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Final Report

POLYCHLORINATED BIPHENYLS IN HUMAN ADIPOSE TISSUE AND MOTHER'S MILK

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EPA Contract Number: 68-01-5848

Project Officer: Joseph Carra
Task Manager: Richard Levy

U. S. Environmental Protection Agency
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1. EXECUTIVE SUMMARY

This report gives a concise summary of the prevalence and levels of polychlorinated biphenyls (PCBs) in human adipose tissue and mother's milk. Data collected from the National Adipose Tissue Survey are reviewed and summarized. Additional material on PCBs in human mother's milk supplied by the U.S. Environmental Protection Agency is also included.

The percent of persons in the U.S. with detectable levels and with levels greater than 3 parts per million (ppm) were investigated to ascertain changes among the fiscal years 1972 to 1979 and 1981. Different subpopulations defined by the factors age, sex, race, Census Region and PCB industries were investigated to ascertain their association with the PCB levels.

The estimated percentage of U.S. population with detectable levels of PCBs was found to be increased from approximately 85 percent in fiscal 1972 to nearly 100 percent in fiscal 1979. (The fiscal 1981 estimates based on a subsample of 97 specimens indicates 100 percent of the U.S. population have detectable levels of PCB). However, the estimated percentage of the U.S. population with greater than 3 parts per million PCB in their tissue has increased from approximately 2.7 percent in fiscal 1972 to 8 percent in fiscal 1976 and then has decreased to less than 1 percent in fiscal 1981.

Age is the only factor associated with the direction and amplitude of trends. The percentage of persons with detectable levels of PCBs is increasing in all age groups but is lower in amplitude in young persons (0-14 years). The trends in the percentage of persons with greater than 3 parts per million PCB in the two older age categories (15-44 years and 45+ years) are similar to the overall trend. The percentage of persons in the young age category with greater than 3 parts per million PCB is nearly constant during the decade and generally lower than the other two age groups. No other factors were found to be associated with the general shape of trends, but males and nonwhites tended to have a higher percentage of persons with greater than 3 ppm PCBs than females and whites, respectively.

A special study that measured the levels of PCB residue in human mothers' milk in 1977 was not inconsistence with adipose tissue in percentage of persons with detectable levels but the magnitude of the levels was lower than that found in adipose tissue.

2. INTRODUCTION

This report presents concise but comprehensive summary of the prevalence and levels of polychlorinated biphenyls (PCBs) in humans and the environment. The primary sources for this report are previously prepared preliminary reports on the U.S. Environmental Protection Agency's (US EPA) monitoring program for human adipose tissue and its computer accessible data files. Additional material provided by the US EPA on PCBs in human mother's milk is also included.

Chapter three addresses PCBs in humans. The first section concentrates on the National Human Monitoring Program's Adipose Tissue Survey. That survey is an ongoing program that has been measuring PCBs in human adipose tissue since fiscal 1972. The second section summarizes the PCB data measured in human mother's milk collected in a special study sponsored by the US EPA. Chapter four includes a list of all documents referenced in the report.

In order to limit the amount of material presented, only brief descriptions of the monitoring program, the study of human mother's milk, and their survey designs are included in the text. Additional information is contained in the appendices. The reader is advised of potential limitations in making inferences beyond the sample data and efforts are made to assess the impact of the limitations on the conclusions. References are included to guide the reader interested in more detail.

Several terms that have rigorous statistical definitions are used in the report. Below are generic definitions for these terms.

Target Population: The universe to which an investigator wishes to make inferences. Examples are the civilian population in the U.S. or all rural soils in the U.S. to a depth of three inches, as of a specific point in time.

Sampling Frame: A list or inventory of units in the entire universe to be sampled. Examples are a list of all counties in the U.S. or a conceptualized list of all 3-inch cubes of top-soil in the U.S.

Probability Sampling: A process by which each unit on a sampling frame may be selected for study with a known and positive probability.

3. HUMAN DATA SUMMARY

3.1 General Description of the National Adipose Tissue Survey

The National Human Monitoring Program (NHMP) was established in 1967 to monitor levels and prevalence of pesticide residues in the general population of the United States and to assess changes and trends in these levels. The program was initiated by the United States Public Health Service and was transferred in 1970 to the then newly created United States Environmental Protection Agency (EPA).

The National Adipose Tissue Survey (NATS) is one of the major ongoing components of NHMP. Specimens of adipose tissue are collected from surgical patients and autopsied cadavers through the cooperation of local pathologists and medical examiners. The adipose tissue specimens are chemically analyzed for twenty chlorinated hydrocarbon compounds including PCBs. These are listed in Lucas RM et al. 1980. This report also includes a description and evaluation of the chemical analysis method. This section includes a summary of all PCB data currently available from the NATS computer accessible data files. This includes all data for fiscal 1972 through 1979 and approximately a 10 percent subsample of fiscal 1981.

3.1.1 Objectives of the NHMP Adipose Tissue Survey

The defined primary objectives of the adipose tissue survey are:

(i) to measure average concentration of pesticides and other toxic substances in the general U.S. population;

(ii) to measure time trends of these concentrations; and

(iii) to assess the effects of regulatory actions.

As a secondary objective, the adipose tissue survey

(iv) provides baseline data.

The baseline data may help in detecting and evaluating suspected pesticide poisonings. Besides achieving the above objectives on a national basis, several subpopulations or domains are of interest. These domains are sex, race, age subgroups, and geographic regions.

Based on these objectives, the following definition seems appropriate as a target population.

Target Population: All non-institutionalized persons in the United States.

3.1.2 Overview of Current Survey Design

A brief description of the current NATS survey design that was implemented in fiscal 1977 is given below. The survey design was modified twice in the past. A description of all survey designs and their time periods is given in Hartwell et al. (1979). The modifications have had little impact on the inferential capabilities of the network or the ability to make comparisons among the fiscal years.

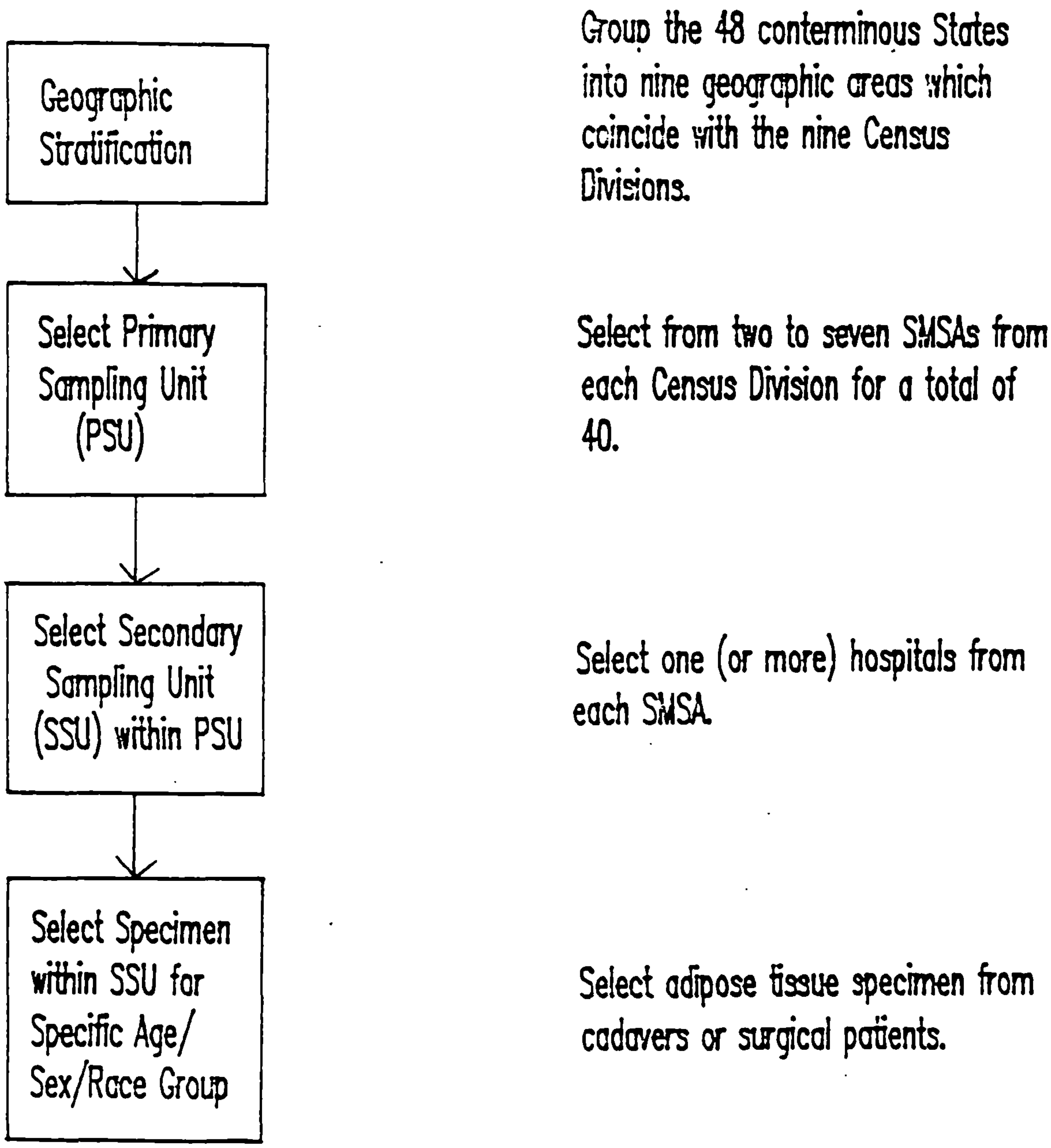
The specimens of adipose tissue are collected through cooperation of local pathologists and medical examiners. The complex process, involving several stages of selection, is illustrated in Figure 1. The 48 conterminous States are stratified into nine geographic regions coinciding with the Census Divisions. The stratification ensures that the sample is dispersed across Census Divisions, potentially improving the ability to make regional estimates and the accuracy of national estimates. Standard Metropolitan Statistical Areas (SMSAs) within each Census Division are the primary sampling units (PSUs), and a total of 40 are selected with probability proportional to their population based on the 1970 Census. The number of SMSAs selected in each Census Division (given in Appendix A) is proportional to the total population of the Census Division. Within each SMSA, a cooperating pathologist or medical examiner is solicited for cooperation and asked to select specimens according to EPA guidelines (described in Lucas et al. 1980). The guidelines include a quota for each pathologist based on the age, sex, and race distribution of the Census Division; instructions for exclusion of "unrepresentative" patients such as ones suspected of pesticide poisoning or exhibiting cachexia; and instructions on shipping and storage.

The sample SMSAs are a valid probability sample of SMSAs. Hence, it is defensible to present inferences about all SMSAs in the U.S. if one has accurate information for sample SMSAs. The accuracy and precision of these inferences, however, also depend on the sampling methodology within each SMSA. Within each SMSA, the hospitals, medical examiners' offices and specimens are selected in a non-probabilistic manner based on the EPA guidelines and judgement of the cooperating professionals. Useful interpretation of the statistical analysis, requires that we assume that all the tissue specimens within each SMSA, although they come largely from cadavers, are "representative" of the target population of non-institutionalized persons living in the corresponding Census Division. All statements of significance included in the statistical analysis below are based on this and other assumption. Other necessary assumptions are stated in the following sections as appropriate.

