5 Breast Milk Intake Rates

5.1 Terminology and Nomenclature

In this chapter, we review breast milk intake estimates reported in the published literature. In the prior version of these guidelines, published rates as well as unpublished rates derived by OEHHA were presented. The OEHHA derived rates have been updated and revised to reflect breastfeeding practices most likely to occur in the United States (U.S.) (i.e., following the American Academy of Pediatrics recommendations). The revised OEHHA derived rates have been published in a peer-reviewed journal (Arcus-Arth et al, 2005) and are presented along with other published rates in these guidelines.

Specific terms and definitions have been adopted for use throughout this chapter (Table 5.1), because different and sometimes contradictory terms for various breastfeeding patterns are used in the literature.

Table 5.1 Breastfeeding Terminology[a]

Term	Definition
Fully breastfed	
Exclusively breastfed	Breast milk is sole source of calories.
Almost exclusively breastfed	Breast milk is primary if not sole milk source with no significant calories from other liquid or solid food sources.
Predominantly breastfed	Breast milk is the primary if not sole milk source with significant calories from other liquid or solid food sources.
Partially breastfed	Combined breast milk and other milk intake where non-breast milk (e.g., formula) is a significant milk source whether or not the infant is consuming significant calories from other liquid or solid food sources.
Token breastfeeding	Minimal, irregular or occasional breastfeeding contributing minimal nutrition and few calories.
Extended breastfeeding	Breastfeeding beyond 12 months of age.
Weaning	Discontinuation of breastfeeding.

[a] Adapted from Labbok and Krasovec (1990)

These terms are important for our discussion in this section because breastfeeding patterns are important determinants of breast milk intake rates.

Fully breastfed infants are those that receive breast milk as the primary, if not sole, source of milk. This category encompasses three specific patterns of breastfeeding. Thus, the term “fully breastfed” is probably most often applied to the entire lactation period (0-12 months). For example, an infant who was exclusively breastfed for the first 6 months, then predominantly breastfed from 6 through 12 months, would be considered fully breastfed for the lactation period. We use the term “almost exclusively breastfed” particularly for the common practice of exclusive breastfeeding during the day with a small bottle of formula fed at night. Older infants who are breastfed and do not receive significant amounts of formula (or other non-breast milk) but do receive supplementary solid foods would fit into the category of “predominantly breastfed.” Partially breastfed infants, like fully breastfed infants, receive some breast milk but unlike fully breastfed infants they also receive significant amounts of milk, or formula from non-breast milk sources.

A few words about units and nomenclature are provided to avoid confusion. In toxicology and pharmacology “dose” is typically expressed as the amount received over time divided by body weight (e.g., mg/kg-day). Analogously, breast milk intake rates can be expressed as the amount received by the infant over time divided by the infant’s body weight. Daily breast milk intake rate (e.g., g/kg BW-day) is the most commonly used unit of measure. If multiple days of breast milk intake rate for a single infant are averaged together, the result is the “average daily breast milk intake rate.” This averaging is over time rather than over individuals. This term is useful for characterizing an average intake over time (e.g., over the first 6 months of life).

A final note is that the means and standard deviations (SDs) reported in these guidelines are arithmetic means and arithmetic SDs, unless otherwise indicated.

5.2 Recommendations

OEHHA recommends the following to estimate dose to the infant through breast milk.

5.2.1 Default Point Estimate for Daily Breast Milk Intake During the First Year

For the default point estimate approach to assess dose and risk from breast milk intake by breastfed infants during the first year, OEHHA recommends using the mean and high-end estimates presented in Table 5.2. The average and high end point estimates are 101 and 139 g/kg BW *day.

Table 5.2 Point Estimates of Breast Milk Intake for Breastfed Infants

Infant Group	Intake (g/kg-day)
Fully breastfed over the first year (i.e., fed in accordance with AAP recommendations)[1]	
Mean	101
90th percentile	130
95th percentile	139
Exclusively breastfed during first year[2]	
Mean	113
90th percentile	141
95th percentile	149
Fully breastfed over first 6 months (i.e., fed in accordance with AAP recommendations)[1]	
Mean	130
90th percentile	138
95th percentile	165

[1] AAP = dataset based on American Academy of Pediatrics (1997) infant feeding recommendations;
[2] EBF = dataset of exclusively breastfed infants

As discussed in Section 5.1, fully breastfed infants are those that receive breast milk as the primary, if not sole, source of milk. Thus, the term "fully breastfed" is probably most often applied to the entire lactation period (0-12 months). An infant who was exclusively breastfed for the first 6 months, then predominantly breastfed from 6 through 12 months, would be considered fully breastfed for the lactation period. Exclusively breastfed infants are those in which breast milk is the sole source of calories.

5.2.2 Stochastic Approach to Breast Milk Intake Among Individuals During the First Year of Life

For a stochastic analysis of exposure and dose through the breast milk intake pathway, a normal distribution with a mean of 101 g/kg-day and standard deviation 23 g/kg-day, is recommended as a distribution for breast milk intake (Table 5.3).

Table 5.3 Recommended Breast Milk Intake Rates Among Breastfed Infants (Averaged Over an Individual's First Year of Life)

	Mean (SD)	Percentile							
		5	10	25	50	75	90	95	99
Intake (g/kg-day)	101 (23)	62	71	85	101	116	130	139	154

The recommended values for average and high end breast milk consumption rates are the mean and 95th percentiles (101 and 139 g/kg BW -day) for fully breastfed infants.

The recommended parametric model for stochastic risk assessment is a normal distribution with a mean and standard deviation of 101 ± 23

5.2.3 Consideration of Variable Age of Breastfeeding Mothers

Because some environmental toxicants continue to accumulate, older primiparous mothers could excrete higher concentrations of the toxicant in breast milk than younger mothers could when daily intake is constant over time. For example, Hedley et al (2007) reported that breast milk concentrations of POPs increased in a population of Asian women by 1.45 pg/g-fat/yr. Incorporating a distribution or range of age among breastfeeding mothers into the risk assessment is a refinement that could be considered in the future.

5.2.4 Analysis for Population-wide Impacts from Breast Milk Exposure

If the risk assessor is evaluating a population-wide risk (e.g., for the purpose of developing a range of cancer burden estimates from this pathway), it may be appropriate to incorporate information on the percent of the infant population that is breastfed at various ages. Information on the prevalence of breastfeeding by age of infant in California from the National Immunization Survey (NIS) specific to California is available in Appendix 5A, Table 5A-11 for this purpose. Alternatively, values in Table 5A-17 could be used. This information should be re-evaluated periodically to take into account recent trends in breastfeeding and the outcome of the breastfeeding promotion policies of the last decade.

5.3 Conceptual Framework for Variable Breast Milk Intake Rates

The Hot Spots program provides a tiered approach to risk assessment. Point estimate and stochastic approaches are available. The stochastic approach uses probability distributions for variates with sufficient data to estimate variability. The point estimate approach for the breast milk pathway uses average and high-end breast milk consumption values. Data on the distribution of breast milk intake rates allow selection of point estimates that represent average breast milk consumption and a specified percentile of high-end consumption. To incorporate the variability of breast milk intake into the infant dose of toxicant from breast milk, we use a stochastic approach to characterize parameters related to the breast milk pathway.

The data set that we use for breast milk intake rate distributions includes 130 infants for whom there are at least two measurement time points separated by at least 7 days during the lactation period. This is an unusually robust data set for evaluating variability in breast milk intake rates. The repeated measures help ensure that typical intake over time is captured, thus reducing the effect of intraindividual variability on the distribution of values. Further, milk intake measurements and body weight for individual infants are included and, therefore, breast milk intake can be normalized to body weight for each infant. Breast milk intake is correlated with infant body weight (e.g., large babies consume greater amounts of milk than small ones) and thus the variability simply due to body weight can be eliminated.

The correlation of intake and body weight is taken into account by normalizing intake by body weight for each individual infant. That is, for each infant, their daily intake at that measurement is divided by his/her body weight at that measurement to give intake in units of g/kg-day. Because larger infants consume greater amounts of milk, normalizing to body weight reduces much of the variability due to differences in body weight among infants.

Interindividual variability is explicitly addressed through the distributional approach used in these guidelines. A distribution of intake rate quantifies the probability of the array of intake rate values in the population. This describes variability between individuals in the population.

Intraindividual variability is addressed by allowing intake to be a function of time (e.g., see Arcus-Arth et al., 2005; Burmaster and Maxwell, 1993), thus taking into account variability of an individual's intake over time. Intraindividual variability can also be addressed by assessing the impact of different methods of averaging over time (e.g., Arcus-Arth et al., 2005).

Exposure through mother's milk ingestion ($Dose_m$) is a function of the average substance concentration in mother's milk and the amount of mother's milk ingested. The minimum pathways that the nursing mother is exposed to include inhalation, soil ingestion and dermal, since the chemicals evaluated by the mother's milk pathway are multipathway chemicals. Other pathways may be appropriate depending on site conditions (e.g., presence of vegetable gardens or home grown chickens or the fish consumption). The nursing mother in the mother's milk pathway is not herself subject to the mother's milk pathway. The summed average daily dose (mg/kg BW-day) from all pathways is calculated for the nursing mother using equations in the other chapters of this document.

