

## America's Children and the Environment, Third Edition

### DRAFT Indicators

#### Biomonitoring: Bisphenol A (BPA)

EPA is preparing the third edition of *America's Children and the Environment* (ACE3), following the previous editions published in December 2000 and February 2003. ACE is EPA's compilation of children's environmental health indicators and related information, drawing on the best national data sources available for characterizing important aspects of the relationship between environmental contaminants and children's health. ACE includes four sections: Environments and Contaminants, Biomonitoring, Health, and Special Features.

EPA has prepared draft indicator documents for ACE3 representing 23 children's environmental health topics and presenting a total of 42 proposed children's environmental health indicators. This document presents the draft text, indicators, and documentation for the BPA topic in the Biomonitoring section.

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For more information on America's Children and the Environment, please visit [www.epa.gov/ace](http://www.epa.gov/ace). For instructions on how to submit comments on the draft ACE3 indicators, please visit [www.epa.gov/ace/ace3drafts/](http://www.epa.gov/ace/ace3drafts/).

### 1 **Bisphenol A**

2  
3 Bisphenol A (BPA) is a high-volume industrial chemical used in the production of epoxy resins  
4 and polycarbonate plastics. Polycarbonate plastics may be encountered in many products,  
5 notably food and drink containers, while epoxy resins are frequently used as inner liners of  
6 metallic food and drink containers to prevent corrosion. BPA also serves as a coating on some  
7 types of thermal paper that are often used as receipts from cash registers, automatic teller  
8 machines, and other similar devices. It has also been used in the polyvinyl chloride industries as  
9 well as in metal foundries where it is used to make casts and moldings. The primary route of  
10 human exposure to BPA is believed to be through diet, when BPA migrates from food and drink  
11 containers.<sup>1-3</sup> Migration is more likely to occur when the container is heated.<sup>4</sup>

12  
13 The highest daily exposures to BPA are thought to occur in infants and children. Estimated daily  
14 intakes of BPA for children are higher than those in the general population, because pound for  
15 pound children breathe, eat, and drink more than adults do.<sup>1</sup> Biomonitoring studies demonstrate  
16 that BPA exposure is prevalent in the United States, with detectable levels of BPA present in  
17 93% of tested urine samples.<sup>5</sup> Because BPA is metabolized quickly in the body, the high  
18 frequency of detection indicates that exposures are occurring regularly within the U.S.  
19 population.

20  
21 BPA is a suspected endocrine disruptor.<sup>6</sup> Endocrine disruptors act by interfering with the  
22 biosynthesis, secretion, action, or metabolism of naturally occurring hormones.<sup>7,8</sup> Given the  
23 importance of hormones in human physiology, there is concern in the scientific community over  
24 the potential for endocrine disruptors to adversely affect children's health, particularly in  
25 reproduction, development, and behavior. BPA is described as a "weakly estrogenic" chemical,  
26 because its affinity for binding to estrogen receptors is approximately 10,000-fold weaker than  
27 natural estrogen.<sup>9</sup>

28  
29 There has been increasing attention to the developmental effects of BPA, based on several  
30 laboratory studies and a better understanding of the mechanisms by which BPA exerts an  
31 estrogenic effect.<sup>6,10,11</sup> In animal studies, exposure to high levels of BPA during pregnancy or  
32 lactation resulted in reduced birth weight, slowed growth, reduced survival, and delayed time to  
33 the onset of puberty in offspring.<sup>12-15</sup> Another study found that low-dose BPA exposure in  
34 pregnant animals was associated with symptoms similar to gestational diabetes, suggesting that  
35 BPA exposures may have adverse effects in pregnant women.<sup>16</sup> The effects of low-dose exposure  
36 to BPA in lab animals are debated within the scientific community, with some researchers  
37 finding no developmental effects, while others have identified behavioral and neural effects,  
38 abnormal urinary tract development, development of lesions in the prostate gland, and early  
39 onset of puberty in females.<sup>1,17-27</sup> Based on a critical review of the existing scientific literature, in  
40 2008 the National Toxicology Program determined that there was "some concern" (the midpoint

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1 on a five-level scale ranging from “negligible” to “serious”<sup>i</sup> for effects of BPA on the brain,  
2 behavior, and prostate gland in fetuses, infants, and children; “minimal concern” for effects on  
3 the mammary gland and onset of puberty in females; and “negligible concern” for fetal or  
4 neonatal mortality, birth defects, or reduced birth weight and growth.<sup>1</sup>

5  
6 Epidemiological data on the effects of BPA in human populations are limited. Studies on low-  
7 dose exposures seen in the general population suggest an association in adults between high  
8 urinary BPA concentrations and coronary heart disease, diabetes, and liver enzyme  
9 abnormalities.<sup>28,29</sup> Another study on occupational exposure in adult workers associated exposure  
10 with high levels of BPA to an increased risk of self-reported sexual dysfunction.<sup>30,31</sup> Finally, a  
11 recent study associated general population prenatal BPA exposure with aggression and  
12 hyperactivity in 2-year-old children.<sup>32</sup> In 2009, the National Institutes of Health announced that it  
13 would spend \$30 million over two years to better understand the link between low-dose BPA  
14 exposure and human health effects.

15  
16 Children, particularly developing fetuses and infants, are likely to be more sensitive to the effects  
17 of BPA due to their developmental stage. Previous studies have identified higher levels of BPA  
18 in the urine of children ages 6 to 11 years compared with adults, and found that consumption of  
19 soda and school lunches was also associated with higher urinary BPA concentrations.<sup>33,34</sup> Infants  
20 and children also have a higher estimated daily intake of BPA compared with adults.<sup>1,35</sup>  
21 Although less information is available on BPA levels in infants than in older children, one study  
22 demonstrated that premature infants in intensive care units had greater urinary BPA  
23 concentrations than those observed in other infants or even older children, though the route of  
24 exposure for the premature infants is unclear.<sup>36</sup> Evidence from laboratory animal studies  
25 indicates that younger animals are less effective at metabolizing BPA than older animals are; this  
26 observation may apply to human infants and developing fetuses.<sup>1,27,37</sup>

27  
28 The following indicators present data for BPA levels in the U.S. population. The first indicator  
29 shows the distribution of median BPA concentrations in women ages 16 to 49 years, based on  
30 concerns for effects on children from BPA exposures in women who are pregnant or may  
31 become pregnant. The second indicator shows the distribution of median BPA concentrations in  
32 children ages 6 to 17 years.

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<sup>i</sup> More information on NTP concern levels is available at <http://www.niehs.nih.gov/news/media/questions/sya-bpa.cfm>.

1 **Indicator BPA1: Bisphenol A in women ages 16 to 49 years: Median**  
2 **concentrations in urine, by race/ethnicity and family income, 2003-**  
3 **2006**

4 **Indicator BPA2: Bisphenol A in children ages 6 to 17 years: Median**  
5 **concentrations in urine, by race/ethnicity and family income, 2003-**  
6 **2006**

### Overview

Indicators BPA1 and BPA2 present concentrations of bisphenol A (BPA) in urine of U.S. women ages 16 to 49 years and children ages 6 to 17 years, respectively. The data are from a national survey that collects urine specimens from a representative sample of the population, and then measures the concentration of total BPA in the urine. These indicators present comparisons of BPA in urine of women and children of different race/ethnicities and income levels. The focus on women of child-bearing age is based on concern for potential effects on children from exposures to women who are or may become pregnant.

### NHANES

Data for these indicators are from the National Health and Nutrition Examination Survey (NHANES). NHANES is a nationally representative survey designed to assess the health and nutritional status of the civilian noninstitutionalized U.S. population, conducted by the Centers for Disease Control and Prevention (CDC). Interviews and physical examinations are conducted with approximately 5,000 people each year. CDC's National Center for Environmental Health measures concentrations of environmental chemicals in blood and urine samples collected from NHANES participants.<sup>38</sup> Concentrations of BPA in urine have been measured in a representative subset of NHANES participants ages 6 years and older beginning with the 2003–2004 survey cycle. The NHANES survey did not collect samples from children less than 6 years of age.

### Creatinine Adjustment

NHANES data for BPA are based on a single urine sample for each person surveyed, and can be subject to substantial variability due to normal changes in an individual's urinary output. For example, a urine sample from an individual who is dehydrated would be smaller in volume, and would have a higher chemical concentration than if she or he were well hydrated. This variability is due only to the volume of the urine sample, and may mask differences between individuals in levels of BPA.

To help reduce measurement variability related to fluctuations in urine output, these indicators report BPA measurements in micrograms per gram of creatinine, rather than micrograms per liter

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1 of urine.<sup>39</sup> Creatinine is a byproduct of muscle metabolism that is excreted in urine at a relatively  
2 constant rate, independent of the volume of urine. The constant excretion of creatinine in urine  
3 allows for an adjustment that partially accounts for the measurement variability due to changes in  
4 urinary output.

5  
6 Creatinine correction is widely used in urinary biomonitoring,<sup>38</sup> but the adjustment does have  
7 important limitations. Urinary creatinine concentrations can vary due to age, sex, diet, health  
8 status (specifically renal function), body-mass index, race/ethnicity, and pregnancy status.<sup>40,41</sup>  
9 Thus the creatinine adjustment improves the comparability of chemical measurements across  
10 individuals, but the variability in creatinine concentrations may still affect comparisons between  
11 individuals or populations.