3.1.3 Overview of Weighting

Because the PSUs constitute a valid probability sample of SMSAs, a weight is assigned to each specimen based on the selection protocol (see Appendix A). Adjustments to each weight for fiscal 1972 through 1979 were then performed to assure that the sum of all weights within each age (0-14, 15-44, 45+), sex (male, female), and race (white, nonwhite) category equaled the appropriate population count for the Census Region according to the U.S. Census. The fiscal 1972 survey design was based on the 1960 Census data, also, the weight adjustments were based on 1960 Census data. The survey designs for fiscal 1973 through 1979 were based on 1970 Census data. Because only a small subsample of fiscal 1981 data is currently available, an aggregate

Figure 1. Sample Stages of the National Human Monitoring Program



adjustment, which did not take into account the age, sex and race categories, was performed on the basis of 1980 Census data. The subsample of fiscal 1981 tissue specimens was controlled to assure that the proportions of specimens in the sample in each category were similar to the proportions of persons in each category given in the 1980 Census. When these adjustments were completed, the weights for each fiscal year were inspected to detect extremely large weights. Large weights were reduced. The reduction in large weights (trimming) is felt to result in more accurate population estimates. A detailed description of the weighting procedure is given in Appendix A.

3.1.4 Summary of Polychlorinated Biphenyls in Human Adipose Tissue

PCB levels in adipose tissue are classified into four categories by the chemical analysis laboratory: (i) not detected (ND), (ii) detected but less than 1 part per million (ppm) (DLT1), (iii) between 1 and 3 ppm (1-3) and (iv) greater than 3 ppm (GT3). Because the data are categorized in the above manner, it is not possible to express the individual concentrations on a percent lipid basis. However, it is possible to adjust statistically the estimates of the percent of persons in each category. The adjustment is statistically significant but the magnitude of the adjustment is in consequenital. Hence, all data summaries are on a whole specimen (wet weight) basis, not on a lipid adjusted basis and exclude specimens with less than 10 percent extractable lipid. The data are first summarized for all years by three demographic factors: age, sex, and race and by two geographic factors: Census Region and industry. The PCB industry factor was defined by grouping the tissue specimens into three categories: (i) those collected from States containing no PCB industries, (ii) those collected from States containing one PCB industry, and (iii) those collected from States containing two or more PCB industries. A list of the States in each Census Region and industry category is given in Appendix B. Table 1 summarizes the estimated percentage of persons falling in the four residue categories by the three demographic factors, the two geographic factors and over all factors. Appendix B contains the same summaries for each fiscal year.

Inspection of the tables in Appendix B revealed apparent changes in the percentage of the U.S. population in each residue category by fiscal year. Figure 2 presents a chart of the estimated percentage of the U.S. population falling in the residue categories ND, DLE3, (DLT1 and 1-3 combined) and GT3 for fiscal years 1972 through 1979 and 1981. Several trends become apparent:

(i) the estimated percent of persons in the U.S. without detectable levels of PCBs decreased (the percent with detectable levels increased);

(ii) the estimated percent of persons in the U.S. with detectable levels less than or equal to 3 ppm increased; and

(iii) the estimated percent of persons in the U.S. with PCB levels greater than 3 ppm increased until fiscal 1977 and then began to decrease.

(The reader is cautioned to note that the fiscal 1981 estimates are based on a small subsample of 97 tissue specimens that have been chemically analyzed at this time.)

To quantify the apparent changes over time, trends were estimated for percent in the GT3 category and for percent detected (PD), which is the sum of DLT1, 1-3, and GT3. The trends included a linear term (fiscal year) and a quadratic term (fiscal year squared). In addition to investigating trends, the statistical analysis (see Appendix B) allows one to compare the subpopulations for each factor and their changes over time. The estimated trends are descriptive in nature and intended to give a smoothed picture of the underlying trends, which may be obscured by year to year fluctuations in the estimates.

Figures 3 and 4 illustrate the estimated trends in PD. Figure 3 illustrates the trends for the three age groups. These trends were found to be significant* and increasing but different. The youngest age group had the lowest PD in fiscal 1972 but increased more quickly and approached the two older age groups by fiscal 1981. The trends in the subpopulations of the other factors were statistically tested and found to be significant*, increasing, and equal in both rate of change and amplitude. Hence, the trend illustrated in Figure 4 adequately describes the trends for both sexes, both racial groups, the four Census Regions, and the three industrial categories.

Figures 5, 6, and 7 illustrate the estimated trends in GT3. Figure 5 illustrates the trends for the three age groups. These trends were found to be significant* but different. The two older age groups increase from fiscal 1972 to 1976 and decrease from fiscal 1976 to 1981 with the oldest group highest. The youngest age group remains relatively constant. Figure 6 illustrates the trends for the two racial groups. The two racial groups were found to have significant* trends of the same shape but differing in amplitude. The trends in the subpopulations for the factors sex and Census Region were also found to be significant* but differing in amplitude like the racial groups. The trends in the three industrial categories were found to be significant* also but equal in amplitude when adjusted for the factor Census Region. Because there is overlap between the two geographic factors, the amplitudes of the trends for the industrial subpopulations were also tested and found to be different when not adjusted for the factor Census Region. Figure 7 illustrates the overall trend for GT3.

3.1.5 Limitations of Statistical Inference

The NATS survey samples a surrogate population of surgical patients and autopsied cadavers instead of the general U.S. population. This is done for sound ethical reasons. By obtaining specimens from the sample population no additional risk is assigned to persons selected in the sample. However, because the sampled population is different from the target population, one must be willing to assume that the prevalence

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*Assuming no measurement or sampling bias exist.

Table 1 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissues for all Fiscal Years

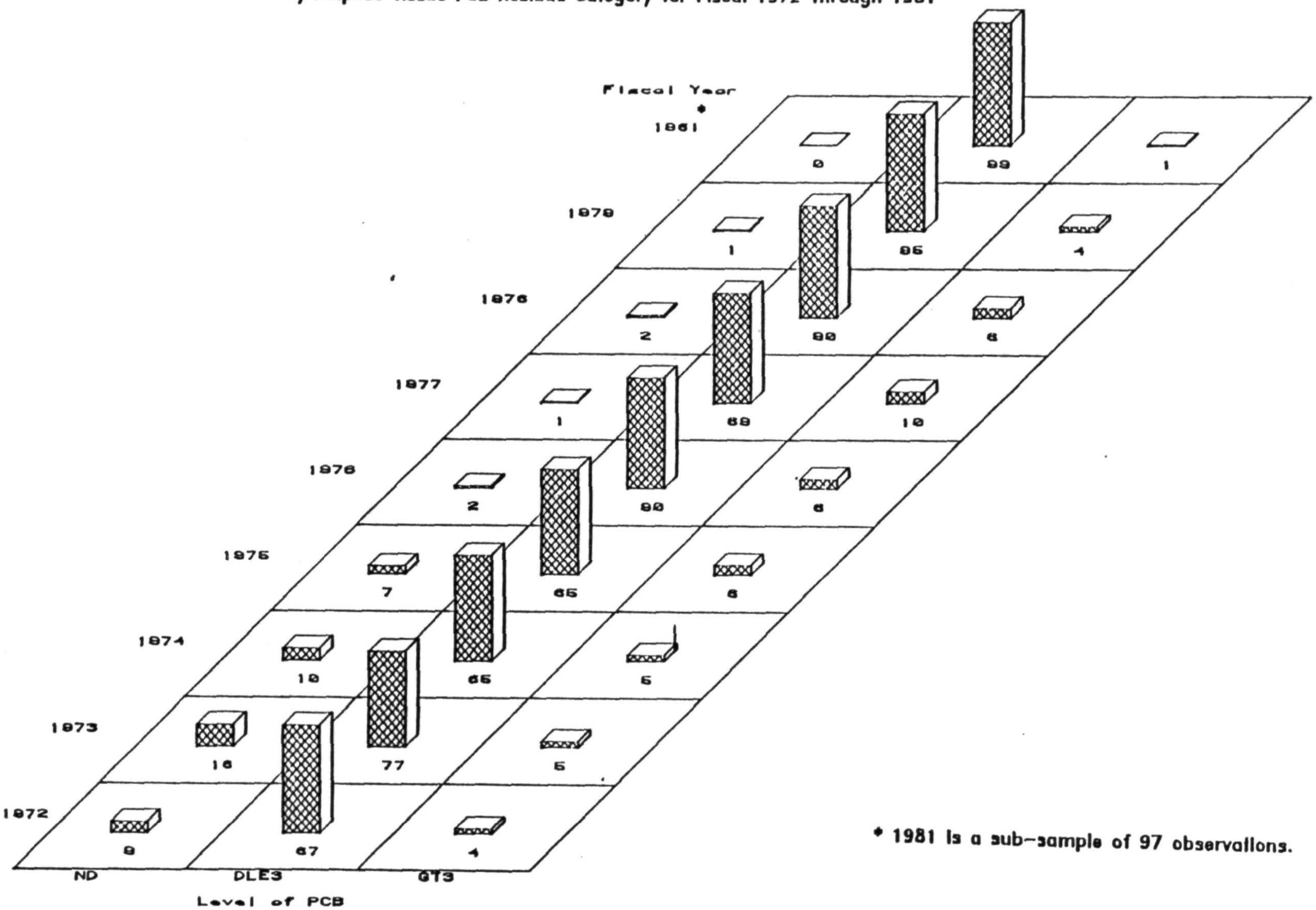
Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	PCB Residue Levels: Detected but Less Than 1 PPM	PCB Residue Levels: Between 1 and 3 PPM*	PCB Residue Levels: Greater than 3 PPM*
			percent (standard error)			
Age (years):						
0 -14	1554	56,942	10.5 (1.6)	76.7 (2.6)	11.3 (1.7)	1.4 (0.5)
15-44	2894	85,718	3.0 (0.6)	59.0 (2.2)	31.9 (2.0)	6.2 (0.7)
45+	4145	60,487	3.6 (0.7)	51.1 (2.3)	36.1 (2.0)	9.3 (1.0)
Sex:						
Male	4403	101,665	5.1 (0.8)	57.4 (2.3)	30.8 (1.9)	6.8 (0.7)
Female	4190	101,482	5.5 (0.7)	65.8 (2.1)	24.0 (1.8)	4.7 (0.6)
Race:						
White	7165	176,141	4.9 (0.6)	63.3 (1.8)	26.5 (1.5)	5.3 (0.5)
Non-white	1428	27,006	7.7 (1.9)	50.4 (3.9)	33.3 (4.1)	8.7 (1.3)
Census Region:						
Northeast	2124	48,567	5.8 (1.5)	51.6 (3.5)	33.3 (3.3)	9.2 (1.0)
North Central	2364	56,276	5.0 (1.2)	65.8 (3.1)	24.7 (2.7)	4.5 (0.9)
South	2969	63,321	5.5 (1.1)	63.2 (3.5)	25.9 (3.0)	5.3 (1.0)
West	1136	34,983	4.4 (1.2)	65.8 (4.2)	26.0 (4.1)	3.7 (1.1)
Number of PCB Industries per State:						
0	2332	57,912	5.1 (1.1)	66.4 (3.8)	23.8 (3.1)	4.7 (1.0)
1	2408	58,386	4.4 (1.1)	67.7 (3.0)	23.7 (2.7)	4.2 (0.8)
2+	3853	86,849	6.0 (1.0)	54.3 (2.6)	32.2 (2.4)	7.5 (0.9)
Overall	8593	203,147	5.3 (0.6)	61.6 (1.8)	27.4 (1.6)	5.8 (0.5)

Source: Calculated by the Research Triangle Institute from the NATS computer accessible data files.

* PPM denote parts per million.

Figure 2.

