Table 2
Percent of Children and Adults by Race

Race	Children	Adults
White	85	88
Black	9	9
Asian	3	1
Multi-Racial	4	1
Total	100	100

Notes: Asian includes Filipino, Indian, Arabic. Multi-Racial includes all categories where more than one race was mentioned. Respondents could mention up to three racial groups. Don't Know, Refused and Other allocated proportionately among White, Black, Asian and Multi Racial. Individuals who chose Hispanic as a race were allocated to White and Black in proportion to the 2000 Census proportions of 97 percent white and 3 percent Black. Based on 551 responses. Totals may not add due to rounding.

In responding to a question as to whether they were of Hispanic origin (in addition to the race question above), 19 percent of adults in the sample said they were Hispanic. The respondents reported that 17 percent of the children were Hispanic.

Data Analysis and Results for Phase I

The mouthing data collected in Phase I from the parents is independent from the data collected in Phase II and therefore will be analyzed and reported on in a separate report[7].

Data Analysis for Phase II (See Appendix B for in-depth report)

For purposes of data analysis, all objects that the subjects mouthed were categorized into an object taxonomy consisting of 13 categories and subcategories. Of special interest for this study were the items classified as soft plastic toys because these items could contain a plasticiser such as DINP. Estimated mouthing times related to these objects are the closest to estimating the amount of time that children are at risk from oral ingestion of these chemicals. DINP is not presently found in Teethers and Rattles; however, estimates based on All Soft Plastic Toys and Teether/Rattles represent the amount of DINP ingestion that might occur if DINP was used in Teethers and Rattles.

Exposure time was defined as the length of time that a child was awake and not eating. This is the time that a child has available to mouth objects. It is necessary to operationally define exposure time in order to extrapolate from the four hours of mouthing observations per child to a measure of mouthing behavior based on a full day. During the second telephone contact, parents were asked to list the times that the child usually woke up on a weekday and went to sleep at night. They were also asked to list the duration of naps, meals and snacks. From this information, exposure time can be calculated as:

[7] Greene, M (2002) "Mouthing Times and DINP Risk for Children Three Years of Age and Older." U.S. Consumer Product Safety Commission, Bethesda, MD.

Exposure Time = Time Child went to sleep – Time Child Woke Up
- Meal Durations - Nap Durations

Meal durations includes snacks.

Average hourly mouthing times were calculated from the two-hour observation period for all the children. The average daily mouthing times were calculated by multiplying the time awake (in hours) by the average hourly mouthing time.

Results

There were 20,807 individual mouthing events recorded from the 169 children observed by the trained observers, for an average of 123 events per child (standard deviation = 73, median =115). The smallest number of observed events was 11, while the maximum was 342.

Estimated average exposure time was about 10 hours for children under 2 and 10.7 hours for children between 2 and 3 years of age. Chart 1 shows that for all objects except pacifiers, estimated average daily mouthing times (which accounts for exposure) were 70 minutes (95% confidence interval 60-80 minutes) for children between 3 months and 1 year of age, 48 minutes (40-57 minutes) for children between 1 year and 2 years, and 37 minutes (27-39 minutes) for children between 2 and 3 years of age.

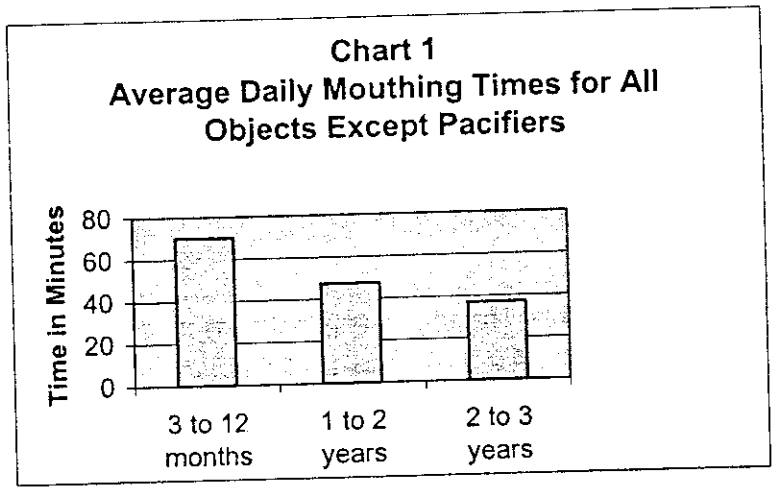


Table 3 contains the average hourly mouthing time by age and object category. The data are not corrected for exposure time (i.e., the length of time available for the child to mouth items). The distribution of mouthing times displayed positive skewness, which means there were only a few children with long mouthing times. In particular, for categories that contained few objects such as All-Soft Plastic objects or Soft Plastic toys, there were many observations where the child did not mouth any items in these categories during the observation period.

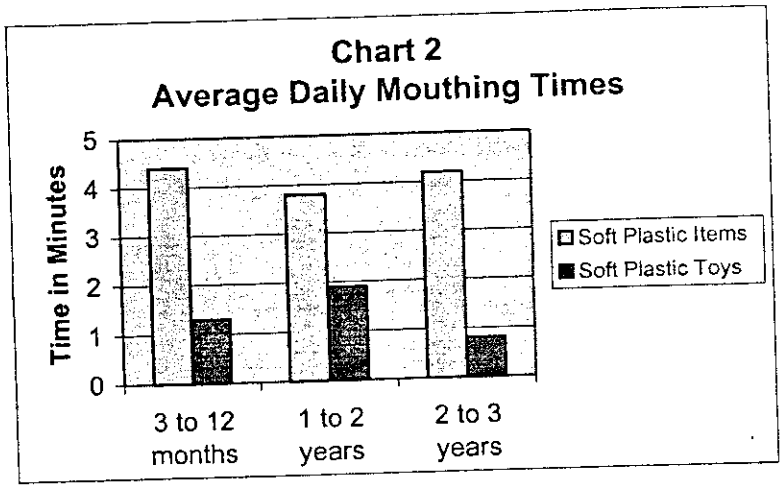
Table 3
Average Mouthing Time in Minutes Per Hour
By Object Category and Age

Object Category	Age			
	All Ages	Under 1 year	1-2 years	2-3 years
All Objects	7.74	10.50	7.33	5.25
Pacifiers	2.61	3.36	2.64	1.76
Non Pacifiers	5.13	7.14	4.69	3.49
All Soft Plastic Items	0.40	0.45	0.38	0.39
Soft Plastic Items Not Food Contact	0.29	0.41	0.27	0.20
Soft Plastic Toys, Teethers and Rattles	0.21	0.32	0.20	0.09
Soft Plastic Toys	0.13	0.13	0.18	0.07
Soft Plastic Teethers and Rattles	0.07	0.19	0.02	0.02
Other Soft Plastic Items	0.09	0.10	0.07	0.11
Soft Plastic Food Contact Items	0.11	0.04	0.11	0.19
Anatomy	1.78	2.39	1.69	1.21
Non Soft Plastic Toys, Teethers and Rattles	0.85	1.77	0.56	0.21
Other Items	2.10	2.53	2.06	1.68

Source: Greene (2001) " Mouthing Times Among Young Children From Observational Data"
Notes: Based on 169 children; 54 less than 1 year old, 66 at least 1 year old but not 2 years and 49 between 2 and 3 years. Note that the age in this table is measured at the time that the observational study was completed. Note also that the oldest age endpoint is not included in the group. Other Items includes non-soft plastic food contact items (tableware, drinking cups, bottle nipples), furniture, clothing and miscellaneous items.

Table 3 shows that average hourly mouthing time decreases with increasing age. For example, children under 1 year mouth all objects an average of 10.5 minutes per hour, which drops to 5.25 minutes per hour for children between 2 and 3 years. Among objects mouthed, pacifiers represent about one third of the total mouthing time, with 3.36 minutes per hour for the youngest children, 2.64 minutes per hour for children between 1 and 2 years and 1.76 minutes for children over 2 years old. The next largest single item category is anatomy, representing children sucking fingers and thumbs. This is 2.39 minutes for the youngest children and declines to 1.2 minutes for the oldest children.

Most of the objects in the non-pacifier category were not soft plastic items. The items classified as "All Soft Plastic Items" are items that could contain DINP. This category represents less than half a minute of mouthing time per hour for each age group. Soft plastic toys were mouthed only a relatively small fraction of time. Chart 2 below shows estimated average daily mouthing times for soft plastic items and soft plastic toys. The daily average mouthing times for soft plastic toys were 1.3 minutes (0.7- 2.0 minutes) for children between 3 months and 1 year, 1.9 minutes (1.2 – 2.6 minutes) for children between 1 and 2 years and 0.8 minutes (0.3 – 1.6 minutes) for children between 2 and 3 years of age. The daily average mouthing times for all soft plastic items were as follows: 4.4 minutes (3.0 – 6.1), 3.8 minutes (2.8 – 4.9) and 4.2 minutes (2.5-6.1) for children under 1 year, 1-2 years and 2-3 years respectively.



There is a significant relationship between mouthing duration and age for Soft Plastic Teethers and Rattles. While a small number of children were observed mouthing these items, most of these children were between 4 and 16 months, with only one child over 16 months. The maximum mouthing times for these items were for children who were under 1 year. On the other hand, soft plastic toys did not show a decreasing mouthing pattern with age, but rather had about the same level of mouthing between 6 months and 24 months, then almost no mouthing for children over 24 months.

