ESTIMATION OF DIETARY LEAD EXPOSURE: UPDATE TO THE DEFAULT VALUES FOR THE INTEGRATED EXPOSURE UPTAKE BIOKINETIC MODEL FOR LEAD IN U.S. CHILDREN

OVERVIEW

Since 1994, the Office of Land and Emergency Management (OLEM), formerly known as the Office of Solid Waste and Emergency Response (OSWER), has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at current or future anticipated residential sites (U.S. EPA, 1994a, b). The IEUBK model predicts blood lead levels (PbB) in young children (birth to 7 years of age) exposed to lead from several sources of exposure and routes. The IEUBK model uses more than 100 input parameters that are initially set to default values. Of these, there are 46 parameters that may be input, or modified, by the user; the remainder are unavailable for modification (U.S. EPA, 1994a).

The IEUBK model uses empirical data from numerous scientific studies of lead uptake and biokinetics, contact and intake rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution centered on the geometric mean (GM) of PbB for a hypothetical child or population of children¹ (EPA, 2020). The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability². From this distribution, the IEUBK model estimates the risk (*i.e.*, probability) that a child's or a population of children's PbB concentration will not exceed a certain PbB concentration (U.S. EPA, 1994a, 1998, White et al., 1998).

The default values for the *Dietary Lead Intake* variable in the IEUBK model (v.1.1, build 11) represent age-specific central tendency estimates for lead intake from food for children (birth to 7 years of age) in the absence of exposures at the site being assessed. Initially, these default intake rates were derived from the U.S. Department of Agriculture's 1977-78 U.S. Nationwide Food Consumption Survey (NFCS; USDA, 1984) and the U.S. Department of Health and Human Services 1976-80 National Health and Nutrition Examination Survey (NHANES; U.S. DHHS, 1983). Of the approximately 6,300 foods obtained from the NFCS and NHANES surveys, a representative list of 234 commonly eaten foods in the U.S. was then paired with dietary-lead concentration data from the U.S. Food and Drug Administration's (U.S. FDA) Total Diet Study

¹The GM represents the central tendency estimate (e.g., mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). The TRW recommends that the soil contribution to dust lead be evaluated by comparing the average or arithmetic mean of soil lead concentrations from a representative area in the child's yard (U.S. EPA, 1994a). If an arithmetic mean (or average) is used, the model provides a central point estimate for risk of an elevated PbB concentration. By definition, a central tendency estimate is equally likely to over- or under-estimate the soil/indoor dust RBA at lead-contaminated sites. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk of an elevated PbB concentration. See U.S. EPA (1994b) for further information.

²The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB concentration, which is used to provide the geometric standard deviation (GSD). In the IEUBK model, the GSD is intended to reflect variability in PbB concentrations where different individuals are exposed to different media concentrations of lead. The recommended default value for GSD (1.6) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

(TDS; 1973-82) to predict dietary lead ingestion (Pennington, 1983). The U.S. EPA (1994a,b) later mapped these dietary lead intake rates to the IEUBK model's 15 age-specific food categories. The U.S. EPA prepared updated estimates for this parameter in 2003 and 2006 using updated TDS and the NHANES data. Default values for the *Dietary Lead Intake* variable in the IEUBK model (v.1.1, build 11) are based on three cycles of NHANES data (1988-1994; U.S. CDC, 1997), eight years of TDS data (1995-2003; U.S. FDA, 2006), and the methodology discussed by Pennington (1983) (U.S. EPA, 2009, 1994a,b).

The purpose of this document is to provide a recommendation for revising the *Dietary Lead Intake* variable in the IEUBK model using: 1) a more representative methodology for estimating food consumption, and 2) more recent TDS and NHANES survey data. The proposed age-specific estimates for the *Dietary Lead Intake* variable in the IEUBK model are based on the most recent two cycles of NHANES *What We Eat in America* (WWEIA) survey data (2003-04 & 2005-06; U.S. CDC, 2010a,b) combined with the most recent ten years of TDS survey data (1995-2005; U.S. FDA, 2006). Estimated consumption rates were calculated using a non-linear regression model developed by the National Cancer Institute (NCI) (Tooze et al., 2006) (Table 1).

This document provides the technical basis for updating the *Dietary Lead Intake* variable in the IEUBK model. The intended audience is risk assessors familiar with the IEUBK model. For more information on the use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website https://www.epa.gov/superfund/lead-superfund-sites-guidance.