Estimated Percentage Distribution of U. S. Population by Adipose Tissue PCB Residue Category for Fiscal 1972 Through 1981



* 1981 is a sub-sample of 97 observations.

LEGEND: ND = Not Detected   DLE3 = Detected and Less Than or Equal to 3 PPM   GT3 = Above 3 PPM

Figure 3. Estimated Trends for Percent of PCB Residue Levels Detected by Age Group for Fiscal 1972 Through 1981

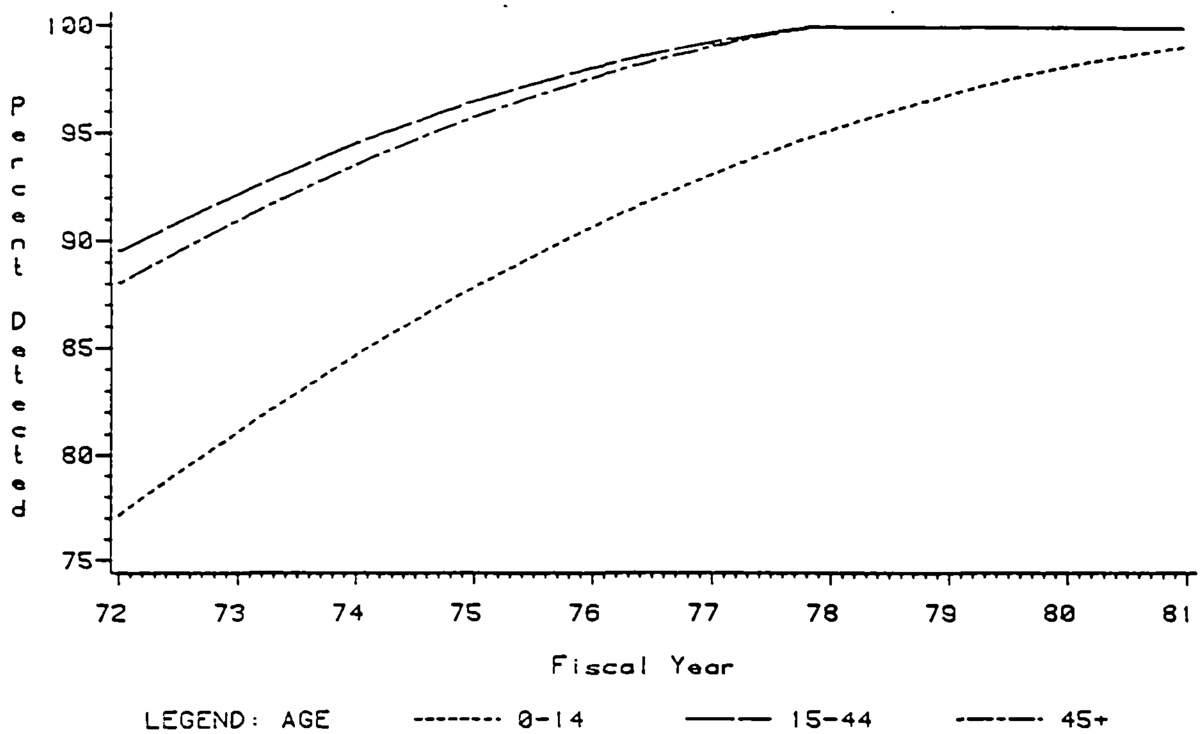


Figure 4. Comparison of Estimated and Observed Trends for Percent of PCB Residue Levels Detected for Fiscal 1972 Through 1981

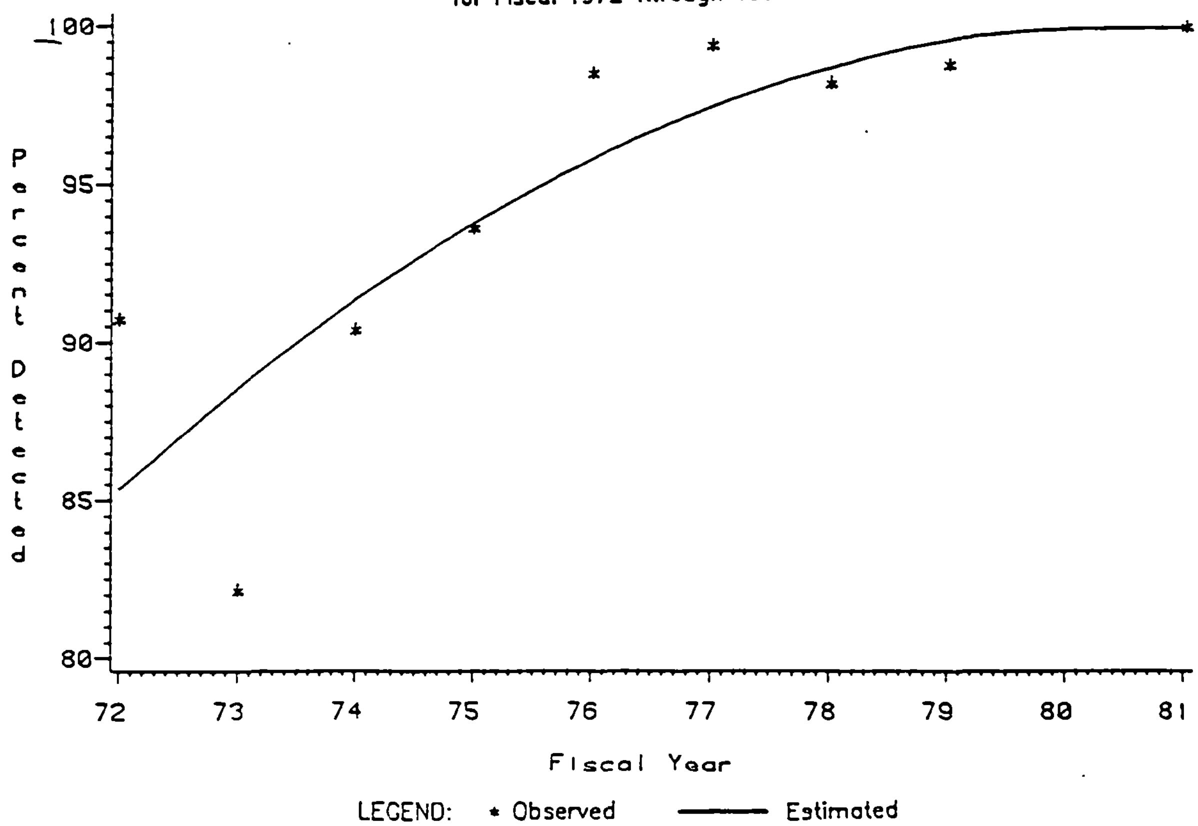


Figure 5. Estimated Trends for Percent of PCB Residue Levels Above 3 PPM by Age Group for Fiscal 1972 Through 1981

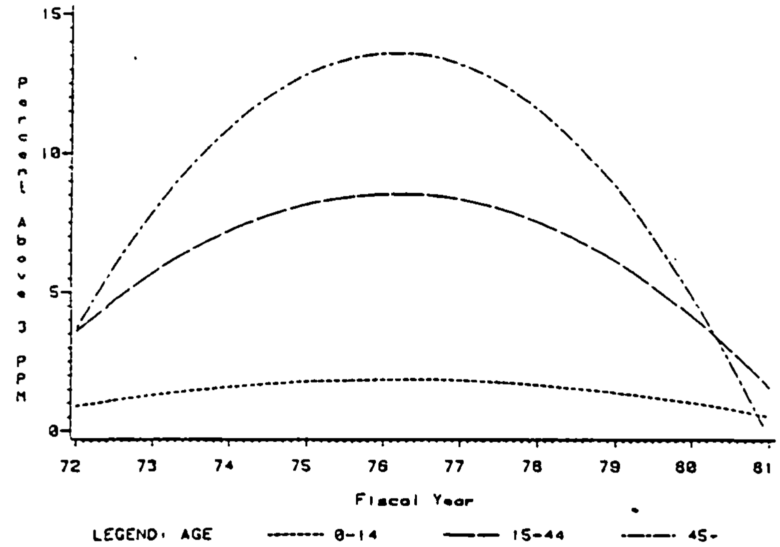


Figure 6. Estimated Trends for Percent of PCB Residue Levels Above 3 PPM by Race Group for Fiscal 1972 Through 1981

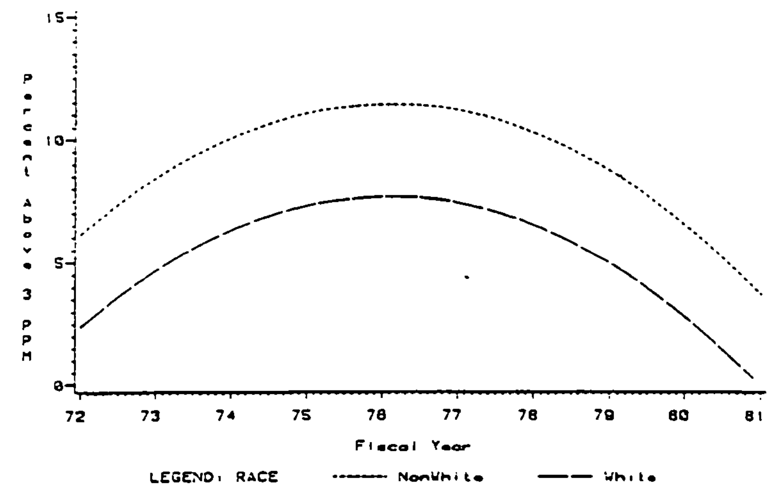
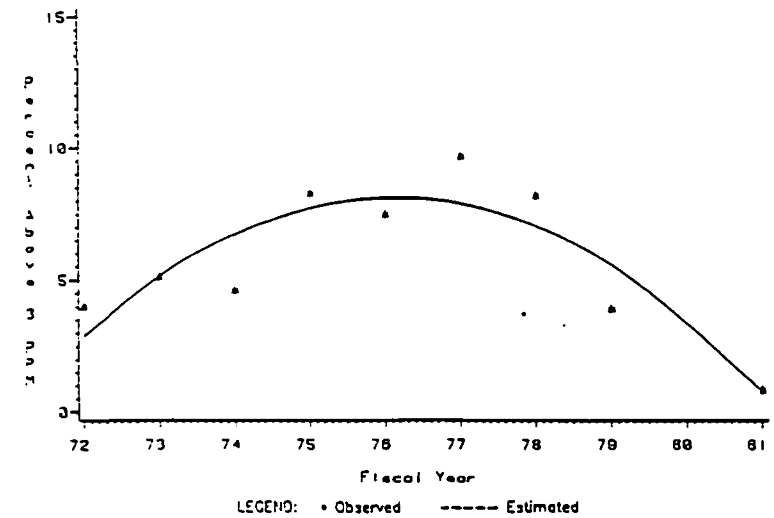


Figure 7. Comparison of Estimated and Observed Trends for Percent of PCB Residue Levels Above 3 PPM for Fiscal 1972 Through 1981



and levels of the substances of interest (chlorinated hydrocarbon compounds) are the same in both populations (age, sex, race adjusted) to make inferences from the sampled population to the target population.

Other limitations result from the survey design and its implementation. Because cities with populations greater than 25,000 persons or SMSAs form the sampling frame, areas that are rural in character are excluded from the sample. A sizable percent (38.3 percent in 1970 (Lucas RM et al. 1980) of the U.S. population resides in these rural areas. The real percentage of omission is most likely less, however, because the service areas of hospitals in cities or SMSAs extend into neighboring rural areas. Obviously, the urban nature of the sample results in an under coverage of the population of interest.