The general algorithm for estimating dose to the infant via the mother's milk pathway is as follows:

$$Dose_m = C_m * BMI_{bw} * EF * (1x10^{-3}) \qquad \text{(Eq 5-1)}$$

where:

$Dose_m$ = Dose to the infant through ingestion of mother's milk (mg/kg BW/day)
C_m = Concentration of contaminant in mother's milk is a function of the mother's exposure through all routes and the contaminant half-life in the body (mg/kg milk). Various equations for estimating Cm are presented in Appendix J
BMI_{bw} = Daily breast-milk ingestion rate (g-milk/kg BW/day). See Table 5.2 for point estimates. See Table 5.3 for distribution for Tier 3 stochastic risk assessments.
EF = Frequency of exposure, unitless, (days/365 days)
$1x10^{-3}$ = Conversion factor (g to kg for milk,)

The exposure frequency (EF) is the fraction of time the infant is exposed daily during the first year (i.e., 365 days) of breast-feeding. Thus, the EF is set at 1. For cancer risk assessment, the risk via the mother's milk pathway ($RISKm_{(0<2\ yr)}$) occurs only during the first year in the 0<2 age group.

The risk is calculated for this age group using the appropriate, unitless, age sensitivity factor (ASF) of 10, (see OEHHA, 2009) and the chemical-specific cancer potency factor (CPF), expressed in units of $(mg/kg\text{-}day)^{-1}$.

$$RISKm_{(0<2\ yr)} = Dose_m * CPF * ASF * ED * 0.5 \qquad \textbf{(Eq. 5-2)}$$

The cancer risk, $RISKm_{(0<2\ yr)}$ is the predicted number of expected cases of cancer over a lifetime as a result of the exposure (e.g., expressed as 1×10^{-6} or 1 case per million people exposed)

Exposure duration (ED) is the number of years within the age grouping, which is 2 years for the 0<2 year age group. Since risk for the mother's milk pathway is assessed only during the first year of the 0<2 year age group, a 0.5 adjustment factor is included in Eq. 5-2. The risk from other exposure pathways (e.g., the inhalation pathway) would not include this factor in the 0<2 age group.

To determine lifetime cancer risks (i.e., 70 years), the total risk for the 0<2 age group is then summed across the total risk of the other age groups:

$$RISK_{(lifetime)} = RISK_{(3rdtri)} + RISK_{(0<2\ yr)} + RISK_{(2<16\ yr)} + RISK_{(16\text{-}70yr)} \qquad \textbf{(Eq. 5-3)}$$

As explained in Chapter 1, different age groups for assessing risk are needed due to different ASFs for each group. We also need to accommodate cancer risk estimates for the average (9 years) and high-end (30 years) length of time at a single residence, as well as the traditional 70-year lifetime cancer risk estimate. For example, assessing risk in a 9-year residential exposure scenario assumes exposure during the most sensitive period, from the third trimester to 9 years of age and would be presented as such:

$$RISK_{(9\text{-}yr\ residency)} = RISK_{(3rdtri)} + RISK_{(0<2\ yr)} + RISK_{(2<9\ yr)} \qquad \textbf{(Eq. 5-4)}$$

For the 30-year residential exposure scenario, the risk for 2<16 and 16<30 age groups would be added to the risks from third trimester and 0<2 exposures. For the 70-year residential exposure scenario risk, Eq 5-3 would apply.

The risk algorithm for the stochastic approach and for the point estimate approach is the same. In the stochastic approach, the distribution of mother's milk consumption is reflected as a distribution of dose to the infant.

The chemicals with human milk transfer coefficients (Tco_{hm}) to be analyzed in the breast milk exposure pathway are described in Appendix J.

5.3.1 Transfer Coefficients for Chemicals From Mother into Milk

Tco_{hm} represent the transfer relationship between the chemical concentration found in milk and the mother's chronic daily dose (i.e. concentration (µg/kg-milk)/dose (µg/day) under steady state conditions. Transfer coefficients can be applied to the mother's chronic daily dose estimated by the Hot Spots exposure model for all applicable exposure pathways to estimate a Cm for a specific chemical concentration in her milk by equation 5-5. Appendix J has additional detail of the derivation of transfer coefficients for specific chemicals.

$$Cm = [DOSEair + DOSEwater + DOSEfood + DOSEsoil + DOSEdermal\ ] \times Tco_{hm} \times BW$$ **(Eq. 5-5)**

where:
- DOSEair = dose to the mother through inhalation (Eq 3-1) (mg/kg/day)
- Dwi = dose though drinking water ingestion (mg/kg/day)
- DOSEfood = dose through ingestion of food sources (Eq 7-1) (mg/kg/day)
- DOSEsoil = dose through incidental ingestion of soil (Eq 4-1) (mg/kg/day)
- DOSEdermal = dose from dermal absorption from contaminated soil (Eq 6-1) (mg/kg/day)
- DOSEwater = dose through ingestion of surface water (Eq 8-2) (mg/kg/day)
- Tco_{hm} = transfer coefficient (see Table 5-4) (day/kg-milk)
- BW = body weight of the mother (default = 70.7 (kg)

However, if bio-transfer information is available for an individual exposure route, route-specific Tcos can be developed resulting in a modification of Eq. 5.5:

$$Cm = [(DOSEair \times Tco_{mi}) + (DOSEwater \times Tco_{mw}) + DOSEfood \times Tco_{mf}) + (DOSEsoil \times Tco_{ms}) + (DOSEdermal \times Tco_{md}] \times BW$$ **(Eq. 5-6)**

where:
- Tcomi = biotransfer coefficient from inhalation to mother's milk (day/kg-milk)
- Tcomw = biotransfer coefficient from drinking water to mother's milk (day/kg-milk)
- Tcomf = biotransfer coefficient from food to mother's milk (day/kg-milk)
- Tcoms = biotransfer coefficient from incidental soil ingestion to mother's milk (day/kg-milk)
- Tcomd = biotransfer coefficient from dermal absorption from contaminated soil (day/kg-milk)

Estimates of toxicant bio-transfer to breast milk are chemical-specific. Table 5.4 shows the transfer coefficients for dioxin-like compounds, carcinogenic PAHs and lead that OEHHA has estimated from data found in the peer-reviewed literature. One key factor that plays a role in the difference between oral and inhalation transfer coefficient (e.g., for PAHs) is first pass metabolism which is lacking in dermal and inhalation exposures. Thus, for simplicity, OEHHA applies the transfer coefficients from inhalation to the dermal absorption pathway for lead and PAHs. For lead, we are using the inhalation Tco for all the other pathways of exposure to the mother. Likewise for PCDD/Fs and dioxin-like PCBs, we are using the oral Tco for the other pathways of exposure to the mother in Eq. 5-7.

$$Cm = [(D\_inh \times Tco_{m\_inh}) + (D\_ing \times Tco_{m\_ing})] \times BW \qquad \textbf{(Eq. 5-7)}$$

where:
- D_ing = the sum of DOSEfood + DOSEsoil + DOSEwater through ingestion (mg/kg-BW-day)
- D_inh = the sum of DOSEair + DOSEdermal through inhalation and dermal absorption (mg/kg-BW-day)
- Tcom_inh = biotransfer coefficient from inhalation to mother's milk (d/kg-milk)
- Tcom_ing = biotransfer coefficient from ingestion to mother's milk (d/kg-milk)

Table 5.4 Mother's Milk Transfer Coefficients (Tcos) (Taken from Appendix J)

Chemical/chem. group	Tco (day/kg-milk)
PCDDs - oral	3.7
PCDFs - oral	1.8
Dioxin-like PCBs - oral	1.7
PAHs – inhalation	1.55
PAHs – oral	0.401
Lead - inhalation	0.064

The chemicals evaluated in the mother's milk pathway are multipathway chemicals (Appendix E) for which sufficient data were available to estimate a Tco.

Each Tco estimate accounts for biological processes from intake to milk that affect the transfer of a toxicant in the mother's body. Appendix J further describes OEHHA's recommendations for estimating the concentration of chemicals in breast milk.

5.4 Available Breast Milk Intake Rate Estimates

The literature contains several studies reporting measured breast milk intakes for infants at various ages and of different breastfeeding patterns. These studies typically have small sample sizes, are cross-sectional and do not represent the U.S. population of breastfeeding infants. However, the U.S. EPA (1997) Exposure Factors Handbook, the prior Hot Spots Exposure guidelines (OEHHA, 2000), and Arcus-Arth et al. (2005) compiled data from selected studies to derive summary intake rates for the population or certain subgroups of the infant population. Below we briefly summarize these reports.

5.4.1 U.S. EPA Exposure Factors Handbook (1997) and Child Specific Exposure Factors Handbook (2008)

The U.S. EPA National Center for Environmental Assessment published an Exposure Factors Handbook in 1997 (U.S. EPA, 19997) that provides a review of the breast milk pathway intake rates, and recommends values for breast milk intake rate, lipid intake rate, and lipid content. The 1997 Exposure Factors Handbook recommended breast milk intake rate values based on data from five publications identified as "key studies" by the Agency: Butte *et al.* (1984a), Dewey and Lonnerdal (1983), Dewey *et al.* (1991a; 1991b), Neville *et al.* (1988), and Pao *et al.* (1980). The Handbook recommended mean time-weighted average milk intakes of 742 ml/day and 688 ml/day for infants 0-6 months and 0-12 months of age, respectively. The Handbook also recommends upper-percentiles for time-weighted average daily intakes of 980 ml/day and 1033 ml/day for 0-6 and 0-12 months of age, respectively. The upper percentiles were calculated as the "mean plus 2 standard deviations." These estimates can be converted from ml to grams of breast milk by multiplying by 1.03. A disadvantage of these rates is that they are not normalized to infant body weight.

