

Health Consultation

Updated Assessment of PCB Exposures in Anniston, AL

ANNISTON PCB SITE

ANNISTON, CALHOUN COUNTY, ALABAMA

EPA FACILITY ID: ALD004019048

OCTOBER 16, 2006

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
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Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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Prepared by:

U.S. Department of Health and Human Services,
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Statement of Issue

In 2001, an Agency for Toxic Substances and Disease Registry (ATSDR) Exposure Investigation (EI) evaluated polychlorinated biphenyl (PCB) levels in the blood of certain persons living near a former PCB production facility in Anniston, Alabama [1,2]. In response to questions and concerns from Anniston-area residents, ATSDR provides here a health consultation containing an updated evaluation of the EI findings. The updated evaluation is based on comparisons with newer data from the “Second National Report on Human Exposures to Environmental Chemicals” (SR) [3] that were unavailable at the time of the original report’s release. It also uses the contemporary reference values from the SR to estimate the number of participants in the EI with unusual exposures to PCBs. The utility of the data and the rationale for their use as a screening tool are demonstrated, and additional advancements that would further aid such screening assessments are discussed.

Background

Between the early 1930s and the early 1970s polychlorinated biphenyls (PCBs) were manufactured in Anniston, AL. During that period the manufacturing process included on-site burial of PCB waste materials and consequent releases of PCBs to the environment. A number of investigations at numerous Anniston-area properties conducted since the mid-1990s have revealed elevated PCB levels in an Anniston-area watershed and in the soil [4,5]. [See Appendix A for a list of reports of investigations relevant to this site]

During the summer of 2000, ATSDR conducted an exposure investigation of 15 Anniston families, including 40 adults over 20 years of age who lived near the former PCB manufacturing facility [1,2]. The primary aim of that investigation was to evaluate children’s PCB exposures — a group ATSDR considers a particularly susceptible population. ATSDR’s exposure investigation evaluated blood samples but, in the children tested, did not find evidence of unusual exposures. ATSDR did however find that a significant portion of the adults tested had elevated PCB levels (21% of the adults tested for the EI) [2]. The work described in this health consultation re-examines the data developed in ATSDR’s EI and extends the previous efforts by making comparisons with newly available information presented in the “Second National Report on Human Exposure to Environmental Chemicals.”

The SR is part of a program that uses biomonitoring to assess the nation’s exposures to environmental chemicals [3]. The biomonitoring effort measures the levels of various contaminants in the blood and urine of selected participants of the National Health and Nutrition Examination Survey (i.e., a survey conducted by the National Center for Health Statistics, with laboratory analyses by the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention). As part of an ongoing project, the “Second Report” was released in January of 2003 and provides exposure data on 116 environmental chemicals (the “First Report” was released in March of 2001 and reported data for 27 chemicals). The SR is designed to provide estimates that describe a representative sample of the “civilian, non-institutionalized U.S. population.” Among the expressed purposes of the “Second Report” are “To determine which chemicals get into Americans and at what concentrations,” and “To establish reference ranges that can be used by physicians and scientists to determine whether a person or a group has an unusually high exposure” [3].

Relevant to the issues in this health consultation, the SR provides data describing a number of PCB congeners. Ten ortho-PCB congeners are reported in the SR as having been detected at concentrations and frequencies that permit reporting relevant statistical descriptions. These 10 congeners are commonly detected in human serum, and serve as the basis of the comparisons described in this health consultation, where those ten congeners are referred to as the “10 common PCB congeners.”

The SR’s up-to-date data, collected using advanced laboratory methodologies, are particularly valuable for several reasons. First, comparisons employing historical reference data, when used to evaluate more recent PCB blood levels, are questionable. Many of those questions arise because PCB exposures have decreased over the last several decades — that is, as exposures have declined, so have human blood levels. Thus the most accurate assessments of recent PCB blood levels require recently collected reference information. Also, significant advancements in laboratory analytical capabilities have occurred since the historical data were gathered. In particular, the laboratory advancements have increased the ability to distinguish individual PCB congeners at trace levels. Still, despite the ability of advanced analytical methods to provide better data, comparisons using recently published data can remain problematic. These problems occur because no standardized methods are available for PCB analyses, and the published data are often difficult to compare: for example, investigators use different methodologies or describe the reported data differently. However, because the comparisons described in this document utilize data from the SR, many of these questions are eliminated.