			Age Ca	Basis for Age-Specific				
Source	0<12	12<24	24<36	36<48	48<60	60<72	72<84	Value
IEUBK Model Default ^a	2.26	1.96	2.13	2.04	1.95	2.05	2.22	<u>Dietary Pb Concentration</u> 1995-2003 TDS (U.S. FDA, 2006) <u>Dietary Intake</u> 1988-1994 NHANES (U.S. CDC, 1997) <u>Methodology</u> Pennington, 1983, U.S. EPA, 1994a,b
Updated Dietary Intake Values ^b	2.66	5.03	5.21	5.38	5.64	6.04	5.95	Dietary Pb Concentration 1995-2005 TDS (U.S. FDA, 2010) Dietary Intake 2003-06 NHANES WWEIA (U.S. CDC, 2010a,b) Methodology NCI Method (Parsons, 2009; Tooze et al., 2006)

Table 1. Comparison of age-specific dietary lead intake rates (µg Pb/day) for use in the IEUBK model

TDS: Total Diet Study; NHANES: National Health and Nutrition Examination Survey; WWEIA: What We Eat in America survey; NCI: National Cancer Institute ^aIEUBK model v. 1.1, build 11. ^bIEUBK model v. 2.

INTRODUCTION

The IEUBK model predicts PbB concentrations in young children (birth to 7 years of age) exposed to lead from several sources of exposure and routes (U.S. EPA, 1994a). The IEUBK model uses more than 100 input parameters that are initially set to default values. Of these, there are 46 parameters that may be input, or modified, by the user; the remainder are locked (U.S. EPA, 1994a). Default values represent national averages or other central tendency values that were derived from empirical data in the open literature. Default values include lead concentrations in a) exposure media (*e.g.*, diet representative of national food sources); b) contact and intake rates (e.g., soil/dust ingestion); and c) exposure durations (White et al., 1998). The representativeness of IEUBK model output is wholly dependent on the representativeness of the data (often assessed in terms of completeness, comparability, precision, and accuracy [U.S. EPA, 1994a]).

Representative site-specific data are essential for developing a risk assessment (as well as cleanup goals) that reflect the current or potential future conditions. The most common type of site-specific data is media-specific lead concentration information (air, water, soil, dust). Until

recently, an inexpensive, EPA validated method³ (U.S. EPA 2017) to estimate bioavailability of lead in soil or dust was not available. Receptor data (*e.g.*, age, body weight, breathing rate, or soil ingestion rate) does not typically vary due to site-specific factors.

To promote defensible and reproducible site investigations and decision making, while maintaining flexibility needed to respond to different site conditions, the U.S. EPA recommends the Data Quality Objectives process (U.S. EPA, 2006). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making: <u>http://www.epa.gov/QUALITY/dqos.html</u>.

The TDS is an ongoing U.S. FDA program that has measured the level of nutrients and contaminants, including Pb, in food consumed in the U.S. since 1961 (Egan, 2002) through 'Market Basket' surveys. Using data from nationwide food consumption surveys, a list of foods that represents the diet of the U.S. population is routinely updated to reflect current eating patterns (Egan, 2002, 2007). The data reflect contaminant levels in 260-290 foods as they are consumed. Ingredients required to prepare the TDS foods are purchased from grocery stores and supermarkets four times per year (once in each of four geographic regions of the country).

The NHANES is a continuous survey that is designed to assess the health and nutritional status of children and adults in the U.S. (<u>http://www.cdc.gov/nchs/nhanes.htm</u>). U.S. CDC releases data from the NHANES in 2-year increments as one dataset, and recommends using four or more years of data (*i.e.*, two or more datasets) when estimating parameters for demographic sub-domains (U.S. CDC, 2006).

The dietary component of the NHANES survey [*i.e.*, *What We Eat in America* (WWEIA)] is conducted as a partnership between USDA and the U.S. DHHS. The WWEIA includes two 24-hour dietary recall interviews to query all foods and portion sizes consumed during the prior 24 hours. Although the recall is limited to foods consumed for a single day, it provides very detailed and reliable data (*e.g.*, including brand names for certain foods; whether they were cooked in animal or vegetable fat). The second most commonly used dietary survey instrument is the food frequency questionnaire (FFQ) which typically collects information about food consumption over a much longer period of time (*e.g.*, the year preceding the date of the interview). However, the FFQ typically collects only data on consumption frequency. Information about the quantity of food consumption, which is required to estimate dietary intake rates, is not collected.