In September 2008, the U.S. EPA released the Child-specific Exposure Factors Handbook (CEFH). The CEFH reviewed relevant breast milk intake studies and provided recommended values (Table 5.3). In order to conform to the new standardized age groupings used in the CEFH, U.S. EPA used breast milk intake data from Pao et al. (1980), Dewey and Lönnerdal (1983), Butte et al. (1984), Neville et al. (1988), Dewey et al. (1991a), Dewey et al. (1991b), Butte et al. (2000) and Arcus-Arth et al. (2005). These data were compiled for each month of the first year of life.

Recommendations were converted to mL/day using a density of human milk of 1.03 g/mL rounded up to two significant figures. Only two studies (i.e., Butte et al., 1984 and Arcus-Arth et al., 2005) provided data on a body weight basis. For some months multiple studies were available; for others only one study was available. Weighted means were calculated for each age in months. When upper percentiles were not available from a study, these were estimated by adding two standard deviations to the mean value. Recommendations for upper percentiles, when multiple studies were available, were calculated as the midpoint of the range of upper percentile values of the studies available for each age in months. These month-by-month intakes were composited to yield intake rates for the standardized age groups by calculating a weighted average.

U.S.EPA provides recommendations for the population of exclusively breastfed infants (Table 5.5) since this population may have higher exposures than partially breastfed infants. For U.S. EPA, exclusively breastfed refers to infants whose sole source of milk comes from human milk, with no other milk substitutes. Partially breastfed refers to infants whose source of milk comes from both human milk and milk substitutes (i.e., formula). Note that some studies define partially breastfed as infants whose dietary intake comes from not only human milk and formula, but also from other solid foods (e.g., strained fruits, vegetables, meats).

Table 5.5. Recommended Values for Human Milk and Lipid Intake Rates for Exclusively Breastfed Infants by U.S. EPA Child-specific Exposure Factors Handbook (2008)

Age Group	Mean (mL/day)	Upper %ile[a] (mL/day)	Mean (mL/kg BW-day)	Upper %ile[a] (mL/kg BW-day)	Source
Human Milk Intake					
Birth to <1 month	510	950	150	220	b
1 to <3 months	690	980	140	190	b, c, d, e, f
3 to <6 months	770	1,000	110	150	b, c, d, e, f, g
6 to <12 months	620	1,000	83	130	b, c, e, g
Lipid Intake [h]					
Birth to <1 month	20	38	6.0	8.7	i
1 to <3 months	27	40	5.5	8.0	d, i
3 to <6 months	30	42	4.2	6.0	d, i
6 to <12 months	25	42	3.3	5.2	i

a Upper percentile is reported as mean plus 2 standard deviations
b. Neville et al., 1988.
c. Pao et al., 1980.
d. Butte et al., 1984.
e. Dewey and Lönnerdal, 1983.
f. Butte et al., 2000.
g. Dewey et al., 1991b.
h. The recommended value for the lipid content of human milk is 4.0 percent.
i. Arcus- Arth et al., 2005.

5.4.2 OEHHA Hot Spots Exposure Assessment and Stochastic Analysis Guidelines (OEHHA, 2000)

In the prior version of this document (OEHHA, 2000), breast milk intake studies were identified using specified criteria (described in the prior guidelines). The studies are briefly described in the prior guidelines and are divided into two categories: those for which breast milk intake is reported as amount (e.g., ml or grams) per day and those for which intake is reported as amount per body weight per day. Mothers were described as healthy, well-nourished, and at or near normal body weight. Infants were described as healthy, near- or full-term, and single born.

In reviewing and evaluating studies, several factors potentially affecting the accuracy of breast milk intake estimates and their applicability to the general population of infants were considered. These are discussed in the prior guidelines and include (1) the methods for measuring the volume of breast milk consumed, (2) the correlation of breast milk intake with age and with body weight, (3) insensible water loss, and (4) the effect of maternal factors on breast milk intake.

In the prior version of this document (OEHHA, 2000), two datasets were selected with which to derive breast milk intake rates: Hofvander *et al.* (1982) and Dewey *et al.* (1991a; 1991b). These datasets were selected because the data were on a body weight and individual infant basis and the combined datasets provided data covering the 1-12 month age period (the majority of the typical breastfeeding period). For the Hofvander study, all infants were exclusively breast fed while infants in the Dewey et al. study were exclusively breastfed to about 4 months of age and many through 6 months of age. However, in Dewey et al., some infants (exactly who and how many were unspecified) were introduced to solid foods as early as 4 months of age (based on the age of food introduction of 5.3 $\pm$ 1.1 months reported in the published report). Therefore, the Dewey et al. infants did not fit the AAP recommendations at 6 months of age (i.e., exclusively breastfed). Nonetheless, the 3 (exclusive breastfeeding), 9 (fully breastfeeding), and 12 (fully breastfeeding) month ages were in accordance with AAP recommendations.

The normal distribution described the combined datasets fairly well and fit much better than the log normal distribution. The means at the 3-month age group were not statistically different between the Hofvander et al. and Dewey et al. studies. There was considerable variability in the intakes reported at any given age, with the range (60-120 g/kg-day) and standard deviation (18-25 g/kg-day) consistent among the different age groups.

There is an overall trend of decreasing consumption on a per kg basis with increasing age, with daily intake greatest at 30 days of age. A linear relationship fits the age versus consumption rate data fairly well. From this combined data set, an intake averaged across breastfeeding infants during the first year of life is estimated to be 102.4 g/kg-day. Assuming a normal distribution of intake among the infants in this population (with mean and standard deviation 102.4 and 21.82 g/kg-day, respectively), the different levels of intake are derived and provided in Table 5.6. Similarly, an estimate of average intake during the first 6 months of life is estimated to be 131.4 g/kg-day.

Table 5.6 OEHHA (2000) - Distribution of daily breast milk intake (g/kg-day) for fully breastfed infants during their first 6 and 12 months of life*

Percentile	6 months	12 months
5	95.5	66.5
10	103	74.3
15	109	79.7
20	113	84.1
25	116	87.7
30	120	90.9
35	123	94.0
50	131	102
65	140	111
70	143	114
75	146	117
80	150	121
85	154	125
90	159	130
95	167	138
99	182	153

*****Data from Hofvander et al. (1982) and Dewey et al. (1991a; 1991b), analysis conducted by OEHHA (2000).

5.4.3 Arcus-Arth et al. (2005)

Arcus-Arth et al. (2005) extended the work presented in OEHHA (2000) and reported statistical distributions (i.e., percentiles and parameters) of breast milk intake rates for infants fed in accordance with the 1997 American Academy of Pediatrics recommendations (AAP, 1997). The AAP recommendations were for infants to be exclusively breast fed through 6 months of age, and then to receive breast milk as the sole source of milk through 12 months of age during which time solid foods and non-milk liquids are being introduced.

Arcus-Arth et al. also presented distributions of breast milk intake rates for infants exclusively breastfed for 0-12 months. The Arcus-Arth et al. rates are based on breast milk intakes normalized to body weight (g/kg-day) of individual infants seven days to one year of age, with many infants providing data at more than one age period but no infant providing intake measurements from early to late infancy (i.e., at periodic time points throughout the first year). The rates were found to be normally distributed at each measurement age (e.g., at 3 months) as well as over the one year age period (i.e., 7 days through 12 months).

Two methods were used to analyze the data. In the first method (Method 1), the daily intake per kg infant body weight was regressed on age. Intake was integrated over a 6 or 12 month period, and divided by 182.5 or 365 days, respectively. This resulted in a daily intake rate averaged over that period, i.e., an average daily intake. A pooled SD was calculated using the SD's at each measurement age. A distribution was then derived using an integrated average value calculated from the regression, the pooled SD, and an assumption of normality.

For the second method (Method 2), a dataset of breast milk intake over each of 6 or 12 months for 2500 hypothetical infants was created by randomly selecting values at each measurement age from the empirical distribution at that age and assuming normality. For each hypothetical infant, a line was fit using the generated "intake versus age" data, and an average daily intake for each infant was derived. The results are presented in Table 5.7 below.