### 13 **Bisphenol A and its Metabolites**

14 The reported measurements of BPA in urine represent “total BPA,” which includes both BPA  
15 itself and biologically inactive metabolites of BPA. Measured levels in the U.S. population may  
16 be composed predominantly of the inactive metabolites, but total BPA levels reflect previous  
17 exposure to the biologically active form of BPA.<sup>42</sup> Recent work has also highlighted the potential  
18 for conversion of inactive metabolites of BPA to the active form when crossing the placenta,  
19 increasing the relevance of total BPA measurements to children’s health.<sup>43</sup>

### 21 **Birthrate Adjustment**

22 Measurements of BPA in urine of women ages 16 to 49 years are used to reflect the potential  
23 distribution of BPA exposures to women who are pregnant or may become pregnant. However,  
24 women of different ages have a different likelihood of giving birth. For example, in 2003–2004,  
25 women aged 27 had a 12% probability of giving birth, and women aged 37 had a 4% probability  
26 of giving birth. A birthrate-adjusted distribution of women’s BPA levels is used in calculating  
27 this indicator, meaning that the data are weighted using the age-specific probability of a woman  
28 giving birth.<sup>44</sup>

### 30 **Data Presented in the Indicators**

31 The BPA levels presented in these indicators are for the combined survey years 2003–2004 and  
32 2005–2006. The data from two NHANES cycles are combined to increase the statistical  
33 reliability of the estimates for each race/ethnicity and income group. No time series is shown  
34 because data from only two NHANES cycles are too limited to depict possible changes over  
35 time. These indicators present the median (50<sup>th</sup> percentile) of BPA levels. The median is the  
36 value in the middle of the distribution of BPA levels in urine: half of the measured population  
37 has BPA levels greater than the median, and half has levels below the median. The median can  
38 be thought of as representing a typical exposure. Four race/ethnicity groups are presented: White  
39 non-Hispanic, Black non-Hispanic, Mexican-American, and “Other.” The “Other” race/ethnicity  
40 category includes Asian non-Hispanic, Native American non-Hispanic, Hispanic other than  
41 Mexican-American, those reporting multiple racial categories, and those with a missing value for  
42 race/ethnicity. The data are also tabulated across three income categories: all incomes, below the  
43 poverty level, and greater than or equal to the poverty level. Data tables provide more specific

## Biomonitoring: Bisphenol A (BPA)

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1 breakdowns of median BPA concentrations by race/ethnicity and poverty level, as well as 95<sup>th</sup>  
2 percentile values for each group.

3

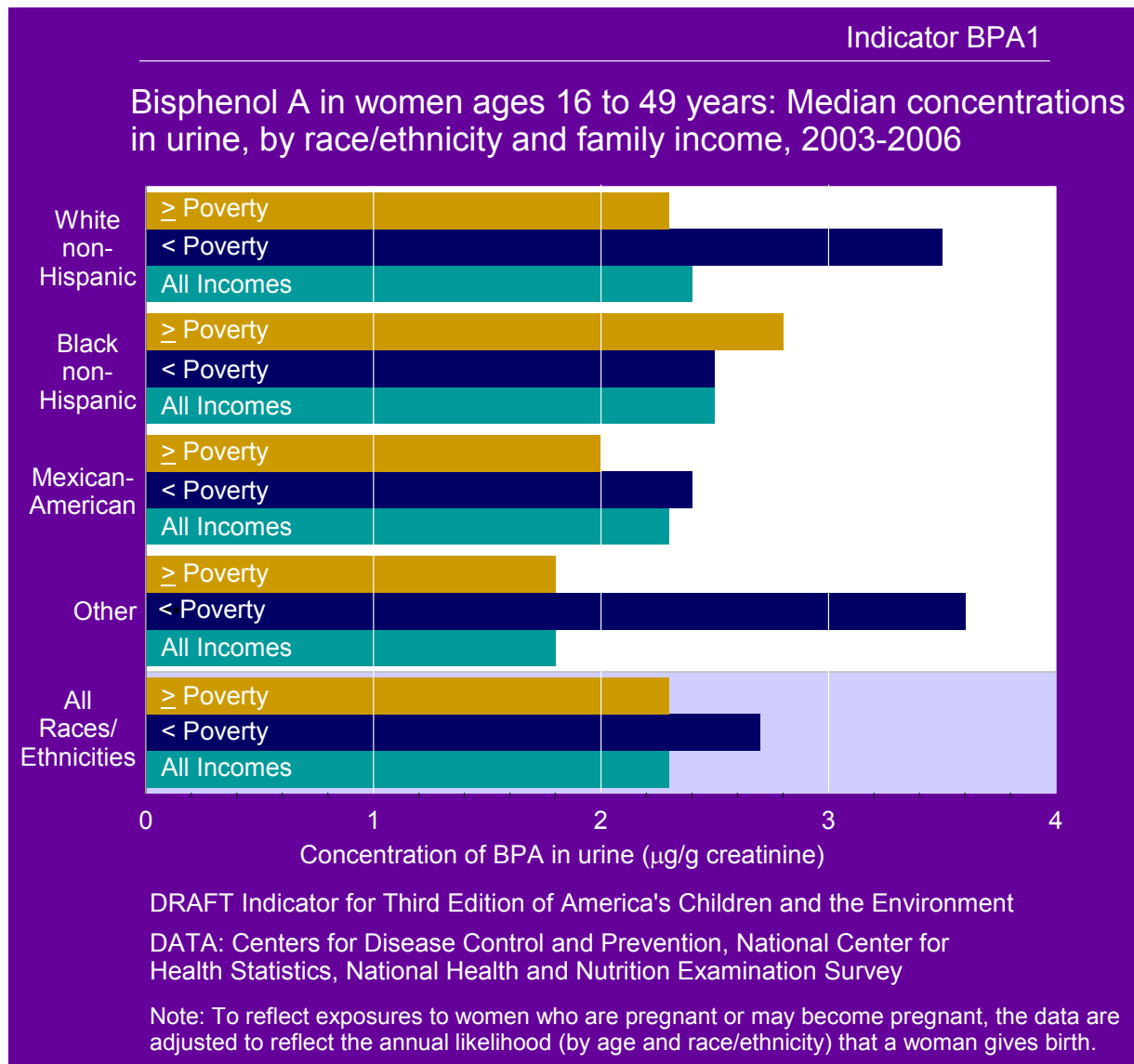
### 4 **Statistical Testing**

5 Statistical analysis has been applied to the biomonitoring indicators to determine whether any  
6 changes in chemical concentrations over time, or any differences in chemical concentrations  
7 between demographic groups, are statistically significant. These analyses use a 5% significance  
8 level ( $p \leq 0.05$ ), meaning that a conclusion of statistical significance is made only when there is  
9 no more than a 5% chance that the observed change over time or difference between  
10 demographic groups occurred randomly. It should be noted that when statistical testing is  
11 conducted for differences among multiple demographic groups (e.g., considering both  
12 race/ethnicity and income level), the large number of comparisons involved increases the  
13 probability that some differences identified as statistically significant may actually have occurred  
14 randomly.

15

16 A finding of statistical significance for a biomonitoring indicator depends not only on the  
17 numerical difference in the value of a reported statistic between two groups, but also on the  
18 number of observations in the survey, the amount of variability among the observations, and  
19 various aspects of the survey design. For example, if two groups have different median levels of  
20 a chemical in blood or urine, the statistical test is more likely to detect a difference when samples  
21 have been obtained from a larger number of people in those groups. Similarly, if there is low  
22 variability in levels of the chemical within each group, then a difference between groups is more  
23 likely to be detected. A finding that there is or is not a statistically significant difference in  
24 exposure levels between two groups or in exposure levels over time does not necessarily suggest  
25 any interpretation regarding the health implications of those differences.

## Biomonitoring: Bisphenol A (BPA)



- 1
- 2
- 3 • The median concentration of BPA in women ages 16 to 49 years was 2.3 µg/g creatinine.
- 4 The median concentration of BPA for women living below the poverty level was 2.7 µg/g
- 5 creatinine, and for women living at or above the poverty level it was 2.3 µg/g creatinine. This
- 6 difference is not statistically significant.
- 7 ○ Statistical Note: After adjustment for age and race/ethnicity, the differences in median
- 8 BPA concentrations by income groups were statistically significant.
- 9
- 10 • From 2003–2006, median concentrations of BPA in White non-Hispanic (2.4 µg/g
- 11 creatinine) and Black non-Hispanic (2.5 µg/g creatinine) women's populations were slightly
- 12 higher than the national median BPA concentration (2.3 µg/g creatinine).
- 13 ○ Statistical Note: After adjustment for age and income difference, White non-Hispanic,