Three attributes of the SR and EI data facilitate the comparisons and evaluations described in this health consultation. First, the data for both the SR (reference group) and the exposure investigation participants were developed from blood samples collected in the same time frame (1999–2000). Second, the samples were analyzed by the same laboratory at the NCEH, using similar high resolution, mass spectrometry methodologies. Third, common units for the serum PCB concentrations (nanogram (ng) / gram (g) lipid) were reported for both the EI [2] and the SR [3] data.

Methods

Description of the Data Sets Employed

The “Second Report”

The “Second National Report on Human Exposure to Environmental Chemicals” describes findings from biomonitoring efforts to determine national reference ranges for 116 environmental contaminants [3]. The data describing blood PCB concentrations were selected from participants in the National Health and Nutrition Examination Survey conducted in 1999–2000. (The “Second Report” is available at <http://www.cdc.gov/exposurereport/pdf/nersummary.pdf>, and more information about the NHANES program is available at <http://www.cdc.gov/nceh/nhanes.htm>). A stratified multistage probability design was used to obtain a representative sample of the total civilian, non-institutionalized U.S. population. Reported PCB data include values that define specific percentiles and 95% confidence limits. Data describing the PCBs are categorized by various age groups, and by sex and race/ethnicity [3]. For the analyses presented in this paper, the demographic using all persons 20 years and older was employed as a best estimate of an “adult population.” Of the 1300 persons over 20

years of age, the weighted mean age is 44.9 years. The sex profiles for all persons in the SR are approximately 52% female and 48% male. The racial demographics reported for all persons in the SR are approximately: 35% Mexican-American, 23% non-Hispanic black, and 41% non-Hispanic white.

ATSDR's Exposure Investigation

The investigation design and methodological details for ATSDR's Exposure Investigation have been reported previously [1, 2]. The following summary information is provided as a brief overview:

The EI targeted selected families with young children who lived in the vicinity of the former PCB manufacturing facility. Self-selected volunteers were recruited by ATSDR staff and community representatives. These volunteers went door-to-door to invite families to participate. Persons with known occupational exposures were excluded from the investigation. Eighty-three persons were included in the test population for the EI. Of those, the data for the 40 adults (persons over 20 years of age; ages ranged from 20–90 with a mean age of 40) were considered in most of the analyses described in this report. The definition of adult, as “over 20 years old” was chosen to match the “all adult” demographic described in the SR. (NOTE: The adults defined in the original EI report [2] were defined as over 17 years old and that group of adults consisted of 43 individuals. Forty of those individuals met the criteria of “over 20 years old,” and the data for those 40 persons were used to match the data classification presented in the SR.) The sex profile for the EI adults is 62% female and 38% male. The racial demographic reported for all of the EI participants (including children) was approximately 80% black and 20% white [2].

Analytical Methods Used for both the EI and SR Data Sets

A complete description of the analytical techniques used for the EI serum sample is reported elsewhere [6]. Briefly, blood samples collected by a phlebotomist were allowed to clot such that the serum was separated, placed on ice, and delivered to the laboratory for analysis. The samples were spiked with isotopically labeled, internal PCB standards, extracted, and the PCB congeners were separated and quantified by a high-resolution gas chromatography-isotope dilution, high resolution mass spectrometry. The analytical results were reviewed using comprehensive quality assurance and quality control procedures. Serum lipids were determined by an enzymatic summation method [7]. The SR data are reported as ng PCB congener/g lipid.

Data Analyses

Data provided by the SR [3] show that common PCB congeners (i.e., PCB congeners 74, 99, 118, 138, 146, 153, 156, 170, 180, and 187) were detected in serum at levels and frequencies that permitted derivation of their 95th percentile concentrations (Table 1). For the purpose of this health consultation, these 10-PCB congeners are described as the “10 common PCB congeners.” This health consultation evaluates only the 10 common PCB congeners from the SR as well as those same 10 congeners from the EI.