The data in Table 3 include children who did not have any object mouthing time during the four-hour observation period for some object categories. In Table 4, the percent of children who were observed mouthing objects by the category of object is shown.

Table 4
Percent of Children Mouthing Toys by Category

	Age			
Object Category	All Ages	Under 1 year	1-2 years	2-3 years
All Objects	100	100	100	100
Pacifiers	27	43	27	10
Non Pacifiers	100	100	100	100
All Soft Plastic Items	80	78	88	73
Soft Plastic Items Not Food Contact	72	76	76	61
Soft Plastic Toys, Teethers and Rattles	57	61	61	47
Soft Plastic Toys	50	43	58	47
Soft Plastic Teethers and Rattles	14	30	9	2
Other Soft Plastic Items	43	46	47	35
Soft Plastic Food Contact Items	28	13	30	41
Anatomy	99	100	97	100
Non Soft Plastic Toys, Teethers and Rattles	91	94	91	86
Other Items	98	98	97	98

Notes: See table 3.

Table 4 shows that during the observation period, every child was observed putting some object in his or her mouth. Children who mouthed pacifiers also mouthed other objects, as shown in the 100 percent values for non-pacifiers. Almost all of the children mouthed fingers and skin as shown in the values for anatomy. Between 73 and 88 percent of children (depending on age) mouthed some soft plastic item. Overall about 50 percent mouthed soft plastic toys, varying between 43 and 58 percent, depending on age. Pacifier use was 43 percent for children under a year, 27 percent for children between 1 and 2 years and 10 percent for children over 2 years.

Discussion

This study was undertaken to estimate children's exposure to phthalates as a result of mouthing soft plastic toys. The data from the 169 children observed by the trained observers confirmed that children mouth such items but at a very low rate. In 1998, to estimate risk of potential exposure, CPSC used the Dutch daily mouthing duration data which estimated a geometric mean of 12 minutes for 3 –12 month olds and 2 minutes for 13-26 month olds for teethers, rattles, and toys. Based on these data, CPSC concluded that few, if any, children were at risk from liver or other organ toxicity from the release of DINP from soft plastic toys. However, CPSC staff recommended performing this more precise study to obtain a broader range of data to better define the amount of time children mouth products that could contain phthalates. These new data show that for soft plastic toys, the daily average mouthing times were 1.3 minutes for children between 3 months and 1 year, 1.9 minutes for children between 1 and 2 years and 0.8 minutes for children between 2 and 3 years of age. One reason for the differences in mouthing times is because the Dutch study's data represent mouthing of teethers, rattles and soft plastic toys but the new CPSC data represent mouthing times of soft plastic toys only. Teethers and rattles sold in the United States are not made with phthalates and therefore were not included in the mouthing times used to estimate phthalates exposure.

As with the previous studies conducted, this study demonstrated that children mouth a wide variety of items, those both intended to be mouthed and not intended to be mouthed. Because this study sample was conducted in two large metropolitan areas that were geographically diverse, and the subjects were ethnically and demographically diverse, the data can be used to project potential exposure to a larger population than just the subject sample. In addition, these data may be more accurate than from previous studies of frequency and duration of repeated mouthing behaviors because the trained observers used stopwatches that recorded and stored the separate mouthing events. The observer was able to click the stopwatch on and off as quickly as the child mouthed the object, which frequently lasted only seconds. In Juberg's study, the parents were told to record mouthing times to the nearest minute.

Children's mouthing behavior has been viewed as a part of childhood development. With these data, CPSC can develop better exposure data for potential ingestion hazards. The extensive data and diversity of the sample allows CPSC staff to make hazard assessments across a wide variety of consumer products.

Acknowledgement

CPSC staff wants to sincerely thank the parents and families who participated in this exhaustive study by conducting observations themselves and/or permitting the trained observers to come into their homes to conduct these observations. We especially want to thank S. Luhrs, B. Ridenour, T. Weeks, and T. Wiseman Brown who collectively conducted 67% of all the observations. As author of this paper, I want to personally extend my deepest gratitude to my co-worker, Timothy P. Smith, for all his tremendous help with the project, especially while I was on both of my maternity leaves.

References

CPSC (1998), *The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products.* U.S. Consumer Product Safety Commission, Bethesda, MD.

CPSC (2001), *Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP).* U.S. Consumer Product Safety Commission, Bethesda, MD

Groot, ME, Lekkerkerk, MC, and Steenbekkers, LPA, (1998). *Mouthing Behavior of Young Children: An Observational Study.* Wageningen Agricultural University, Household and Consumer Studies. Wageningen, The Netherlands.

Juberg, DR, Alfano, K, Coughlin, RJ, and Thompson, KM, (2001). "An Observational Study of Object Mouthing Behavior by Young Children," Pediatrics 107, 1, pp 135-141.

Smith, TP, and Kiss, CT, (1998), "Empirical Observations of Children's Mouthing Behaviors: Baseline Frequencies and Durations." U.S. Consumer Product Safety Commission, Bethesda, MD.

Appendix A – Phthalate Observational Study & Telephone Study: Telephone Study Implementation Report

Phthalate Observational Study & Telephone Study:

Telephone Study Implementation Report

Contract No. CPSC-C-99-1150 – Task Order No. 0001

August 2001

Prepared for:

William Zamula
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814-4407

Prepared by:

ORC Macro
126 College Street
Burlington, VT 05401

Chapter I: Study Overview

1.1 Project Background

The U.S. Consumer Product Safety Commission (CPSC) has been concerned with the potential exposure and health risks to children under 6 years of age who "mouth" objects (e.g., teethers, rattles, and toys) that contain polyvinyl chloride (PVC) with various dialkyl phthalate (DAP) plasticizers, such as diisononyl phthalate (DINP). Manufacturers use DAP plasticizers to soften PVC. A preliminary CPSC study (1998)[1] concluded that children's exposure to ingested DINP did not reach harmful levels and, as a result few children were at risk of toxicity from mouthing PVC toys that contain DINP. However, CPSC staff noted that this study did not adequately account for two important factors that may influence phthalate exposure:

1. Potential variations in the specific types of objects mouthed by children and the intensity with which children mouthed these objects.
2. The duration of time children mouthed certain objects containing phthalates.

A separate study conducted by the Dutch Consensus Group[2] also suggested that mouthing behavior frequency and duration was more intense among very young children (i.e. between 3 and 27 months). However, the study did not clearly identify the age at which intense mouthing behavior by children subsides. These results supported the CPSC's interest in acquiring additional data on children's mouthing behavior and their exposure to phthalates.

[1] U.S. Consumer Product Safety Commission. (1998) "The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products." Washington D.C.
[2] Groot, M.E., Lekkerkerk, M.C., and Steenbekkers, L.P.A. (1998). "Mouthing Behavior of Young Children." Agricultural University Wageningen, Wageningen, The Netherlands.

1.2 Project Objectives & Scope

Data from the initial CPSC and Dutch Consensus Group studies indicate a need for further research on phthalate exposure among children. In response to this need, CPSC instituted the Observational Study on Children's Mouthing Behavior. This study had two primary objectives:

1. To determine the proportion of children at each age who mouth toys and other objects.
2. To quantify the amount of time per day young children (i.e., under the age of 3 years) spend mouthing objects, including items that include phthalates.

CPSC concluded that behavioral observations with a nationally representative sample of children under the age of 6 were required to provide data to inform these two objectives. To this end, the Observational Study was designed to encompass three data collection phases:

1. An initial telephone survey to recruit households with children under 6 years of age for study participation and future observation by parents and trained observers.[3]
2. A parent observation study in which parents were asked to observe their child for four 15-minute time periods and to keep a diary of their child's mouthing behavior during these periods. A follow-up telephone survey was conducted with these parents to collect the information contained in the diary.
3. In-home child observations by trained observers. This portion of the study was only conducted with children less than 36 months of age.

[3] A random digit dial (RDD) approach was used for this telephone survey to ensure all households with telephones and children less than 6 years of age in selected geographic areas would have an equal probability of selection.

CPSC selected a contractor to conduct the Observational Study in two cities, subject to the constraints that the cities should be located in different regions of the country and that between the two cities there should be enough demographic diversity to allow sampling that would reflect national averages. The contractor proposed to conduct the study in Chicago, IL and Houston, TX. Given the need for in-home observations, conducting the study on a national scale would not be cost effective. Survey samples in both metropolitan areas were developed to ensure demographic representation (e.g., race/ethnicity, rural/urban geography) that reflected national characteristics.

1.3 Summary of Telephone Survey Operations

Over an 11-month period, ORC Macro recruited 1,745 households with at least one child under the age of 6 years for study participation using an RDD methodology. A specific child was randomly selected in households that had more than one child in the home. A total of 115,289 households were screened for study participation.

Of the recruited households, 491 families participated in the parent observation study. It is important to note that the parent observation portion of the study was dropped for later study participants, based on parental complaints about the level of effort required to observe their child and keep a diary of his/her behavior.

1.4 Contractor Roles

CPSC contracted with ORC Macro to complete the first two data collection phases. A separate contractor, ITS RAM (also known as RAM Consulting), was selected to complete the in-home child observations. ORC Macro assisted CPSC with survey design and implementation tasks, including survey sampling, instrumentation, and telephone data collection related to the first two data collection phases. The following chapters provide additional detail on those tasks completed by ORC Macro; a summary of ITS-RAM's involvement is forthcoming in a separate report.