Table 5.7 Daily Breast Milk Intake Rates Averaged Over 6 or 12 Months (g/kg-day)

Averaging Period	Mean (SD)	Population Percentile							
		5	10	25	50	75	90	95	99
AAP [1] 0-6 Months Method 1	129.6 (21.3)	94.5	102.3	115.2	129.6	144.0	157.0	164.6	179.3
AAP [1] 0-6 Months Method 2	126.3 (6.8)	115.2	117.7	121.8	126.3	130.9	135.0	137.5	142.1
AAP [1] 0-12 Months Method 1	100.7 (22.7)	62.4	70.9	85.0	100.7	116.3	130.4	138.9	154.9
AAP [1] 0-12 Months Method 2	101.6 (5.3)	92.8	94.8	98.0	101.6	105.2	108.4	110.3	113.4
EBF [2] 0-12 Months	113.0 (21.8)	77.1	85.0	98.3	113.0	127.7	140.9	148.8	163.8

[1] AAP = dataset based on American Academy of Pediatrics (1997) infant feeding recommendations
[2] EBF = dataset of exclusively breastfed infants

The variability, as measured by the SD and the range in values of the distribution, differ between Methods 1 and 2. Method 1 incorporated the correlation for an individual infant over time in their intake pattern (e.g., high-end consumers remained high-end consumers throughout the lactation period). Method 2 randomly selected intake values for a hypothetical infant at each age (measurement) point, and thus did not incorporate correlation between intakes. Because higher-end consumers tended to remain higher-end consumers while lower-end consumers remained lower-end, the range of values from the 5th-percentile to the 99th-percentile is much greater for Method 1 than for Method 2.

In comparison to the breast milk intake rates derived for the prior Hot Spots Exposure guidelines (2000), the Arcus-Arth et al. (2005) rates are based on a larger sample size, include intake measurements as young as 7 days of age (the prior guidelines used data from infants only as young as 3 months), and are in accordance with AAP recommendations. Because pediatricians tend to refer to AAP guidance, it is likely that they would encourage mothers to follow AAP breastfeeding recommendations.

5.5 Representativeness of Breast Milk Intake Estimates

The Exposure Factors Handbook (1997), prior Hot Spots Exposure and Stochastic Guidelines (2000), and Arcus-Arth et al. (2005) used data from mothers who were predominantly white, well-nourished and of relatively high socioeconomic (SES) and educational status, and therefore do not represent a cross-section of all California mothers. However, the literature indicates that SES does not affect the amount of breast milk produced by the mother or the amount of breast milk consumed by the infant, except when the mother is severely undernourished. This was the conclusion made by Ahn and MacLean (1980) who reported that studies generally agreed "that the milk output of mothers in [developing and industrialized countries are] comparable, except in populations of markedly undernourished women." Further, the World Health Organization (WHO, 1985) concluded that, for most mother-infant pairs, the volume of breast milk consumed by the infant is considerably less than the mother's potential supply. Thus, the breast milk intake rates reviewed in these guidelines are likely representative of the population of California infants.

5.6 Conclusion

Breastfeeding is an important indirect pathway of exposure for environmental toxicants, particularly persistent lipophilic chemicals, other substances that may accumulate in the body, and substances that are preferentially transferred into breast milk. Significantly larger quantities of some environmental toxicants stored in maternal tissue are delivered to breastfed infants compared to non-breastfed infants. Factors such as the duration of breastfeeding and maternal age at first breast feeding period can influence dose estimates. Breast milk intake should be considered when evaluating risks from environmental toxicants transferred to breast milk. This chapter provides a framework and the values needed for estimating the range of exposures to breast milk pollutants for breastfeeding infants.

The benefits of breastfeeding are widely recognized, and public health institutions promote and encourage breast feeding. In most situations, the benefits for the general infant population appear to outweigh the risks from exposure to toxicants in breast milk. It is a public health goal to minimize the risk and to understand the magnitude of the risk. Because the patterns of breastfeeding are changing, the duration of breastfeeding and intake of breast milk at different ages should be re-evaluated periodically to ensure a sound basis for such calculations.

Appendix 5A

Appendix 5A includes some background information on the mother's milk exposure pathway that may be useful for some specialized risk assessment applications but is not currently used in the Hot Spots exposure assessment model.

5A-1 Breast Milk Lipid

5A-1.1 Breast Milk Lipid Content

Many chemicals of concern in breast milk are primarily found in the breast milk lipid. Thus information on the lipid content of breast milk may be useful for some risk assessment applications. The average lipid composition of breast milk is significantly different among women (Harmann, et al., 1998). Some researchers have reported monthly increases in breast milk lipid during the breastfeeding period (Ferris et al. 1988; Clark *et al.* 1982), while others have found that breast milk lipid does not change significantly over time (Butte *et al.* 1984b; Dewey and Lonnerdal, 1983). Mean reported values from various studies are provided in Table 5A-1.

Nommsen et al. (1991) measured lipid content in breast milk of 39 women at four measurement periods (3, 6, 9, and 12 months of infant age). The data were collected to be representative of a 24-hour nursing duration, thus accounting for within feeding and diurnal variation in lipid content. Examination of the subjects' lipid levels longitudinally reveals that a subject with high lipid levels in breast milk produced at three months will tend to have high levels at subsequent months. An analysis of variance (ANOVA) using the 39 subjects for which four lipid level measurements are available confirms that there is a highly significant subject effect. Some studies have reported that lipid levels increase over the lactation period (Allen et al., 1991). For the Nommsen et al. study, the average lipid levels among the 39 subjects increase from 3.63 g/100 ml at 3 months to 4.02 g/100 ml at 12 months. However, for 14 of the 39 individuals, the lipid level shows a downward trend (e.g., the 12-month lipid level is lower than the 3 month). There is increased variability in lipid content at later measurement periods relative to earlier periods.

Table 5A-1 Lipid Content of Breast Milk Reported by Various Researchers

Study	Study Findings
Butte *et al.* (1984c)	3.92 g lipid /dl - mean for preterm infants 4.31 g lipid /dl - mean for full term infants For infants aged 2 to 12 weeks. 13 full term and 8 preterm infants. Measurements taken at 2, 4, 6, 8, 10, 12 weeks postpartum. No significant changes in content noted over time. Standard deviations ranged from 0.78 to 1.57 g lipid /dl.
Clark *et al.* (1982)	Mean total lipid content in units g/100 ml increased between 2 and 16 weeks postpartum for 10 subjects: 3.9, 4.1, 4.6 and 5.2 at 2, 6, 12, and 16 weeks postpartum.
Ferris *et al.* (1988)	Mean lipid in g/100 ml were 3.98, 4.41, 4.87, and 5.50 at, respectively, 2, 6, 12, and 16 weeks postpartum in 12 subjects. Standard deviations ranged from 0.99 to 1.09 g/100 ml.
Dewey and Lonnerdal (1983)	Overall mean lipid content ranged from 4.3 to 4.9 g/100 ml 1-6 months postpartum, without significant differences at different months. Standard deviations ranged from 0.97 to 1.96 g/100 ml. Measurements taken at 1, 2, 3, 4, 5, and 6 months postpartum. Number of subjects at each month ranged from 13 to 18.
Dewey *et al.* (1991a; 1991b) – raw data provided by K. Dewey	Percent of Lipid in Breast Milk (mean +/- SD) (n=sample size) 3 Months age = 3.67 +/- 0.84 (n=72) 6 Months age = 3.92 +/- 1.04 (n=53) 9 Months age = 4.16 +/- 1.07 (n=46) 12 Months age = 4.02 +/- 1.55 (n=39) All ages = 3.9 +/- 1.1 (n=210)
Mitoulas et al. (2003)	3.55 g lipid/dl (mean for 1-12 months)

5A-1.2 Breast Milk Lipid Intake Rates – Point Estimates

The Exposure Factors Handbook (U.S. EPA, 1997) recommends values for breast milk lipid intake rates (Table 5A-2). Values for infants under one year were based on data of Butte *et al.* (1984a) and the Maxwell and Burmaster (1993) analysis of the Dewey *et al.* (1991a) study. A lipid intake rate of 26 ml/day (equivalent to 26.8 g/day) was recommended for risk assessment purposes, with an upper percentile value of 40.4 ml/day (equivalent to 41.6 g/day) ("based on the mean plus 2 standard deviations"). The high-end value is based on a statistical model but falls within the range of empirical values (maximum 51.2 g/day) from Dewey et al. (1991a). A disadvantage of these rates is that they are not normalized to infant body weight.

Table 5A-2. Recommended Values for Lipid Intake Rates for Exclusively Breastfed Infants by U.S. EPA Child-specific Exposure Factors Handbook[a] (2008)

Age Group	Mean (mL/day)	Upper 95 %ile (mL/day)	Mean (mL/kg BW-day)	Upper 95 %ile (mL/kg BW-day)	Source
Birth to <1 month	20	38	6.0	8.7	b
1 to <3 months	27	40	5.5	8.0	b,c
3 to <6 months	30	42	4.2	6.0	b,c,
6 to <12 months	25	42	3.3	5.2	b

a The recommended value for the lipid content of human milk is 4.0 percent.
b. Arcus- Arth et al., 2005
c. Butte et al., 1984.

Mitoulas et al. (2003) studied breast milk intake and lipid levels in 30 Australian mother-infant pairs. The infants were fully breastfed for at least 4 months, with complementary foods added between 4 and 6 months age. Measurements were made at 1, 2, 4, 6, 9, and 12 months of age. For the 0-6 and 0-12 month periods, the mean lipid intake was 13.50 and 12.96 g/day, respectively. For the period of exclusive breastfeeding (1-4 months age), mean lipid intake was 13.33 g/day.