## Biomonitoring: Bisphenol A (BPA)

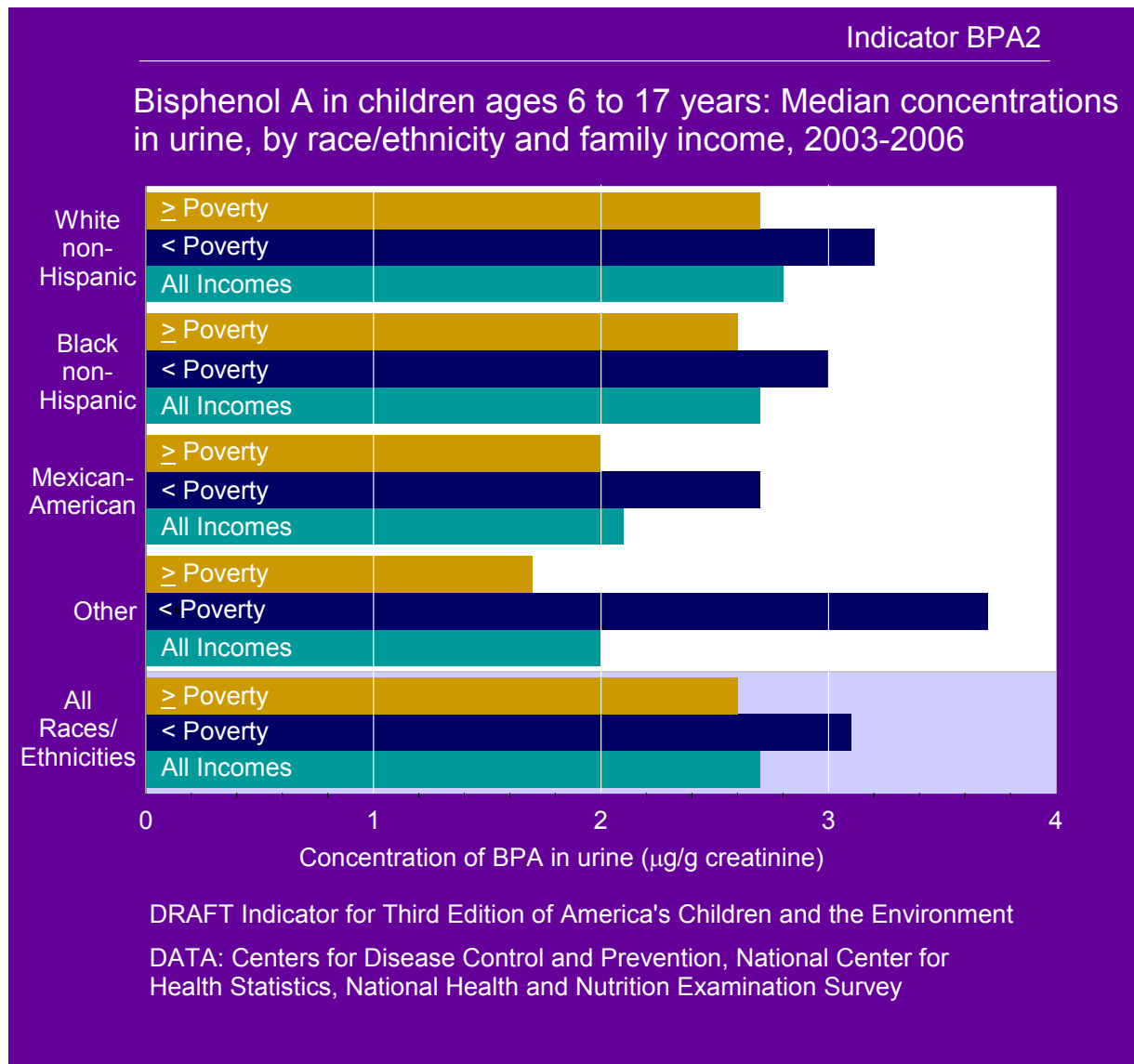
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1 significantly higher median BPA levels than women in the “Other” race/ethnicity  
2 group.

- 3 • While the median BPA levels in White non-Hispanics and the “Other” race/ethnicity group  
4 below the poverty level appear greater than for other race/ethnicity/income groups, these  
5 differences are frequently not statistically significant.  
6
- 7 • The 95<sup>th</sup> percentile value of BPA concentrations was 8.3 µg/g creatinine. The ratio of the 95<sup>th</sup>  
8 percentile to 50<sup>th</sup> percentile of BPA concentrations for women ages 16 to 49 years was 3.6,  
9 indicating that BPA concentrations in the most exposed members of the population were  
10 nearly four times greater than the population median. (See Table BPA1a.)



## Biomonitoring: Bisphenol A (BPA)



- 1
- 2
- 3 • The median concentration of BPA in children ages 6 to 17 years for the survey period 2003–
- 4 2006 was 2.7 µg/g creatinine. The median concentration of BPA for children living below
- 5 the poverty level was 3.1 µg/g creatinine, and for children living at or above the poverty level
- 6 it was 2.5 µg/g creatinine. The difference in BPA levels between income groups is
- 7 statistically significant.
- 8
- 9 • The highest median BPA concentrations were observed in children of “Other” race/ethnicity
- 10 identification (3.7 µg/g creatinine) who were below the poverty level.
- 11 ○ Statistical note: While the median concentration was higher in children of “Other”
- 12 race-ethnicity identification below the poverty level, the value is not generally
- 13 statistically significantly different from median concentrations observed in the
- 14 remaining race/ethnicity/income groups.

## Biomonitoring: Bisphenol A (BPA)

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- 1
- 2 • Overall, the median BPA concentrations were greater for children living below the poverty
- 3 level compared with children living at or above the poverty level.
- 4     ○ Statistical note: While higher median BPA concentrations were observed in each
- 5 race/ethnicity group for children living below the poverty level compared with
- 6 children living at or above the poverty level, these differences were statistically
- 7 significant only for the Mexican-American and “Other” race/ethnicity groups.
- 8
- 9 • The urinary BPA concentrations in highly exposed children ages 6 to 17 years (those in the
- 10 95<sup>th</sup> percentile) were more than 5 times the median (see Tables BPA2 and BPA2a). The 95<sup>th</sup>
- 11 percentile urinary BPA concentrations in children ages 6 to 17 years were nearly twice those
- 12 in women of child-bearing age. (See Tables BPA1a and BPA2a.)
- 13
- 14 • BPA concentrations in urine decrease as children grow older. Regardless of race or income,
- 15 children ages 6 to 10 years had median BPA concentrations of 3.6 µg/g creatinine and 95<sup>th</sup>
- 16 percentile concentrations of 19.9 µg/g creatinine. Children ages 11 to 15 years had median
- 17 BPA concentrations of 2.2 µg/g creatinine and 95<sup>th</sup> percentile concentrations of 12.7 µg/g
- 18 creatinine, while children ages 16 to 17 years had median BPA concentrations of 1.8 µg/g
- 19 creatinine and 95<sup>th</sup> percentile concentrations of 7.8 µg/g creatinine. The age differences were
- 20 statistically significant. (See Table BPA2b.)
- 21

# Biomonitoring: Bisphenol A (BPA)

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## Data Tables

**Table BPA1: Bisphenol A in women ages 16 to 49 years: Median concentrations in urine, by race/ethnicity and family income, 2003-2006**

Race / Ethnicity	Median concentration of BPA in urine ( $\mu\text{g/g}$ creatinine)					Unknown Income
	All Incomes	< Poverty Level	$\geq$ Poverty Level	$\geq$ Poverty Level (Detail)		
				100-200% of Poverty Level	> 200% of Poverty Level	
<b>All Races/Ethnicities</b>	2.3	2.7	2.3	2.7	2.2	1.8
<b>White non-Hispanic</b>	2.4	3.5	2.3	3.0	2.2	NA**
<b>Black non-Hispanic</b>	2.5	2.5	2.8	2.8	2.7	NA**
<b>Mexican-American</b>	2.3	2.4	2.0	2.4	2.0	1.9
<b>Other†</b>	1.8	3.6	1.8	1.8	1.7	NA**

DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey

NOTES:

- The distribution of the data for women ages 16 to 49 years is adjusted for the likelihood that a woman of a particular age and race/ethnicity gives birth in a particular year. The intent of this adjustment is to approximate the distribution of exposure to pregnant women. Results will therefore differ from a characterization of exposure to adult women without consideration of birthrates.
- The reported measurements of BPA in urine include both BPA itself and biologically inactive metabolites of BPA.

† "Other" includes Asian non-Hispanic; Native American non-Hispanic; Hispanic other than Mexican-American; those reporting multi-racial; and those with a missing value for race/ethnicity.

\*\* The estimate is not reported because it has large uncertainty: the relative standard error, RSE, is at least 40% (RSE = standard error divided by the estimate).

# Biomonitoring: Bisphenol A (BPA)

**Table BPA1a: Bisphenol A in women ages 16 to 49 years: 95<sup>th</sup> percentile concentrations in urine, by race/ethnicity and family income, 2003-2006**

Race / Ethnicity	95 <sup>th</sup> percentile concentration of BPA in urine (µg/g creatinine)					
	All Incomes	< Poverty Level	≥ Poverty Level	≥Poverty Level (Detail)		Unknown Income
				100-200% of Poverty Level	> 200% of Poverty Level	
<b>All Races/Ethnicities</b>	8.3	NA**	7.7	8.2*	7.2	24.5
<b>White non-Hispanic</b>	9.3*	NA**	7.7	NA**	6.5	NA**
<b>Black non-Hispanic</b>	7.9	NA**	7.5	7.5	NA**	NA**
<b>Mexican-American</b>	6.8*	8.9*	6.4*	NA**	6.0	4.8
<b>Other†</b>	NA**	8.1	NA**	7.6	NA**	NA**

DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey

NOTES:

- The distribution of the data for women ages 16 to 49 years is adjusted for the likelihood that a woman of a particular age and race/ethnicity gives birth in a particular year. The intent of this adjustment is to approximate the distribution of exposure to pregnant women. Results will therefore differ from a characterization of exposure to adult women without consideration of birthrates.
- The reported measurements of BPA in urine include both BPA itself and biologically inactive metabolites of BPA.
- BPA does not appear to accumulate in bodily tissues; thus the distribution of NHANES urinary BPA levels may overestimate high-end exposures as a result of collecting one-time urine samples rather than collecting urine for a longer time period.<sup>45</sup>

† "Other" includes Asian non-Hispanic; Native American non-Hispanic; Hispanic other than Mexican-American; those reporting multi-racial; and those with a missing value for race/ethnicity.

