REQUEST FOR CLEARANCE
FOR FOCUS GROUP STUDY
OF AUDIENCE ANALYSIS FOR BIOMONITORING

201011-0920-009

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January 31, 2011

LIST OF TABLES

ATTACHMENTS

A. JUSTIFICATION

A.1 Circumstances That Make the Collection of Information Necessary

Background

This Information Collection Request (ICR) is for a new data collection entitled "Audience Analysis for Biomonitoring."

People's exposure to environmental chemicals can be a risk to their health. Scientists at the Centers for Disease Control and Prevention (CDC) use biomonitoring, which is the measurement of environmental chemicals in human tissues and fluids, to assess such exposure (Sexton, Needham, & Pirkle, 2004). Biomonitoring findings, however, do not typically provide information on health risks and toxicity data often lag behind new biomonitoring data. The health effects on humans are, therefore, often uncertain or unknown. Furthermore, there is lack of published health standards, particularly because new sources or pathways to humans are being investigated or a new detection method or technology may still be evolving for many new or "emerging" chemicals.

Findings from biomonitoring studies pose enormous challenges for those charged with interpreting and communicating results, particularly to scientific and nonscientific audiences without a biomonitoring background. In their 2006 report, Human Biomonitoring for Environmental Chemicals, the National Research Council (NRC) describes communicating biomonitoring results as the most challenging issue facing the field, yet critical to the accurate interpretation and use of biomonitoring data (NRC, 2006). Further complicating matters are the growing media coverage and public concern about chemicals found in the human body. As additional biomonitoring data are released, there is demand for answers and decreasing patience with the uncertainty that characterizes the interpretation of such results.

Communication of risk information is a fundamental aspect of nearly all health promotion interventions. However, no consensus exists regarding the most effective way to provide people with risk information (Rothman & Kiviniemi, 1999). For example, numerical probability information offers people precise information regarding the probability that a health problem will occur. However, the effectiveness of this communication approach is constrained by people's inability to accurately interpret and use numerical probabilities.

The CDC is interested in developing a framework for communicating health risk messages, particularly, about emerging environmental chemicals. Bisphenol A (BPA) and phthalates are examples of such emerging chemicals, which are included in the present study. There are other chemicals, such as mercury, where there is relatively more information available about health risks. However public awareness about such risks is not always accurate and decisions are often made that result in missing certain health benefits. Fish avoidance during pregnancy is a case in point (Frithsen & Goodnight, 2009).

The three chemicals BPA, phthalates, and mercury have been selected to test health risk messages with the target audience of selected women who are pregnant or have young children. These chemicals have received attention from the media and have raised concerns from attentive public audiences. These chemicals are of particular concern to selected women because the risks of exposure are higher for young children due to their hand-to-mouth behaviors and direct oral (mouth) contact with materials containing these chemicals. In addition, young children eat and drink more per pound of body weight than adults and, hence, more vulnerable to exposures from such chemicals. Furthermore, BPA and phthalates are found in products used by children. For example, BPA is used in plastics to make a number of products including beverage containers, baby bottles, and toys. Phthalates are also used in

plastics and found in children's toys as well as in a number of other personal-care products, such as detergents, soaps, and shampoos. Mercury, though not present in plastics, is found in air, water, and soil and exists in three forms that have different properties, usage, and toxicity. Methylmercury is one form of mercury that accumulates in the food chain. People can be exposed to mercury by eating fish or shellfish contaminated with methylmercury. Methylmercury can pass through the placenta exposing the developing fetus.

For both BPA and phthalates, general exposure at low levels comes from consuming food or drinks stored in containers that have these chemicals. At these low levels of exposure, human health effects of both these chemicals are unknown. Laboratory studies with animals have shown that BPA and some types of phthalates affect the reproductive system of animals. More research is needed to assess the human health effects of exposure to these chemicals. For mercury, the health effects at high levels or at low but prolonged levels of exposure include lung damage neurological disturbances, memory problems, skin rash, kidney abnormalities, and damage to the nervous system (e.g., infants born to women who were poisoned with methylmercury had developmental abnormalities and cerebral palsy).

CDC provides fact sheets on these chemicals, including biomonitoring information, on its website. However, these materials have not been tested with its various public audiences to see how the information about health risks is interpreted and understood. Feedback from selected women who are an attentive public audience with an interest in their young or unborn child's health would be valuable for CDC to inform its communication.

As part of CDC's broad goal of protecting health, communicating risk information effectively is crucial for prevention and control of disease, injury, and disability and promoting a healthy life for all people. This project's goal of developing a framework for communicating health risk information about chemical exposures is a step in this direction.

CDC is authorized to collect this data under Section 301 of the Public Health Service Act (42 USC 241) (See Attachment 1).