5A-1.3 Breast Milk Lipid Intake Rates - Distributions

The Maxwell and Burmaster (1993) study presented a distribution of breast milk lipid intake by infants less than one year of age. They report that, at any given time, “approximately 22% of infants less than one year of age are being breastfed, the remaining 78% have no exposure to chemicals in their mother’s breast milk.” They found the mean lipid intake among nursing infants to be characterized by a normal distribution with mean 26.81 g/day and standard deviation 7.39 g/day. Their results are based on the fraction of infants at different ages being breastfed according to the reports of Ryan *et al.* (1991a, 1991b) and “on data for lipid intake from a sample of white, middle- to upper-income, highly educated women living near Davis, California” (Dewey *et al.*, 1991a).

Advantages of this study include the detailed analysis of the breast milk pathway, which addressed several of the key factors contributing to variable intakes among individual infants. However, some features of this study limit its usefulness for evaluation of acute and chronic exposure of breastfed infants to environmental toxicants. First, the study did not analyze data on breast milk intake during the first three months of life and instead extrapolated from the Davis study to predict intake during this period. Second, intake was expressed as amount per day, rather than amount per body weight per day;

the latter would facilitate more accurate dose calculations. Third, estimates of the breastfeeding population are made for the fraction of current feeders on any given day rather than the fraction of infants who breastfed at any time during their first year of life. For chronic exposure analyses it is important to consider prior intakes in addition to current intake of individual infants.

Arcus-Arth et al. (2005) presented lipid intake rates normalized to body weight by combining measured milk intake values with lipid content values. The first set of lipid intakes was derived using only Dewey et al. data (raw data provided by K. Dewey, and methodology described in Dewey et al. 1991a, b). The infants were exclusively breastfed through 3 months of age and fully breast fed thereafter. Milk intake and lipid content were measured at 3 (n=72), 6 (n=53), 9 (n=46), and 12 (n=39) months of age. The milk intake from each infant was multiplied by the corresponding measured lipid content value for that infant at that age to give lipid intake. These lipid intake rates were normally distributed at the 6-, 9-, and 12-month measurement ages.

The researchers also derived a second set of lipid intakes using the same milk intake values of Dewey et al. and a 4% lipid content value, which is the lipid content value commonly used as a default in risk assessment. The 4% lipid content derived rates differed by 2-10% from the measured lipid content derived rates, with probable overestimation at the mean and underestimation at the low- and high-end percentiles. Because the differences were not substantial, and because a dataset of lipid content values representing the population is not available, the 4% lipid content value was considered a reasonable default.

A third set of lipid intakes was derived to represent the subpopulation of infants fed in accordance with AAP recommendations (AAP, 1997). Because a few infants in the Dewey et al. study had consumed solid foods between 4 and 6 months of age, and because it is not known which infants these were, the 6-month data did not follow AAP recommendations and thus could not be used for this purpose. Therefore, Arcus-Arth et al. used the AAP dataset they had created and the default 4% lipid content value to derive a set of “AAP lipid intake rates.”

For each set of lipid intakes, the values were regressed by age to derive average daily lipid intake rates over the 0-6 and 0-12 month periods. While the 0-12 month derived lipid intake rates were available in the Arcus-Arth et al. journal article, the 0-6 month rates were not published but were obtained from the authors (Arcus-Arth, personal communication, 2008).

Arcus-Arth et al. derived lipid intakes and average daily lipid intake rates only for breastfed infants, not the entire infant population, resulting in intakes that are not directly comparable to those of Maxwell and Burmaster (1993). An advantage of the Arcus-Arth et al. derived rates is that they are normalized to infant body weight. A disadvantage is that lipid intake values for infants 0-3 months of age were derived using extrapolation because measured values for this age group were not available.

Inter- and intraindividual variation of lipid content over time should be considered when evaluating lipid intake for the infant population. We chose to use the average daily lipid intake rates of Arcus-Arth et al. because they have incorporated variability over time and have been normalized to body weight. The mean and selected percentiles of the average daily lipid intake rates are presented in Tables 5A-4, below.

Table 5A-3 suggests that assuming a 4% lipid content value tends to slightly overestimate the mean and slightly underestimate the high-end percentile of average daily lipid intake. Nonetheless, the values are similar, supporting the use of a 4% lipid content value as a reasonable default. Further, the Exposure Factors Handbook (U.S. EPA, 1997) recommends assigning a value of 4% (i.e., 4 g/dl) to breast milk lipid content based on data of the National Research Council (1991), Butte *et al.* (1984a), and Maxwell and Burmaster (1993).

Table 5A-3 Comparison of Lipid Content Assumptions: average daily lipid intake (g/kg day) of breastfed infants for the 0–12 month age period*

	Mean	Population Percentiles							
		5	**10**	**25**	**50**	**75**	**90**	**95**	**99**
Measured lipid content [a]	3.70	2.01	2.38	3.00	3.70	4.39	5.01	5.38	6.08
4% lipid content [b]	4.03	2.53	2.85	3.37	3.96	4.54	5.07	5.38	5.98

[a] Lipid intake derived by multiplying the lipid content measurement by the milk intake measurement for each infant in the dataset provided by K. Dewey. Includes a few infants who may have received some solid foods between 4-6 months age.
[b] Lipid intake derived by multiplying a 4% lipid content value by the milk intake measurements provided by K. Dewey. Includes a few infants who may have received some solid foods between 4-6 months age.
* Data source: Arcus-Arth et al. (2005)

Assuming a 4% lipid content value, the distribution of average daily lipid intake rates for the AAP dataset is presented in Table 5A-4, below.

Table 5A-4 Distributions of Average Daily Lipid Intake (g/kg day) over the 0-6 and 0–12 month age periods for AAP infants and assuming 4% milk lipid content*

Age	Mean	Population Percentiles							
		5	**10**	**25**	**50**	**75**	**90**	**95**	**99**
0-6 months	5.18	3.78	4.09	4.61	5.18	5.76	6.28	6.58	7.17
0-12 [a] months	4.03	2.50	2.84	3.40	4.03	4.65	5.22	5.56	6.20

[a] includes infants exclusively breast fed through 6 months age and thereafter fully breast fed
* Data source: Arcus-Arth et al. (2005)

5A-2 Prevalence of Breastfeeding

Information on the prevalence of breastfeeding may be useful for assessing population impacts of pollutants. The majority of infants receive at least some breast milk during infancy. Of these infants, a significant number receive breast milk through at least 12 months of age. Using survey data, the prevalence of breastfeeding (i.e., percent of infants who are breastfed) can be estimated. The prevalence of in-hospital and early postpartum breastfeeding provides information regarding the initiation of breastfeeding and therefore the potential number of infants that may be exposed via the breast milk pathway. The prevalence of breastfeeding at later ages in the lactation period provides information on the duration of breastfeeding, which is a key determinant of the amount of breast milk, and therefore the total dose, to an infant over the lactation period.

Until recently, the only nationwide survey of breastfeeding prevalence was the Ross Mothers Survey (Ross Products Division, Abbott Laboratories). More recently, the National Immunization Survey and the National Survey of Children's Health have collected national data on breastfeeding prevalence, while the California Newborn Screening Program has collected data on infants in California (but only at an early postpartum (in-hospital) age). In addition, Hammer et al. (1999) provide prevalence data on a subpopulation of California infants (i.e., SF Bay area infants). These studies are briefly described below, and results are presented in Tables 5A-5 and 5A-6. The prevalence data could potentially be used in conjunction with breast milk intake rates to derive breast milk intake rates over the entire population of infants for the estimation of population cancer burden.

5A-2.1 The Ross Mothers Survey

The Ross Mothers Survey (RMS) is an annual nationwide mail survey conducted by Ross Products Division of Abbott Laboratories and is sent periodically to a probability sample of new mothers. Prior to January 1997, mothers received the survey at the time their babies turned six months of age. Since that time, surveys are sent to mothers at each month of age, from one through 12 months.

The survey asks mothers to recall the types of milk their babies received (1) in the hospital, (2) at one week of age, (3) in the last 30 days, and (4) most often in the last week. By using a multiple choice question, mothers select the kinds of milk fed to their infants from a listing that includes breast milk, commercially available infant formulas, and cow milk.

The weighting of the results reflects national demographics associated with the geography, race, age, and education of mothers throughout the United States. The 1998-2002 rates were weighted using U.S. Department of Health and Human Services 1997 natality data, while the 2002-2003 rates were weighted using year 2000 natality data. For 2002, the response rate was 21% (290,000 questionnaires returned out of 1,380,000 mailed) (Ryan, 2005).

The majority of infants in the U.S. receive breast milk at some time. The survey has consistently found that the percent of mothers breastfeeding in the U.S. varies considerably with geographic region. The highest rates of breastfeeding are in the Mountain and Pacific states (U.S. census regions). In the Pacific states in 2001, 82.9% of newborns were breastfed in-hospital, and 44.2% of infants were breastfed at 6 months (Ryan et al., 2002).

These rates are higher than the 1996 rates (75.1% and 30.9%, respectively for in-hospital and at 6 months age) reported in the prior guidelines. In addition to geographic differences, breastfeeding patterns vary considerably with maternal age and education, race/ethnicity, and economic status (National Research Council, 1991; Ross Products Division, Abbott Laboratories, 1996).

5A-2.2 The National Immunization Survey

The National Immunization Survey is conducted annually with approximately 35,600 questionnaires completed each year. Beginning July 2001 and continuing through December 2002, a sample of respondents was asked about breastfeeding using a set of breastfeeding questions. Starting January 2003, all respondents to the household telephone survey were asked these breastfeeding questions.