\* The estimate should be interpreted with caution because the standard error of the estimate is relatively large: the relative standard error, RSE, is at least 30% but is less than 40% (RSE = standard error divided by the estimate).

\*\* The estimate is not reported because it has large uncertainty: the relative standard error, RSE, is at least 40% (RSE = standard error divided by the estimate).

## Biomonitoring: Bisphenol A (BPA)

**Table BPA2: Bisphenol A in children ages 6 to 17 years: Median concentrations in urine, by race/ethnicity and family income, 2003-2006**

Race / Ethnicity	Median concentration of BPA in urine ( $\mu\text{g/g}$ creatinine)					
	All Incomes	< Poverty Level	$\geq$ Poverty Level	>Poverty Level (Detail)		Unknown Income
				100-200% of Poverty Level	> 200% of Poverty Level	
<b>All Races/Ethnicities</b>	2.7	3.1	2.6	3.1	2.3	3.0
<b>White non-Hispanic</b>	2.8	3.2	2.7	3.5	2.5	NA**
<b>Black non-Hispanic</b>	2.7	3.0	2.6	2.6	2.7	NA**
<b>Mexican-American</b>	2.1	2.7	2.0	2.0	2.0	2.3*
<b>Other†</b>	2.0	3.7	1.7	2.9*	1.6	NA**

DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey

NOTE: The reported measurements of BPA in urine include both BPA itself and biologically inactive metabolites of BPA.

† "Other" includes Asian non-Hispanic; Native American non-Hispanic; Hispanic other than Mexican-American; those reporting multi-racial; and those with a missing value for race/ethnicity.

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\*\* The estimate is not reported because it has large uncertainty: the relative standard error, RSE, is at least 40% (RSE = standard error divided by the estimate).

## Biomonitoring: Bisphenol A (BPA)

**Table BPA2a: Bisphenol A in children ages 6 to 17 years: 95<sup>th</sup> percentile concentrations in urine, by race/ethnicity and family income, 2003-2006**

Race / Ethnicity	95 <sup>th</sup> percentile concentration of BPA in urine (µg/g creatinine)					
	All Incomes	< Poverty Level	≥ Poverty Level	≥Poverty Level (Detail)		Unknown Income
				100-200% of Poverty Level	> 200% of Poverty Level	
<b>All Races/Ethnicities</b>	14.6	14.5	14.2	18.9	12.2	61.3
<b>White non-Hispanic</b>	14.2	13.3*	12.2	19.9	11.7	61.3
<b>Black non-Hispanic</b>	12.8	13.2	NA**	11.3	24.1*	NA**
<b>Mexican-American</b>	13.0	14.1	11.2	11.2	NA**	14.6*
<b>Other†</b>	NA**	107.9	NA**	32.1	NA**	NA**

DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey

NOTES:

- The reported measurements of BPA in urine include both BPA itself and biologically inactive metabolites of BPA.
- BPA does not appear to accumulate in bodily tissues; thus the distribution of NHANES urinary BPA levels may overestimate high-end exposures as a result of collecting one-time urine samples rather than collecting urine for a longer time period.<sup>45</sup>

† "Other" includes Asian non-Hispanic; Native American non-Hispanic; Hispanic other than Mexican-American; those reporting multi-racial; and those with a missing value for race/ethnicity.

\* The estimate should be interpreted with caution because the standard error of the estimate is relatively large: the relative standard error, RSE, is at least 30% but is less than 40% (RSE = standard error divided by the estimate).

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## Biomonitoring: Bisphenol A (BPA)

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1 **Table BPA 2b: Bisphenol A in children ages 6 to 17 years: Median and 95<sup>th</sup> percentile**  
2 **concentrations by age group, 2003–2006**  
3

	Concentration of Bisphenol A in urine (µg/g creatinine)			
	All ages	Age 6 to <11 years	Age 11 to <16 years	Age 16 to <18 years
<b>Median</b>	2.7	3.6	2.2	1.8
<b>95<sup>th</sup> percentile</b>	14.6	19.9	12.7	7.8

4 DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National  
5 Health and Nutrition Examination Survey  
6

7 NOTE: The reported measurements of BPA in urine include both BPA itself and biologically inactive  
8 metabolites of BPA.  
9

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# Biomonitoring: Bisphenol A (BPA)

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## Biomonitoring: Bisphenol A (BPA)

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### 1 Metadata

2

Metadata for	<b>National Health and Nutrition Examination Survey (NHANES)</b>
Brief description of the data set	The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States, using a combination of interviews, physical examinations, and laboratory analysis of biological specimens.
Who provides the data set?	Centers for Disease Control and Prevention, National Center for Health Statistics.
How are the data gathered?	Laboratory data are obtained by analysis of blood and urine samples collected from survey participants at NHANES Mobile Examination Centers. Health status is assessed by physical examination. Demographic and other survey data regarding health status, nutrition and health-related behaviors are collected by personal interview, either by self-reporting or, for children under 16 and some others, as reported by an informant.
What documentation is available describing data collection procedures?	See <a href="http://www.cdc.gov/nchs/nhanes.htm">http://www.cdc.gov/nchs/nhanes.htm</a> for detailed survey and laboratory documentation by survey period.
What types of data relevant for children's environmental health indicators are available from this database?	Concentrations of environmental chemicals in urine, blood, and serum. Body measurements. Health status, as assessed by physical examination, laboratory measurements and interview responses. Demographic information.
What is the spatial representation of the database (national or other)?	NHANES sampling procedures provide nationally-representative data. Analysis of data for any other geographic area (region, state, etc.) is possible only by special arrangement with the NCHS Research Data Center, and such analyses may not be representative of the specified area.
Are raw data (individual measurements or survey responses) available?	Individual laboratory measurements and survey responses are generally available. Individual survey responses for some questions are not publicly released.
How are database files obtained?	<a href="http://www.cdc.gov/nchs/nhanes.htm">http://www.cdc.gov/nchs/nhanes.htm</a>
Are there any known data quality or data analysis concerns?	Some environmental chemicals have large percentages of values below the detection limit. Data gathered by interview, including demographic information, and responses regarding health status, nutrition and health-related behaviors are self-reported, or (for individuals age 16 years and younger)

## Biomonitoring: Bisphenol A (BPA)

<b>Metadata for</b>	<b>National Health and Nutrition Examination Survey (NHANES)</b>
	reported by an adult informant.
What documentation is available describing QA procedures?	<a href="http://www.cdc.gov/nchs/nhanes.htm">http://www.cdc.gov/nchs/nhanes.htm</a> includes detailed documentation on laboratory and other QA procedures. Data quality information is available at <a href="http://www.cdc.gov/nchs/about/policy/quality.htm">http://www.cdc.gov/nchs/about/policy/quality.htm</a> .
For what years are data available?	Some data elements were collected in predecessors to NHANES beginning in 1959; collection of data on environmental chemicals began with measurement of blood lead in NHANES II, 1976-1980. The range of years for measurement of environmental chemicals varies; apart from lead and cotinine (initiated in NHANES III), measurement of environmental chemicals began with 1999-2000 or later NHANES.
What is the frequency of data collection?	Data are collected on continuous basis, but are grouped into NHANES cycles: NHANES II (1976-1980); NHANES III phase 1 (1988-1991); NHANES III phase 2 (1991-1994); and continuous two-year cycles beginning with 1999-2000 and continuing to the present.
What is the frequency of data release?	Data are released in two-year cycles (e.g. 1999-2000); particular data sets from a two-year NHANES cycle are released as available.
Are the data comparable across time and space?	Detection limits can vary across time, affecting some comparisons. Some contaminants are not measured in every NHANES cycle. Within any NHANES two-year cycle, data are generally collected and analyzed in the same manner for all sampling locations.
Can the data be stratified by race/ethnicity, income, and location (region, state, county or other geographic unit)?	Data are collected to be representative of the U.S. population based on age, sex, and race/ethnicity. The public release files allow stratification by these and other demographic variables, including family income range and poverty income ratio. Data cannot be stratified geographically except by special arrangement with the NCHS Research Data Center.

1

# Biomonitoring: Bisphenol A (BPA)

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1

## 2 **Methods**

3

### 4 **Indicator**

5

6 BPA1. Bisphenol A in women ages 16 to 49 years: Median concentrations in urine, by  
7 race/ethnicity and family income, 2003-2006

8

9 BPA2. Bisphenol A in children ages 6 to 17 years: Median concentrations in urine, by  
10 race/ethnicity and family income, 2003-2006

11

### 12 **Summary**

13

14 Since the 1970s, the National Center for Health Statistics, a division of the Centers for Disease  
15 Control and Prevention, has conducted the National Health and Nutrition Examination Surveys  
16 (NHANES), a series of U.S. national surveys of the health and nutrition status of the  
17 noninstitutionalized civilian population. The National Center for Environmental Health at CDC  
18 measures environmental chemicals in blood and urine samples collected from NHANES  
19 participants.<sup>ii</sup> This indicator uses creatinine-adjusted urine measurements of bisphenol A (BPA)  
20 in women ages 16 to 49 years and children ages 6 to 17 years. The NHANES 2003-2004 and  
21 2005-2006 surveys included urine BPA data for children and adults ages 6 years and over.

22

23 Indicator BPA1 gives the median creatinine-adjusted concentrations of BPA for women ages 16  
24 to 49 years for 2003-2006, stratified both by race/ethnicity and family income. The median is the  
25 estimated concentration such that 50% of all noninstitutionalized civilian women ages 16 to 49  
26 years during the survey period have a BPA concentration below this level; a birthrate-adjusted  
27 distribution of women's BPA levels is used in calculating this indicator, meaning that the data  
28 are weighted using the age-specific probability of a woman giving birth. Table BPA1a gives the  
29 95<sup>th</sup> percentile concentrations of BPA for women ages 16 to 49 years for 2003-2006, stratified by  
30 race/ethnicity. The 95<sup>th</sup> percentile for women is the estimated concentration such that 95% of all  
31 noninstitutionalized civilian women ages 16 to 49 years during the survey period have a BPA  
32 concentration below this level.