Limitations also result from the purposeful selection of cooperating professionals and the lack of probability sampling used by them in selecting tissue specimens within the PSUs. The purposeful selection methods may result in biases in estimates derived from the sample. In an effort to minimize potential biases, the data collected in the network were assigned weights to be used in the statistical analysis. The weights can be thought of as the number of persons in the target population that each sample specimen represents. The reader is cautioned that even though the weighting is felt to reduce bias; due to the lack of probability sampling within the SMSAs, this bias is not necessarily overcome by the weighting procedure. Even the estimates based on the weights may be substantially biased.

The chemical analysis methods are another potential source of bias. A detailed description of the current chemical analysis methods for PCBs is given in Lucas R M et al. (1980). The report also gives a comprehensive evaluation of the current analytical method which includes extraction according to the modified Mills-Olney-Gaither procedures (USEPA 1974 Section 5A[1]) and analyzed by gas chromatography with electron capture detection (GC/ECD) on two columns. The report (Lucas R M et al. 1980) also contains a brief assessment of the analytical method, thin layer chromatography (TLC) (USEPA 1977 and Mulhern et al. 1971) used prior to November 1974. The measurement errors for the techniques are quite large. For the TLC method the error is estimated to be ±50 percent (Lucas R M et al. 1980) and for the GC/ECD method ± 50 percent is the best-case estimate and ±100 percent is felt to be a reasonable estimate of the measurement error in this particular application. The measurement errors can be partitioned into two components, systematic errors that bias estimates and random errors that affect the precision of estimates. The statistical analysis techniques properly incorporate the random component in the estimates of precision. However, any systematic errors that may exist could not be accounted for in the analysis.

To obtain some insight into how biases may affect the conclusions with regard to trends and differences among demographic or geographic groups, additional material is presented below. First the trends are investigated for fiscal 1976 through 1981 to assess the effect of the change in chemical analysis.

To investigate the impact on trends resulting from the change in chemical analysis methods, trends were estimated for the categories PD and GT3 using only fiscal 1976 to 1978 and the 1981 subsample. Figure 8 presents the estimated percentage of the U.S. population falling in the three residue categories ND, DLT3 and GT3.

Figures 9 and 10 present the estimated trends for the residue categories PD and GT3 respectively. The trends illustrated in these figures are consistent with the trends estimated using all nine fiscal years of data. Hence, the change in chemical analysis method does not have a noticable impact on the estimated trends for fiscal 1976 through 1981. Because the analytical technique did not change during the last six years, the minimal detectable level should not substantially change, and thus, should have little effect on the PD trend.

The trends are highly significant* (the probability of no trend is very small) and the two racial groups and sexes are highly significantly* different for GT3. Tables 2 and 3 summarize the results of the statistical tests. Because of the relatively high levels of significance here, it is unlikely that actual biases in the population estimates would change the conclusion about trends or race and sex group differences. Biases are more likely to have an effect on the conclusion about the different trends for the age groups in PD and for differences among the Census Regions. A table is given in Appendix B illustrating the effect of bias on the significance level of statistical test.

The potential for bias is a two-edged sword. Biases may mislead the investigator into making false conclusions, but biases in the data may also hide real differences in the population and mislead the investigator into believing that no differences exist when in fact they do. It is impossible to estimate the magnitude or direction of biases in the present situation, if they exist, with the available information.

3.2 Polychlorinated Biphenyls in Human Milk

3.2.1 General Description of the Study

This section summarizes the data present in a special project report on PCBs in human milk (SPR 1977). The survey design is described in Savage et al. (1981) and was originally targeted at five chlorinated hydrocarbon insecticide residues. Approximately 72 percent of the milk specimens had sufficient volume to permit a second chemical analysis for PCBs. The chemical analysis method is described in SPR 1977.

3.2.2 Overview of the PCBs in Human Milk Study Design

A total of 163 hospitals was randomly selected from a list of approximately 7,000 general care hospitals in the United States. The hospitals were grouped into five geographic regions: (i) Northeast, (ii) Southeast, (iii) Midwest, (iv) Southwest, and (v) Northwest. From the selected hospitals, a subsample of nursing mothers who had given

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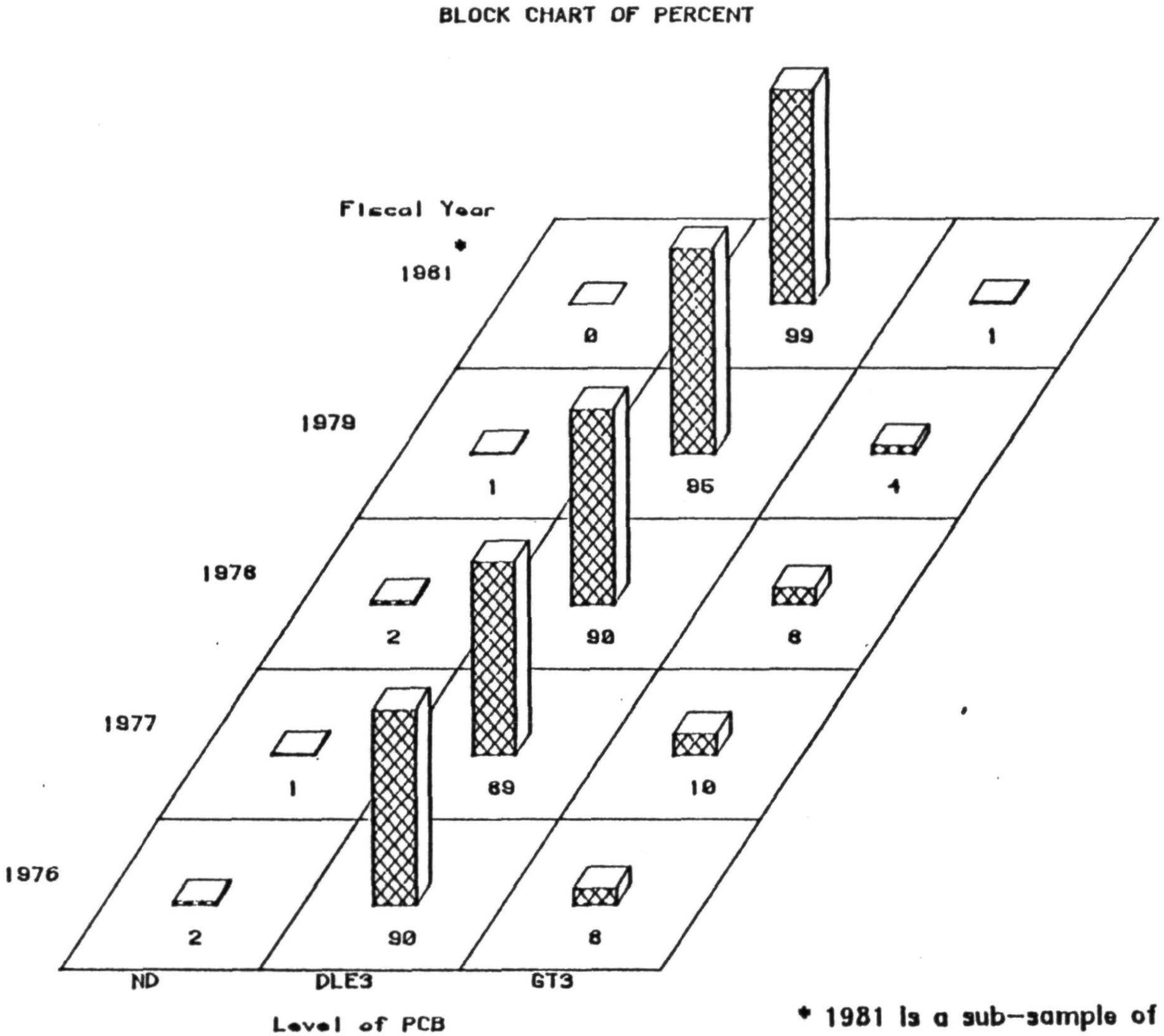
*Assuming no measurement or sampling bias.

Figure 8. Estimated Percentage Distribution of U.S. Population by Adipose Tissue PCB Residue Category for Fiscal 1976 Through 1981



* 1981 is a sub-sample of 97 observations.

LEGEND: ND = Not Detected DLE3 = Detected and Less Than or Equal to 3 PPM GT3 = Above 3 PPM

Figure 9. Comparison of Estimated and Observed Trends for Percent of PCB Residue Levels Detected for Fiscal 1976 Through 1981

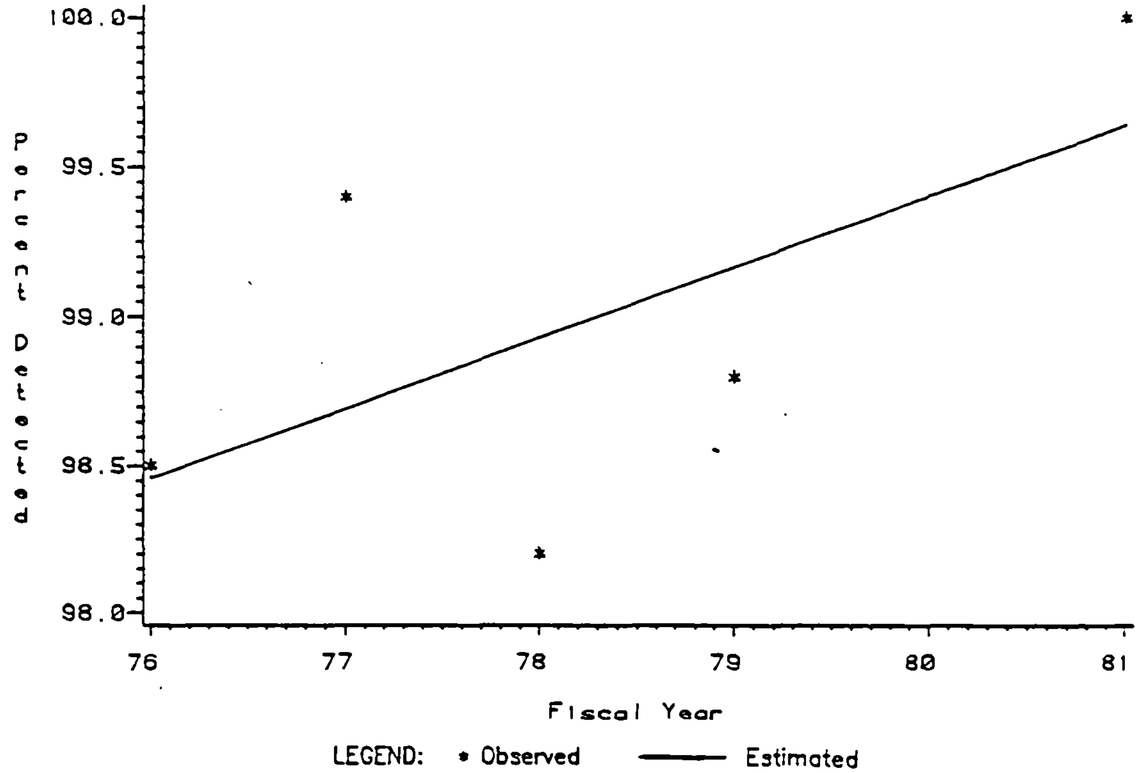


Figure 10. Comparison of Estimated and Observed Trends for Percent of PCB Residue Levels Above 3 PPM for Fiscal 1976 Through 1981