The NIS uses random-digit dialing to survey households about childhood immunization for children aged 19–35 months of age. The response rates for NIS years 2001–2006 ranged from 64.5% to 76.1%. Because children are 19–35 months of age at the time of the parent interview, each survey year represents children born sometime during a three calendar year period (Table A2 in NIS report). All analyses were conducted using statistical software that accounts for complex sample design. A more detailed description of the methods can be found at http://www.cdc.gov/nis.
Three modifications were made to the breastfeeding questions in 2004 and 2006. Only the change in January 2006 to Question 3, which consisted of asking the one question as two separate questions, resulted in significant effects on the prevalence rates (i.e., yielded significantly lower estimates of exclusive breastfeeding). Because of this large effect, the trends of exclusive breastfeeding by year of birth are shown separately for children whose caregivers were interviewed before and after January 2006.

Advantages of the NIS study include the relatively high response rates, California-specific data, and the inclusion in the survey of specific questions regarding the consumption by the infant of other foods or liquids in addition to breast milk. A disadvantage is the lengthy time interval between when the infant was breastfed and when the parent was asked questions pertinent to breastfeeding that infant, which may lead to inaccuracies in recall.

Table 5A-5 Prevalence of breastfeeding in the United States by birth year (percent ± ½ of confidence interval)

Age	Year					
	1999	2000	2001	2002	2003	2004
Early postpartum	68 ± 3	71 ± 2	71 ± 1	71 ± 1	73 ± 1	74 ± 1
At 6 months	33 ± 3	34 ± 2	37 ± 1	38 ± 1	39 ± 1	42 ± 1
At 12 months	15 ± 2	16 ± 2	18 ± 1	19 ± 1	20 ± 1	21 ± 1

* Exclusive breastfeeding information is from 2006 NIS survey data only and is defined as only breast milk — no solids, water, or other liquids.
* percent represents the proportion of infants
* Source: National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services

Table 5A-6 Prevalence of Breastfeeding California Infants by Birth Year and Type of Breastfeeding (percent ± ½ of confidence interval)[1]

	N	Ever Breast-fed	Breast-fed at 6 Months	Breast-fed at 12 Months	N	Exclusive Breast-fed[2] at 3 Months	Exclusive Breast-fed[2] at 6 Months
Born in 2004	1702	83.8 ± 3.3	52.9 ± 4.3	30.4 ± 4.0	1438	38.7 ± 4.5	17.4 ± 3.5
Born in 2003	1688	83.8 ± 3.2	49.3 ± 4.0	26.6 ± 3.5			

[1] percent represents the proportion of infants
[2] Exclusive breastfeeding information is from 2006 NIS survey data only and is defined as only breast milk — no solids, water, and other liquids.
* Source: National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services

5A-2.3 California Newborn Screening Program (MCAH, 2007)

In-hospital infant feeding practices in California are monitored using data collected by the Newborn Screening (NBS) Program. All non-military hospitals providing maternity services are required to complete the Newborn Screening Test Form prior to an infant's discharge. In addition to tracking genetic diseases and metabolic disorders, the NBS program gathers data on all infant feedings from birth to time of collecting the specimen for the genetic disease/metabolic disorder. The Maternal, Child and Adolescent Health (MCAH) Program staff, of the California Department of Public Health, analyze these data and publish the in-hospital breastfeeding rates (accessible at: http://www.cdph.ca.gov/data/statistics/Pages/BreastfeedingStatistics.aspx).

In September 2007, the MCAH published rates using 2006 Newborn Screening Program data. The prevalence rate for any breastfeeding in-hospital was 86.5% of mothers, while the rate of exclusive breastfeeding was 42.8%. The relatively low exclusive breastfeeding rate is only applicable to the in-hospital stay and not to the later period at home. This is because infants frequently receive some formula while in the hospital to prevent infant hypoglycemia which may result from an inability of the infant to properly nurse (e.g., latch on) initially or from the mother not producing sufficient milk for nursing yet.

5A-2.4 Hammer et al. (1999)

Hammer et al. (1999) prospectively studied the feeding patterns of 216 infants in the San Francisco Bay area from birth through weaning. Information on infant feeding practices was collected via an Infant Feeding Report form completed by the mother for a 3-day period at the end of every month. Parent-infant pairs were recruited from the well newborn nurseries at a university hospital, community hospital, and health maintenance organization (HMO). The parents' intention to feed the infant by a particular feeding pattern (e.g., bottle feeding) was not considered in selecting infants for the study.

Investigators or their staff in the laboratory did not give information or advice on feeding practices to parents, and all infants received routine health maintenance care from local physicians or clinics. Thus, the feeding patterns for these infants were not dictated by the study but instead are likely to have reflected prevalent feeding patterns in the general infant population of the SF Bay area. These patterns are likely to also be applicable to similar areas (e.g., urban) in California.

5A-2.5 Taylor (2006)

Taylor et al. (2006) analyzed data of singleton children of primiparous mothers from the 2002 National Survey of Family Growth. The data set included information on 3229 mother-child pairs when the child was 1-18 years of age. Women were asked if they had breastfed their child, and, if so, the number of completed weeks. A limitation of this study is the sometimes lengthy interval between infancy and when the mother was asked about infant feeding practices. An advantage of this study is the inclusion of only primiparous women, which is consistent with the assumption of the child being from a primiparous mother in these guidelines.

5A-2.6 Summary of Prevalence Data

Breastfeeding prevalence rates from the above studies are summarized in Table 5A-7, below. For the Ross Mothers Survey, rates for the Pacific region are presented because the Pacific region better represents California than the entire U.S.

Table 5A-7 Prevalence of Breastfeeding

Study	NIS [1]	Ross Mothers Survey [2] (Pacific region)	New Born Screening Program [3]	Hammer et al. (1999) [4]	Taylor et al. (2006) [5]
Study Background					
Sample Size	1702	39,600 (estimated 1999 sample size)	506,442	175	3229 primiparous, singleton
Geographic Region	U.S.	Pacific region	California	SF Bay Area, northern CA	U.S.
Year	2004	2001	2006	1997-1998 (presumed)	2002 (interview)1986-2001(birth year)
Percent of Infants Breastfeeding – Any Breastfeeding Pattern					
Ever breastfed	83.3%			90%	62%
In-hospital		82.9%	86.5%		
At 3 months					36%of all infants,58% of those who ever breastfed
At 6 months	52.9%	44.2%		48%	23% of all 38% of those who ever breastfed
At 12 months	30.4%			19%	6% of all,13% of those who ever breastfed

Table 5A-7 Prevalence of Breastfeeding (Cont.)

Study	NIS [1]	Ross Mothers Survey [2] (Pacific region)	New Born Screening Program [3]	Hammer et al. (1999) [4]	Taylor et al. (2006) [5]
Study Background					
Sample Size	1702	39,600 (estimated 1999 sample size)	506,442	175	3229 primiparous, singleton
Geographic Region	U.S.	Pacific region	California	SF Bay Area, northern CA	U.S.
Year	2004	2001	2006	1997-1998 (presumed)	2002 (interview)1986-2001(birth year)
Percent of Infants Breastfeeding - Exclusive Breastfeeding					
In-hospital		54.2%	42.8%		
At 2 months				31%	
At 3 months	38.7%				
At 6 months	17.4%	24.1%		14%	
At 12 months				7% ("sole breast-feeding")	

[1] National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services
[2] Ryan et al. (2002)
[3] MCAH of the California Department of Public Health
[4] fed directly from the breast, does not include feedings from a bottle of breast milk
[5] data from the National Survey of Family Growth (2002)

5A-2.7 Trends in Breastfeeding at Early-postpartum, 6 month, and 12 Month Ages

The Ross Mothers Survey, National Immunization Survey, National Survey of Children's Health, and Hammer et al. (1999) collected data on the prevalence of breastfeeding at various times of the lactation period, and thus provide information on the initiation and duration of breastfeeding. The California Newborn Screening Program only provides information on in-hospital infants (i.e., initiation of breastfeeding).

The Ross Mothers Survey showed increases in breastfeeding both for in-hospital and at 6 months age between 1993 and 2003 for California (Mothers Survey, Ross Products Division of Abbott (2004) (Table 5A-8). It is of note that the in-hospital rate stabilized at about 80% from 1999-2002 but then decreased to 73.9% in 2003. Upon examination of rates for the other states (not shown here), a similar decrease of in-hospital rates occurred for 47 of the other 49 states (the exceptions being Delaware and North Dakota, which were noted as having 'variable' data associated with low sample sizes). A systematic calculation in the rates or a change in hospital policy might be responsible for this decrease. A decrease from 2002 to 2003 is also seen in 6-month rates for California and a little over half of the other states, but the decrease is much less than for the in-hospital rates and possibly not statistically significant. Thus, there appears to be a sudden unexplained decrease in the initiation of breastfeeding but the duration of breastfeeding has not significantly changed.