Dodd et al. (2006) provides an overview of the challenges of estimating long-term average dietary intake from 24-hour recall data, as well as the development of statistical methods to meet these challenges. Briefly, surveys are dependent upon memory. Dodd et al. (2006) demonstrated that the reliability and resolution of a dietary survey decreases as the duration of the survey increases. Secondly, estimating long-term average daily consumption rates from short-term 24-hour dietary recalls requires an assumption that the 24-hour recalls provide an unbiased estimate of population intake, provided a sufficient amount of the recalls are collected (Dodd et al., 2006). Lastly, a major challenge in estimating dietary intake with 24-hour recall data is the large within-person day-to-day variability in diet relative to the between-person variability.

The NCI method is a two-part nonlinear model that describes the relationship between usual dietary intake and covariates (*e.g.*, age, sex, body mass index) and is used to estimate the distribution of daily ingestion rates for populations and individuals (Tooze et al., 2006). Average

³Method 1340- In Vitro Bioaccessibility Assay for Lead in Soils, https://www.epa.gov/hw-sw846

daily consumption of a specific food item is estimated as the product of the amount of the food item and the probability that the food item is consumed during a given day.⁴ This method addresses the uncertainty related to using information obtained from just two 24-hour recalls to estimate the long-term average daily consumption for each of the many food items that make up the typical diet. The NCI method has been validated and performs better than other commonly used methods for estimating food consumption based on direct measures of energy expenditure (Kipnis et al., 2009; Tooze et al., 2006; Institute of Medicine, 2005).⁵

TECHNICAL ANALYSIS

The annual mean lead concentration measured in TDS foods between 1995-2005 is fairly constant, varying within a relatively narrow range (Figure 1). For this analysis, these data were pooled to increase the sample size for each of the IEUBK model food categories. The TDS foods were mapped to the Exposure Core Food (ECF) groups as shown in Figure 2. ECF groups with more than one TDS food mapped to them were assigned the mean lead concentration for those TDS foods. Non-detects were replaced by $\frac{1}{2}$ the limit of detection, and results reported as 'trace' (*i.e.*, between the limit of detection and the limit of quantitation) were not adjusted (Table 2). This approach was applied only to the TDS data. The mean lead concentration for each of the 15 IEUBK model food groups was calculated as the weighted average of the lead concentrations of the ECF groups that are mapped to the IEUBK model food group. In calculating the weighted average, the products of lead concentration and mass (grams) for each particular ECF food that was consumed (as reported on the WWEIA survey) were summed and divided by the mass (grams) of all ECF foods eaten in a given IEUBK model category. The estimated mean lead concentration (μ g Pb/gram food) for each IEUBK model food category is provided in Table 3.

Information on dietary intakes (grams food/day) for children 0-7 years of age was extracted from the NHANES WWEIA data files (U.S. CDC, 2010a,b). Data from the two most recent 2-year cycles (2003-04 & 2005-06)⁶ were used, in accordance with U.S. CDC recommendations (U.S. CDC, 2006). The individual food consumption rates were mapped to one of the IEUBK model food categories, via the ECF groups, as shown in Figures 2 and 3.

The WWEIA database included a very small number of children 36 months and older whose parents reported them as consuming infant food and formula. Because data for fewer than 10 children were available, estimates for formula and infant food consumption rates for ages 36 months and older were not calculated. The effect of omitting these data is addressed in the Uncertainty section.

Mean daily ingestion rates (grams food/day) were calculated for each IEUBK model food category using the NCI method (Table 4). Estimated daily lead intakes (µg Pb/day) were calculated by multiplying the estimated ingestion rates by the mean lead concentration (Table 5). The proposed dietary Pb intake rates provided in Table 1 were then calculated as the sum of the 15 IEUBK model food category-specific Pb intake rates.

SAS[®] software (Version 9.1) was used to estimate lead concentration and dietary intakes. Parameter estimates used the sample weights provided in the NHANES data files (U.S. CDC,

⁵Some of the apparent differences between dietary survey energy versus doubly labeled water energy may be attributed to energy directed at growth vs. maintenance of body mass (IOM, 2005).

⁴When estimating daily ingestion rates, the data for the *amount of food item that is consumed* are daily <u>totals</u> for the amount of the food that is consumed. Usually, these daily totals are equivalent to meal sizes, or the sum of meal sizes when the food item is consumed more than once in a given day. Note, these data may include many zeros for foods that are consumed infrequently.