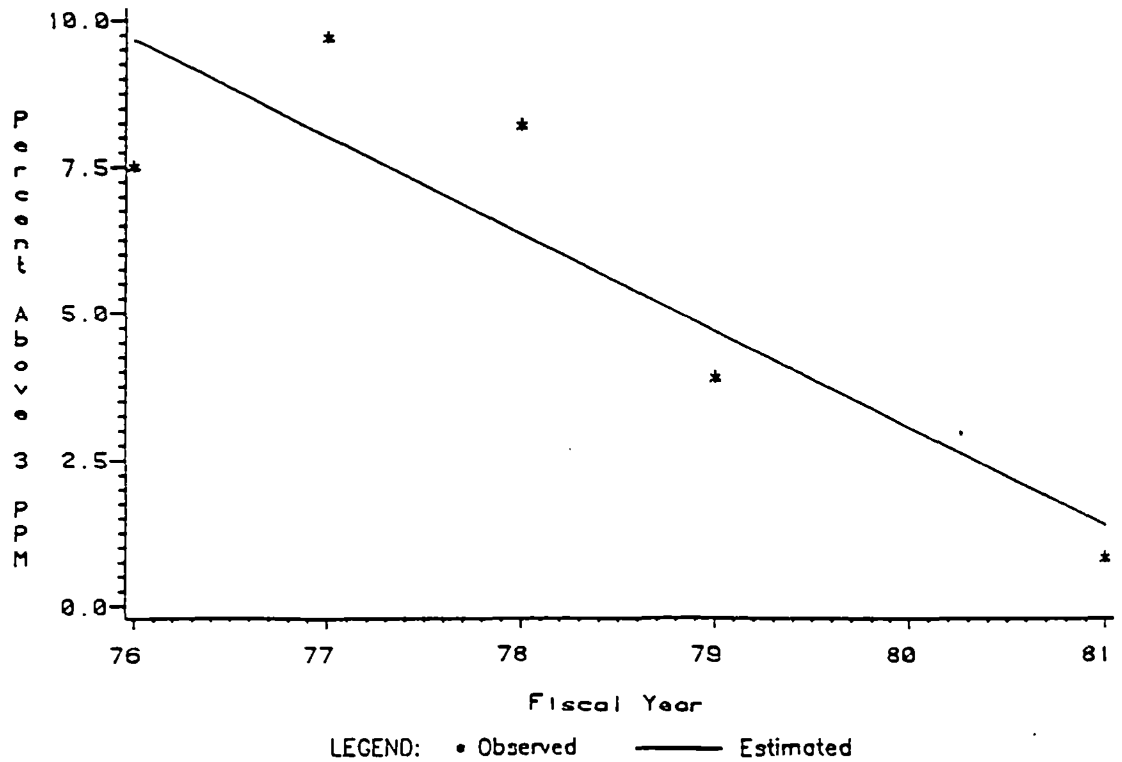


Table 2. Significance Levels* of Estimated Trends in PCBs for Fiscal Years 1972 through 1981**

Trend	Probability* of No Trend: Percent Detected	Probability* of No Trend: Percent Greater Than 3 ppm
Linear Term	.0000	.9519
Quadratic Term	.0017	.0000
	Probability* of Equal Trends Among Age Groups	
Linear Term	.0307	.3753
Quadratic Term	.0857	.0000

* Assuming no measurement or sampling bias.

** Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey sponsored by the U.S. Environmental Protection Agency.

NS Not significant*, probability > .05.

Table 3. Significance Levels* of Estimated Effects of Demographic and Geographic Factors**

Factor	Probability* that the Subpopulations within Each Factor are Equal	
	Percent Detected	Percent Greater than 3 ppm
Age Group	NA	NA
Race	.1362	.0005
Sex	.8267	.0003
Census Region	.8725	.0397
Industry	.1157	.4373

* Assuming no measurement or sampling bias and adjusted for the other factors.

** Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey sponsored by the U.S. Environmental Protection Agency.

NA Because the difference among age groups changes by fiscal year, it is not appropriate to test for this effect.

birth in the selected hospitals were solicited for cooperation. Milk specimens were collected from 1,436 participants.

3.2.3 Limitations of Statistical Inferences for PCBs in Human Milk

The available material is not sufficiently detailed to fully evaluate the survey design or to incorporate the design into the statistical analysis. Also, the statistical method used to summarize the PCB data presented in SPR 1977 are not described. Hence, there is insufficient information to fully evaluate the limitations of making inferences from the sample data to the target population of nursing mothers giving birth in U.S. general care hospitals during the study period. However, one important limiting factor is the fact that a nonrandom subsample (only specimens with sufficient volume for the second chemical analysis) of 1,033 milk specimens were analyzed for PCBs from the original 1,436. This admits the possibility of biases which might result in making inferences to the intended target population. Hence, statements that the levels measured in the sample are indicative of those one would find in the target population may be misleading.

3.2.4 Summary of Polychlorinated Biphenyls in Human Milk Data

To summarize the levels of PCBs in human milk, the measured values are grouped into the three categories: (i) not detected (ND), (ii) trace (detected but less than 0.05 parts per million (ppm)), and (iii) positive (greater than 0.05 ppm). Table 4 contains these summaries by the five geographic regions (not Census Regions) and overall. The Northeast and Southeast have the highest percent positive (38.2 and 37.7 percent respectively) and the Southwest region the lowest (21.5 percent). The maximum positive value (not adjusted for percent lipid) was 0.563 ppm in Texas in the Southwest region. In comparing this human milk data with the adipose tissue data, both similarities and differences are noticable. The percent of specimens containing detectable levels (99.1 percent) are similar, but the levels in milk are much lower than the levels in adipose tissue.

The data given in SPR (1977) also included the positive amounts adjusted for percent lipid. These adjusted data were not included in this report because of noncomparability with the adipose tissue data that could not be directly adjusted for percent lipid.

Table 4. Summary of Polychlorinated Biphenyls in Human Milk*

Levels (parts per million)	Region Northeast percent	Southeast percent	Midwest percent	Southwest percent	Northwest percent	Total
Not Detected	2.2	0.0	1.0	0.7	0.0	0.9
Trace	59.7	62.3	70.6	78.5	67.6	69.3
Positive**	38.2	37.7	28.4	20.9	32.4	29.8
Sample Size	186	159	289	297	102	1033

*Source: Calculated by the Research Triangle Institute from data provided by the U.S. EPA (SPR 1977).

**Greater than the minimum quantifiable level of 0.05 parts per million in whole milk.

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Appendix A

Sampling Weighting Methodology

Appendix A.

Sample Weighting Methodology

A.1 Introduction

The true probability of selection for specimens collected in the adipose tissue network could not be calculated because some stages of the sample selection involved nonprobability sampling. Even if the selection probabilities of a specimen within sample cities were assumed to be equal, the sample design of the NHMP adipose tissue network did not give a self-weighting sample with regard to the living population because of discrepancies between samples and the quotas. Therefore, a weight was calculated for each specimen that reflects its approximate probability of selection*. Including these weights in the analysis may reduce bias in estimating means or proportions. The following paragraphs describe the procedures used for computing approximate weights for the NHMP data.

A.2 Initial Sample Weights

The calculation of the initial sample weights considered two stages of selection. In the first stage, primarily sampling units (PSUs) were selected within each stratum with probability approximately proportional to their population. Table A.1 gives the number of PSUs specified by the survey design for the fiscal years. In the second stage, samples of cadavers and surgical patients were selected in a nonprobabilistic manner from a hospital(s) or other facility located in the sample cities. Equal probabilities of selection* were assumed for this stage. Table A.2 gives the number of tissue specimens included in the statistical analysis by fiscal year.

*Probabilities of selection at the final stage are with reference to a sampling rate for the living population rather than for the population of cadavers and surgical patients.

Table A.1. Number of Primary Sampling Units* Per Stratum by Fiscal Year as Specified by Survey Design**

Fiscal 1972

Census Region	Number	Percent
Northeast	11	28.2
North Central	12	30.8
South	9	23.1
West†	7	17.9
Total	39	100.0

Fiscal 1973-1981

Census Division	Fiscal 1973-1976		Fiscal 1977-1981	
	Number	Percent	Number	Percent
New England	4	5.3	2	5.0
Middle Atlantic	14	18.7	7	17.5
East North Central	15	20.0	8	20.0
West North Central	6	8.0	3	7.5
South Atlantic	11	14.7	6	15.0
East South Central	5	6.7	3	7.5
West South Central	7	9.3	4	10.0
Mountain	3	4.0	2	5.0
Pacific†	10	13.3	5	12.5
Total	75	100.0	40	100.0

* For fiscal years 1972 through 1976 the primary sampling units were cities with populations over 25,000 persons and from fiscal 1977 to 1981 the PSUs were Standard Metropolitan Statistical Areas (SMSAs).

** Source: Hartwell et al, 1979.

† Excludes Alaska and Hawaii.

Table A.2. Number of Tissue Specimens Used in Statistical Analysis by Fiscal Year*

Fiscal Year	Number
1972	1826
1973	1183
1974	1025
1975	895
1976	779
1977	927
1978	951
1979	910
1981	97
Total	8593

*Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files sponsored by the U.S. Environmental Protection Agency.

The initial sample weight for specimen (j) in PSU (i) and stratum (h) was calculated as the inverse product of the approximate probabilities of selection* for each stage and is expressed as

$$W1(hij) = [P_{hi} P_{j|hi}]^{-1},$$

where P_{hi} denotes the probability of selecting the i-th PSU in the h-th stratum (for large PSUs selected with probability 1 this is more accurately described as the expected number of times the PSU is selected in the sample); and $P_{j|hi}$ denotes the sampling rate of specimens to the living population given PSU (i) in stratum (h).

The PSUs were selected independently within each stratum. For each stratum, the cumulative total population of eligible PSUs was divided by the number of PSUs to be selected in the h-th stratum. This calculation gave the sample selection interval. A random start was obtained by selecting a random number between "1" and the value of the selection interval. The method then involved listing the cities in a random order, calculating the cumulative totals and selecting cities by matching the cumulative totals to the random start and integer multiples of the selection interval plus the random start (USEPA 1973).

The above can be expressed algebraically in the following manner. For each stratum, the selection interval is

$$I_h = N_h/m_h,$$

where I_h, N_h, and m_h denote the selection interval, cumulative population total, and number of PSUs to be selected for the h-th stratum, respectively. The PSUs selected in the sample are those for which the cumulative totals match $r_h + K \times I_h$ for K=0,...., m_h-1, where r_h is the random start for the h-th stratum.

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*Probabilities of selection at the final stage are with reference to a sampling rate for the living population rather than for the population of cadavers and surgical patients.

This method assigned a probability of selection to each PSU equal to the population of the PSU divided by the selection interval. This can be expressed algebraically as

$$P_{hi} = N_{hi}/I_h,$$

where N_{hi} denotes the population of the PSU (i) in stratum (h) and P_{hi} and I_h are defined above.

Under the assumption made above for selection of samples within a PSU, the calculation is straightforward. The pseudo probability of selection is given by dividing the number of specimens selected in each PSU by the population of the PSU. This can be expressed algebraically as

$$P_{j|hi} = n_{hi}/N_{hi}$$

for j=1, ..., n_{hi}, were n_{hi} denotes the number of samples collected in the i-th city in the h-th stratm and $P_{j|hi}$ and N_{hi} are defined above.

The initial weight can be written as

$$W1(hij) = [N_{hi}/I_h \times n_{ni}/N_{hi}]^{-1},$$

which simplifies to

$$W1(hij) = I_h/n_{hi}$$

Hence, the approximate initial sampling weight for the PSU (i) in the stratum (h) is the same for all samples collected in the city and is calculated by dividing the selection interval for the h-th stratum by the number of specimens collected in the city.