Table 5A-8 California-specific Breastfeeding Rates from the Ross Mothers Survey*

	In-hospital	At 6 months
1993	69.5	25.8
1994	70.6	27.1
1995	73.2	29.8
1996	72.0	29.4
1997	75.2	35.0
1998	76.9	38.4
1999	79.1	39.1
2000	80.2	40.1
2001	81.7	43.6
2002	79.7	41.7
2003	73.9	39.8

* Source: Mothers Survey, Ross Products Division of Abbott, 2004

The prevalence of infants who are exclusively breastfed at 6 months has also increased according to the RMS data (Table 5A-9, below). However, in-hospital exclusive breastfeeding does not appear to have changed. This might be because the mother's milk has not yet come in or that the infant has not yet learned how to latch on during the short stay in the hospital. Hospital staff may be anxious to feed the infant formula due to concern over hypoglycemia, which can occur very quickly in neonates.

Table 5A-9 Prevalence (percent of infants) of Breastfeeding for the United States from the Ross Mothers' Survey[1]

	Breastfeeding		Exclusive Breastfeeding	
	In-hospital	**At 6 months**	**In-hospital**	**At 6 months**
1994	57.4	19.7	46.8	11.2
1995	58.9	20.8	47.6	11.9
1996	59.2	21.7	47.3	12.2
1997	62.4	26.0	46.1	12.7
1998	64.3	28.6	46.2	13.8
1999	67.2	30.7	46.3	15.8
2000	68.4	31.4	46.0	16.0
2001	69.5	32.5	46.3	17.2
2001 – Pacific Region			54.2	24.1

[1] source: Ryan et al. (2002)

The National Immunization Survey Study (NIS) provides data from 1999 to 2004 for the entire U.S, which is sufficient for the assessment of trend over time. The NIS U.S. data show that from 2001 to 2006 slight to moderate progressive increases in breastfeeding prevalence occurred at the early postpartum period and at 6 and 12 months of age (Table 5A-10). California-specific data are available, but only for 2003 and 2004, which is insufficient for evaluating statistical trends over time (Table 5A.11). However, the data do reveal an increase from 2003 to 2004 in 6- and 12-month prevalence rates for California.

Table 5A-10 Prevalence of Breastfeeding in the United States by Birth Year (percent ± ½ of confidence interval)[1,2]

	Birth Year					
	1999	**2000**	**2001**	**2002**	**2003**	**2004**
Early postpartum	68 ± 3	71 ± 2	71 ± 1	71 ± 1	73 ± 1	74 ± 1
At 6 months	33 ± 3	34 ± 2	37 ± 1	38 ± 1	39 ± 1	42 ± 1
At 12 months	15 ± 2	16 ± 2	18 ± 1	19 ± 1	20 ± 1	21 ± 1

[1] Percent represents the proportion of infants
[2] Source: National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services

Table 5A-11 Prevalence of Breastfeeding for California Infants by Birth Year and Type of Breastfeeding (percent ± ½ of confidence interval)[1]

	N	Ever Breast-fed	Breast-fed at 6 Months	Breast-fed at 12 Months		N	Exclusively Breastfed [2] at 3 Months (2006)	Exclusively Breastfed[2] at 6 Months (2006)
Birth Year 2003	1688	83.8 ± 3.2	49.3 ± 4.0	26.6 ± 3.5				
Birth Year 2004	1702	83.8 ± 3.3	52.9 ± 4.3	30.4 ± 4.0		1438	38.7 ± 4.5	17.4 ± 3.5

[1] Percent represents the proportion of infants
[2] Exclusive breastfeeding information is from interviews in 2006 and is defined as consumption of only breast milk (i.e., no solids, water, or other liquids).
* Source: National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services

Maternal education and age, and family socioeconomic status have been correlated with both initiation and duration of breastfeeding (NIS, National Research Council, 1991; Ross Products Division, Abbott Laboratories, 1996). The NIS data for infants born in 2004 shows that infants were more likely to have ever been breastfed, breastfed at 6 months, or exclusively breastfed if they were born to mothers 30 years of age or older, born to mothers who were college graduates, or born to families at the highest income level studied (i.e., the highest level over the poverty-to-income ratio).

Because the above data demonstrate continued trends towards increases in the initiation and duration of breastfeeding (including exclusive breastfeeding), these trends should be re-evaluated periodically. Factors affecting breastfeeding prevalence, such as maternal age and the promotion of breastfeeding (both discussed below), can help to assess breastfeeding trends.

5A-2.8 Age at Weaning

A few studies have examined the rate of breastfeeding cessation. Maxwell and Burmaster (1993) found that the fraction of infants breastfeeding (f) in the U.S. in 1989 was well described by a negative exponential distribution (e.g., $f = a\, e^{-c\, t}$) with a cessation rate of 0.5% per day for the 0-12 month period. Arcus-Arth et al. (2005) used Ross Mothers Survey data from the year 2000 and found a cessation rate of 0.2027% per day for the 0-6 month period and 0.07563% for the 6-12 month period.

We evaluated data from the National Survey of Children's Health (NSCH, CDC, 2003) to assess age of weaning data that are more recent and that are specific to California. The NSCH is a national survey funded by the Maternal and Child Health Bureau, U.S. Department of Health and Human Services, and administered by the National Center for Health Statistics, Centers for Disease Control and Prevention. The survey collects data on national and state-level prevalence of a variety of physical, emotional, and behavioral child health indicators, including the age at which the child was completely weaned from breast milk.

The survey uses the State and Local Area Integrated Telephone Survey, which provides a consistent means to collect data across states. Phone numbers are selected randomly to identify households with one or more children less than 18 years of age. For these households, one child is randomly selected for inclusion in the study. Over 102,350 surveys were completed for children 0-17 years of age.

Survey results are weighted to represent the population of non-institutionalized children 0-17 years of age on both national and state levels. For the question on the age of weaning from breast milk, NSCH used only data from mothers whose children were 0-5 years of age at the time of interview. The reported age at weaning was reported as age intervals rather than age points.

These age intervals were <3, 3-6, 7-12, and over 12 months of age. Some women were still breastfeeding their child at the time of interview so it is unknown when these children were weaned. Data were available specific to California, with the most recent year being 2003. Results were based on those infants who were fed breast milk (versus based on all breastfed plus non-breastfed infants).

The NSCH Data Resource Center provides a website with an interactive data query feature for hands-on access to the survey data (http://www.nschdata.org/DataQuery/SurveyAreas.aspx). We used the website query system to assess age at weaning in California, by selecting "Survey Sections", then "California", "2003" and "Early Childhood", then "at what age did young children completely stop breastfeeding? (S6Q60 -- ages 0-5 who have been breastfed)." Results are presented in Table 5A-12, below.

Table 5A.12 Age interval when completely weaned from breast milk – California Infants[1]

	< 3 months	3-6 months	7-12 months	> 12 months	Total
Percent of breastfed infants[2]	19.9	30.2	31.3	18.6	100
Sample size	118	179	185	110	592

[1] Data from the National Survey of Children's Health from 2003
[2] Excluding those still breastfeeding at time of interview

To evaluate the distribution of breast milk weaning age in California we used the data in Table 5A-13 and applied simulation and curve fitting functions in Crystal Ball version 7.2.1 (Decisioneering, 2007) to find the best-fit distribution and to identify distributional parameters. We excluded infants (N=67) who were still breastfeeding at the time of interview, and adjusted the remaining data (i.e., percent weaned, N=592) to account for the exclusions. We found that the data best fit a gamma distribution with location = -0.17, scale = 3.60, and shape = 2.41464. The median age of weaning was 7.0 months and 75% of infants were weaned by 12 months, 90% by 16 months, and 95% by 18 months of age. It is noteworthy that a significant percentage of infants can be considered extended breast feeders (i.e., breastfed past 12 months of age). Our results are presented in Table 5A.13.

Table 5A.13 Mean and percentiles of the parametric model of age at weaning from breast milk for California infants in 2003 (in months) [1,2]

	mean	50%-ile	75%-ile	90%-ile	95%-ile
Weaning age (months)	8	8	12	16	18

[1] derived by OEHHA from the National Survey of Children's Health 2003 data
[2] excludes infants still breastfeeding at time of interview with mother

Other studies that provide information on the cessation of breastfeeding (weaning) include Hammer et al. (1999) (described above in Section 5A-2.4 and Rempel (2004). These two studies are summarized in Table 5A-14, below.

The Rempel (2004) study followed a cohort of Canadian mother-infant pairs from birth until 12 months of age. Of the 317 mothers who agreed to participate in the study, 289 initiated breastfeeding. The results are based on the 289 infants that breastfed. At 9 months of infant age, 27% of infants were still consuming some breast milk and 14% of the original 289 weaned between 9 and 12 months. Though the Rempel (2004) study involved Canadian mother-infant pairs, the results are likely similar to similar subpopulations in the U.S.

The mothers in the Rempel study were from Ontario (a fairly large cosmopolitan city), 16-42 years of age, had a mean +/- SD number years of education of 15 ± 2.8, 59% were employed full-time, 16% were employed part-time, 67% were married, 13% were born outside Canada. According to the authors "the participants represented a wide variety of cultural backgrounds." These demographics may be similar to some subpopulations of women in California cities.