⁶The 2003-04 & 2005-06 dietary data were the most recent available data at the time this research was initiated.

2010a, b). The sample weights accounted for the unequal probabilities of selection of survey participants, the non-response of some participants, and were adjusted to population controls. While the NCI method estimates approximate standard errors for the regression model parameters, the current version does not accept the NHANES masked-variance units that account for the multistage sampling design which would be required to produce more reliable standard errors for parameter estimates.

UNCERTAINTY

The estimated dietary ingestion rates may be biased high. The current method for mapping the dietary data into the IEUBK model food groups does not calculate the mass of each ingredient of the foods reported on the WWEIA 24-hour dietary recalls. For example, the total mass of a beef stew dish would be mapped to the IEUBK model meat category rather than just the mass of meat ingredients. The dietary ingestion rates could be revised in the future to incorporate updated recipe files when available for the WWEIA data.

Estimating long-term dietary intake rates with 24-hr dietary recall data is problematic (Dodd et al., 2006; IOM, 2005). As highlighted by the Institute of Medicine (2005), indirect measures of dietary consumption (*i.e.*, 24-hour recall data) are subject to error. There are a variety of variables (e.g., age, sex, socioeconomic status, ethnic considerations) or behaviors (*i.e.*, foods that are "perceived to be bad or sinful" including pies, fried foods, sugars) that have been attributed to under reporting on dietary surveys (IOM, 2005). Other potential sources of systematic error include temporal effects related to when the surveys are administered (e.g., day of the week), mode of interview (e.g., in-person vs. telephone interviews) (Nusser et al., 1996) and data reduction which involves converting meal descriptions provided by the survey participant into ingredient weights using standardized databases (Dodd et al., 2006). The 24hour recall is also subject to large random error, including day-to-day, within-person variability in diet (e.g., Dodd et al., 2006). To date, the NCI method has been shown to produce estimates of daily ingestion rates that are less biased than the previous methods (Tooze et al., 2006; Kipnis et al., 2009). In addition, estimating daily ingestion rates for food groups, such as the IEUBK model food categories, are not subject to some of the challenges of estimating ingestion rates for individual food items; particularly those that are consumed infrequently (*e.g.*, fish).

As discussed above, consumption data for respondents ages 36 months and older whose caregiver or parent reported consuming infant food or formula were omitted from the estimated consumption rates and dietary lead intakes shown in Table 4 through Table 7. The TRW Lead Committee determined that these food items were not typically consumed by children 36 months and older. Had these data been retained in the analysis, the IEUBK model (v. 2) dietary intake rates for ages 36 months and older would be $0.1 - 0.3 \mu g/day$ higher. The effect of removing these data on the IEUBK (v. 2)-predicted GM PbB and P10 is negligible (Table 6). The GM and P10 would be less than $0.1 \mu g/dL$ and 0.1% higher, respectively, than the values shown in Table 6. Similarly, each of the PRGs in Table 6 would increase by less than 2 ppm if the data were retained.

RECOMMENDATIONS FOR THE IEUBK MODEL

The proposed update of the *Dietary Intake* parameter in the IEUBK model (v. 2) is the first update that includes new estimates for consumption and concentration. Previous updates used the consumption rates found in the IEUBK model code, which are based on Pennington (1983) (Table 6). Similar to previous updates, the TRW recommends using national Pb concentration

and dietary intake estimates (*e.g.*, estimates for specific geographic regions of the U.S. are not recommended).

Based on the analysis outlined in this document, the TRW recommends that the IEUBK model's (v. 2) default *Dietary Intake* values be estimated using a combination of the results of the most recent TDS (1995-2005, U.S. FDA, 2010), the NHANES WWEIA (2003-04 and 2005-06; U.S. CDC, 2010a,b) and the NCI method (Parsons, 2009; Tooze et al., 2006) as shown in Figure 4. These default values are considered appropriate for all applications of the IEUBK model (v. 2) where current and future residential scenarios are being assessed. The TRW does not recommend changing this value unless representative site-specific information is available that meet the Data Quality Objectives of the site. The recommended values based on this update are shown in Figure 4.

The recommended values are based on national averages; however, these values may not necessarily represent subpopulations of children that may have higher exposure (*e.g.*, due to cultural practices or diets heavy in canned foods). As shown in Figure 4, the IEUBK model (v. 2) will continue to allow for input of site-specific dietary intake information (*e.g.*, homegrown fruits and vegetables) to accommodate this and other site-specific circumstances that could impact exposure to lead from food.