The method described above does yield selection probabilities proportional to the population of the PSUs when certain precautions are followed. Adequate methods for selecting alternate (substitute) cities were not taken. Hence, the procedures followed in the study alter the probability of selection for some PSUs, but the degree, although probably minor, is undetermined. For the purpose of calculating approximate weights, these special situations were treated the same as all others.

A.3 Missing Data Adjustments and Poststratification

Survey estimates of means and proportions may be biased if specimens that were identified for selection, but not collected, had different levels of PCB residue than those actually collected. Furthermore, estimates of population totals will be underestimated unless some allowance is made for the loss of the missing data. Therefore, the initial sample weights were adjusted by stratum so that the sum of the weights equaled national Census population counts in each stratum. This included only those data that were suitable for statistical analysis. Data was classified as suitable for analysis by percent extractable lipid (> 10 percent) and valid chemical analysis confidence codes.

The missing data adjustment process began with the definition of a response indicator for specimen (k) of the form

$$\text{RESP}(k) = \begin{cases} 1 & \text{if specimen (k) had data suitable for analysis} \\ 0 & \text{otherwise.} \end{cases}$$

Missing data occurred at different rates among demographic domains. Therefore, ratio adjustments to the initial weights were made within demographic domains referred to as poststrata. These poststrata were formed by crossing some or all of the following classification variables:

Fiscal year: 1972,...,1979,1981

Census Region: North East, North Central, South, West

Age Group: 0-14, 15-44, 45+

Race: White, Non-White

Sex: Male, Female

Once a poststratum (ℓ) was formed, N(ℓ), the Census population count for that poststratum, was obtained. The Census counts used depended on the fiscal year the sample data were obtained. Fiscal 1972 used 1960 Census data (US Census 1960), while fiscal 1973 through fiscal 1979 used 1970 Census data (US Census 1970). The fiscal 1981 sample was partitioned into poststrata formed by the nine Census Divisions and used 1980 Census data (US Census 1980).

The Census counts for each poststratum were divided by the weighted number of tissue specimens to form a poststratum adjustment factor:

$$ADJ(\ell) = N(\ell) \;/\; [\sum_{k\varepsilon\ell} W1(k) \cdot RESP(k)],$$

where $k\varepsilon\ell$ indicates that the summation is over all specimens belonging to poststratum (ℓ).

Each responding specimen (k) received an adjusted sample weight, W2 (k), which was its poststratum adjustment factor times its initial sample weight:

$$W2(k) = ADJ(\ell) \cdot W1(k).$$

Hence, within a poststratum, the sum of the adjusted sample weights equaled the corresponding Census population count.

Excessive sampling variances may be caused by unequal weighting effects. Therefore, a maximum increase of fifty percent over the standard deviation of an equally weighted sample was imposed on each of the nine fiscal year samples. Because fiscal 1972, 1973, and 1976 had unacceptable unequal weighting effects under this rule, the following calculations were undertaken to reduce the extreme values among the weights for these fiscal years.

First, the poststratum containing the largest adjusted weight in the fiscal years was found. Next, this largest adjusted weight was set equal to the second largest adjusted weight within the poststratum. Then, the difference between these two largest weights was spread equally over the remaining adjusted weights in the poststratum. This weight trimming process reduced the unequal weighting effect for fiscal 1973 and 1976 to below 50 percent. The unequal weighting effect for fiscal 1972 was still 57 percent after trimming, but was considered acceptable since there were several large weights. The adjusted weight sums for the affected poststrata remained equal to their Census population counts and the resulting mean square errors of estimation should be reduced using the trimmed weights.

A.4 References

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APPENDIX B

Statistical Methods Used in Analysis of Polychlorinated Biphenyls in Adipose Tissue

Appendix B

Statistical Methods in Analysis of Polychlorinated Biphenyls in Adipose Tissue

B.1 Statistical Analysis of Polychlorinated Biphenyls in Human Adipose Tissue

The statistical analysis that was performed on PCB residue levels used the NATS computer accessible data files and software that was specifically developed to take into account the survey design and weights. Estimates of the percentage of the U.S. population in the PCB residue categories for geographic, demographic, and overall categories are produced. These estimates were computed using a software package called SESUDAAN (Shah 1979). Tables B.1 through B.9 summarize these estimates by fiscal year. Table 2 in chapter three summarizes these estimates over all fiscal years.

To investigate differences among the categories for PD and percent GT3 and their changes over time, statistical models were developed using a software package called SURREGR (Holt 1977). Before the models are discussed, it is important to note that because of the limitations of the survey design, implementation and chemical analysis, all statements of statistical significance are asterisked. The purpose is to remind the reader that unverified assumptions about the survey design were required to assign weights to the specimens collected in NATS and to estimate the precision of the estimates. Additional reservations about the statistical significance result from the potential bias in population estimates that may result from the chemical analysis limitations.

Table B.1 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissues for Fiscal Year 1972

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	Less than 1 PPM†	Between 1 and 3 PPM†	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	223	55,786	11.7 (3.3)	42.2 (6.6)	44.2 (4.9)	2.0 (1.4)
15-44	446	70,920	7.0 (2.1)	24.6 (4.1)	63.3 (4.0)	5.1 (1.7)
45+	1157	52,626	9.8 (2.7)	22.0 (3.2)	63.4 (3.8)	4.8 (0.9)
Sex:						
Male	1029	89,990	8.0 (1.5)	27.6 (4.3)	58.3 (3.6)	6.2 (1.9)
Female	797	89,342	10.6 (2.0)	31.0 (3.5)	56.5 (3.9)	1.9 (0.6)
Race:						
White	1501	159,081	9.0 (1.6)	29.5 (3.2)	57.6 (3.1)	3.9 (1.1)
Nonwhite	325	20,252	11.5 (3.9)	27.4 (6.3)	55.8 (6.1)	5.3 (2.0)
Census Region:						
Northeast	630	44,678	11.2 (3.5)	15.9 (6.1)	67.7 (8.0)	5.3 (2.8)
North Central	476	51,628	13.1 (3.6)	35.8 (6.0)	48.1 (3.0)	2.9 (1.2)
South	486	54,973	6.1 (2.5)	28.0 (5.0)	60.1 (3.4)	5.8 (2.4)
West	234	28,053	5.3 (1.7)	41.3 (12.4)	52.8 (12.6)	.6 (0.3)
Number of PCB Industries per State:						
0	462	69,863	6.2 (2.4)	33.8 (5.0)	55.4 (3.0)	4.6 (2.0)
1	419	32,337	10.4 (3.0)	30.0 (9.4)	55.9 (7.8)	3.8 (1.5)
2+	945	77,133	11.6 (2.5)	24.9 (5.0)	59.8 (6.0)	3.6 (1.7)
Overall	1826	179,332	9.3 (1.6)	29.3 (3.3)	57.4 (3.1)	4.0 (1.1)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.2 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissues for Fiscal Year 1973

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels			
			Not Detected	Less than 1 PPM†	Between 1 and 3 PPM†	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	188	57,900	26.8 (5.9)	61.3 (6.4)	9.7 (2.8)	2.1 (1.4)
15-44	419	83,437	13.6 (3.7)	45.9 (4.3)	36.4 (4.2)	4.1 (1.3)
45+	576	61,875	15.4 (3.8)	33.6 (3.8)	41.8 (3.7)	9.2 (1.6)
Sex:						
Male	549	101,124	18.0 (4.0)	38.7 (3.9)	37.1 (4.1)	6.2 (1.3)
Female	634	102,088	17.9 (3.7)	54.3 (4.1)	23.8 (2.9)	4.0 (1.0)
Race:						
White	1026	176,345	15.8 (2.9)	49.1 (3.6)	30.8 (3.2)	4.2 (0.9)
Nonwhite	157	26,867	31.8 (10.3)	29.7 (7.0)	27.7 (5.3)	10.8 (2.8)
Census Region:						
Northeast	204	49,041	19.0 (11.1)	34.5 (11.2)	39.7 (9.2)	6.8 (2.4)
North Central	359	56,572	11.1 (3.7)	51.9 (5.7)	32.1 (6.3)	5.0 (2.3)
South	439	62,795	24.1 (5.8)	47.4 (4.7)	23.6 (3.0)	4.9 (1.1)
West	181	34,804	16.5 (7.3)	53.2 (6.0)	27.0 (4.6)	3.3 (2.1)
Number of PCB Industries per State:						
0	282	52,448	21.5 (6.7)	49.5 (6.7)	26.2 (4.4)	2.9 (1.1)
1	390	61,080	13.2 (3.5)	53.2 (4.3)	28.1 (5.5)	5.5 (2.1)
2+	511	89,684	19.1 (6.6)	40.3 (6.3)	34.5 (5.2)	6.1 (1.5)
Overall	1183	203,212	17.9 (3.6)	46.5 (3.5)	30.4 (3.0)	5.1 (1.0)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.3 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissue for Fiscal Year 1974

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	Less than 1 PPM †	Between 1 and 3 PPM †	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	207	57,900	19.1 (5.6)	72.9 (6.5)	8.0 (1.9)	0.0 (*)
15-44	362	83,437	5.5 (1.9)	50.7 (4.2)	38.6 (4.2)	5.2 (1.6)
45+	456	61,875	6.3 (2.6)	41.7 (4.3)	43.8 (3.9)	8.1 (2.5)
Sex:						
Male	521	98,912	9.8 (2.9)	49.3 (3.5)	36.9 (4.1)	4.0 (1.0)
Female	504	104,300	9.5 (2.7)	59.1 (3.3)	26.3 (2.9)	5.2 (1.9)
Race:						
White	868	177,066	9.2 (2.2)	55.5 (2.8)	30.9 (2.9)	4.5 (1.3)
Nonwhite	157	26,146	12.8 (5.0)	46.0 (7.3)	35.4 (5.7)	5.7 (2.0)
Census Region:						
Northeast	225	49,041	13.5 (5.4)	40.7 (4.9)	37.8 (6.5)	8.0 (4.1)
North Central	304	56,572	13.4 (5.3)	55.0 (4.8)	28.7 (4.5)	3.0 (1.4)
South	374	62,795	6.5 (2.4)	57.4 (3.6)	31.2 (3.5)	4.9 (1.7)
West	122	34,804	3.9 (2.2)	66.7 (8.9)	27.4 (9.2)	2.0 (1.1)
Number of PCB Industries per State:						
0	242	49,439	12.0 (5.3)	60.3 (6.7)	22.4 (4.3)	5.3 (2.3)
1	306	64,057	8.0 (2.9)	57.2 (2.9)	32.3 (3.9)	2.4 (0.8)
2+	477	89,716	9.5 (3.4)	48.9 (4.5)	35.8 (5.1)	5.8 (2.3)
Overall	1025	203,212	9.6 (2.2)	54.3 (2.6)	31.4 (2.8)	4.6 (1.2)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.5 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissue for Fiscal Year 1976