Chapter II: Survey Overview

CPSC's Observational Study utilized a combination of telephone survey interviewing and in-home child observations as its primary data collection approaches. Initially, telephone surveys were used to screen and recruit eligible households and for the first follow-up with study participants that collected parent observation data. All telephone surveys were conducted using computer-assisted telephone interviewing (CATI) at ORC Macro's CATI Research Center in Burlington, VT. In-home child observations were conducted as the study's third phase, after the follow-up telephone survey. After data collection began, this initial study design was modified to address attrition problems resulting from parents' perceptions of the level of burden associated with study participation.

The following sections provide a detailed summary of the initial and modified data collection approaches used in the Observational Study. This written overview is augmented by Figure 2.1: Overview of Survey Data Collection Approaches, which provides additional information on the overall data collection effort.

2.1 Initial Study Design

The Observational Study's initial design included two telephone survey data collection phases: 1) an initial RDD telephone recruitment survey; and 2) a follow-up telephone survey to collect data from parent's observations. Additionally, parents were mailed a log to record observed mouthing behavior for a specific child. The initial RDD survey effort was used to screen and recruit households with children between the ages of 3 and 71 months. In households with multiple children under the age of 71 months, the

CATI survey prompted interviewers to randomly select a child from the list of eligible children within the household. This was the only child in the household for which data was collected throughout the study and parents were not allowed to substitute another child into the study. Random selection of a child was accomplished using a specific algorithm that accounted for the study's age-group quotas (also see Chapter 3).

In addition to recruiting the family for study participation and identifying a child, the RDD survey also requested parents to provide the participating child's name and their household contact information so that they could be sent a parental observation log. A copy of the RDD survey instrument used for household recruitment is included as Appendix A.

Within two days of completing the initial RDD survey and agreeing to participate in the study, parents were mailed an observational log package via overnight delivery service. This log package included detailed instructions for conducting child observations. Specifically, parents were asked to observe the selected child for four 15-minute intervals during a two-week time period and to record in the log the name of the items "mouthed" by that child and the duration for which each item was mouthed. A copy of the observation package mailed to parents is included as Appendix B.

Telephone survey interviewers contacted parents approximately two weeks following their receipt of the log to collect this information in a telephone survey format. Parents were not asked to return their written logs to CPSC or ORC Macro; all information contained in parents' logs was collected verbally using the CATI follow-up survey instrument. The follow-up survey also recruited families with a child less than 35 months old for participation in the in-home observation study; families with a child older

than 35 months were not invited to participate in the study's third phase. Families who were invited to participate in the in-home study were offered an incentive payment of $100 for their participation. Contact information was confirmed with parents who agreed to participate and was passed along to ITS-RAM, the contractor responsible for the in-home study component. A copy of the survey instrument used for the follow-up study is included as Appendix C.

2.2 Study Design Modification 1: Elimination of the Parent Observation Log Requirement

During the study's initial data collection effort, an attrition rate of 30% between the initial RDD survey and follow-up surveys was realized, although the anticipated attrition rate had been 25%. Upon review, it was discovered that some parents objected to the level of burden associated with making their observations and completing the observational log. This attrition rate proved particularly problematic for two related reasons:

1. Higher levels of initial study participant recruitment were required to overcome the attrition rate. This increased recruitment required multiple sample additions and an extended recruitment period (which resulted in an additional 178 participants).

2. Under the initial study design, families did not qualify for this portion of the study unless they completed the parent observation component. For this reason, a significant number of recruited families were ineligible for the in-home child observation.

In an effort to minimize participant burden and reduce study attrition, CPSC and ORC Macro modified the study design to eliminate the parent observation component. The follow-up survey questionnaire was adapted to collect demographic data only, and to recruit households with a child less than 35 months old for in-home observations. All households originally recruited for the study that had not yet completed the parent

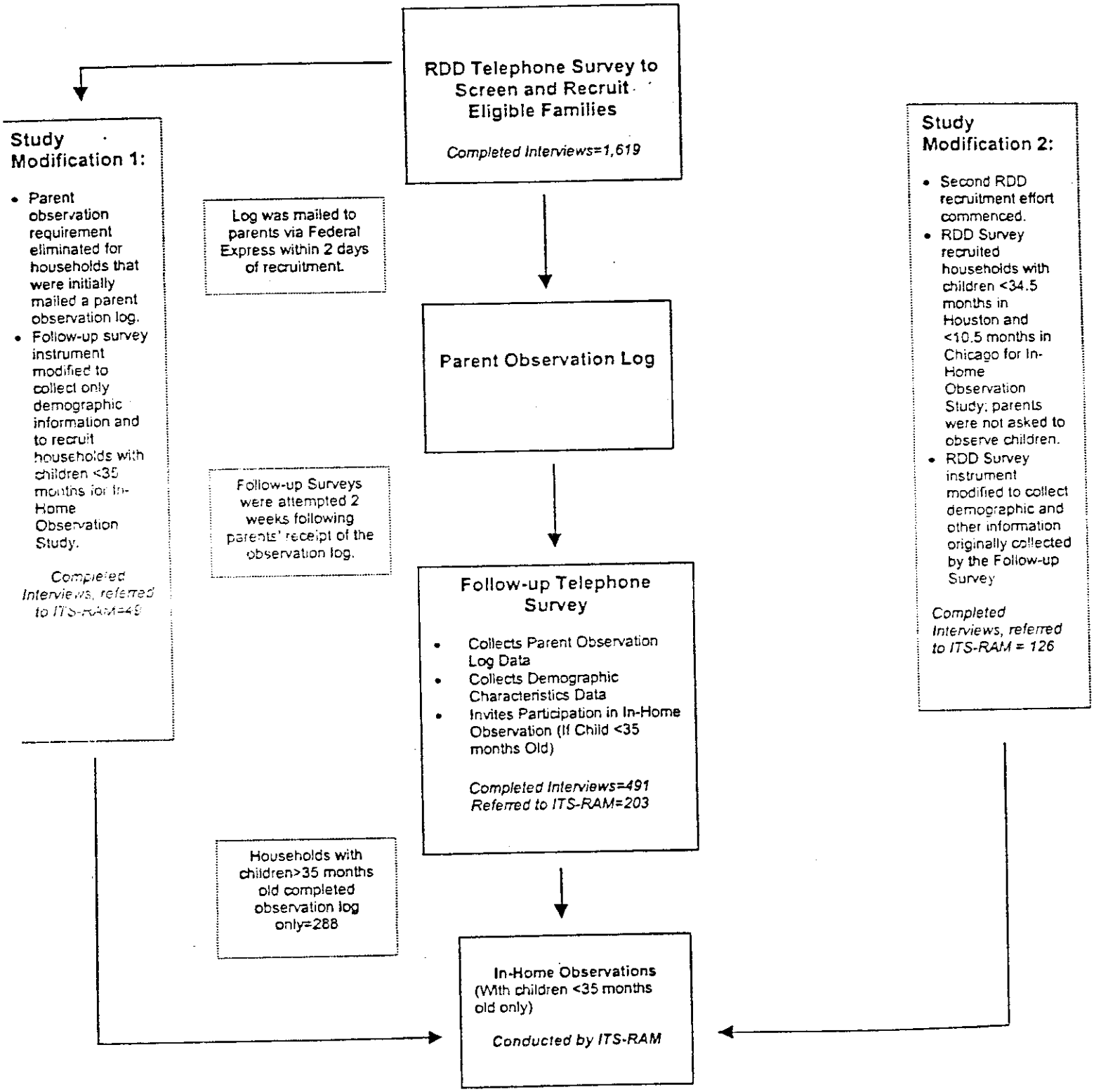
observation component were recontacted for the modified follow-up survey. A copy of the modified follow-up survey instrument is included as Appendix D.

2.3 Study Modification 2: Second RDD Recruitment Effort

The observational contractor, ITS-RAM, also experienced higher-than-expected attrition rates for the in-home child observation study component (see forthcoming Observational Study Report for attrition rates). For the second recruitment effort, CPSC and ORC Macro modified the RDD survey instrument to reflect the previous study modification. Given that the parent observation study component had been eliminated, the follow-up survey was no longer necessary. Accordingly, the initial RDD instrument was modified to include the demographic data and in-home child observation recruitment language that had previously been included in the follow-up survey.

In addition to the questionnaire modifications, the second RDD survey effort sought only to recruit targeted only at recruiting households with children in certain age groups for in-home child observations. Specifically, this second recruitment effort continued to be targeted at children younger than 34.5 months in Houston, but was only targeted at children younger than 10.5 months in Chicago in order to fill remaining child sample quotas.

Figure 2.1: Overview of Survey Data Collection Approaches Used



CHAPTER III: SURVEY SAMPLE DESIGN AND SAMPLE WEIGHTS

This chapter describes the sampling approach and weighting methodology for the Phthalate Observation Study. The following sections explain the rationale, processes and procedures for selecting and interpreting a representative sample of households large enough to meet study objectives. Additional information is provided concerning the use of data collected, the use of weights, standard error computations, and data limitations.

3.1 Target Population

The population of interest for this study was children aged 3-71 months who are potentially at risk for exposure to diisononyl phthalate (DINP) plasticizers, used to soften the polyvinyl chloride (PVC) plastics used in the manufacture of teethers, rattles and toys. The populations surveyed by the study was a subset of the target population, consisting of children aged 3-71 months in two metropolitan areas purposefully selected as sites for this study. The two metropolitan areas selected were Chicago and Houston. Estimates of the size of both the target population and the purposefully selected subset were developed prior to the study and are shown in Table 3.1.