33

34 Indicator BPA2 gives the median creatinine-adjusted concentrations of BPA for children ages 6  
35 to 17 years for 2003-2006, stratified both by race/ethnicity and family income. Table BPA2a  
36 gives the 95<sup>th</sup> percentile for children ages 6 to 17 for 2003-2006, stratified by race/ethnicity. The  
37 95<sup>th</sup> percentile for children is the estimated concentration such that 95% of all  
38 noninstitutionalized civilian children ages 6 to 17 years have a BPA concentration below this  
39 level. Table BPA2b gives the median and 95<sup>th</sup> percentile creatinine-adjusted concentrations of

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<sup>ii</sup> Centers for Disease Control and Prevention. 2009. Fourth National Report on Human Exposure to Environmental Chemicals. Atlanta, GA. Available at: [www.cdc.gov/exposurereport](http://www.cdc.gov/exposurereport).

## Biomonitoring: Bisphenol A (BPA)

1 BPA for children ages 6 to 17 years for 2003-2006, stratified by age. The survey data were  
 2 weighted to account for the complex multi-stage, stratified, clustered sampling design.

### 3 4 **Data Summary**

Indicator	BPA1. Bisphenol A in women ages 16 to 49 years: Median concentrations in urine, by race/ethnicity and family income, 2003-2006. BPA2. Bisphenol A in children ages 6 to 17 years: Median concentrations in urine, by race/ethnicity and family income, 2003-2006.			
Time Period	2003-2006			
Data	Urine BPA (creatinine adjusted)			
Years/Subgroup	2003-2004/ Women 16- 49	2005-2006/ Women 16- 49	2003-2004/ Children 6- 17	2005-2006/ Children 6- 17
Limits of Detection ( $\mu\text{g/L}$ )*	0.4	0.4	0.4	0.4
Number of Non-missing Values**	611	616	852	896
Number of Missing Values	16	18	32	31
Percentage Below Limit of Detection***	5	8	3	4

6 \* The Limit of Detection (LOD) is defined as the level at which the measurement has a 95% probability of being  
 7 greater than zero.

8 \*\*Non-missing values include those below the analytical LOD, which are reported as  $\text{LOD}/\sqrt{2}$ .

9 \*\*\*This percentage is survey-weighted using the NHANES survey weights for the given period and, for women  
 10 ages 16 to 49, is weighted by age-specific birthrates.

### 11 12 **Overview of Data Files**

13  
 14 The following files are needed to calculate this indicator. The files together with the survey  
 15 documentation and SAS programs for reading in the data are available at the NHANES website:  
 16 [http://www.cdc.gov/nchs/nhanes/nhanes\\_questionnaires.htm](http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm).

- 17  
 18 • NHANES 2003-2004: Demographic file demo\_c.xpt. Environmental Phenols Laboratory  
 19 file l24eph\_c.xpt. The demographic file demo\_c.xpt is a SAS transport file that contains  
 20 the subject identifier (SEQN), age (RIDAGEYR), sex (RIAGENDR), race/ethnicity  
 21 (RIDRETH1), poverty income ratio (INDFMPIR), pseudo-stratum (SDMVSTRA) and  
 22 the pseudo-PSU (SDMVPSU). The Environmental Phenols laboratory file l24eph\_c.xpt  
 23 contains SEQN, urine BPA (URXBPH), the BPA non-detect comment code  
 24 (URDBPHLC), urine creatinine (URXUCR) and the sub-sample C survey weight  
 25 (WTSC2YR). The two files are merged using the common variable SEQN.
- 26  
 27 • NHANES 2005-2006: Demographic file demo\_d.xpt. Environmental Phenols and  
 28 Parabens Laboratory file eph\_d.xpt. The demographic file demo\_d.xpt is a SAS transport



## Biomonitoring: Bisphenol A (BPA)

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1 file that contains the subject identifier (SEQN), age (RIDAGEYR), sex (RIAGENDR),  
2 race/ethnicity (RIDRETH1), poverty income ratio (INDFMPIR), pseudo-stratum  
3 (SDMVSTRA) and the pseudo-PSU (SDMVPSU). The Environmental Phenols and  
4 Parabens laboratory file eph\_d.xpt contains SEQN, urine BPA (URXBPH), the BPA non-  
5 detect comment code (URDBPHLC), urine creatinine (URXUCR) and the sub-sample B  
6 survey weight (WTSB2YR). The two files are merged using the common variable SEQN.  
7

### 8 **National Health and Nutrition Examination Surveys (NHANES)**

9

10 Since the 1970s, the National Center for Health Statistics, a division of the Centers for Disease  
11 Control and Prevention, has conducted the National Health and Nutrition Examination Surveys  
12 (NHANES), a series of U.S. national surveys of the health and nutrition status of the  
13 noninstitutionalized civilian population. The National Center for Environmental Health at CDC  
14 measures environmental chemicals in blood and urine samples collected from NHANES  
15 participants. This indicator uses urine BPA measurements from NHANES 2003-2004 and 2005-  
16 2006 in women ages 16 to 49 and children ages 6 to 17. The NHANES data were obtained from  
17 the NHANES website: <http://www.cdc.gov/nchs/nhanes.htm>. Following the CDC recommended  
18 approach, values below the analytical limit of detection (LOD) were replaced by  $LOD/\sqrt{2}$ .<sup>iii</sup>

19 This analysis uses the creatinine-adjusted urine BPA concentration ( $\mu\text{g/g}$  creatinine). The  
20 unadjusted BPA (Bisphenol A, (2,2-[4-Hydroxyphenol] propane)) concentration is reported as  
21  $\mu\text{g/L}$ . The creatinine concentration is reported as  $\text{mg/dL}$ . The creatinine-adjusted BPA  
22 concentration was calculated from the raw data as the ratio  $\text{Unadjusted BPA}/(0.01 \times \text{Creatinine})$   
23  $\mu\text{g/g}$  creatinine.  
24

25 The NHANES use a complex multi-stage, stratified, clustered sampling design. Certain  
26 demographic groups were deliberately over-sampled, including Mexican-Americans and Blacks.  
27 Oversampling is performed to increase the reliability and precision of estimates of health status  
28 indicators for these population subgroups. The publicly released data includes survey weights to  
29 adjust for the over-sampling, non-response, and non-coverage. The statistical analyses used the  
30 sub-sample laboratory survey weights (WTC2YR for 2003-2004 and WTSB2YR for 2005-2006)  
31 to re-adjust the urine BPA data to represent the national population.  
32

### 33 **Age-Specific Birthrates**

34

35 In addition to the NHANES survey weights, the data for women of child-bearing age (ages 16 to  
36 49) were also weighted by the birthrate for women of the given age and race/ethnicity to estimate  
37 pre-natal exposures. Thus the overall weight in each two year period is the product of the  
38 NHANES survey weight and the total number of births in the two calendar years for the given

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<sup>iii</sup> See Hornung RW, Reed LD. 1990. Estimation of average concentration in the presence of nondetectable values. *Applied Occupational and Environmental Hygiene* 5:46-51.



## Biomonitoring: Bisphenol A (BPA)

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1 age and race/ethnicity, divided by twice the corresponding population of women at the midpoint  
2 of the two year period.<sup>iv</sup>

### 4 **Race/Ethnicity and Family Income**

6 For this indicator, the percentiles were calculated for demographic strata defined by the  
7 combination of race/ethnicity and family income.

9 The family income was characterized based on the INDFMPIR variable, which is the ratio of the  
10 family income to the poverty level. The National Center for Health Statistics used the U.S.  
11 Census Bureau Current Population Survey to define the family units, and the family income for  
12 the respondent was obtained during the interview. The U.S. Census Bureau defines annual  
13 poverty level money thresholds varying by family size and composition. The poverty income  
14 ratio (PIR) is the family income divided by the poverty level for that family. Family income was  
15 stratified into the following groups:

- 17 • Below Poverty Level:  $PIR < 1$
- 18 • Between 100% and 200% of Poverty Level:  $1 \leq PIR \leq 2$
- 19 • Above 200% of Poverty level:  $PIR > 2$
- 20 • Above Poverty Level:  $PIR \geq 1$  (combines the previous two groups)
- 21 • Unknown Income: PIR is missing

23 Race/ethnicity was characterized using the RIDRETH1 variable. The possible values of this  
24 variable are:

- 26 • 1. Mexican American
- 27 • 2. Other Hispanic
- 28 • 3. Non-Hispanic White
- 29 • 4. Non-Hispanic Black
- 30 • 5. Other Race – Including Multi-racial
- 31 • “.” Missing

33 Category 5 includes: all Non-Hispanic single race responses other than White or Black; and  
34 multi-racial responses.

36 For this indicator, the RIDRETH1 categories 2, 5, and missing were combined into a single  
37 “Other” category. This produced the following categories:

- 39 • White non-Hispanic: RIDRETH1 = 3
- 40 • Black non-Hispanic: RIDRETH1 = 4
- 41 • Mexican-American: RIDRETH1 = 1

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<sup>iv</sup> Axelrad, D.A., Cohen, J. 2011. Calculating summary statistics for population chemical biomonitoring in women of childbearing age with adjustment for age-specific natality. *Environmental Research* 111 (1) 149-155.