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels			
			Not Detected	Less than 1 PPM†	Between 1 and 3 PPM†	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	165	57,900	4.5 (1.8)	86.6 (3.4)	7.7 (2.6)	1.2 (0.8)
15-44	248	83,437	0.5 (0.5)	56.3 (2.6)	35.7 (2.9)	7.4 (2.2)
45+	366	61,875	0.0 (*)	52.4 (5.1)	34.1 (4.7)	13.4 (3.0)
Sex:						
Male	397	97,391	1.8 (0.8)	56.5 (4.2)	32.4 (3.6)	9.3 (2.1)
Female	382	105,821	1.3 (0.8)	70.4 (3.7)	22.5 (3.6)	5.8 (2.0)
Race:						
White	642	177,887	1.2 (0.7)	64.2 (2.8)	27.8 (2.6)	6.8 (1.5)
Non-white	137	25,325	3.7 (2.5)	60.3 (6.5)	23.4 (5.1)	12.6 (3.6)
Census Region:						
Northeast	229	49,041	0.1 (0.1)	47.4 (3.0)	37.0 (5.0)	15.5 (3.4)
North Central	205	56,572	2.1 (1.9)	77.1 (6.1)	19.5 (5.7)	1.3 (0.6)
South	254	62,795	1.4 (1.0)	62.5 (5.4)	29.5 (4.6)	6.5 (2.5)
West	91	34,804	2.6 (1.0)	67.2 (10.1)	22.2 (5.6)	8.0 (5.2)
Number of PCB Industries per State:						
0	181	42,997	0.3 (0.3)	81.8 (3.6)	15.5 (3.2)	2.4 (1.8)
1	216	63,566	1.7 (1.0)	69.3 (6.1)	25.2 (5.3)	3.8 (2.2)
2+	382	96,649	1.9 (1.1)	52.0 (3.4)	33.9 (3.4)	12.1 (2.5)
Overall	779	203,212	1.5 (0.6)	63.7 (2.8)	27.3 (2.5)	7.5 (1.5)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.4 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissue for Fiscal Year 1975

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	Less than 1 PPM †	Between 1 and 3 PPM †	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	163	57,900	19.7 (6.8)	71.1 (7.9)	8.6 (2.6)	0.5 (0.4)
15-44	304	83,437	1.5 (0.7)	59.5 (4.1)	30.6 (3.8)	8.4 (1.9)
45+	428	61,875	0.7 (0.4)	57.0 (5.0)	26.9 (3.4)	15.4 (3.6)
Sex:						
Male	445	98,912	6.9 (3.1)	63.0 (4.4)	21.4 (3.2)	8.7 (2.3)
Female	450	104,300	6.0 (2.0)	61.1 (4.7)	25.0 (3.3)	7.9 (1.6)
Race:						
White	747	177,067	6.5 (2.6)	62.9 (4.1)	22.9 (2.6)	7.7 (1.4)
Nonwhite	148	26,145	6.0 (2.3)	56.4 (6.8)	25.2 (4.8)	12.4 (3.3)
Census Region:						
Northeast	206	49,041	7.0 (3.9)	54.9 (10.6)	21.9 (5.9)	16.3 (3.0)
North Central	339	56,572	4.6 (2.2)	62.6 (6.9)	25.1 (4.6)	7.8 (2.9)
South	231	62,795	7.1 (6.1)	63.0 (6.1)	23.8 (4.2)	6.1 (3.1)
West	119	34,804	7.5 (3.4)	69.4 (9.0)	21.1 (6.3)	2.0 (2.1)
Number of PCB Industries per State:						
0	222	46,815	3.5 (1.8)	66.2 (7.4)	21.7 (5.1)	8.6 (3.4)
1	256	69,481	6.8 (5.4)	66.3 (5.6)	22.9 (4.0)	4.0 (2.4)
2+	417	86,916	7.7 (2.6)	56.3 (7.0)	24.3 (4.3)	11.6 (2.2)
Overall	895	203,212	6.4 (2.3)	62.0 (4.0)	23.2 (2.6)	8.3 (1.5)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.6 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissue for Fiscal Year 1977

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels			
			Not Detected	Less than 1 PPM†	Between 1 and 3 PPM†	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	174	57,900	2.0 (1.6)	90.1 (2.9)	3.7 (1.6)	4.2 (2.3)
15-44	357	83,437	0.0 (*)	66.8 (3.6)	24.9 (2.8)	8.3 (2.1)
45+	396	61,875	0.0 (*)	59.8 (4.1)	23.6 (2.6)	16.6 (3.5)
Sex:						
Male	457	98,912	0.3 (0.3)	66.7 (3.4)	22.4 (2.3)	10.5 (2.5)
Female	470	104,300	0.8 (0.8)	75.6 (2.6)	14.7 (1.9)	8.9 (1.8)
Race:						
White	794	178,972	0.7 (0.5)	71.5 (2.3)	18.8 (1.6)	9.0 (1.7)
Nonwhite	133	24,240	0.0 (*)	69.7 (5.1)	15.9 (4.2)	14.4 (4.6)
Census Region:						
Northeast	206	49,041	0.7 (0.7)	69.5 (3.4)	19.2 (3.3)	10.7 (4.5)
North Central	257	56,572	0.0 (*)	68.6 (4.8)	21.7 (3.1)	9.7 (2.4)
South	341	62,795	1.3 (1.3)	75.2 (5.2)	13.8 (2.4)	9.6 (3.2)
West	123	34,804	0.0 (*)	71.2 (4.2)	20.6 (3.6)	8.2 (3.7)
Number of PCB Industries per State:						
0	312	59,410	0.0 (*)	77.6 (4.0)	14.4 (2.6)	8.0 (2.0)
1	262	60,641	0.0 (*)	67.9 (4.8)	21.6 (2.8)	10.5 (3.5)
2+	353	83,161	1.4 (1.0)	69.3 (2.7)	19.1 (2.1)	10.3 (3.0)
Overall	927	203,212	0.6 (0.4)	71.3 (2.4)	18.5 (1.5)	9.7 (1.7)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.7 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissue for Fiscal Year 1978

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	Less than 1 PPM †	Between 1 and 3 PPM †	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	205	57,900	5.7 (1.7)	85.1 (4.3)	6.5 (2.4)	2.7 (1.6)
15-44	365	83,437	0.3 (0.3)	67.9 (4.4)	19.6 (2.9)	12.2 (2.8)
45+	381	61,875	0.3 (0.2)	64.7 (5.1)	27.0 (4.4)	8.0 (2.5)
Sex:						
Male	475	98,912	1.0 (0.5)	67.0 (3.9)	20.3 (2.9)	11.7 (2.8)
Female	476	104,300	2.6 (0.9)	76.4 (3.6)	16.0 (2.9)	5.0 (1.5)
Race:						
White	771	177,749	1.5 (0.6)	72.8 (3.8)	17.8 (2.7)	8.0 (2.0)
Non-white	180	25,463	4.4 (3.0)	65.2 (5.6)	20.3 (4.3)	10.1 (3.4)
Census Region:						
Northeast	216	49,041	0.6 (0.5)	69.4 (8.9)	22.6 (7.0)	7.4 (3.3)
North Central	211	56,572	2.0 (1.1)	70.9 (5.4)	19.6 (5.0)	7.5 (3.4)
South	372	62,795	1.6 (1.1)	74.0 (7.5)	13.8 (3.7)	10.6 (4.3)
West	152	34,804	3.6 (2.0)	72.8 (3.9)	17.2 (3.5)	6.4 (3.6)
Number of PCB Industries per State:						
0	316	74,356	2.4 (1.1)	77.5 (5.2)	12.9 (3.5)	7.2 (2.7)
1	270	48,062	0.8 (0.6)	74.5 (4.4)	17.9 (3.9)	6.9 (2.8)
2+	365	80,794	1.9 (0.9)	65.0 (6.2)	23.1 (4.3)	10.0 (3.6)
Overall	951	203,212	1.8 (0.6)	71.8 (3.5)	18.1 (2.5)	8.2 (1.9)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.8 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissue for Fiscal Year 1979

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	PCB Residue Levels: Less than 1 PPM †	PCB Residue Levels: Between 1 and 3 PPM †	PCB Residue Levels: Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	203	57,900	4.1 (2.2)	89.0 (3.5)	6.9 (3.1)	0.0 (*)
15-44	346	84,167	0.0 (*)	80.3 (4.2)	15.0 (2.8)	4.7 (2.9)
45+	361	61,145	0.2 (0.2)	66.6 (3.9)	26.5 (3.9)	6.6 (4.3)
Sex:						
Male	477	104,131	1.3 (0.6)	76.5 (3.5)	17.7 (3.1)	4.5 (1.9)
Female	433	99,081	1.2 (0.8)	80.9 (3.5)	14.6 (2.3)	3.3 (3.2)
Race:						
White	740	178,897	1.0 (0.4)	79.5 (3.2)	15.9 (2.6)	3.7 (2.5)
Non-white	170	24,315	3.1 (2.3)	72.7 (6.1)	18.4 (3.8)	5.8 (2.8)
Census Region:						
Northeast	189	49,041	0.9 (0.7)	55.7 (11.7)	30.5 (6.7)	12.9 (10.5)
North Central	189	56,572	0.0 (*)	93.0 (2.8)	6.9 (2.8)	0.1 (0.1)
South	438	62,795	2.7 (1.5)	81.4 (4.4)	15.4 (3.3)	0.6 (0.4)
West	94	34,804	1.1 (1.3)	82.9 (5.7)	12.4 (6.5)	3.5 (2.1)
Number of PCB Industries per State:						
0	281	57,160	2.3 (1.6)	85.6 (5.2)	11.2 (3.6)	0.8 (0.6)
1	259	60,086	0.8 (0.8)	92.2 (1.9)	5.5 (1.8)	1.5 (1.3)
2+	370	85,966	0.9 (0.5)	64.6 (6.8)	26.9 (4.0)	7.7 (6.0)
Overall	910	203,212	1.2 (0.6)	78.7 (3.3)	16.2 (2.4)	3.9 (2.5)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

Table B.9 Weighted Percentage Distribution of PCB Residue Levels in Adipose Tissues for Fiscal Year 1981

Domain	Sample Size	Population Estimate (in thous.)	PCB Residue Levels: Not Detected	Less than 1 PPM†	Between 1 and 3 PPM†	Greater than 3 PPM†
			percent (standard error)			
Age (years):						
0 -14	26	51,390	0.0 (*)	92.8 (5.3)	7.2 (5.3)	0.0 (*)
15-44	47	115,750	0.0 (*)	69.5 (10.6)	29.0 (10.5)	1.5 (1.5)
45+	24	59,365	0.0 (*)	58.4 (12.8)	41.6 (12.8)	0.0 (*)
Sex:						
Male	53	126,700	0.0 (*)	65.9 (10.8)	32.7 (10.4)	1.4 (1.4)
Female	44	99,805	0.0 (*)	79.4 (9.3)	20.6 (9.3)	0.0 (*)
Race:						
White	76	182,205	0.0 (*)	80.7 (6.8)	19.3 (6.8)	0.0 (*)
Nonwhite	21	44,299	0.0 (*)	35.4 (13.3)	60.7 (14.0)	3.9 (4.0)
Census Region:						
Northeast	19	49,137	0.0 (*)	73.5 (15.9)	26.5 (15.9)	0.0 (*)
North Central	24	58,854	0.0 (*)	74.0 (13.4)	23.0 (12.2)	3.0 (3.0)
South	34	75,349	0.0 (*)	73.8 (16.4)	26.2 (16.4)	0.0 (*)
West	20	43,165	0.0 (*)	63.6 (22.6)	36.4 (22.6)	0.0 (*)
Number of PCB Industries per State:						
0	34	68,718	0.0 (*)	69.2 (1.7)	28.3 (16.0)	2.5 (2.5)
1	30	66,161	0.0 (*)	82.5 (10.6)	17.5 (10.6)	0.0 (*)
2+	33	91,626	0.0 (*)	66.1 (13.0)	33.9 (13.0)	0.0 (*)
Overall	97	226,505	0.0 (*)	71.8 (8.5)	27.4 (8.4)	0.8 (0.8)

† parts per million
*Standard error not estimable.
Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey's computer accessible data files.