Table 3.1: Target Population and Respondent Universe Size Estimates

Age (Months)	Total Target Population	Metropolitan Sample
0-11*	2,959,481	112,422
12-23	3,768,154	364,609
24-35	3,701,195	
36-71	10,976,097	506,892

Source: U.S. Bureau of the Census, 1990
* Exact population figures for children aged 0-11 months were obtained, and the aged 3-11 month population estimated as ¾ of this figure.

3.2 Sample Size Calculations

CPSC statisticians computed study sample sizes and determined that data from 200 observations would be sufficient to make reliable estimates of DINP exposure for children 35 months or younger in three age-based subgroups: 3-11 months, 12-23 months, and 24-35 months. Sample sizes and allocations for these subgroups were computed by simulating confidence intervals under a variety of designs until decreases in the confidence intervals corresponding with decreases in sample sizes were no longer important under a constraint of equal standard errors among groups. Data underlying the simulation study was obtained from a DINP intake study undertaken by the Dutch Consensus Group[1]

The sample size for children 36-71 months was designed to support an examination of trends in mouthing behaviors as children age. Specifically, this sample size would make it possible to detect the presence or absence of a declining trend in mouthing behaviors with age past the three-year mark.

[1] Groot, M., Lekkerkerk, M. and Steenbekkers, L. (1998) "Mouthing Behavior of Young Children." Agricultural University Wageningen, The Netherlands.

3.3 Stratification and Sample Allocation

The sample was stratified by metropolitan area (Chicago or Houston Standard Metropolitan Statistical Areas (SMSA)), age, and selected site within each SMSA. The sample was equally allocated across the two metropolitan areas. CPSC staff statisticians provided age allocations within metropolitan areas. The sample allocation scheme is shown in Table 3.2.

Table 3.2: Number of Interviews by Age, SMSA, and Data Collection Method

Age (Months)	Houston	Chicago	Total	Data Collection Methods
3-11	40	40	80	- Telephone recruitment - Parent observation, with pen and paper recording - Telephone collection of recorded data - Professional observation
12-23	30	30	60	
24-35	30	30	60	
Subtotal (Age 3-35 months)	100	100	200	
36-71	200	200	400	- Telephone recruitment - Parent observation, with pen and paper recording - Telephone collection of recorded data
Total (All Ages)	300	300	600	

3.4 Sampling Methodology

The sample design included four selection stages:

Stage 1: SMSA.

Stage 2: Selected sites within SMSA.

Stage 3: Households within selected sites and SMSA.

Stage 4: Children within households, selected sites, and SMSA

The first two selection stages were conducted purposefully and served to construct what this report terms "study areas." This process is described in detail in section 3.4.1. Random sampling occurred at the household and child levels, with households drawn as a stratified simple random sample from the study areas, and children drawn from sampled households. These procedures are described in sections 3.4.2 and 3.4.3, below.

3.4.1 Selection of Study Areas

The purposive selection of study areas was guided by a single goal: To identify and select geographic regions with composite demographic characteristics that mirrored those of the larger target population of families with children nationwide.[2] It was not feasible to conduct the study with a full-scale national probabilistic sample. In the absence of a formal first-stage probability sample of geographic areas, it was assumed that careful consideration given to demographic factors during the selection of both the SMSAs and sites within them would provide a certain degree of representation in the

resulting sample. This assumption was based on the fact that certain demographic criteria act as proxies for environmental factors that influence the exposure to and health risks from mouthing teethers and toys. By creating a sample that represented a balanced distribution of these proxies, the behaviors under study would be well represented. Factors that may be correlated with mouthing behavior were carefully considered, including household or family income, race and ethnicity, and urban or rural residency.

A set of sites was selected to support the selection of a household sample that would be similar to the U.S. population with respect to the characteristics that stand as proxies for factors thought to explain variations in health risks and exposure.[3] Therefore, site selection would support a household sample that represents families with children with respect a set of demographic characteristics that included ethnicity and income.

Before areas could be selected, they had to be defined. Here we considered a variety of issues with respect to the physical size[4] of the areas, and need for creating areas

[2] By construction, the telephone survey methodology excludes households without telephones. To the extent that households in the target population without phones differ from those in the target population with phones, survey results will be biased. Census data (Subject Summary Tape File 7: Metropolitan Housing Characteristics, 1980) suggest that approximately 7 percent of all U.S. households do not have a telephone, and that 12 percent of households with children under the age of six do not have a telephone. Some potential biases will be unavoidable because of the telephone methodology.

[3] The observational contractor proposed to conduct the study in Chicago, IL and Houston, TX, subject to the constraints that the cities should be located in different regions of the country and that between the two cities there should be enough demographic diversity to allow sampling that would reflect national averages. The second stage was selected purposively by statisticians at ORC Macro in an attempt to get a demographically balanced sample in a relatively compact area from each SMSA or metropolitan area.

[4] Two considerations were primary in defining the geographic areas in terms of size. The first was an awareness of local effects as a threat to the representative nature of a sample based on purposeful selection. Purposive site selection may be adversely influenced by unique local effects that dominate the environment, even among populations that otherwise appear representative. The second consideration was related to the fact that response rates vary from area to area. Specifically, lower response rates typically encountered in areas that are tightly focused on the urban core of large urban areas could unduly lower overall response rates.

Large geographic areas, consisting of whole counties or large sets of contiguous U.S. Postal zip codes, were used so as to mitigate these effects. The risks associated with local effects in the selected areas were minimized by this approach, as the areas under consideration were large and contained enough families to encompass a wide variety of unique local factors. Defining the areas broadly also minimized the impact of local variations in response rates.

from coterminous geographic units. Ultimately, large geographic areas, consisting of whole counties or large sets of contiguous U.S. Postal zip codes, were considered in the selection process

Although the research plan defined by CPSC did not require the survey sample to coincide with any specific geographic boundaries (e.g., town, city, county, etc.), the use of an RDD telephone methodology for conducting the recruitment phase of the study drove the decision to construct areas that were contiguous in terms of their underlying geographic units. Sampling in RDD telephone surveys occurs within a selected set of exchanges that serve the target area; contiguity guarantees the tightest fit between selected exchanges and the area of interest, allowing excellent coverage without including a large percentage of geographically ineligible households in the sampling frame. Using these geographic definitions also minimized the amount of screening necessary to verify the geographic eligibility of respondents. This was critical because the amount of screening required to identify eligible children within sampled households was already burdensome.

3.4.1.1 SMSA Selection

As mentioned above, two SMSAs were selected by CPSC as study sites: Chicago, IL and Houston, TX. These sites were selected by the observational contractor as meeting the criteria set forth in the observational study RFP. The RFP stated that sites were to be selected subject to the constraints that the cities should be located in different regions of the country and that between the two cities there should be enough demographic diversity to allow sampling that would reflect national averages.

3.4.1.2 Selecting Sites within SMSA

In the second stage of the sampling process, ORC Macro selected specific sites within each SMSA from which to draw the household sample. This was accomplished by first dividing the SMSA into a set of mutually exclusive, exhaustive geographic areas. Then, sample yields (in terms of specific demographic characteristics of respondents) were examined for a variety of samples of sites and household sample allocations across sites. The purpose of this examination was to match the expected sample yield to (with respect to these demographic characteristics) to those of the U.S. population.

Samples comprising whole counties and large blocks of contiguous zip codes within each SMSA were evaluated. Whole counties outside the urban core were considered as sampling units. Within the urban core of each SMSA, whole counties were thought to be too large to be considered as sampling units, because their populations would dominate the demographic mix of the resulting sample. In these cases, the urban core counties were subdivided into blocks of contiguous zip codes along geographic

features corresponding to boundaries such as major thoroughfares, interstate highways, or rivers. The following demographic characteristics of the population were considered critical to matching selected areas with the United States population as a whole, and were examined during the site selection process:

- Persons of African-American and Hispanic race/ethnicity.
- Children under 5 years of age who lived below the U.S. Poverty Measure as defined by the U.S. Census Bureau.
- Households located in rural areas.[5]

U.S. population estimates for these demographic characteristics and corresponding percentages for sites within each SMSA under consideration were obtained from the U.S. Census Bureau.[6]

Following sampling unit definition and the creation of maps of key indicators across sampling units, a spreadsheet was constructed to estimate the expected sample yield in terms of percentage composition of these indicators. The spreadsheet indicated the difference between the estimated sample yield and the composition of the U.S. population in terms of these indicators. The selection process involved evaluating different samples and allocations, using the spreadsheet to evaluate yield, and using maps to evaluate geographic compactness. Through this iterative inspection process, a set of geographic areas within each SMSA and a corresponding household sample allocation was identified. Table 3.3 lists the population and sample values for each characteristic.

[5] Rural areas were designated using U.S. Census Bureau guidelines, which define a household as urban if it resides in a place with 2,500 or more persons incorporated as a city or village, but excluding the rural portions of extended cities; census designated places of 2,500 or more persons; or, other territory, incorporated or unincorporated, included in an urbanized area. Households not classified as urban are rural.

[6] 1999 population estimates provided by the U.S. Census were used when available. 1990 population count data provided by the U.S. Census was used when current estimates for specific demographic or geographic breakdowns were not available.

The resulting sample was comprised of all zip codes, rather than counties, in Houston and Chicago. This was done to maximize the sample concentration within the urban areas. The resulting sample also drew on the non-urban counties surrounding the urban core of each SMSA to match the percentage of rural households nationwide. In the Chicago SMSA, the following non-urban counties were selected: DeKalb, Grundy, Kendall, and Lake. In the Houston SMSA, the following non-urban counties were selected: Chambers, Montgomery, and Waller.