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- Other: RIDRETH1 = 2 or 5 or missing

The “Other” category includes Asian non-Hispanic; Native American non-Hispanic; Hispanic other than Mexican-American; those reporting multi-racial; and those with a missing value for race/ethnicity.

### Calculation of Indicator

Indicator BPA1 is the median for urine BPA in women of ages 16 to 49 years, stratified by race/ethnicity and family income. Indicator BPA2 is the median for urine BPA in children of ages 6 to 17 years, stratified by race/ethnicity and family income. Table BPA1a is the 95<sup>th</sup> percentile for urine BPA in women of ages 16 to 49 years, stratified by race/ethnicity. Table BPA2a is the 95<sup>th</sup> percentile for urine BPA in children of ages 6 to 17, stratified by race/ethnicity. Table BPA2b is the median and 95<sup>th</sup> percentile for urine BPA in children of ages 6 to 17, stratified by age. The median for women ages 16 to 49 is the estimated concentration such that 50% of all noninstitutionalized civilian women ages 16 to 49 years during the survey period have urine BPA concentrations below this level. The 95<sup>th</sup> percentile for women ages 16 to 49 is the estimated concentration such that 95% of all noninstitutionalized civilian women ages 16 to 49 years during the survey period have urine BPA concentrations below this level. To adjust the NHANES data to represent prenatal exposures, the data for each woman surveyed was multiplied by the estimated number of births per woman of the given age and race/ethnicity. The birthrate adjustment was not applied to children ages 6 to 17.

To simply demonstrate the calculations, we will use the NHANES 2003-2006 urine BPA values for women ages 16 to 49 years of all race/ethnicities and all incomes as an example. We have rounded all the numbers to make the calculations easier:

We begin with all the non-missing NHANES 2003-2006 urine BPA values for women ages 16 to 49 years. Assume for the sake of simplicity that valid BPA data were available for every sampled woman. Each sampled woman has an associated annual survey weight that estimates the annual number of U.S. women represented by that sampled woman. Since two 2-year periods are combined for these analyses, the associated annual survey weight for each woman is defined as WTSC2YR/2 for 2003-2004 and WTSB2YR/2 for 2005-2006, so that the combined 2003-2006 sample represents the annual population. Each sampled woman also has an associated birthrate giving the numbers of annual births per woman of the given age, race, and ethnicity. The product of the annual survey weight and the birthrate estimates the annual number of U.S. births represented by that sampled woman, which we will refer to as the adjusted survey weight. For example, the lowest urine BPA measurement for a woman between 16 and 49 years of age is 0.2 µg/g creatinine with an annual survey weight of 5,000, a birthrate of 0.2, and thus an adjusted survey weight of 1,000, and so represents 1,000 births. The total of the adjusted survey weights for the sampled women equals 4 million, the total number of annual U.S. births to women ages 16 to 49 years. The second lowest measurement is also 0.2 µg/g creatinine with an adjusted survey weight of 500, and so represents another 500 U.S. births. The highest measurement is

## Biomonitoring: Bisphenol A (BPA)

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1 386.9 µg/g creatinine with an adjusted survey weight of 400, and so represents another 400 U.S.  
2 births.

3  
4 To calculate the median, we can use the adjusted survey weights to expand the data to the entire  
5 U.S. population of births to women ages 16 to 49. We have 1,000 values of 0.2 µg/g creatinine  
6 from the lowest measurement, 500 values of 0.2 µg/g creatinine from the second lowest  
7 measurement, and so on, up to 400 values of 386.9 µg/g creatinine from the highest  
8 measurement. Arranging these 4 million values in increasing order, the 2 millionth value is 2.3  
9 µg/g creatinine. Since half of the values are below 2.3 and half of the values are above 2.3, the  
10 median equals 2.3 µg/g creatinine. To calculate the 95<sup>th</sup> percentile, note that 95% of 4 million  
11 equals 3.8 million. The 3.8 millionth value is 8.3 µg/g creatinine. Since 95% of the values are  
12 below 8.3, the 95<sup>th</sup> percentile equals 8.3 µg/g creatinine.

13  
14 In reality, the calculations need to take into account that urine BPA measurements were not  
15 available for every respondent, and to use exact rather than rounded numbers. There were urine  
16 BPA measurements for only 1,226 of the 1,261 sampled women ages 16 to 49 years. The  
17 adjusted survey weights for all 1,261 sampled women add up to 4.2 million, the U.S. population  
18 of births to women ages 16 to 49. The adjusted survey weights for the 1,226 sampled women  
19 with urine BPA data add up to 4.1 million. Thus the available data represent 4.1 million values  
20 and so represent only 98% of the U.S. population of births. The median and 95<sup>th</sup> percentiles are  
21 given by the 2.05 millionth (50% of 4.1 million) and 3.90 millionth (95% of 4.1 million) U.S.  
22 birth's value. These calculations assume that the sampled women with valid urine BPA data are  
23 representative of women giving birth without valid urine BPA data. The calculations also assume  
24 that the sampled women are representative of women that actually gave birth in 2003-2006, since  
25 NHANES information on pregnancy and births was not incorporated into the analysis.

### 26 27 Equations

28  
29 These percentile calculations can also be given as the following mathematical equations, which  
30 are based on the default percentile calculation formulas from Statistical Analysis System (SAS)  
31 software. Exclude all missing urine BPA values. Suppose there are n women of ages 16 to 49  
32 years with valid urine BPA values. Arrange the urine BPA concentrations in increasing order  
33 (including tied values) so that the lowest concentration is x(1) with an adjusted survey weight of  
34 w(1), the second lowest concentration is x(2) with an adjusted survey weight of w(2), ..., and the  
35 highest concentration is x(n) with an adjusted survey weight of w(n).

36  
37 1. Sum all the adjusted survey weights to get the total weight W:

$$38 \quad W = \sum_{1 \leq i \leq n} w(i)$$

39  
40  
41 2. Find the largest number i so that the total of the weights for the i lowest values is less than or  
42 equal to W/2.

$$43 \quad \sum_{j \leq i} w(j) \leq W/2 < \sum_{j \leq i+1} w(j)$$

44

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1  
2 3. Calculate the median using the results of the second step. We either have

3  
4 
$$\Sigma[j \leq i] w(j) = W/2 < \Sigma[j \leq i + 1] w(j)$$

5  
6 or

7  
8 
$$\Sigma[j \leq i] w(j) < W/2 < \Sigma[j \leq i + 1] w(j)$$

9  
10 In the first case we define the median as the average of the  $i$ 'th and  $i + 1$ 'th values:

11  
12 
$$\text{Median} = [x(i) + x(i + 1)]/2 \text{ if } \Sigma[j \leq i] w(j) = W/2$$

13  
14 In the second case we define the median as the  $i + 1$ 'th value:

15  
16 
$$\text{Median} = x(i + 1) \text{ if } \Sigma[j \leq i] w(j) < W/2$$

17  
18 (The estimated median does not depend upon how the tied values of  $x(j)$  are ordered).

19  
20 A similar calculation applies to the 95<sup>th</sup> percentile. The first step to calculate the sum of the  
21 weights,  $W$ , is the same. In the second step, find the largest number  $i$  so that the total of the  
22 weights for the  $i$  lowest values is less than or equal to  $0.95W$ .

23  
24 
$$\Sigma[j \leq i] w(j) \leq 0.95W < \Sigma[j \leq i + 1] w(j)$$

25  
26 In the third step we calculate the 95<sup>th</sup> percentile using the results of the second step. We either  
27 have

28  
29 
$$\Sigma[j \leq i] w(j) = 0.95W < \Sigma[j \leq i + 1] w(j)$$

30  
31 or

32  
33 
$$\Sigma[j \leq i] w(j) < 0.95W < \Sigma[j \leq i + 1] w(j)$$

34  
35 In the first case we define the 95<sup>th</sup> percentile as the average of the  $i$ 'th and  $i + 1$ 'th values:

36  
37 
$$95^{\text{th}} \text{ Percentile} = [x(i) + x(i + 1)]/2 \text{ if } \Sigma[j \leq i] w(j) = 0.95W$$

38  
39 In the second case we define the 95<sup>th</sup> percentile as the  $i + 1$ 'th value:

40  
41 
$$95^{\text{th}} \text{ Percentile} = x(i + 1) \text{ if } \Sigma[j \leq i] w(j) < 0.95W$$

42  
43  
44

# Biomonitoring: Bisphenol A (BPA)

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## Relative Standard Error

The uncertainties of the median and 95<sup>th</sup> percentile values were calculated using a revised version of the CDC method given in CDC 2005,<sup>v</sup> Appendix C, and the SAS® program provided by CDC. The method uses the Clopper-Pearson binomial confidence intervals adapted for complex surveys by Korn and Graubard (see Korn and Graubard, 1999,<sup>vi</sup> p. 65). The following text is a revised version of the Appendix C. For the birthrate adjusted calculations for women ages 16 to 49, the sample weight is adjusted by multiplying by the age-specific birthrate.

**Step 1:** Use SAS® Proc Univariate to obtain a point estimate  $P_{SAS}$  of the percentile value. Use the Weight option to assign the exact correct sample weight for each chemical result.