Unusual Exposure Points

For the discussion that follows, the 95th percentiles are defined as an “Unusual Exposure Point,” or UEP. For the individual PCB congeners the UEP is employed as a marker from which to identify individuals who have unusual exposures. That is, the UEP is used to identify persons with exposures that are not simply the result of “typical” or “background” level exposures.

Comparisons between the SR and the EI data, employing the individual values for each of the 10 common congeners (ng/g lipid) were used to enumerate numbers of individuals with unusual exposures to individual PCB congeners.

The 95th percentile of the sums of the 10 common PCB congeners from the 1300 subjects over 20 years old included in the SR was also calculated and examined in this report. This percentile was obtained by first computing a sum of the 10 common PCB congeners separately for each of the 1300 subjects in the SR and then using the method described in Appendix B of the SR (3). This 95th percentile was used as an estimate of a “10 common congener UEP” and reported in units of ng/g lipid.

Results

Number of Persons Exceeding the Unusual Exposure Points for Individual PCB Congeners

As defined in this report, the UEP for an individual PCB congener is simply the 95th percentile for that congener, as found in the SR (see Table 1 for the 95th percentiles for specific PCBs). Given this definition, simple comparisons of the EI data for individual congener concentrations in the 40 adults vs. the UEP provide the number of individuals with a congener concentration considered an unusual exposure.

The number of participants of the exposure investigation who had serum PCB concentrations exceeding the UEPs for the individual congeners are as follows: 11 persons exceeded for PCB74; 20 persons exceeded for PCB99; 17 persons exceeded for PCB118; 18 persons exceeded for PCB138; 18 persons exceeded for PCB146; 15 persons exceeded for PCB153; 13 persons exceeded for, PCB156; 13 persons exceeded for, PCB170; 13 persons exceeded for PCB180; 17 persons exceeded for PCB187.

Number of Persons Exceeding the Unusual Exposure Point for the 10 Congener Sum

As defined in this report, the UEP for sum of “the 10 common PCB congeners” in serum is the 95th percentile of the sums for each individual of the 10 common congeners in the original SR data. This 10 common congener UEP value is 445 ng PCB /g lipid (only the 10 PCB congeners from the SR that have 95th percentile values are included in this sum; 95 % CI = 386-509 ng/g lipid; n = 1300).

A relevant assessment for the participants in ATSDR’s EI answers the question: how many of the EI participants exceed the sum of the 10 common-congener UEP? This question was answered by enumerating the persons from the EI who exceeded the 10-congener UEP of 445 ng PCB/g lipid. When comparing the 10-congener UEP (derived from the SR) with the data from the EI, 16 persons (or 40% the 40 adult total) had 10-congener sums of PCBs that exceeded the UEP of 445 ng PCB /g lipid. The serum PCB values for those exceeding the UEP were 446; 496; 556; 606; 956; 1,041; 1,176; 1,203; 1,223; 1,619; 1,987; 2,832; 7,440; 11,539; 11,853; and 32,835 ng/g lipid. The 16 persons who exceeded the 10-congener UEP had a mean age of 51 years (range = 29–90); 6 were males, 10 were females (18 persons exceeded the lower confidence interval (CI), and 14 persons exceeded the upper CI, data not shown). For the 24 persons with serum PCB concentrations below the 10-congener UEP, the mean age was 33 years (range = 20–58); 15 were females, and 9 were males. Of the 25 females in the EI, 21 were

between 20 and 44 years of age. Of those 21 females between the ages of 20 and 44, 7 exceeded the 10-congener UEP (8 exceed the lower CI, and 5 exceed the upper CI).

Discussion

The work described in this document takes advantage of attributes of rather unique EI and SR data sets. Because the serum samples for both data sets were collected in the same time frame, and the data were developed using similar methods in the same laboratory, they can be directly compared; such direct comparisons are not typical of other human serum PCB data sets. While we acknowledge that demographic differences between the two data sets exist (see discussion below), using the SR data set as a reference for the data collected in the Anniston EI represents an important advance in this updated assessment of the PCB exposures in the Anniston Community. Use of the UEP — again, defined as the 95th percentile from the SR data set — affords several advantages when considering commonly encountered assessments. First, using the UEP negates discussion or argument related to how values below the instrument detection levels are to be treated when calculating summary statistics. Second, discussions required to designate the use of a mathematical factor applied to a background level — for the purpose of assigning a point at which unusual exposures are defined — are also irrelevant.