B.2 Statistical Models for Trends

To estimate the trends in PD and percent GT3 for the U.S. Population, the regression model:

$$Y(i) = B(0) + B(1)\,(FY-\overline{FY}) + B(2)\,(FY-\overline{FY})^2 \qquad (B.2.1)$$

was used where Y(i), i=1,2, is the dependent variable, FY denotes fiscal year, $\overline{FY}$ denotes the mean of the fiscal years. Y is an indicator random variable taking on the values:

$$Y(1) = \begin{cases} 0 \text{ if } PCB = 0 \\ 1 \text{ if } PCB > 0 \end{cases}$$

when PD is being investigated and

$$Y(2) = \begin{cases} 0 \text{ if } PCB \leq 3 \text{ ppm} \\ 1 \text{ if } PCB > 3 \text{ ppm} \end{cases}$$

when percent GT3 is being investigated.

For the dependent variable Y(1), both the linear and quadratic terms were significant*. Only the quadratic term was significant* for Y(2). Hence, the estimated trend equations are

$$PD = 96.0 + 1.80\,(FY - 76.11) - .189\,(FY-76.11)^2$$

and

$$GT3 = 8.15 - .31\,(FY-76.11)^2.$$

These equations are plotted in Figures 4 and 7 in Chapter 3.

Besides the overall model, the complex design model

$$\begin{aligned} Y(i) = {} & AGEG+RACE+SEX+CR+IND+(FY-\overline{FY})+(FY-\overline{FY})^2+ \\ & (FY-\overline{FY}) * (AGEG+RACE+SEX+CR+IND) \\ & +(FY-\overline{FY})^2 * (AGEG+RACE+SEX+CR+IND) \qquad (B.2.2) \end{aligned}$$

*Assuming no sampling or measurement bias.

was tested using SURREGR (Holt 1977) where was Y(i), i=1,2, is defined as in equation (B.2.1),

AGEG	denotes the age effect for the three levels 0-14, 15-44 and 45+,
RACE	denotes the race effect for the two levels white and nonwhite,
SEX	denotes the sex effect for the two levels male and female,
CR	denotes the Census Region effect for the four levels Northeast, North Central, South and West,
IND	denotes the PCB industry effect for the three levels none (0), one (1) and more than one (2+),
$FY-\overline{FY}$	denotes the difference between the fiscal year and the mean of the fiscal years,

$(FY-\overline{FY})$*(AGEG+RACE+SEX+CR+IND) denotes the linear interactions of fiscal year with the main effects, and

$(FY-\overline{FY})^2$*(AGEG+RACE+SEX+CR+IND) denotes the quadratic interactions of fiscal year with the main effects.

The categories CR and IND are defined in Tables B.10 and B.11 respectively. Each observation is assigned to the appropriate category by using the State in which the tissue specimen was collected.

The statistical test indicated only one significant* second order interaction (significance level (SL) < .05), $(FY-\overline{FY})^2$*AGEG for GT3 and none for PD. The model in equation (B.2.2) was simplified by dropping all second order terms with the exception of the $(FY-\overline{FY})^2$*AGEG for GT3. The statistical test on the first order interactions indicated no significant* interactions among $(FY-\overline{FY})$ and RACE, SEX, CR or IND. The model was again simplified yielding the two models:

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*Assuming no sampling or measurement bias.

Table B.10 List of States by Census Region and Census Division Within Region

Region	Division	States	Region	Division	States
North East	New England	Connecticut Maine Massachusetts New Hampshire Rhode Island Vermont	North Central	East North Central	Illinois Indiana Michigan Ohio Wisconsin
	Middle Atlantic	New Jersey New York Pennsylvania		West North Central	Iowa Kansas Minnesota Missouri Nebraska North Dakota South Dakota
South	South Atlantic	Delaware District of Columbia Florida Georgia Maryland North Carolina South Carolina Virginia West Virginia	West	Mountain	Arizona Colorado Idaho Montana Nevada New Mexico Utah Wyoming
	East South Central	Alabama Kentucky Mississippi Tennessee		Pacific	Alaska California Hawaii Oregon Washington
	West South Central	Arkansas Louisiana Oklahoma Texas			

Table B.11 List of States By PCB Industry Category

<u>No PCB Industries</u>

Alaska
Arkansas
Connecticut
Delaware
Florida
Hawaii
Idaho
Iowa
Kansas
Louisiana
Maine
Michigan
Minnesota
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Mexico
North Dakota
Oklahoma
Rhode Island
South Dakota
Utah
Washington
West Virginia
Wisconsin
Wyoming

<u>One PCB Industry</u>

Arizona
Colorado
Georgia
Indiana
Mississippi
North Carolina
Ohio
Oregon
Tennessee
Texas
Vermont

<u>Two or more PCB Industries</u>

Alabama
California
Illinois
Massachusetts
New Jersey
New York
Pennsylvania
South Carolina
Virginia

Source: Compiled by the Research Triangle Institute from lists of U.S. transformer and capacitor manufacturing industries using PCBs provided by the U.S. Environmental Protection Agency.

$$Y(1) = AGEG+RACE+SEX+CR+IND+(FY-\overline{FY})+(FY-\overline{FY})^2+(FY-\overline{FY})*AGEG$$

and

$$Y(2) = AGEG+RACE+SEX+CR+IND+(FY-\overline{FY})+(FY-\overline{FY})^2+(FY-\overline{FY})*AGEG+(FY-\overline{FY})^2*AGEG \quad (B.2.3)$$

for PD and GT3 respectively. The above models was used to test for the main effects with the exception of AGEG. The results of this test are summarized in Chapter 3.

To illustrate the trends in the three age groups, the coefficients for two simple models were estimated. The equations for PD are

$$PD = 91.0 + 2.58\ (FY-76.11) - .189(FY-76.11)^2$$

for the 0-14 age group,

$$PD = 98.2 + 1.35(FY-76.11) - .189(FY-76.11)^2$$

for the 15-44 age group, and

$$PD = 97.8 + 1.60(FY-76.11) - .189(FY-76.11)^2$$

for the 45+ age group. These equations were used to calculate the trends illustrated in Figure 3. The equations for percent GT3 are

$$GT3 = 1.83 - .055\ (FY-76.11)^2$$

for the 0-14 age group,

$$GT3 = 8.55 - .293\ (FY-76.11)^2$$

for the 15-44 age group, and

$$GT3 = 13.6 - .585\ (FY-76.11)^2$$

for the 45+ age group. The linear term in FY was excluded because it did not contribute significantly* to explaining the changes in GT3 over time. These equations were used to calculate the trends in Figure 5.

To illustrate the trends in the race groups, the equations for percent GT3 are

$$GT3 = 7.8 - .34(FY-\overline{FY})^2$$

*Assuming no sampling or measurement bias.

for whites and

$$GT3 = 11.5 - .34(FY-\overline{FY})^2$$

for nonwhites were plotted in Figure 6. Trends for the two sex groups and the Census Regions would have essentially the same coefficients for the fiscal year terms but would have different intercepts. Table B.12 summarizes the intercepts for the factors race, sex, Census Region and industry.

B.3 Assessing Limitations of the Data

In an attempt to ascertain the impact of the change in chemical analysis on the estimated trends, overall trends were calculated using data collected during fiscal 1976 to 1979 and 1981. The overall trend equation for PD is:

$$PD = 98.98 + .24\ (FY-78.2),$$

and the overall trend equation for percent GT3 is:

$$GT3 = 6.00 - 1.66\ (FY-78.2).$$

The trends for PD and GT3 are illustrated in Figures 9 and 10 respectively. The slopes of the lines are significant*, with the slope for PD having a significance level* of .0199 and the slope for GT3 having a significance level* of .0000.

To compare the slopes in the above equations with the estimated trend using all fiscal years, one can calculate the average change per year from fiscal 1976 to 1981. Using the equations:

$$PD(FY) = 96.0 + 1.80\ (FY-76.11) - .189\ (FY-76.11)^2$$

and

$$GT3(FY) = 8.15 - .31\ (FY-76.11)^2,$$

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*Assuming no measurement of sampling bias.

Table B.12. Intercepts for Trends of Percent Greater Than 3 PPM* by Factors**

Factor	Subpopulation	Intercept (Percent)
Race	White	7.7
	Nonwhite	11.4
Sex	Male	9.3
	Female	7.1
Census Region	Northeast	11.6
	North Central	6.8
	South	7.7
	West	6.2
Industry	0	7.4
	1	6.4
	2+	9.9

* PPM denotes parts per million.

** Source: Calculated by the Research Triangle Institute from the National Adipose Tissue Survey computer accessible data file.

the average change for PD is (PD(81) - PD(76))/(81-76) = .90 and the average change for GT3 is (GT3(81) - GT3(76)) / (81-76) = -1.48. The average changes per year are consistent in direction. The two estimated rates of change for GT3 are comparable for the time period. The magnitudes for PD are not as comparable but this can be explained by the relatively low value in PD for fiscal 1973 which pulls down the trend equation for all years. Hence, the change in chemical analysis method does not appear to consequentially affect the estimated trends.

To develop an understanding of the impact of bias on the significance level of trends and subpopulation differences, Table B.13 was calculated. The table illustrates the true significance of a two sided test of hypothesis when no bias exists and for levels of bias ranging from one fourth the standard error (SE) to four times the SE. For simplicity, the significance levels are calculated using the normal density function. Even though the tests discussed in the report were based on the F distribution, the table is not misleading because the degrees of freedom for the denominator were large (69 for fiscal 1976-1981 and 103 for all fiscal years) and the degrees of freedom for the numerator were often only 1 (at most 3).

Using the table, one can estimate the magnitude of the relative bias that may mislead the investigator into drawing erroneous conclusions. For example, if a test was calculated to have a significance level of .0001, then a bias of more than twice the size of the SE would be required to raise the true significance level above the traditional .05 level. Hence, because the significance level of trends were generally .0001 or lower, it is unlikely that magnitude of the bias is large enough to

Table B.13. Impact of Bias on the Significnace Level of Statistical Test of Hypothesis*

BIAS/SE	Significance Level					
0.00	.0500	.0250	.0100	.0010	.0001	.00001
0.25	.0572	.0297	.0124	.0012	.0001	.00002
0.50	.0791	.0440	.0190	.0028	.0003	.00004
1.00	.1701	.1081	.0578	.0113	.0019	.00032
1.50	.3230	.2297	.1412	.0375	.0084	.00177
2.00	.5160	.4052	.2826	.1003	.0294	.00782
3.00	.8508	.7764	.6646	.3897	.1867	.07825
4.00	.9793	.9608	.9229	.7642	.5438	.33834

*Calculated by the Research Triangle Institute using the equation:

$$SL = \int_{-z(\alpha) + BIAS/SE}^{z(\alpha) + BIAS/SE} \exp(-x^2/2)/\sqrt{2\pi}\, dx$$

where z(.0500) = 1.960, z(.0250) = 2.24, z(.0100) = 2.576, z(.0010) = 3.291, z(.0001) = 3.891, z(.00001) = 4.417 and SE denotes the standard error.

affect the conclusions about trends. Similar reasoning can be used to allow the reader to evaluate the conclusions about race, sex, or geographic differences.

B.4 References

Holt MM 1977 SURREGR: Standard errors of regression coefficients from sample survey data. Research Triangle Institute, Research Triangle Park, NC 27709.

Shah DV 1979 SESUDAAN: Standard errors program for computing of standardized rates from sample survey data. Research Triangle Institute, Research Triangle Park, NC 27709, RTI/1789/00-01F.