**Step 2:** Use SUDAAN® Proc Descript with Taylor Linearization DESIGN = WR (i.e., sampling with replacement) and the proper sampling weight to estimate the proportion ( $p$ ) of subjects with results less than and not equal to the percentile estimate  $P_{SAS}$  obtained in Step 1 and to obtain the standard error ( $se_p$ ) associated with this proportion estimate. Compute the degrees-of-freedom adjusted effective sample size

$$n_{df} = (t_{num}/t_{denom})^2 p(1 - p) / (se_p^2)$$

where  $t_{num}$  and  $t_{denom}$  are 0.975 critical values of the Student's t distribution with degrees of freedom equal to the sample size minus 1 and the number of PSUs minus the number of strata, respectively. Note: the degrees of freedom for  $t_{denom}$  can vary with the demographic sub-group of interest.

**Step 3:** After obtaining an estimate of  $p$  (i.e., the proportion obtained in Step 2), compute the Clopper-Pearson 95% confidence interval ( $P_L(x, n_{df}), P_U(x, n_{df})$ ) as follows:

$$P_L(x, n_{df}) = v_1 F_{v_1, v_2}(0.025) / (v_2 + v_1 F_{v_1, v_2}(0.025))$$
$$P_U(x, n_{df}) = v_3 F_{v_3, v_4}(0.975) / (v_4 + v_3 F_{v_3, v_4}(0.975))$$

where  $x$  is equal to  $p$  times  $n_{df}$ ,  $v_1 = 2x$ ,  $v_2 = 2(n_{df} - x + 1)$ ,  $v_3 = 2(x + 1)$ ,  $v_4 = 2(n_{df} - x)$ , and  $F_{d1, d2}(\beta)$  is the  $\beta$  quantile of an F distribution with  $d1$  and  $d2$  degrees of freedom. (Note: If  $n_{df}$  is greater than the actual sample size or if  $p$  is equal to zero, then the actual sample size should be used.) This step will produce a lower and an upper limit for the estimated proportion obtained in Step 2.

**Step 4:** Use SAS Proc Univariate (again using the Weight option to assign weights) to determine the chemical percentile values  $P_{CDC}$ ,  $L_{CDC}$  and  $U_{CDC}$  that correspond to the proportion  $p$  obtained in Step 2 and its lower and upper limits obtained in Step 3. Do not round the values of  $p$  and the lower and upper limits. For example, if  $p = 0.4832$ , then  $P_{CDC}$  is the 48.32<sup>th</sup> percentile value of the chemical. The alternative percentile estimates  $P_{CDC}$  and  $P_{SAS}$  are not necessarily equal.

**Step 5:** Use the confidence interval from Step 4 to estimate the standard error of the estimated percentile  $P_{CDC}$ :

$$\text{Standard Error } (P_{CDC}) = (U_{CDC} - L_{CDC}) / (2t_{denom})$$

**Step 6:** Use the estimated percentile  $P_{CDC}$  and the standard error from Step 4 to estimate the relative standard error of the estimated percentile  $P_{CDC}$ :

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<sup>v</sup> CDC Third National Report on Human Exposure to Environmental Chemicals. 2005

<sup>vi</sup> Korn E. L., Graubard B. I. 1999. *Analysis of Health Surveys*. Wiley.



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## 1 **Statistical Comparisons**

2  
3 Statistical analyses of the percentiles were used to determine whether the differences between  
4 percentiles for different demographic groups were statistically significant. For these analyses, the  
5 percentiles and their standard errors were calculated for each combination of age group, sex (in  
6 the cases of children), income group (below poverty, at or above poverty, unknown income), and  
7 race/ethnicity group using the method described in the “Relative Standard Error” section. In the  
8 notation of that section, the percentile and standard error are the values of  $P_{\text{CDC}}$  and Standard  
9 Error ( $P_{\text{CDC}}$ ), respectively. These calculated standard errors account for the survey weighting and  
10 design and, for women, for the age-specific birthrate.

11  
12 Using a weighted linear regression model, the percentile was assumed to be the sum of  
13 explanatory terms for age, sex, income and/or race/ethnicity and a random error term; the error  
14 terms were assumed to be approximately independent and normally distributed with a mean of  
15 zero and a variance equal to the square of the standard error. Using this model, the difference in  
16 the value of a percentile between different demographic groups is statistically significant if the  
17 difference between the corresponding sums of explanatory terms is statistically significantly  
18 different from zero. A p-value at or below 0.05 implies that the difference is statistically  
19 significant at the 5% significance level. No adjustment is made for multiple comparisons.

20  
21 For each type of comparison, we present unadjusted and adjusted analyses. The unadjusted  
22 analyses directly compare a percentile between different demographic groups. The adjusted  
23 analyses add other demographic explanatory variables to the statistical model and use the  
24 statistical model to account for the possible confounding effects of these other demographic  
25 variables. For example, the unadjusted race/ethnicity comparisons use and compare the  
26 percentiles between different race/ethnicity pairs. The adjusted race/ethnicity comparisons use  
27 the percentiles for each age/sex/income/race/ethnicity combination. The adjusted analyses add  
28 age, sex, and income terms to the statistical model and compare the percentiles between different  
29 race/ethnicity pairs after accounting for the effects of the other demographic variables. For  
30 example, if White non-Hispanics tend to have higher family incomes than Black non-Hispanics,  
31 and if the BPA level strongly depends on family income only, then the unadjusted differences  
32 between these two race/ethnicity groups would be significant but the adjusted difference (taking  
33 into account income) would not be significant.

34  
35 Comparisons between pairs of race/ethnicity groups are shown in Tables 1 and 2 for women ages  
36 16 to 49 years and in Tables 3 and 4 for children ages 6 to 17 years. In Tables 1 and 3, for the  
37 unadjusted “All incomes” comparisons, the only explanatory variables are terms for each  
38 race/ethnicity group. For these unadjusted comparisons, the statistical tests compare the  
39 percentiles for each pair of race/ethnicity groups. For the adjusted “All incomes (adjusted for  
40 age, sex, income)” comparisons, the explanatory variables are terms for each race/ethnicity  
41 group together with terms for each age, sex, and income group. For these adjusted comparisons,  
42 the statistical test compares the pair of race/ethnicity groups after accounting for any differences  
43 in the age, sex, and income distributions between the race/ethnicity groups. The adjustment for  
44 sex is applicable only for children, and thus appears only in Tables 3 and 4.



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1  
2 In Tables 1 and 3, for the unadjusted “Below Poverty Level” and “At or Above Poverty Level”  
3 comparisons, the only explanatory variables are terms for each of the twelve  
4 race/ethnicity/income combinations (combinations of four race/ethnicity groups and three  
5 income groups). For example, in row 1, the p-value for “Below Poverty Level” compares White  
6 non-Hispanics below the poverty level with Black non-Hispanics below the poverty level. The  
7 same set of explanatory variables are used in Tables 2 and 4 for the unadjusted comparisons  
8 between one race/ethnicity group below the poverty level and the same or another race/ethnicity  
9 group at or above the poverty level. The corresponding adjusted analyses include extra  
10 explanatory variables for age and sex, so that race/ethnicity/income groups are compared after  
11 accounting for any differences due to age or sex.

12  
13 Additional comparisons are shown in Table 5 for women ages 16 to 49 years and in Table 6 for  
14 children ages 6 to 17 years. The AGAINST = “income” unadjusted p-value compares the BPA  
15 levels for those below poverty level with those at or above poverty level, using the explanatory  
16 variables for the three income groups (below poverty, at or above poverty, unknown income).  
17 The adjusted p-value includes adjustment terms for age, sex, and race/ethnicity in the model.

18  
19 For women, the age groups used were 16-19, 20-24, 25-29, 30-39, and 40-49. For children, the  
20 age groups used were 6-10, 11-15, and 16-17.

21  
22 For more details on these statistical analyses, see the memorandum by Cohen (2010).<sup>vii</sup>  
23

24 Table 1. Statistical significance tests comparing the percentiles of BPA levels in women ages 16  
25 to 49 years, between pairs of race/ethnicity groups, for 2003-2006.  
26

Variable	Percentile	RACE1	RACE2	P-VALUES					
				All incomes	All incomes (adjusted for age, income)	Below Poverty Level	Below Poverty Level (adjusted for age)	At or Above Poverty Level	At or Above Poverty Level (adjusted for age)
BPA	50	White non-Hispanic	Black non-Hispanic	0.317	< 0.0005	0.132	0.003	0.029	0.826
BPA	50	White non-Hispanic	Mexican-American	0.763	0.386	0.215	0.181	0.264	0.099
BPA	50	White non-Hispanic	Other	< 0.0005	0.003	0.993	0.084	0.004	0.001
BPA	50	Black non-Hispanic	Mexican-American	0.376	< 0.0005	0.897	< 0.0005	0.016	0.210
BPA	50	Black non-Hispanic	Other	< 0.0005	0.518	0.192	0.131	< 0.0005	0.005
BPA	50	Mexican-American	Other	0.025	0.009	0.256	0.450	0.413	0.046
BPA	95	White non-Hispanic	Black non-Hispanic	0.698	< 0.0005	0.816	< 0.0005	0.948	0.139
BPA	95	White non-Hispanic	Mexican-American	0.453	0.819	0.829	< 0.0005	0.552	0.145

<sup>vii</sup> Cohen, J. 2010. *Selected statistical methods for testing for trends and comparing years or demographic groups in ACE NHIS and NHANES indicators*. Memorandum submitted to Dan Axelrad, EPA, 21 March, 2010.