IMPACT ON THE IEUBK MODEL PREDICTIONS

Using IEUBK model (v. 2) defaults for all parameters, including the proposed dietary intake rates, the GM PbB for children (0-7 years of age⁷) decreases from 2.7 μ g Pb/dL to 2.3 μ g/dL and the preliminary remediation goals (PRGs) increase (Table 6). Table 6 presents the updated estimates as well as the estimates from the previous analyses.

The blood lead level in Table 6 are used to illustrate the impact when developing a screening level for lead in soil. As examples, the PRGs corresponding to PbBs of 10 μ g/dL and 5 μ g/dL are presented in Table 6. This information is presented for illustrative purposes.

As shown in Table 7, the increase in the recommended dietary lead intake values relative to the IEUBK model (v. 1.1, build 11) default values is largely due to an increase in the estimated average daily dietary consumption values relative to the IEUBK model's (v. 1.1, build 11) default values, which were based on Pennington (Pennington, 1983; as cited in U.S. EPA 1994a, b), rather than higher dietary lead concentrations.

⁷ To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in IEUBK model be modified to match the 1-5 year age range (12-72 months).

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IFUDIZ		2	006 Update	e	Proposed Update				
IEUBK		(19	95-2003 TI	DS)	(1995-2005 TDS)				
Food Category	N	Non Detectsª	Detection Rate	LOD	N	Non Detectsª	Detection Rate	LOD	
Beverage	428	362	0.15	0.004 ± 0.00 ^b	524	448	0.15	0.004 ± 0.00 ^b	
Bread	145 8	1064	0.27	0.010 ± 0.003	1794	1332	0.26	0.010 ± 0.003	
Candy	340	203	0.40	0.011 ± 0.004	420	264	0.37	0.011 ± 0.004	
Canned Fruit	140	26	0.81	0.006 ± 0.001	180	31	0.83	0.006 ± 0.001	
Canned Veg.	196	154	0.21	0.007 ± 0.001	228	182	0.20	0.007 ± 0.001	
Dairy	906	822	0.09	0.010 ± 0.006	1098	1002	0.09	0.010 ± 0.006	
Fresh Fruit	558	468	0.16	0.007 ± 0.003	662	556	0.16	0.007 ± 0.003	
Fresh Veg.	148 8	1204	0.19	0.008 ± 0.004	1824	1492	0.18	0.008 ± 0.004	
Infant Food	946	749	0.20	0.007 ± 0.001	1176	929	0.21	0.007 ± 0.001	
Infant Formula	102	99	0.03	0.005 ± 0.00	126	121	0.04	0.005 ± 0.00	
Juice	216	148	0.31	0.004 ± 0.00	288	197	0.32	0.004 ± 0.000	
Meat	133 0	1143	0.14	0.011 ± 0.005	1650	1442	0.13	0.011 ± 0.004	
Nuts	242	220	0.09	0.011 ± 0.005	306	283	0.08	0.011 ± 0.005	
Pasta	272	227	0.17	0.008 ± 0.001	336	285	0.15	0.008 ± 0.001	
Sauce	144	111	0.23	0.017 ± 0.008	192	149	0.22	0.016 ± 0.008	

Table 2. Detection level (mg/kg) calculations for lead in the 1995-2005 TDS data

LOD: level of detection; TDS: Total Diet Study. ^aNondetects (ND) were replaced by ¹/₂ the limit of detection (ND=0.5 * LOD). ^bValues are presented as mean ± SD.

IEUBK Model	2006 Update	Proposed Update	
Food Category	(1995-2003 TDS)	(1995-2005 TDS)	Difference (%)
Beverage	2.31	2.47	6.54
Bread	6.96	7.10	1.91
Candy	8.02	6.84	-17.3
Canned Fruit	12.83	12.95	0.97
Canned Veg.	5.21	4.92	-5.90
Dairy	3.64	3.68	1.05
Fresh Fruit	4.40	4.33	-1.80
Fresh Veg.	8.99	9.33	3.58
Infant Food	4.42	5.01	11.8
Infant Formula	2.56	2.52	-1.56
Juice	2.28	2.26	-0.88
Meat	4.44	4.45	0.22
Nuts	5.95	7.26	18.0
Pasta	5.67	5.75	1.28
Sauce	12.44	12.81	2.95

Table 3. Mean concentration of lead (µg Pb/kg food) for each IEUBK model food category based on data from the TDS

TDS: Total Diet Study.