Table 3.3: Target and Estimated Sample Characteristics for Households in Combined Survey Areas in Houston and Chicago vs. U.S. Population

	Percentage African American Households	Percentage of Hispanic Households	Percentage of 5 year olds at or below Poverty Level	Percentage of Rural Households
U.S. Population Estimate	12.80%	11.50%	19.39%	25.48%
Expected Sample Yield	18.46%	12.69%	18.01%	29.72%
Difference Between U.S. and Expected Yield	5.66%	1.19%	-1.38%	4.24%

3.4.2 Selecting Households within Selected Sites

Households were sampled by drawing a sample of telephone numbers using a Random Digit Dialing (RDD) methodology from a list-assisted frame. The frame used, the Genesys system, is licensed to ORC Macro by Marketing Systems Group, and contains information on area code-exchange combinations with working numbers. The frame also contains geographic information defining census tracts, zip codes, and

counties. The frame is updated quarterly using an area code-exchange database belonging to Bell Communications Research.

This study used a subset of the national frame, including only exchanges in the selected areas. A sample of telephone numbers was drawn to produce the desired number of interviews after accounting for non-residential numbers, ineligible households, and non-response. Telephone numbers were drawn systematically from all possible telephone numbers in working 100-banks with at least one listed number.

3.4.3 Selecting Children within Households

After the sample was constructed, as described above, interviewers began contacting households in the target areas to identify and recruit eligible respondents. The recruiting process was conducted in three steps.

First, a list of eligible children living in an eligible household was obtained, and divided into two groups: younger (children aged 3-35 months) and older (children aged 36-71 months). The first stage consisted of the selection of one of these two age groups from which to sample the child. The second stage consisted of selecting a child from the chosen age group.

Initially, the age groups were selected with probabilities equal to the relative number of completed interviews required in each group (assuming that at least one child was present in each group). The probability of selecting the older group was therefore set at 0.67, as two-thirds of the completed interviews were to be taken from among this age group. As the study progressed, interviews were obtained in the two age groups at different rates, changing the relative number of interviews required in each age group. The age group selection probability was therefore recomputed periodically so that it

would be more likely to obtain interviews in the age group where there was the most need. The interviews were completed in the younger age group more quickly than in the older age group, so the probability of selecting from among the older age group was increased. This probability eventually reached a value of 1.0 – so that children were sampled exclusively from among children aged 36-71 months – once the required number of interviews was obtained from the younger age group.

This periodic adjustment was based on monitoring the number of completed interviews within each SMSA and age group, and the adjustment was made at several-week intervals. When monitoring revealed the need for an adjustment, data from the calling process were entered into the CATI program used to conduct the interviewing, with the probabilities automatically recomputed by the software as households were contacted (See Figure 3.4: Algorithm for computing P(older)). Note that once set during the initial contact with a household, the age-group selection probability did not change. Within the selected age group, one child was selected from among all children in the age group with equal probability.

Figure 3:4: Algorithm for computing P(older)

Notes –

- P(older) is the probability of selecting a child from the older age group within a given household.
- The probability of selecting a child from the younger age group is equal to 1 – P(older)
- P(older) was computed following the rostering of the number of children by age in each household by the CATI program
- P(older) and associated variables were stored in the data record for each household

Algorithm –

- Set Constants – These constants were initially set to the values below. Periodically throughout fielding response rates and number of interviews needed were updated based on calling process data.
  - If site = Houston Then
    - Resp_rate_older = 1
    - Resp_rate_younger = 1
    - Need_older = 200
    - Need_younger= 100
  - End If
  - If site = Chicago Then
    - Resp_rate_older = 1
    - Resp_rate_younger = 1
    - Need_older = 200
    - Need_younger = 100
  - End If

- Count Children in Household
  - Num_younger = 0
  - Num_older = 0
  - For each child in the household
    - Compute age_in_months
    - If age_in_months Ge 3 and age_in_mos Le 34 Then num_younger = num_younger + 1
    - If age_in_months Ge 35 and age_in_mos Le 71 Then num_older = num_older + 1
  - End For

- Compute Probability of Selecting from older age group (assumes have at least one eligible child)

  - If num_younger Eq 0 and num_older Ne 0 Then p_older = 1
  - If num_younger Ne 0 and num_older Eq 0 Then p_older = 0
  - If num_younger Ne 0 and num_older Ne 0 Then
    - Want_older = need_older / resp_rate_older
    - Want_younger = need_younger / resp_rate_younger
    - P_older = want_older / (want_older + want_younger)
  - End If

3.5 Weighting

The weights attached to each record in the analytic data file compensate for unequal sampling fractions in each area, for unequal selection probabilities of children within households, and for non-response. The weights were computed starting with a sampling weight for each record, which was then adjusted for non-response within the set of eligible households, as well as for households with unknown eligibility status and unknown residential status. The following sections detail each of these computations. A summary of notations and variables used in this section is provided in Figure 3.5: Notations and Variables.

Figure 3.5: Notations and Variables

Notation

Indices:

i - site
j – household within site
p – fielding period
g – age group

Input Variables

N_wb – Number of Working Banks on the sampling frame, indexed by site
N_ph – Number of residential telephone lines ringing into a household, indexed by site and household.
N_pop – Population count, number of children aged 3 – 71 months, indexed by site
n_cases – Number of completed interviews, indexed by site
n_child – Number of children within age group within household, indexed by site, household, and age group
P_older – computed probability of selecting a child from among the older age group, indexed by site, household, and fielding period

Weight Variables

WH – Household component of sampling weight, indexed by site and household
WC – Child component of sampling weight, indexed by site and household
WS – Sampling weight, indexed by site and household
WS' – Sampling weight with post-stratification adjustment, indexed by site and household
WS'' – Centered sampling weight with post-stratification adjustment, indexed by site and household
PSA – Post-stratification adjustment, indexed by site
SC – Scaling constant for centering, constant across file

3.5.1 Sampling Weight

Sample weights accounted for the selection probabilities within each site and consisted of two multiplicative components, a household selection weight and a child selection weight (discussed below). Each weight was computed as the inverse of the corresponding selection probability.

3.5.2 Household Selection Weight

Households were sampled using telephone numbers. Therefore, the sampling weight for a household was computed as the inverse of the selection probability for the telephone number corresponding to that household. Under RDD, the number of possible telephone numbers that can be sampled – the frame size – is the number of working banks defined by the area-code + exchange + the first two digits of the telephone number (###-###-##) multiplied by 100. For example, the working bank 802-863-96 contains the 100 telephone numbers in the range of 802-863-9600 through 802-863-9699. The first term in the sampling weight for a household within the ith site was therefore computed as the first term in Equation 1, by dividing the number of possible telephone numbers to select from by the number of completed interviews. The second term in Equation 1 corrects this probability for the number of residential telephone lines ringing into the household. A household with two telephone lines is twice as likely to be drawn into the sample as a household with one telephone line. In the case of a households with two phone lines, the second term in the household sampling weight would adjust the weight

downward by one half. Note that the sampling weights are the same for all households with the same number of residential telephone numbers sampled from a given site.

Equation 1:

$$WH_{i,j} = \left(\frac{N_wb_i * 100}{n_cases_i} \right) * \left(\frac{1}{N_ph_{i,j}} \right)$$

3.5.3 Child Selection Weight

As noted in Section 3.4.3, children were selected from within households using a two-stage process. The child selection weight had to reflect sampling at both stages, and was therefore computed as the inverse of the probability of selecting an age range, multiplied by the inverse of the probability of selecting a child within that age range.

The probability of selecting a child from among the older age group, P_older, was adjusted periodically during fielding (see Section 3.4.3) to bring expected sample yields by age group into line with age-group targets. Thus, while the probability was not constant across the study, it was constant within SMSA for a given time period, indexed by the p in Equation 2. Note that the resulting weight, WC, is not indexed by time period, for each child was sampled in a given household at a single point in time, or equivalently, for a single value of p.

For the children sampled from the younger age group, the probability of selecting the younger age group is 1 minus the probability of selecting the older age group. The value of P_older used in the weighting was the actual value set in the CATI program, recorded in each respondent's data record. Equation 2 details these computations for the jth household in the ith site.

Equation 2:

$$WC_{i,j} = \begin{cases} \dfrac{n_child_{i,j,older}}{P_older_{i,j,p}}, \text{child aged } 35-71 \text{ mos.} \\ \dfrac{n_child_{i,j,younger}}{\left(1-P_older_{i,j,p}\right)}, \text{child aged } 0-34 \text{ mos.} \end{cases}$$

3.5.4 Overall Sampling Weight

The overall sampling weight for each child in a given site was the product of the household sampling weight for that site and the child selection weight.

Equation 3:

$$WS_{i,j} = WH_{i,j} \cdot WC_{i,j}$$

3.5.5 Weight Adjustments

The weights were post-stratified to population counts of eligible children within site, according to the 1990 U.S. Census STF1 data series. This adjustment inflated the weights so that all eligible households, that is, households with a child aged 3-71 months, were represented. Households may not have been represented in the response data if residential status for the household was undetermined, if eligibility status for residential telephone numbers was not determined, or if no interview was obtained.

Post-stratification ensured that the data collected would represent the total population of eligible children in the correct proportions across sampled sites within the pre-selected SMSA. Noting that the sum of the weights in a given site was an estimate of the total number of children represented by the sampled, responding households, the adjustment was taken as the ratio of the total eligible population for that site to the sum of the weights in that site, as detailed in Equation 4.