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Variable	Percentile	RACE1	RACE2	P-VALUES					
				All incomes	All incomes (adjusted for age, income)	Below Poverty Level	Below Poverty Level (adjusted for age)	At or Above Poverty Level	At or Above Poverty Level (adjusted for age)
BPA	95	White non-Hispanic	Other	0.963	< 0.0005	0.802	< 0.0005	0.997	< 0.0005
BPA	95	Black non-Hispanic	Mexican-American	0.645	< 0.0005	0.939	< 0.0005	0.587	0.822
BPA	95	Black non-Hispanic	Other	0.994	< 0.0005	0.971	0.340	0.997	< 0.0005
BPA	95	Mexican-American	Other	0.950	< 0.0005	0.826	0.007	0.947	< 0.0005

1  
2 Table 2. Statistical significance tests comparing the percentiles of BPA levels in women ages 16  
3 to 49 years, between pairs of race/ethnicity/income groups at different income levels, for 2003-  
4 2006.  
5

Variable	Percentile	RACEINC1	RACEINC2	P-VALUES	
				Unadjusted	Adjusted (for age)
BPA	50	White non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.083	0.014
BPA	50	White non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.308	0.010
BPA	50	White non-Hispanic, < PL	Mexican-American, ≥ PL	0.041	0.002
BPA	50	White non-Hispanic, < PL	Other, ≥ PL	0.015	< 0.0005
BPA	50	Black non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.329	0.059
BPA	50	Black non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.171	0.350
BPA	50	Black non-Hispanic, < PL	Mexican-American, ≥ PL	0.114	0.606
BPA	50	Black non-Hispanic, < PL	Other, ≥ PL	0.001	0.010
BPA	50	Mexican-American, < PL	White non-Hispanic, ≥ PL	0.912	0.001
BPA	50	Mexican-American, < PL	Black non-Hispanic, ≥ PL	0.524	0.008
BPA	50	Mexican-American, < PL	Mexican-American, ≥ PL	0.589	< 0.0005
BPA	50	Mexican-American, < PL	Other, ≥ PL	0.345	< 0.0005
BPA	50	Other, < PL	White non-Hispanic, ≥ PL	0.135	0.409
BPA	50	Other, < PL	Black non-Hispanic, ≥ PL	0.373	0.330
BPA	50	Other, < PL	Mexican-American, ≥ PL	0.075	0.075
BPA	50	Other, < PL	Other, ≥ PL	0.035	0.003
BPA	95	White non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.787	0.001
BPA	95	White non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.780	0.003
BPA	95	White non-Hispanic, < PL	Mexican-American, ≥ PL	0.724	0.010
BPA	95	White non-Hispanic, < PL	Other, ≥ PL	0.857	< 0.0005
BPA	95	Black non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.917	0.001
BPA	95	Black non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.893	< 0.0005
BPA	95	Black non-Hispanic, < PL	Mexican-American, ≥ PL	0.697	< 0.0005
BPA	95	Black non-Hispanic, < PL	Other, ≥ PL	0.977	0.015
BPA	95	Mexican-American, < PL	White non-Hispanic, ≥ PL	0.761	0.972
BPA	95	Mexican-American, < PL	Black non-Hispanic, ≥ PL	0.720	0.024
BPA	95	Mexican-American, < PL	Mexican-American, ≥ PL	0.443	0.095
BPA	95	Mexican-American, < PL	Other, ≥ PL	0.960	< 0.0005

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Variable	Percentile	RACEINC1	RACEINC2	P-VALUES	
				Unadjusted	Adjusted (for age)
BPA	95	Other, < PL	White non-Hispanic, ≥ PL	0.850	0.013
BPA	95	Other, < PL	Black non-Hispanic, ≥ PL	0.778	0.001
BPA	95	Other, < PL	Mexican-American, ≥ PL	0.342	0.001
BPA	95	Other, < PL	Other, ≥ PL	0.983	0.753

Table 3. Statistical significance tests comparing the percentiles of BPA levels in children ages 6 to 17 years, between pairs of race/ethnicity groups, for 2003-2006.

Variable	Percentile	RACE1	RACE2	P-VALUES					
				All incomes	All incomes (adjusted for age, sex, income)	Below Poverty Level	Below Poverty Level (adjusted for age, sex)	At or Above Poverty Level	At or Above Poverty Level (adjusted for age, sex)
BPA	50	White non-Hispanic	Black non-Hispanic	0.866	0.409	0.714	0.477	0.536	0.490
BPA	50	White non-Hispanic	Mexican-American	0.006	0.001	0.286	0.271	0.001	0.002
BPA	50	White non-Hispanic	Other	0.139	0.013	0.645		0.001	0.015
BPA	50	Black non-Hispanic	Mexican-American	0.011	0.015	0.389	0.251	0.009	0.033
BPA	50	Black non-Hispanic	Other	0.162	0.054	0.489		0.004	0.059
BPA	50	Mexican-American	Other	0.830	0.599	0.282		0.321	0.605
BPA	95	White non-Hispanic	Black non-Hispanic	0.888	< 0.0005	0.607	< 0.0005	0.994	0.839
BPA	95	White non-Hispanic	Mexican-American	0.889	< 0.0005	0.376	< 0.0005	0.645	0.428
BPA	95	White non-Hispanic	Other	0.459	< 0.0005	< 0.0005		0.565	< 0.0005
BPA	95	Black non-Hispanic	Mexican-American	0.956	0.178	0.805	0.062	0.857	0.362
BPA	95	Black non-Hispanic	Other	0.446	< 0.0005	< 0.0005		0.589	< 0.0005
BPA	95	Mexican-American	Other	0.448	< 0.0005	< 0.0005		0.524	0.001

Table 4. Statistical significance tests comparing the percentiles of BPA levels in children ages 6 to 17 years, between pairs of race/ethnicity/income groups at different income levels, for 2003-2006.

Variable	Percentile	RACEINC1	RACEINC2	P-VALUES	
				Unadjusted	Adjusted (for age, sex)
BPA	50	White non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.325	0.328
BPA	50	White non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.190	0.271
BPA	50	White non-Hispanic, < PL	Mexican-American, ≥ PL	0.009	0.125
BPA	50	White non-Hispanic, < PL	Other, ≥ PL	0.003	0.101

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Variable	Percentile	RACEINC1	RACEINC2	P-VALUES	
				Unadjusted	Adjusted (for age, sex)
BPA	50	Black non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.450	0.357
BPA	50	Black non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.234	0.191
BPA	50	Black non-Hispanic, < PL	Mexican-American, ≥ PL	0.003	0.003
BPA	50	Black non-Hispanic, < PL	Other, ≥ PL	0.001	0.007
BPA	50	Mexican-American, < PL	White non-Hispanic, ≥ PL	0.796	0.600
BPA	50	Mexican-American, < PL	Black non-Hispanic, ≥ PL	0.819	0.961
BPA	50	Mexican-American, < PL	Mexican-American, ≥ PL	0.028	0.128
BPA	50	Mexican-American, < PL	Other, ≥ PL	0.010	0.108
BPA	50	Other, < PL	White non-Hispanic, ≥ PL	0.312	
BPA	50	Other, < PL	Black non-Hispanic, ≥ PL	0.237	
BPA	50	Other, < PL	Mexican-American, ≥ PL	0.067	
BPA	50	Other, < PL	Other, ≥ PL	0.038	
BPA	95	White non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.700	< 0.0005
BPA	95	White non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.865	< 0.0005
BPA	95	White non-Hispanic, < PL	Mexican-American, ≥ PL	0.992	< 0.0005
BPA	95	White non-Hispanic, < PL	Other, ≥ PL	0.527	< 0.0005
BPA	95	Black non-Hispanic, < PL	White non-Hispanic, ≥ PL	0.796	0.930
BPA	95	Black non-Hispanic, < PL	Black non-Hispanic, ≥ PL	0.920	0.872
BPA	95	Black non-Hispanic, < PL	Mexican-American, ≥ PL	0.566	0.370
BPA	95	Black non-Hispanic, < PL	Other, ≥ PL	0.597	< 0.0005
BPA	95	Mexican-American, < PL	White non-Hispanic, ≥ PL	0.444	0.091
BPA	95	Mexican-American, < PL	Black non-Hispanic, ≥ PL	0.830	0.084
BPA	95	Mexican-American, < PL	Mexican-American, ≥ PL	0.299	0.577
BPA	95	Mexican-American, < PL	Other, ≥ PL	0.622	0.001
BPA	95	Other, < PL	White non-Hispanic, ≥ PL	< 0.0005	
BPA	95	Other, < PL	Black non-Hispanic, ≥ PL	< 0.0005	
BPA	95	Other, < PL	Mexican-American, ≥ PL	< 0.0005	
BPA	95	Other, < PL	Other, ≥ PL	0.004	

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2 Table 5. Other statistical significance tests comparing the percentiles of BPA levels in women  
3 ages 16 to 49 years, for 2003-2006.  
4

Variable	Percentile	From	To	Against	P-VALUES	
					Unadjusted	Adjusted*
BPA	50	2003	2006	income	0.124	< 0.0005
BPA	95	2003	2006	income	0.382	< 0.0005

5 For AGAINST = "income" the p-values are adjusted for age and race/ethnicity.  
6

7 Table 6. Other statistical significance tests comparing the percentiles of BPA levels in children  
8 ages 6 to 17 years, for 2003-2006.  
9

Variable	Percentile	From	To	Against	P-VALUES	
					Unadjusted	Adjusted*

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Variable	Percentile	From	To	Against	P-VALUES	
					Unadjusted	Adjusted*
BPA	50	2003	2006	age	< 0.0005	< 0.0005
BPA	50	2003	2006	income	0.009	0.032
BPA	95	2003	2006	age	< 0.0005	< 0.0005
BPA	95	2003	2006	income	0.866	< 0.0005

\*For AGAINST = "age" the p-values are adjusted for sex, race/ethnicity, and income.  
 For AGAINST = "income" the p-values are adjusted for age, sex, and race/ethnicity.

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