IEUBK	Age Category (months)										
Model											
Food											
Category	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84				
IEUBK model (v. 1.1, build 11) ^a											
Beverage	88.0	116.5	209.7	195.0	177.1	183.3	188.7				
Bread	5.0	15.9	13.3	16.6	20.0	22.6	27.9				
Canned Fruit	13.9	8.2	8.1	7.7	7.2	7.5	7.9				
Canned Veg.	0.7	2.3	2.6	2.7	2.8	2.6	2.4				
Candy	10.0	11.3	32.9	24.4	16.0	14.8	12.5				
Dairy	41.8	35.3	38.5	38.3	38.2	40.6	45.6				
Infant Formula	45.2	23.0	0.8	0.0	0.0	0.0	0.0				
Fresh Fruit	2.5	12.5	11.2	11.2	11.5	13.0	16.1				
Fresh Veg.	8.8	15.9	28.2	27.6	27.0	29.2	33.4				
Infant Food	132.2	66.9	1.6	0.0	0.0	0.0	0.0				
Juices	2.0	11.7	15.7	15.7	15.7	19.6	27.5				
Meat	10.6	29.6	38.1	40.9	43.8	47.4	54.6				
Nuts	0.1	1.0	0.9	1.0	1.0	1.0	0.9				
Pasta	10.4	18.9	26.3	25.9	25.6	27.1	30.2				
Sauce	1.6	4.8	5.6	6.9	8.2	8.2	8.2				
NCL	Method wi	th Data Fro	om NHANE	S/WWEIA	(2003-048	& 2005-06)					
Beverage	62.6	162	169	188	202	234	243				
Bread	31.9	91.5	113	135	142	162	174				
Candy	6.5	11.4	16.9	20.6	23.5	24.5	25.8				
Canned Fruit	10.2	8.7	9.4	11.4	12.5	14.4	12.2				
Canned Veg.	4.2	4.6	5.5	7.0	6.5	8.1	7.4				
Dairy	171	501	424	413	397	429	394				
Fresh Fruit	36.1	60.4	63.0	75.3	74.3	76.1	86.7				
Fresh Veg.	34.0	51.5	59.5	63.2	72.6	74.0	69.5				
Infant Food	20.5	21.7	30.0	NC ^b	NC	NC	NC				
Infant Formula	124	68.4	55.7	NC	NC	NC	NC				
Juice	53.3	106	107	121	116	109	98.3				
Meat	34.8	64.4	79.9	87.8	98.4	98.8	100				
Nuts	6.2	4.9	5.2	7.0	6.4	10.3	7.3				
Pasta	39.8	56.3	68.8	80.1	95.3	92.7	91.8				
Sauce	0.8	1.6	1.8	2.1	2.6	2.1	2.3				

Table 4. Estimated dietary intake rates (grams food/day)

^aValues were derived from the 1995-2003 TDS (U.S. FDA, 2006), the 1988-1994 NHANES WWEIA (U.S. CDC, 1997), and Pennington, 1983 (U.S. EPA, 2009).

^bNC: Not calculated; estimates were not calculated for infant food and formula for these age groups due to very low number of respondents who reported consumption.

