consumption
- Age

## Why a PCB Panel?

- Public concern
- Clarify health information
- Reflect range of scientific opinion
- Discuss current science
- Set foundation for the future

## Charge to Panel

- Typical background serum PCB levels and their public health significance
- Adverse health outcomes associated with exposure to PCBs
- Importance of various exposure pathways
- Interactions of PCBs with other chemicals

# INFORMATION BOOKLET

for

## THE FINAL REPORT ON THE HOUSATONIC RIVER AREA PCB EXPOSURE ASSESSMENT

and

## RELATED HEALTH ISSUES

prepared by
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
BUREAU OF ENVIRONMENTAL HEALTH ASSESSMENT

September 1997

## QUESTIONS AND ANSWERS

1. **Q. Why was the "Housatonic River Area PCB Exposure Assessment" conducted?**

   **A.** The assessment was conducted to identify the frequency of different activities that might lead to opportunities for PCB exposure, and to determine, through the use of blood testing, how various activities may have contributed to higher serum PCB levels among HRA residents.

2. **Q. What is meant by the "Housatonic River Area" (or "HRA")?**

   **A.** The Housatonic River Area or HRA comprises eight communities in Berkshire County, Massachusetts: Dalton, Great Barrington, Lanesborough, Lee, Lenox, Pittsfield, Sheffield, and Stockbridge.

3. **Q. What are PCBs?**

   **A.** PCBs or polychlorinated biphenyls are man-made, odorless chemicals. They do not evaporate and do not dissolve easily in water. In the HRA, PCBs were largely used in the manufacture of electrical transformers.

4. **Q. How did PCBs get into the Housatonic River and the surrounding communities?**

   **A.** PCBs were used in the manufacture of electrical and associated products in Pittsfield from 1932 to 1972, and they reached the Housatonic River in large quantities. This contamination was first discovered in the 1970s, in fish and sediments in lakes along the Housatonic. Extensive environmental sampling has revealed widespread contamination of Housatonic River sediments, floodplain soil, fish and other biota. Very recently, some residential properties were found to be contaminated with PCBs due to contaminated fills.

5. **Q. Who conducted the study?**

   **A.** The Housatonic River Area PCB Exposure Assessment was conducted by the Massachusetts Department of Public Health (MDPH), Bureau of Environmental Health Assessment, with support from the Massachusetts Department of Environmental Protection and the federal Agency for Toxic Substances and Disease Registry. The MDPH received input from local citizens or citizens' groups (e.g. Housatonic River Initiative), especially during the study design and protocol development. The MDPH also formed the Housatonic River Area Advisory Committee for Health Studies and MDPH staff held periodic meetings with committee members to report status and get feed back on the conduct of the study.



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6. **Q. How were participants chosen for the Exposure Prevalence Study?**

   **A.** In the Exposure Prevalence Study, 800 households were randomly chosen from among all those located within one-half mile of the Housatonic River in the following eight communities: Dalton, Great Barrington, Lanesborough, Lee, Lenox, Pittsfield, Sheffield, and Stockbridge. Four hundred of those households were from Pittsfield, and four hundred were from the other seven communities.

7. **Q. How were participants chosen for the Volunteer Study?**

   **A.** In the Volunteer Study, subjects were recruited by means of a Public Service Announcement in local newspapers and radio stations, and through a mass mailing to interested parties. The Volunteer Study allowed those residents who were concerned about PCB exposure, but who were not selected to participate in the Exposure Prevalence Study, to be scheduled for a blood test. MDPH arranged to administer questionnaires to the volunteers in person at three walk-in sites: the Great Barrington Senior Center, the Tri-town Health Department in Lee, and the Berkshire Athenaeum in Pittsfield. The questionnaire administered to the volunteers was the same as the one used in the Exposure Prevalence Study.

8. **Q. How were opportunities for exposure to PCBs assessed?**

   **A.** A household screening questionnaire was administered to the 800 households. A representative of each household answered questions for all the members of his or her family. After the questionnaires were completed, the responses of every household member were weighted, with those activities more likely to lead to greater potential for PCB exposure weighted more heavily. Thus, those with the greatest potential for PCB exposure would receive the highest weights or scores.

9. **Q. How were respondents selected to participate in blood testing?**

   **A.** In the Exposure Prevalence Study, individuals with the highest potential exposure to PCBs based on screening questionnaire scores were offered the opportunity for a blood test. Results of blood tests allowed MDPH to determine whether those individuals who were suspected to have had greater opportunities for exposure to PCBs did in fact have higher levels than those with lesser opportunities for exposure. All respondents in the Volunteer Study were offered blood testing.

10. **Q. What was the range of serum PCB levels found in the Exposure Prevalence and Volunteer Studies?**

    **A.** Sixty-nine residents who participated in the Exposure Prevalence Study had serum PCB levels as follows:

| Concentrations of PCBs in Parts Per Billion (ppb) | Number of Individuals |
|---|---|
| 0-4 | 43 |
| 5-9 | 18 |
| 10-14 | 6 |
| 15-20 | 1 |
| over 20 | 1 |

Seventy-nine residents who participated in the Volunteer Study had serum PCB levels shown as follows:

| Concentrations of PCBs in Parts Per Billion (ppb) | Number of Individuals |
|---|---|
| 0-4 | 32 |
| 5-9 | 25 |
| 10-14 | 15 |
| 15-20 | 2 |
| over 20 | 5 |

The average serum PCB level in the Exposure Prevalence Study among non-occupationally exposed participants was 4.49 ppb, and in the Volunteer Study, the average was 5.77 ppb. These levels were generally within the normal background range for non-occupationally exposed individuals.