Sixteen adults in the Anniston EI (40 % of the total) are described in this document as having unusual exposures. A previous assessment, which could only consider older information, made use of a 1993 report that provided an approximate 90th percentile (about 10 ppb for total PCBs in serum) for describing the exposed individuals. Using that criterion, it was estimated that 9 adults in the EI had unusual exposures [2]. The lowest serum PCB level in that group of 9 was 1176 ng/g lipid (derived from the sum of the 10 congeners). As a further illustration of the influence that the newest reference information (SR) exerts on the outcome of the exposure assessment, another reference value scenario is presented. If information from an oft-cited but nearly 30-year-old data set [8] is used for comparison, four persons in the Anniston EI would be evaluated as having unusual exposures (exceeding a 95th percentile of 20 ppb for total PCBs in serum [8]). Our increased confidence in the newer evaluation is supported by knowing that the data used to establish the UEP reference points and the EI data were collected in the same time frame and were developed with similar methodologies by the same laboratory.

The UEP values developed in this document were generated with the intention of aiding in the exposure assessments for the Anniston community. In this health consultation, they are employed as a screening tool. The values should not be used to suggest or imply that health effects are observed at a PCB blood levels that approach or exceed the UEP levels.

We expect that the general utility of the UEPs and their application for exposure assessments will be tested through additional examinations. While facilitating the updated exposure analyses for the Anniston community, it should be remembered that the UEPs have limitations that must be considered:

- The Anniston EI participants are slightly younger than the persons comprising the SR data set (mean of 40 years vs. weighted mean of 45), and the lack of age-class data for both data sets introduces additional uncertainties. We acknowledge the lack of specific age-class data for use in the assessments presented in this report, and also point out that age-class data is lacking from most of the historical literature. Nevertheless, one general

finding is common for most PCB studies: older study participants generally show higher PCB levels than do the younger participants. The findings from the EI are consistent with that general result [1, 2]. For the Anniston EI participants, only the general age-class of “adult” is used for this updated assessment. Clearly, making judgments based on “adult” population-based information could be aided by data that defines exposures for various age classes.

- The utility of such age-class data is demonstrated in the assessments of children. The available data describing PCB levels in children were insufficient to develop UEPs specifically for children. Therefore, an accurate assessment of exposures for the children that participated in the EI is not possible. It is, however, worth noting that two persons classed as children (defined as below 20 years of age) exceeded the 10-congener UEP for adults. One was a male, 9 years of age (466 ng/g lipid; sum of the 10 congeners); the other was a male, 18 years of age (1039 ng/g lipid; sum of the 10 congeners).
- With respect to the Anniston EI participants, the racial demographic of the community is different when compared with the SR population. The SR data is drawn from a predominantly non-Hispanic white demographic [3], while most of the EI participants are non-Hispanic blacks [1,2]. This difference could be significant, as many of the 95th-percentile values for the individual PCBs are higher in non-Hispanic blacks vs. non-Hispanic whites [3]. In an effort to examine that point further, the 95th percentiles of the sums of the 10 common PCB congeners from each person in each specific demographic group, for persons 20 years and older, was calculated. Those calculations showed: for Mexican Americans the 95th percentile for 10 congener sums was 272 ng/g lipid (n = 353; 95 % CI = 239-313), for non-Hispanic whites that value was 415 ng/g lipid (n = 596; 95 % CI = 354-509), and for non-Hispanic blacks that value was 844 ng/g lipid (n = 232; 95 % CI = 459-1182). The difference between the non-Hispanic whites vs. non-Hispanic blacks was not statistically significant. However, it is noted that the data set describing the non-Hispanic blacks was the smallest of the three, and also showed the most variability of the three demographic groups. Those attributes of the non-Hispanic Black data add uncertainty to the estimates presented in this document. It is also noted that the Mexican Americans had statistically lower PCB levels when compared to the other two groups. A document published while this manuscript was being constructed has presented additional data relevant to the SR, and that report provides further details regarding the PCB levels found in different demographic groups [9].