IEUBK	Age Category (months)								
Model									
Food									
Category	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84		
IEUBK model (v. 1.1, build 11) ^a									
Beverage	0.203	0.269	0.484	0.450	0.409	0.423	0.435		
Bread	0.035	0.110	0.093	0.116	0.139	0.158	0.194		
Canned Fruit	0.957	0.562	0.559	0.528	0.497	0.512	0.543		
Canned Veg.	0.003	0.012	0.013	0.014	0.014	0.014	0.012		
Candy	0.080	0.090	0.264	0.196	0.128	0.119	0.100		
Dairy	0.152	0.128	0.140	0.139	0.139	0.148	0.166		
Infant Formula	0.116	0.059	0.002	0.000	0.000	0.000	0.000		
Fresh Fruit	0.010	0.051	0.046	0.046	0.047	0.053	0.066		
Fresh Veg.	0.010	0.019	0.033	0.032	0.032	0.034	0.039		
Infant Food	0.584	0.296	0.007	0.000	0.000	0.000	0.000		
Juices	0.007	0.041	0.055	0.055	0.055	0.069	0.097		
Meat	0.047	0.131	0.169	0.182	0.194	0.210	0.242		
Nuts	0.001	0.006	0.005	0.006	0.006	0.006	0.005		
Pasta	0.059	0.107	0.149	0.147	0.145	0.154	0.171		
Sauce	0.020	0.060	0.069	0.086	0.101	0.102	0.102		
NCL	Method u	vith Data Fr	om NHANI	ES/WWEIA	(2003-048	& 2005-06)			
Beverage	0.155	0.399	0.417	0.465	0.500	0.577	0.601		
Bread	0.227	0.650	0.802	0.958	1.005	1.150	1.233		
Candy	0.044	0.078	0.115	0.141	0.161	0.168	0.176		
Canned Fruit	0.132	0.112	0.122	0.147	0.161	0.186	0.158		
Canned Veg.	0.021	0.023	0.027	0.035	0.032	0.040	0.036		
Dairy	0.630	1.843	1.558	1.518	1.459	1.577	1.448		
Fresh Fruit	0.156	0.261	0.272	0.326	0.322	0.329	0.375		
Fresh Veg.	0.317	0.480	0.555	0.589	0.677	0.690	0.648		
Infant Formula	0.103	0.109	0.150	NC ^b	NC	NC	NC		
Infant Food	0.313	0.173	0.141	NC	NC	NC	NC		
Juice	0.120	0.238	0.241	0.273	0.262	0.245	0.222		
Meat	0.155	0.286	0.355	0.390	0.438	0.440	0.445		
Nuts	0.045	0.035	0.038	0.051	0.046	0.075	0.053		
Pasta	0.229	0.324	0.395	0.460	0.548	0.533	0.528		
Sauce	0.011	0.020	0.023	0.027	0.034	0.027	0.029		

Table 5. Estimated dietary lead intake rates (µg Pb/day)

^aValues were derived from the 1995-2003 TDS (U.S. FDA, 2006), the 1988-1994 NHANES WWEIA (U.S. CDC, 1997), and Pennington, 1983 (U.S. EPA, 2009). ^bNC: Not calculated; estimates were not calculated for infant food and formula for these age

groups due to very low number of respondents who reported consumption.

IEUBK		Dietary Intake (µg Pb/day)							GM	_	PRG for 5% NTE (ppm)°	
Model Version	Basis for Age-Specific Value	0 < 12 (months)	12 < 24 (months)	24 < 36 (months)	36 < 48 (months)	48 < 60 (months)	60 < 72 (months)	72 < 84 (months)	PbB¢ (µg/dL)	P10 ^c (%)	5 µg/dL	10 μg/dL
1994 Defaultª	1965-82 TDS (as cited in Pennington, 1983); 1977-78 NFCS (USDA, 1984); 1976-1980 NHANES (U.S. DHHS, 1983); Pennington, 1983; U.S. EPA, 1994a,b	5.53	5.78	6.49	6.24	6.01	6.34	7.00	3.4	1.0	81	345
2003 Update ^a	1991-1999 TDS (U.S. FDA, 2001); 1988-1994 NHANES WWEIA (U.S. CDC, 1997); Pennington, 1983; U.S. EPA, 2009, 1994a,b	3.16	2.60	2.87	2.74	2.61	2.74	2.99	2.9	0.4	140	404
2006 Update ^a	1995-2003 TDS (U.S. FDA, 2006) ; 1988-1994 NHANES (U.S. CDC, 1997); Pennington, 1983; U.S. EPA, 2009, 1994a,b	2.26	1.96	2.13	2.04	1.95	2.05	2.22	2.7	0.3	153	418
Proposed Update ^b	1995-2005 TDS (U.S. FDA, 2010); 2003-06 NHANES WWEIA (U.S. CDC, 2010 a,b) NCI Method (Parsons, 2009; Tooze et al., 2006)	2.66	5.03	5.21	5.38	5.64	6.04	5.95	2.3	0.09	200	605

Table 6. Effects of changing the Dietary Lead Intake (µg Pb/day) in the IEUBK model

GM PbB: geometric mean blood lead concentration for 0-84 month age range; P10: probability children's PbB will exceed 10 µg/dL; PRG: preliminary remediation goal; NTE: not to exceed; TDS: Total Diet Study; NFCS: U.S. Nationwide Food Consumption Survey; NHANES: National Health and Nutrition Examination Survey; NCI: National Cancer Institute.

^aCalculated values were based on IEUBK model v. 1.1, build 11 default input values, with the exception of the dietary intake rates specified in the table. ^bCalculated values were based on IEUBK model v. 2. default input values.