**11. Q. Was occupational exposure related to serum PCB levels?**

**A.** Yes. Among all participants who had blood testing, those who had had opportunities for occupational exposure had higher serum PCB levels than the rest.

**12. Q. Was age related to serum PCB levels?**

**A.** Yes. Age was found to be the prominent predictor of serum PCB level.

**13. Q. Do most people in the United States have PCBs in their bodies?**

**A.** PCBs have been measured in human blood, fatty tissue, and breast milk throughout the country. Ninety-five percent of the U.S. population have serum levels of less than 20 ppb. Ninety-nine percent of the U.S. population have serum levels of less than 30 ppb. The national average for serum PCB level in persons non-occupationally exposed is between 4 and 8 ppb. The greatest on-going source of public exposure to PCBs is from food, particularly fish.



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**14. Q. Is there anything I can do to reduce PCB levels in my blood?**

A. Currently, there is no treatment available to lower PCB blood levels. However, if an individual was exposed, PCB levels will decrease over time once exposure to PCBs has been reduced.

**15. Q. Is it safe to eat fish from the Housatonic River and its tributaries?**

A. No. In 1982, the MDPH restricted fish, frog, and turtle consumption in the Housatonic River and its tributaries. Because of continued evidence of PCB contamination, it is expected that PCB levels in these species still remain elevated.

Both the Exposure Prevalence Study and the Volunteer Study showed that study participants who had higher frequency and duration of contaminated fish consumption had higher serum PCB levels. Due to health effects that have been suggested as potentially related to PCB exposure, the MDPH maintains that the current ban on these activities in or near the river remain in effect.

**16. Q. Is it safe to eat fish from restaurants, supermarkets, and local markets in the Housatonic River Area?**

A. Yes. In general, fish caught in marine open and bay waters is the source of most commercial catches in New England and is not affected by PCB contamination from local and freshwater areas. State and federal health regulatory officials regulate fish sold for the commercial markets.

**17. Q. Was consumption of fiddlehead ferns associated with higher serum PCB levels?**

A. Individuals who reported greater frequency and duration of fiddlehead fern consumption had slightly higher serum PCB levels.

**18. Q. If my only exposure to PCBs is through soil contact, should I be concerned?**

A. Previous studies conducted by MDPH have not shown that exposure through soil contact alone has resulted in appreciable increases in serum PCB levels. MDPH continues to consider consumption of contaminated fish to be the most significant non-occupational exposure concern. However, due to the recent discovery of widespread residential PCB contamination, MDPH is coordinating a separate study of residents who may be concerned about exposure.

**19. Q. If PCBs have been discovered in soils on my property, what can I do about getting my health concerns addressed or my blood tested?**

**A.** MDPH has established a toll free hot-line to advise local area residents about any health related concerns or questions they may have. The exposure assessment questionnaire will be provided to all residents who wish to have their opportunities for exposure evaluated and a blood test taken. The hot-line number is 1-800-240-4266.

**20. Q. What health effects are caused by exposure to PCBs?**

**A.** PCBs are not very acutely toxic. Large amounts of PCBs are necessary to produce acute effects. These effects can include skin lesions or irritations, fatigue, and hyperpigmentation (increased pigmentation) of the skin and nails. Chronic effects occur after weeks or years of exposure or long after initial exposure to PCBs. A number of studies have suggested that these effects include immune system suppression, liver damage, neurological effects, and possibly cancer.

**21. Q. What happens to PCBs in your body?**

**A.** Once PCBs enter the body they are first distributed in the liver and muscles and then are stored in fatty tissues. PCBs can be stored in fat tissue for years. Also, breast milk may concentrate PCBs because of its fat content. The PCBs can then be transferred to children through breastfeeding.

**22. Q. Are cancer rates elevated in the HRA?**

**A.** According to the most recent data from the Massachusetts Cancer Registry, cancer rates during 1982-1986 and 1987-1992 for the eight communities (i.e., Dalton, Great Barrington, Lanesborough, Lee, Lenox, Pittsfield, Sheffield, and Stockbridge) showed that, with the exception of bladder cancer in Pittsfield males during the 1982-1986 period, no statistically significant elevation was noted.

**23. Q. Do PCBs cause reproductive effects?**

**A.** Studies have reported that infants born to mothers who were environmentally or occupationally exposed to PCBs had decreases in birth weight, gestational age, and neonatal performance. However, the strength of the association with PCBs is unclear. PCBs have been shown to cause these and other reproductive effects in a variety of mammalian species.

**24. Q. Are there any problems with reproductive outcomes for the HRA?**

**A.** According to 1990-1994 birth data from the MDPH Registry of Vital Records and Statistics, infant mortality and the proportion of low birth weight in the HRA were similar to those of the state averages.