Equation 4:

$$PSA_i = \frac{N_pop_i}{\sum_{over\ j} WS_{i,j}}.$$

With

$$WS'_{i,j} = WS_{i,j} \cdot PSA_i$$

The weights were then scaled to case counts. This operation, often called centering, produces a weight with a mean of 1, and prevents the over-inflation of degrees of freedom in statistical tests due to the weighting. However, scaling the weights to case counts precludes the estimation of population totals from the data. As this adjustment multiplies all weights by a constant scaling factor, estimates of percentages will be unchanged by this adjustment. The adjustment is computed as the ratio of the number of cases in the response data file to the sum of the weights over the file, as detailed in equation 5.

Equation 5:

$$SC = \frac{n_cases}{\sum_{over\ i,j} WS'_{i,j}}$$

With

$$WS''_{i,j} = WS'_{i,j} \cdot SC$$

WS'' was the final weight attached to the response data file.

3.6 Data Use

This section outlines known limitations of the data in terms of the types of statistical inferences that can be based upon it, and describes how the weight variable computed in the prior section should be used. This is followed by a discussion of the methods used to compute standard errors and statistics based on these standard errors.

3.6.1 Data Limitations

The main limitation of these data is related to the use of purposive selection at the first two sampling stages. It is important to note the implications of purposive site selection and areas within each site. Purposive selection means that sites and areas were selected using independent judgment, with prior knowledge of the population characteristics of the areas and with reference to overall study objectives. Given this sampling approach, it is not safe to make statistical inferences with respect to the larger population of families and children throughout the United States. However, the sampling procedures and weighting methods do allow inferences to be made with respect to the two sites. That is, statistics based on these data may be used to make formal statistical inferences regarding the overall population of families with children in the selected study areas within the Chicago and Houston SMSAs. It is possible to make generalizations based on these data to the broader U.S. population of families with children, albeit not in a formal statistical sense. While caution should be used in making such generalizations, and formal statistical tests are unavailable, these data should paint a reasonable picture of mouthing behaviors among children nationwide.

Additionally, the data are subject to the usual limitations of survey data. Specifically, the data may be affected by the following error sources:

- Sampling error (the study was conducted with a sample rather than the entire population).
- Error arising from non-response.
- Response error due to question interpretation or individual recall.
- Interviewer error.

3.6.2 Computing Standard Errors

Standard errors underlying reported confidence intervals for means and percentages were computed using "Proc SurveyMeans" in SAS Version 8. This procedure uses the Taylor expansion method to estimate sampling errors of estimators based on complex sample designs. This method obtains a linear approximation for the estimator and then uses the variance estimate for this approximation to estimate the variance of the estimate itself. This procedure proved necessary for the Phthalate Observation Study because the sample design was a two-stage cluster sample with disproportionate allocation of telephone numbers across strata (areas). Other methods that could be used to compute standard errors and related statistics appropriately include balanced repeated replication and jackknife repeated replication. These methods, implemented in such software packages as SUDAAN, WestVar and STATA, give similar, satisfactory results.

3.6.3 Use of Weights

Summary statistics should be computed using the weight variable provided. This variable weights the data to represent all children in the selected areas, and accounts for the sampling design in the computation of standard errors and related statistics.

Chapter IV: Summary of Data Collection Activities

4.1 Description and Schedule

Interviews were conducted from ORC Macro's telephone interviewing facility in Burlington, VT, using computer-assisted telephone interviewing (CATI). Initial interviewer training took place on November 11, 1999. Interviews began on November 11, 1999, with final interviews completed by October 3, 2000.

For the first contact, an adult member of the household provided a roster of children under the age of 71 months living in the household. Once a child was selected, the guardian was asked to fill out an observational log to record the mouthing behaviors of that child. At least 10 attempts were made to obtain an answered call for each sample telephone number that was not obviously non-working. Observational logs were sent daily via Federal Express to respondents who agreed to participate. Approximately two weeks later, respondents were re-contacted to see what they had found when observing their child. If respondents had not yet completed the observations, they were asked to finish the remaining observation and a callback was scheduled for two days later. At the end of the second contact, if the child was under 3 years old, respondents were asked whether they would participate in the Observational Study, conducted by ITS-RAM. Respondents were informed they would receive $100 at the conclusion of the observations. Information on all respondents who agreed to participate was forwarded within two days to a member of the project team at ITS-RAM as well as CPSC.

Data collection was stopped between December 28, 1999 and January 4, 2000 when a problem with the sampling frame was detected. (For more details on the problem and steps taken to solve it, please see Section 4.3: Problems Encountered and Resolved.)

On January 17, 2000, refusal conversion studies for both Chicago and Houston were put into place. Only the most productive interviewers worked on these studies to try to convince respondents of the benefits of their participation.

Due to difficulties obtaining enough completed interviews in the second contact, in May 2000, ORC Macro and CPSC made a decision to remove the observational log portion of the study for the remaining households with children under 3 years old. Instead, respondents would provide demographic information, and then be asked whether they would participate in the Observational Study with ITS-RAM. At this point, the incentive was also raised to $150 for completing the Observational Study.

Finally, in August of 2000, another set of studies, one in Chicago and one in Houston, began with the goal of filling unmet age quotas. In one phone call to each respondent, these studies attempted to obtain the household roster of children under 10.5 months in Chicago, and less than 34.5 months in Houston, selected a child, collected demographic information, and recruited respondents for the Observational Study.

4.2 . Quality Control

CPSC and ORC Macro implemented a range of steps to ensure the high quality of final data. These steps included extensive questionnaire pre-testing, interviewer training, data checks built into the programmed version of the questionnaire, and interviewer monitoring during data collection.

4.2.1 Survey Pretesting

The first contact questionnaire was pre-tested with respondents in Houston on November 11, 1999 with three interviewers. Members from the CPSC project team monitored over the telephone using ORC Macro's remote monitoring system.

After the pretest, it became apparent to both CPSC and ORC Macro that many households would have to be screened in order to find people with children in the appropriate age categories. Another lesson learned was that many respondents were hesitant to give out the names and dates of birth of their children over the telephone. To combat this aversion, interviewers provided a toll-free hotline to the CPSC that respondents could call to verify the validity of the study.

A live pre-test was not conducted for the second contact due to the fact that no changes could be made to the questionnaire after fielding began. In order for survey results to be comparable, wording of questions had to remain the same for all respondents. However, the second contact was thoroughly tested by members of the project management staff to ensure the questionnaire was ready to be fielded.

4.2.2 Interviewer Training

Two initial interviewer trainings were conducted on November 11, 1999: one for day-shift interviewers and one for evening-shift interviewers, with a combined total of seventeen interviewers. At these trainings, interviewers were provided with a paper version of the survey instrument, as well as a project overview defining the overall scope and purpose of the Phthalate Observational Study. Because the first contact also involved the use of tape recorders to play a message from CPSC Chairman, Ann Brown, use of this equipment was also covered in the training. Before calling live on the project, all

interviewers were required to go through the survey on their computer screens in practice mode so they could become familiar with the script, as well as to become familiar with project-specific programming conventions. Additional trainings were given throughout the study period to account for study modifications and interviewer staffing changes.

4.2.3 Data Collection Control and Monitoring

Controlling and monitoring the data collection process began with members of the project management team manually verifying all hard, soft, and logic edits and skip patterns to ensure the study was programmed properly. Random Data Generation (RDG), a questionnaire testing program that generates a fictitious data set, was also performed, and that data was checked for accuracy. Members of ORC Macro's survey interviewing team underwent the same project-specific training, which included time to "practice" working with the on-screen survey so they would become familiar with the program and its nuances before live data collection.

The programmed version of the questionnaire was also set up with quality control measures. Wherever a numeric response was requested from a respondent, the program used ranges that accepted only reasonable responses. These ranges proved especially important when collecting the age of children in the household. Because the entire study was based on completing surveys with respondents with children in certain age groups, the instrument was programmed to allow only children who would fill the age quotas beyond the screener.

During data collection, at least 10% of interviews were monitored. Data collection managers or supervisors silently monitored interviews in progress, via

telephone, while simultaneously viewing a copy of the interviewer's computer screen on their computers. Neither interviewers nor respondents were aware that the conversation was being monitored. This setup afforded two important reliability checks: managers or supervisors could verify an interviewer's accuracy by listening to the interview and watching to see if the interviewer correctly entered data.

A final component of quality control was the review and editing of completed survey data. Once the recruitment information was collected, the data were checked for valid addresses before ORC Macro forwarded information to ITS-RAM. A member of the project management staff also reviewed all completed survey data for completeness and backcoded open-ended responses that fit into pre-existing response categories.

4.3 Problems Encountered and Resolved

Multi-phased projects such as the Phthalate Observational Study are often challenging. The following outlines the two major problems that were encountered in the fielding of this study, and the steps that were taken to solve them.

During the course of fielding, an error was found in the sampling specifications that were passed to the CATI implementation team. This error resulted in a misallocation of sample loaded for the initial part of the fielding period. Specifically, too much sample was loaded in the non-urban counties (Dekalb, Grundy, Kendall, and Lake in Chicago, and Chambers, Montgomery, and Waller in Houston) and not enough in the city centers. To correct this error, the following steps were taken:

- Completed interviews, along with a corresponding portion of the sampled telephone numbers were sub-sampled to the correct proportions in Chambers,

Kendall, and Dekalb Counties. All non-completed records in the sub-sample completed the study protocol.