The data developed in these analyses provide an updated view of the extent of PCB exposures for the EI participants in the Anniston Community. In addition, the data developed and the assessment rationale using information from the SR could carry the flexibility needed to aid exposure assessments at other PCB-contaminated sites. Also, the data and rationale described in this report are facilitating our ongoing analyses, which address additional PCB exposure-related questions. That work could provide additional advancements in our understanding of the PCB exposures to Anniston-area residents.

Conclusions

1. Using the newly available reference information and the development of additional 95th percentile data that describes the national population, 16 adults of the 40 who participated in ATSDR's exposure investigation are evaluated as having unusual PCB exposures. This assessment almost doubles the number of adult exposure investigation participants who were previously considered to have unusual PCB exposures.
2. The available data are not sufficient to provide evaluations of specific age classes, nor are they able to provide reference information for children. It is noted, however, that two children, both less than 20 years age, exceeded the reference value developed for evaluating adults.

Recommendations

No specific recommendations are needed. However, it is noted that given the initiation of a series of projects collectively described as the "Anniston Health Study," the information in this health consultation could be of value to investigators evaluating PCB exposures as part of that study.

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Appendix A

Recent Documents Related to Investigations in Anniston, Alabama

Recent Documents Related to Investigations in Anniston, Alabama

ATSDR Documents

Polychlorinated Biphenyls in Fish from Choccolocco Creek (Health Consultation; Final document released on December 17, 2004)

Polychlorinated Biphenyls, Dioxins, and Pesticides in Soil, Blood, and Air from Anniston, Alabama (Health Consultation; Final document released in July, 2003)

Assessment of Four Activities Addressing Childhood Blood Lead Levels In Anniston, Alabama. (Final document released on June 26, 2003.)

Anniston PCB Air Sampling (Health Consultation; Draft for Public Comment released on January. 17, 2003)

ATSDR Childhood Blood Lead Screening Project (Final document released in February of 2002)

Exposure Investigation Report (Monsanto Company; Final document released in October 2001.)

Exploring Opportunities for PCB Related Health Studies. Report from ATSDR's Expert Panel (Final document released in Spring 2002)

Evaluation of Lead in Residential Surface Soil from Anniston, Alabama (Health Consultation; Final document released on January 8, 2001.)

Evaluation of Lead in the Surface Soil at the Oxford Lake Softball Complex (Health Consultation; Final document released on January 22, 2001.)

Toxicological Profile for Polychlorinated Biphenyls (Update), November, 2000

Alabama Department of Public Health Documents

Health consultation. Monsanto Company, Anniston, Calhoun County, Alabama. (Final document released in January 1996)

Cobbtown/Sweet Valley Community PCB Exposure Investigation (Health Consultation; Final document released in June 1996)

Monsanto/Solutia, Inc. (Public Health Assessment; Final document released in May 2001)

Table 1. Data from the “Second Report” Used to Define Unusual Exposure Points for Specific Polychlorinated Biphenyls”*

<i>PCB Congener[†]</i>	<i>Structure</i>	<i>95th Percentile ng/g lipid (confidence interval)</i>
74	2,4,4',5	30.0 (25.6-35.9)
99	2,2',4,4'5	19.9 (16.1-23.5)
118	2,3',4,4'5	43.6 (34.5-53.3)
138	2,2'3,4,4',5'	72.8 (65.3-90.5)
146	2,2',3,4',5,5	14.2 (<LOD-17.1) [‡]
153	2,2',4,4',5,5'	122.0 (98.9-139)
156	2,3,3',4,4'5	17.5 (15.8-20.1)
170	2,2',3,3',4,4',5	33.9 (28.2-38.3)
180	2,2',3,4,4',5,5'	83.8 (75.6-96.3)
187	2,2',3,4',5,5',6	25.9 (24.1-29.4)

* “Second Report” = “Second National Report on Human Exposure to Environmental Chemicals” by the National Center for Environmental Health; Center for Disease Control and Prevention (CDC) [3].

[†] Congener number designations and structures according to IUPAC.

[‡] LOD = limit of detection