^cThe GM, P10 and PRGs are for the 0-84 month age range. To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in IEUBK model be modified to match the 1-5 year age range (12-72 months).

Table 7. Comparison between IEUBK model default values for average daily dietary lead intake (μg Pb/day), food consumption and consumption-weighted average lead concentration

		Age Category (months)								
Basis for Parameter	0 < 12	12 < 24	24 < 36	36 < 48	48 < 60	60 < 72	72 < 84			
IEUBK Model v 1.1, Build 11 Default Dietary Intake Rates (μg Pb/day) ^a	2.26	1.96	2.13	2.04	1.95	2.05	2.22			
IEUBK Model v 2 Dietary Intake Rates (μg Pb/day) ^b	2.66	5.03	5.21	5.38	5.64	6.04	5.95			
Food Intake (% change)	+17.6%	+157%	+145%	+164%	+189%	+194%	+168%			
Mean Food-Pb Concentration (% change) ^c	-1.1%	-3.1%	1.7%	2.7%	3.5%	3.1%	3.1%			
Relative Consumption Rate (NCI - default) (%) ^d	71%	225%	179%	193%	217%	220%	188%			

^aIEUBK model (v. 1.1, build 11) default values. Values were derived using data from the TDS (1995-2003; U.S. FDA, 2006), NHANES WWEIA (1988-1994, U.S. CDC, 1997), and the methodology discussed in U.S. EPA (1994a,b) and Pennington (1983).

^bIEUBK model (v 2) values derived using data from the TDS (1995-2005; U.S. FDA, 2010), NHANES WWEIA (1995-2005), and the NCI Method (Parsons, 2009; Tooze et al., 2006)

^cValues were calculated using the consumption-weighted average concentrations.

^dCalculated as the consumption values estimated by the NCI method with data from NHANES/WWEIA (2003-06;U.S. CDC 2010 a, b), relative to the default consumption values in IEUBK model (v.1.1, build 11) (U.S. EPA 1994a,b).



Figure 1. Average dietary-lead concentrations from the TDS (1995-2005). Since 1995, the quarterly market basket averages (blue diamonds) have generally been below 4 μ g Pb/kg food.



Figure 2. Mapping food consumption data to food residue data using the approach developed by Tomerlin et al. (1997). The *What We Eat In America* (WWEIA) dietary survey is administered during the National Health and Nutrition Examination Survey. The Exposure Core Food (ECF) groups were created for the U.S. EPA dietary exposure potential model (Tomerlin et al., 1997) to connect consumption data from the 1997-98 and 1987-88 Nationwide Food Consumption Surveys and the 1989-1992 USDA Continuing Surveys of Food Intake by Individuals to food residue data from the U.S. Food and Drug Administration Total Diet Study (TDS). Additional USDA and TDS foods were mapped to ECF groups by Lockwood et al. (1998) and the current research. The FDA's TDS has been monitoring contaminant levels in foods since 1961 (Egan, 2002, 2007) through their 'Market Basket' surveys that are conducted in different regions of the country on a quarterly basis (*i.e.*, every 3 months).



Figure 3. Mapping the Exposure Core Food (ECF) codes (Tomerlin et al., 1997) to the IEUBK model food groups. In most cases, each ECF code could be mapped to a single IEUBK model food group. In cases where an ECF code contained a mixture of foods from different IEUBK model categories, the ECF code was assigned to the IEUBK model category based on what appeared to be the main ingredient (*e.g.*, the total mass of a beef stew dish was mapped to the IEUBK model meat category).

					_					
Dietary Data				? ×						
Dietary Lead Intake (µg/day) 0-1 2.66	1-2 5.03	AGE (Years) 2-3 3-4 5.21 5.38) 4-5 5-6 6-7 5.64 6.04 5.95	<u>0</u> K]					
Dietary Values				<u>C</u> ancel						
Use alternate dietary values?	No	⊖ Yes		<u>R</u> eset						
	Help?									
Concentration (µg Pb/g) Percent of Food Class										
Home Grown Fruits	0	0	(% of all fruits)							
Home Grown Vegetables	0	0	(% of all vegetables)							
Fish from Fishing	0	0	(% of all meat)							
Game Animals from Hunting	0	0	(% of all meat)							
GI Values / Bioavailability GI / Bio Change Values		TRW Homepage: http://www.epa.g	ov/superfund/health/contaminan	<u>ts/lead/index.htm</u>						

Figure 4. Proposed *Dietary Lead Intake* default values for the IEUBK model.