- Additional sample was loaded to the correct proportions in both the Houston and Chicago city centers. This sample was also called to completion following study protocols.

- In all remaining areas, the remaining sample was called to completion following study protocols.

These methods preserved the representative nature of the sample within each site. By completing study protocol in areas that were not sub-sampled, as well as those that were sub-sampled within Chambers, Kendall and Dekalb counties, the probability structure of the sample followed the intended design.

ORC Macro found the actual attrition rate (30%) to be higher than originally anticipated (25%) between the recruitment and follow-up surveys. In response, CPSC and ORC Macro conducted a brief re-contact study of participants who had not yet completed the follow-up survey to inform parents that the observational log no longer needed to be filled out in order to have ITS-RAM observe their child. This re-contact study did produce more cases for the Observational Study, but it did not completely compensate for the high attrition rate. To make up for the rest of the cases that did not complete the study, additional recruitment was initiated to fill unmet age quotas. This effort was completed on October 3, 2000, with the forwarding of the demographic and contact information to ITS-RAM.

4.4 Final Sample Dispositions

Due to the difficult screening process in the Phthalate Observational Study, sample was drawn, loaded and resolved on multiple occasions in order to obtain the needed number of completed interviews in each age quota. Many of the households contacted were not eligible due to the fact that there were no children under 6 years of age living there. Figure 4.1 shows a breakdown of the ways in which the drawn sample was resolved, providing a summary of the final sample dispositions for each survey component.

Figure 4.1: Table of Telephone Survey Dispositions

	HOUSEHOLD RECRUITMENT SURVEY: CHICAGO	HOUSEHOLD RECRUITMENT SURVEY: HOUSTON	TOTAL	PARENTAL OBSERVATION LOG COMPLETED
SCREENED-IN				
Completed interviews	883	862	1,745	491
UNRESOLVED				
No answer	4,537	5,805	10,342	67
Busy	84	108	192	3
Scheduled Callback	1,244	1,706	2,950	138
Answering machine	582	821	1,403	47
Spanish-speaking household	109	191	300	4
INVALID TELEPHONE NUMBERS				
Non-working number	11,700	17,792	29,492	139
Business number	6,156	6,158	12,314	7
Fax machine/modem	2,782	3,036	5,818	7
RESOLVED – NOT COMPLETED				
Refused to complete interview	1,611	1,883	3,494	289
Refused before screener completed	715	847	1,562	0
Refused birth date or name of child	131	144	275	0
Refused to acknowledge guardianship	4	14	18	0
Language barrier – other than Spanish	433	321	754	9
No eligible respondent during time period	132	116	248	19
No child under 6 in household	13,785	12,329	26,114	0
Maximum attempts	6,300	7,274	13,574	213
Over quota	3,044	1,647	4,691	0
TOTAL SAMPLE	54,232	61,054	115,286	1,433

APPENDICES

Appendix A
Initial Household Screening Survey Questionnaire

Mouthing Behavior Study Telephone Survey
November 10, 1999
First Contact
Draft 4 - Pretest

QUESTIONNAIRE INSTRUCTIONS

I. TYPOGRAPHIC CONVENTIONS

[Off-script interviewer instructions are in square brackets]
{Programmer instructions are in curly brackets}
Notes to and questions for client are shown in bold face type
Changes where words are omitted from the text are noted in ~~strikethrough~~
Changes where words are added to the text are noted in <u>underline</u>
Question responses that should be read to respondents are noted in lower caps
Question responses that should not be read to respondents are noted in UPPER CAPS

GENERAL QUESTIONNAIRE FORMATTING

{MUL=#} indicates the number of available answer choices
{NUM=#} indicates the number of available digits for numerical keypunching
Responses in ALL CAPS are not to be read to the respondent by the interviewer
In responses requiring open-ended numeric responses, acceptable range of responses allowed by CAI system are specified
All "other" answer categories are coded as "66" and an open-ended "specify" response is always collected

Section A. Introduction and Screener

HELLO, I'm _____ calling from Macro International for the Consumer Product Safety Commission. CPSC is the federal government agency responsible for regulating consumer products to ensure they are safe. We are doing a study on potential health risks for children under six years of age associated with non-food items, such as toys and other objects. Your phone number has been chosen randomly from telephone numbers in your area. Your responses are voluntary and will be kept completely confidential.

A1. Is this a private residence?

A1.1 YES
A1.2 NO [Thank you very much, but we are only interviewing private residences.] {TERMINATE INTERVIEW} {SET PRIVRES QUOTA}

A1.9 [REF]

A2. I need to speak with someone who is 18 or older. Are you?

A2.1 YES
A2.2 NO [Can I speak with someone who is 18 or older? If no, schedule callback] {Disposition screen}

A2.9 [REF] {Disposition screen}

A3. In your household, how many children are there who are over the age of two months and less than six years of age?

A3.01 [RECORD NUMBER] {Range: 0-9} {SET CHILDNUM}
A3.77 [DK] [Is there someone home who can answer this question? Schedule callback or repeat introduction and question.]
A3.99 [REF] {TERMINATE INTERVIEW}

{IF CHILDNUM=0, GO TO TERM SCREEN 1} {SET NO CHILD QUOTA}
{IF CHILDNUM=1, GO TO B1.}

PREA4. Our study requires that we randomly select a child in your household to discuss during the interview.

[Interviewer prompt: That is, a child who lives with you more than half time during a given month.]

LOOP {ASK A4. FOR NUMBER OF CHILDREN INDICATED IN A3.}

A4. {IF FIRST LOOP} What is the birth date of the oldest child under the age of six years who lives in this household?

{IF AFTER LOOP 1} What is the birth date of the next oldest child under the age of six years who lives in this household?

A4.1 [MM/DD/YY] {SET DOB} {Range, month 1-12, day 1-31, year 93-99}
A4.7 [DK]
A4.9 [REF]

A5. Is this child a boy or a girl?

A5.1 BOY
A5.2 GIRL
A5.9 [REF]

A6. Do you have another child with the same birthday, like a twin or triplet...?

A6.1 YES
A6.2 NO

{ASK IF "YES" TO A6, ELSE CONTINUE LOOP}

A6F. [INTERVIEWER: PLEASE RECORD "1" FOR THE FIRST TWIN, TRIPLET, ETC.
"2" FOR THE SECOND TWIN, TRIPLET
"3" FOR THE THIRD TRIPLET]

A6F. [RECORD SEQUENTIAL NUMBER FOR THE TWIN, TRIPLET, ETC.]

{RETURN TO LOOP UNTIL ASKED FOR ALL CHILDREN}
{IF RESPONDENT INDICATES 77 OR 99 FOR ALL CHILDREN, TERMINATE INTERVIEW}

{INTERVIEWER VERIFICATION SCREEN}

A7. Just to check, I show you have children with the following birthdates. Is this list correct?

{RESTORE EACH CHILD'S BIRTHDATE AND GENDER}

A7.1 YES, THIS LIST IS CORRECT
A7.2 NO, THIS LIST IS NOT CORRECT {GO TO A4.}
{COMPUTERIZED RANDOM SELECTION OF CHILD}

Section B. Toys

{IF COLLECTED NAME AT A4.C, SKIP TO B1.A, ELSE CONTINUE}

B1. The computer has randomly selected the child whose birthday is on {RESTORE BIRTHDATE} and who is {RESTORE GENDER}. What is this child's name?

[INTERVIEWER: IF # SYMBOL IS FOLLOWED BY A NUMBER, IT INDICATES MULTIPLE CHILDREN BORN ON THIS DAY. USE THIS SEQUENCE NUMBER TO SELECT A TWIN, TRIPLET, ETC.]

B1.1 [RECORD NAME] {SET CHILDNAME}
B1.9 REF

B1.A Are you {RESTORE CHILDNAME}'s parent or legal guardian?

B1A.1 YES
B1A.2 NO [Our study requires that we talk with a parent or legal guardian. Can I speak with a parent or guardian? Repeat introduction or schedule callback.]
B1A.9 [REF] {TERMINATE INTERVIEW}

B2. Now I would like to talk to you about the toys {RESTORE CHILDNAME} currently uses. Please list the five toys your child plays with most frequently. If you can provide a brand name and model, please do so. Otherwise, provide a brief description, such as "yellow rubber ducky."

[Interviewer note: probe for up to 5 toys]

{MUL=5}

B2.1 [TOY 1]
B2.2 [TOY 2]
B2.3 [TOY 3]
B2.4 [TOY 4]
B2.5 [TOY 5]
B2.9 [REF]

{Ask B3 for each toy listed in B2.}

B3. From what material or materials is {RECALL TOY NUM}made?

[Interviewer note: Probe to distinguish between hard plastic and soft plastic toys.]

{MUL=6}

B3.1 Fabric/Cloth
B3.2 Metal/Aluminum
B3.3 Plastic – hard
B3.4 Plastic – soft
B3.5 Wood
B3.6 OTHER [SPECIFY]
B3.7 [DK]

B3.8 [REF]

Section C. Demographics

C1. Finally, I have some general questions about your family and children.
Is {RESTORE CHILDNAME} Hispanic or Latino?

C1.1 NO
C1.2 YES
C1.7 [DK]
C1.9 [REF]

C2. What is {RESTORE CHILDNAME}'s race? [Check all that apply]

{MUL=3}

C2.1 White
C2.2 Black or African American
C2.3 Asian
C2.4 American Indian or Alaska Native
C2.5 Native Hawaiian or Other Pacific Islander
C2.6 OTHER [SPECIFY]
C2.7 [DK]
C2.9 [REF]

C4. Are you?