Table 5A.14 Age at Weaning

Study	N	Infants Studied	Infant Age at Weaning (month)	Year(s) of Study	Comments
Hammer et al. (1999)	175	General population	Median: 6.0 Range: 0.9-39.1	1996-1998 (approx)	SF Bay area
Rempel (2004)	312	General population	13% weaned between 9 &12	1999-2000	Canada

5A-3 Subpopulations of Special Concern

5A.3.1 Infants Breastfed for an Extended Period of Time

Documentation of extended breastfeeding is quite limited in this country both because there is little socio-cultural support for extended nursing (Stein et al., 2004) and because many health care practitioners do not consider asking about it (Sugarman and Kendall-Tackett, 1995). However, recent increases in the duration of breastfeeding (see Section 5A-2.7, above) as well as efforts by public agencies and the American Academy of Pediatrics to promote and support breastfeeding would suggest that the number (and proportion) of infants being breastfed beyond the first year of life may be increasing as well. Few studies have evaluated information on extended breastfeeding. These studies are described, and summarized in Table 5A-15, below.

Sugarman and Kendall-Tackett (1995) found that among a group of American women (n = 179) who breastfed past 6 months of infant age, the age of weaning averaged between 2.5 and 3.0 years, with a high end value of 7 years 4 months. Forty-three percent of children in this sample (i.e., breastfed past 6 months) were breastfed beyond their third birthday. The researchers also found in examining mothers who breastfed more than one child past 6 months of age, that in subsequent lactations the younger children were breastfed for longer periods of time than the older child(ren) had been.

Dettwyler (2004) reported results of an informal survey of children who were breastfed for periods greater than 3 years. The sample included 1280 children, most during the 1990s, but some in the 1980s and earlier. The average age at weaning was 4.24 years, with a median of 4.00, a mode of 3.50, and a standard deviation of 1.08 years. Close to half of the children weaned between 3.00 and 4.00 years of age.

Children whose weaning was characterized as “child led” weaned at an average age of 4.39 years, whereas those whose weaning was characterized as “mother led” were weaned at an average age of 3.83 years. The mothers were most often middle-class and upper-class, worked outside the home, and highly educated. More than 50% of the mothers were college graduates, and the sample included numerous women with advanced degrees. Of those who responded to the question on ethnicity of the mother, most said they were European-American. These characteristics mirror those found in previous studies of extended breastfeeding in the U.S. (Sugarman and Kendall-Tackett, 1995).

Although most infants in California are weaned during their first year (see Table 5A-14, above)), there is a subpopulation of infants who are breastfed for an extended period. The Hammer et al. (1999) study (see description in Section 5A-2.8, above), which did not seek to identify extended breastfeeding infants, demonstrates that extended breastfeeding may be more prevalent than is commonly thought. Of the 175 infants who were breastfed, the oldest age at complete weaning from the breast was 39.1 months (extended breastfeeding).

Table 5A.15 Age at Weaning for Extended Breastfeeding Infants

Study	N	Infants Studied	Infant Age at Weaning	Year(s) of Study	Comments
Dettwyler (2004)	1280	Infants breastfed to at least 3 years	Mean: 4.24 yrs Median: 4.0 yrs SD: 1.08	1995-2000	U.S.
Hammer et al. (1999)	175	General population	Median: 6.0 mos Range: 0.9-39.1 mos	1996-1998 (presumed)	SF Bay area
Sugarman and Kendall-Tackett (1995)	134	Infants breastfed to at least 6 months	Mean: 2.5-3.0 yrs Range: 6 mo - 7 yrs 4 mos 43% breastfed past 3 yrs	1989-1991	U.S.

Immigrants to the U.S. may be more likely to practice extended breastfeeding, if they retain breast feeding practices from the home country. The 2003 joint WHO/UNICEF released a joint recommendation in 2003 that advocates exclusive breastfeeding for the first 6 months followed by breastfeeding with supplementation of complementary foods for at least the first two years of life (UNICEF/WHO, 1990). In the study by Buckley (2002), ten Hispanic mothers from Caribbean, South American or Central American countries, residing in the U.S. who breastfed their infant(s) beyond one year of age, stated that breastfeeding a child up to 4 years of age was common in their countries of origin.

Stein et al (2004) report a personal communication with Anne Seshadri (2002) who states “mothers in India frequently breastfeed their infants until 3 or 4 years of age”. Immigration into the U.S. from locations, where extended breast feeding is practiced such as Hispanic countries and India, could cause an overall increase in the incidence of extended breastfeeding.

Currently there are little data on the composition of breast milk during extended breastfeeding. Studies have found that when milk volume decreases (e.g., near the time of weaning) that lipid content increases, while other studies have found the opposite result. It would be helpful to know the lipid content of breast milk during extended breastfeeding to better understand the importance of lipophillic chemical transfer to an extended breastfed infant.

Exposures to infants who are breastfed for an extended period should be further investigated and could potentially be taken into account in non-default analyses. See Appendix J for a more detailed discussion about the accumulation and transfer of chemicals in maternal body tissue and its potential impact on extended breastfed infants.

5A-3.2 Infants of Older Mothers

Older primiparous mothers have longer to accumulate toxicants with long body tissue half-lives (i.e., more than six years) and could therefore eliminate more toxicant to their breast milk than younger mothers would. Furthermore, older mothers tend to breastfeed for a longer duration than younger mothers do (Section 5A.3.1, above). Both conditions could lead to higher dosing of primiparous infants from the breast milk of older mothers than of infants from younger primiparous mothers’ breast milk.

Many chemicals will reach a steady state in the mother’s body before age 25. On the other hand, other substances do not reach steady state within 25 years. For example, lead continues to accumulate in cortical bone over the human lifetime (O’Flaherty 1998). Thus, women giving birth after 25 years of age will have accumulated greater amounts of lead that can be passed to the infant in breast milk relative to mothers 25 years of age and younger.

Older mothers tend to initiate breastfeeding of their infants and breastfeed for longer periods of time. Because substances such as lead can accumulate in maternal tissues past the default 25 years for exposure to facility emissions before birth of a child, it is important to consider maternal age in assessing infant exposure to such toxicants via breast milk.

<u>5A-3.2.1 Breastfeeding Practices of Older Mothers</u>

In Section 5A-2.1, we provide background on the Ross Mothers Survey and the NIS. These surveys have consistently found that both the initiation and duration of breastfeeding increased with maternal age. The Ross Mothers Survey data (Table 5A-

16) show an increasing trend from 1996 to 2001 of older mothers to initiate breastfeeding and to continue to breastfeed for at least 6 months. The NIS data (Table 5A.17) show that older mothers are more likely to breastfeed and to exclusively breastfeed through 6 months in accordance with AAP recommendations (NSCH, 2007).

Table 5A-16 Prevalence (percent) of Breastfeeding by Maternal Age, Ross Mothers Survey

	Maternal Age				
	<20 years	20-24 years	25-29 years	30-34 years	≥35 years
In-hospital					
1996	43	53	62	68	69
2001	57	66	73	76	76
At 6 months					
1996	10	15	23	29	34
2001	20	26	35	42	44

* Source: Ryan et al. (2002)

Table 5A-17 Prevalence (percent) of Types of Breastfeeding by Maternal Age, Infants born in 2004

	Maternal Age		
	<20 years age	20-29 years age	>=30 years age
Ever Breastfeed	53	69	77
Breastfeed at 6 months	18	31	46
Breastfeed at 12 months	6	15	24
Exclusively breastfed at 3 months	17	26	35
Exclusively breastfed at 6 months	6	8	14

* Source: National Immunization Survey, Centers for Disease Control and Prevention, Department of Health and Human Services

5A-3.2.2 Prevalence of Older Women Giving Birth in California

There is an increasing trend toward older women giving birth in California. Births to women 35 years of age and older showed a progressive increase from 1990 to 2006 (Table 5A-18, below) (CDPH, 2006).

Table 5A-18 California Births by Maternal Age and Year of Birth (percent of total births for that year)

	Maternal Age		
	35-39 years	**40-44 years**	**>=45 years**
1990	9	1.6	0.07
1995	11	2.3	0.12
2000	13	2.9	0.18
2006	14	3.3	0.25

Data source: California Department of Public Health, birth records

It should be noted that the above data are for maternal age at primiparous and multiparous births. Data on primiparous-only births are not readily available. For some lipophilic toxicants, primiparous birth is an important parity as this can be when the greatest amount of toxicant may be excreted in the mother's breast milk, and the mother's body burden is reduced, thus lowering the dose to subsequent children.

Increases in maternal age may continue due to the increasing use of in-vitro fertilization for older women, though such increases are likely to be very small relative to the population of women giving birth.

5A-3.3 High-end Consumers

Under certain circumstances, information on individuals exposed at very high levels is of interest. For assessing high-end exposures, Table 5A-19 may be of use. It provides upper-end breast milk and lipid intake rate estimates for the breastfeeding population.

Table 5A-19 Intake estimates for the breastfeeding infant population

	Breast Milk Intake[1] (g/kg-day)		Lipid Intake[2] (g/kg-day)	
	6 month average	**1 year average**	**6 month average**	**1 year average**
99^{th} percentile	179	155	7.1	6.2

[1] From Arcus-Arth et al. (2005)
[2] From correspondence with author (Arcus-Arth et al.) and based on lipid intakes at 3 and 6 months

Arcus-Arth et al. (2005) found that the rate of breast milk intake was highest during the second week of life. At this age, when susceptibility to certain toxicants is high, the mean intake is 160.6 g/kg-day and the 99^{th} percentile is 257.8 g/kg-day.

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