C4.1 Married
C4.2 Divorced
C4.3 Widowed
C4.4 Separated
C4.5 Never been married
C4.6 A member of an unmarried couple
C4.9 [REF]

C5. Are you Hispanic or Latino?

C5.1 NO
C5.2 YES
C5.7 [DK]
C5.9 [REF]

C6. What is your race?
[Check all that apply]

{MUL=3}

C6.1 White
C6.2 Black (or African American)
C6.3 Asian
C6.4 American Indian (or Alaska Native)
C6.5 Native Hawaiian (or Other Pacific Islander)
C6.6 OTHER [SPECIFY_____]
C6.7 [DK]

C6.9 [REF]

C7 How old are you?
C7.1 [AGE] {Range: 18 TO 90}
C7.9 [REF]

C9. What is the highest grade or year of school you completed?

[Read only if necessary]

C9.1 Never attended school or only attended kindergarten
C9.2 Grades 1 through 8 (Elementary school)
C9.3 Grades 9 through 11 (Some high school)
C9.4 Grade 12 or GED (High school graduate)
C9.5 College 1 year to 3 years (Some college or technical school)
C9.6 College 4 years or more (College graduate)
C9.9 [REF]

{IF C4=1 OR C4=6, GO TO C10. ELSE SKIP TO C11.}

C10. What is the highest grade or year of school your spouse or partner has completed?

[Read Only if Necessary]

C10.1 Never attended school or only attended kindergarten
C10.2 Grades 1 through 8 (Elementary)
C10.3 Grades 9 through 11 (Some high school)
C10.4 Grade 12 or GED (High school graduate)
C10.5 College 1 year to 3 years (Some college or technical school)
C10.6 College 4 years or more (College graduate)
C10.9 [REF]

C11. Is your annual household income from all sources:

C11.1 Less than $20,000
C11.2 20,000-39,999
C11.3 40,000-49,999
C11.4 50,000-74,999
C11.5 75,000 or more
C11.7 [DK]
C11.9 [REF]

C12. Is this the only telephone number that rings at your residence? We are asking about Non-Business telephones.

C12.1 YES
C12.2 NO

C13. How many different Non-Business telephone numbers, not phones, ring into your household?
C13.1 [AMOUNT] {Range 2 to 9}

C13.7 [DK]
C13.9 [REF]

Section D: Recruitment

D1. There is another phase of this research called the observational study. In the observational study, a trained researcher will observe your child in his or her natural environment. Your child's regular schedule would not be altered in any way. You will receive $150 for participating in this study. May we have our researchers call you?

D1.1 YES
D1.2 NO

{TERMINATE}

D1.A Thank you for agreeing to be part of our study. A trained researcher from ITS/RAM will be contacting you in the next few days to discuss the second part of this study. What is your mailing address and telephone number?

[Interviewer prompt: Your participation in this study is very important]

D1.A.1 Record Name:
D1.A.2 Record Street:_____ {25 character open-end}
D1.A.3 Record Town/City:_____ {50 character open-end}
D1.A.4 Record Zip Code:_____ {25 character open-end}
D1.A.5 Record Telephone Number: _____ {Range 1,99999}
D1.A.9 [REF] [Code REF as 9999999999]
{SET REFUSED ADDRESS QUOTA, ASSIGN INITIAL REF}

CLOSING

Thank you very much for taking the time to participate in this very important study. We really appreciate your cooperation.

TERMINATION SCREEN 1

[Thank you very much, but we are only interviewing households with children under the age of one.]

Appendix B
Parent Observation Forms
And Letters

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OMB #: 3041-0129

Dear Parent:

Thank you for agreeing to participate in this mouthing behavior study. This study is being conducted for the U.S. Consumer Product Safety Commission, an independent federal regulatory agency directed by Congress to protect the public against unreasonable risks of injuries and deaths associated with consumer products. Children are a vulnerable population and the Commission takes their safety very seriously.

The Commission is concerned that young children who put non-food items into their mouths may be exposed to unforeseen hazards. We know that most children, as a part of their normal development, explore their environment by mouthing whatever they can get their hands on. However, research in this area does not show how often or how long this behavior typically occurs.

Over the next week we would like you to observe your child 4 times for 15 minutes at a time to see what objects he/she is mouthing. By "mouthing", we mean sucking, chewing or otherwise putting an object on his/her lips or into his/her mouth. Please use the attached forms to record the items and the amount of time your child is mouthing. We are particularly interested in the items your child mouthed in addition to how often and how long your child mouthed them. Please fill out a new form for each 15-minute period you watch your child.

We will call you back in about a week to find out what you saw during all 4 sessions. Afterwards, your child will be eligible to participate in a special observational study. If you chose to participate, a representative from ITS-RAM, a nationally recognized research firm, will call you. Families that complete that part of the study will receive a payment of $100.

If you have any questions about this study you can go to CPSC's web site: www.cpsc.gov/cgi-bin/mbs.html or you can call 1-800-638-2772, extension 122

Sincerely,

Celestine T. Kiss

Celestine T. Kiss
Engineering Psychologist
Division of Human Factors

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OMB #: 3041-0129

Dear Parent:

Thank you for agreeing to participate in this mouthing behavior study. This study is being conducted for the U.S. Consumer Product Safety Commission, an independent federal regulatory agency directed by Congress to protect the public against unreasonable risks of injuries and deaths associated with consumer products. Children are a vulnerable population and the Commission takes their safety very seriously.

The Commission is concerned that young children who put non-food items into their mouths may be exposed to unforeseen hazards. We know that most children, as a part of their normal development, explore their environment by mouthing whatever they can get their hands on. However, research in this area does not show how often or how long this behavior typically occurs.

Over the next week we would like you to observe your child 4 times for 15 minutes at a time to see what objects he/she is mouthing. By "mouthing", we mean sucking, chewing or otherwise putting an object on his/her lips or into his/her mouth. Please use the attached forms to record the items and the amount of time your child is mouthing. We are particularly interested in the items your child mouthed in addition to how often and how long your child mouthed them. Please fill out a new form for each 15-minute period you watch your child. We will call you back in about a week to find out what you saw during all 4 sessions.

If you have any questions about this study you can go to CPSC's web site: www.cpsc.gov/cgi-bin/mbs.html or you can call 1-800-638-2772, extension 122

Sincerely,

Celestine T. Kiss

Celestine T. Kiss
Engineering Psychologist
Division of Human Factors

INSTRUCTIONS FOR MOUTHING BEHAVIOR STUDY

When to watch:

- At 4 different periods for 15 minutes each period (not one right after the other, please).
- When your child is at home and not eating or sleeping.
- When you are able to focus on your child and will not be distracted by other chores or responsibilities.

What to look for:

- All non-food items your child puts up to his/her lips and/or tongue and into the mouth. That means anything he/she licks, sucks, or chews that is not food. Examples include toys, fingers, clothing, furniture, and pacifiers.

What you need:

- Booklet of forms
- Pen or pencil
- A watch with a second hand or you can count to yourself. For example, if the item were in your child's mouth for 3 seconds you would have counted one-thousand-one (1001), one-thousand-two (1002), one-thousand-three (1003). For items that seem like they may be in the mouth for longer times (like example 2 below), keep track with your watch.

How to report the information

- Using the forms in this booklet, fill out a new form for each 15-minute period you watch your child. Extra forms are included in case your child mouths more than 25 items in the 15-minute time period when you are watching.
- On each form:
  a) Circle the number that equals the period you are watching
  b) Fill in the Date
  c) Fill in the Time of day, don't forget to mark "AM" or "PM"
  d) Numbered Lines - Each time a non-food item touches your child's mouth fill in a new line with the name of the item and amount of time. If your child puts the same item in his/her mouth several times in a row you can just use a down arrow "↓" under the item's name on each line after that until a new item is placed in the mouth. Don't forget to record the separate times.

Example:

	Item mouthed (short description	Amount of time on the lips or in the mouth
1	thumb	64 sec or 1 min, 4 sec
2	pacifier	10 min, 12 sec
3	carrot soft squeeze toy	7 sec
4	↓	5 sec
5		

OMB Clearance No. 3041-0129

Observation Form for Mouthing Behavior Study

Time Period # 1 2 3 4 (circle one) Date:_____ Time:____AM/PM

	Item Mouthed (short description)	Amount of Time on Lips or in Mouth
Example 1	fingers	1 min, 13 sec
Example 2	carrot squeeze toy	2 sec
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

OMB Clearance No. 3041-0129

Observation Form for Mouthing Behavior Study

Time Period # 1 2 3 4 (circle one) Date:_____ Time:____AM/PM

	Item Mouthed (short description)	Amount of Time on Lips or in Mouth
Example 1	fingers	1 min, 13 sec
Example 2	carrot squeeze toy	2 sec
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

OMB Clearance No. 3041-0129

Observation Form for Mouthing Behavior Study

Time Period # 1 2 3 4 (circle one) Date:_____ Time:____AM/PM

	Item Mouthed (short description)	Amount of Time on Lips or in Mouth
Example 1	fingers	1 min, 13 sec
Example 2	carrot squeeze toy	2 sec
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

OMB Clearance No. 3041-0129

Observation Form for Mouthing Behavior Study

Time Period # 1 2 3 4 (circle one) Date:_____ Time:____AM/PM

	Item Mouthed (short description)	Amount of Time on Lips or in Mouth
Example 1	fingers	1 min, 13 sec
Example 2	carrot squeeze toy	2 sec
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		