Privacy Impact Assessment

i. Overview of the Data Collection System

Eight exploratory focus groups (9 adults per group) and six message testing focus groups (9 adults per group) will be conducted with selected women across the country. Findings from the exploratory groups will be used to develop messaging to be tested in subsequent focus groups. Participants for all groups will be recruited by a professional focus group facility, using a screening instrument (screener) to identify qualifying participants through a brief telephone conversation (see Attachment 3). Groups will be led by a trained moderator using a discussion guide and held in a professional facility that allows for observation by a project staff.

ii. Items of Information to be Collected

A copy of the exploratory focus group discussion guide can be found in Attachment 4.
The focus groups will cover the following topics:

- Awareness of chemical exposures and experience receiving chemical exposures-related information.
- Awareness and knowledge of emerging chemicals such as BPA, phthalates, and mercury.

- Sources of information about chemical exposures.
- How women communicated with others on the subject of people's exposures to chemicals.
- Types of information women would be interested in learning about.
- Means and channels of receiving information.

A copy of the message testing focus group discussion guide can be found in Attachment 5. The message testing focus groups will cover the following topics:

- Knowledge of emerging chemicals such as bisphenol-A (BPA), phthalates, and mercury.
- Feedback on items presented to participants on environmental chemicals, exposures, and health risks (e.g., impressions, importance, clarity, relevance, usefulness, and salience of messages).
- Type of information most compelling for women's attention.
- Presentation of risk information.

No personal identifiers will be linked to data or provided to CDC. However, information in identifiable form (IIF) will be used by the focus group facility to screen participants for the focus groups. The IIF includes respondent name and phone numbers. Participants will only provide their first name during the focus group discussions. The audio tapes of the focus groups will be stored in a locked file cabinet, and accessible only to Westat project staff. The recording will be destroyed at the end of the study which is currently May, 2011.

A.2 Purpose and Use of the Information

CDC is interested in developing a framework for communicating risk information, particularly about emerging environmental chemicals. This proposed qualitative research is designed to inform the revision of existing CDC materials and development of future ones by identifying the concepts and messages needed to communicate health risks by using BPA, phthalates, and mercury as examples and possibly applying the findings more broadly to other chemical exposures, as appropriate. The chemicals selected for this project have a particular interest for women whose unborn or young children have greater health risks of exposures from these chemicals. These selected women are the target audience for this study.

Privacy Impact Assessment

(i) Why the information is being collected

As noted earlier, this information is being collected to develop a framework for communicating risk information, particularly about emerging environmental chemicals. This information is not available from any other source.

(ii) Intended use of the information

The information gathered in this research will be used internally by CDC staff and its contractor Westat to develop messages and methods for communicating with intended audiences.

As noted in section A.1 above, no personal identifier information collected will be transmitted to CDC.

A.3 Use of Improved Technology and Burden Reduction

A number of steps have been planned to ensure the least burden possible is shouldered by the public. These steps include:

(1) A recruitment screener has been designed for recruiters to quickly identify qualifying participants through a brief telephone conversation.

(2) All information from participants will be provided orally.

(3) Moderator's guides have been developed specifically to ensure that the discussion is limited to no more than 2 hours, so that the questions are well-organized and flow well together, and are easy to understand and answer.

(4) Participants are chosen from lists of individuals who have expressed an interest in being in a focus group. Focus groups are common practices among private and public sector organizations, and many individuals look forward to learning about new products and/or ideas. It is a familiar process to them, and often, they comment that it's easier than filling out lengthy forms or being stopped at a mall for an intercept interview.

A.4 Efforts to identify Duplication and Use of Similar Information

CDC has made a significant effort to avoid duplication by conducting a literature review, interviews with experts, data base searches, and participation in workshops and conferences. The proposed data collection is unique and does not duplicate any past, current, or planned information collection by other federal government agencies.

A.5 Impact of Small Business and Other Small Entities

No small entities will be involved in this survey. All respondents will be individuals who participate voluntarily.

A.6 Consequences of Collecting the Information Less Frequently

This is a one time data collection effort, which is essential to CDC's ability to identify messages that will lead to the development of a framework for communicating risk information about environmental chemicals to attentive public audiences. There are no legal obstacles to reduce the burden.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection request fully complies with Guidelines of 5 CFR 1320.5. No special circumstances exist outside the guidelines.

A.8 Comments in Response to Federal Register Notice and Efforts to Consult Outside Agency

A notice of this proposed project was published in the *Federal Register* on June 21, 2010, Volume 75, Number 118, page 35041 , as required by 5 CFR 1320.8(d) (see Attachment 2).

There was a comment requesting a copy of the data collection plans, instruments, and related information which was provided. Another comment asked how CDC plans to interpret the biomonitoring information that it collects in a risk context. CDC responded to this comment by clarifying that the purpose of this study is to assess and improve how CDC communicates its U.S. population biomonitoring data. No change occurred in response to this comment.

The following persons have been consulted on this research since June 2008:

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A.9 Explanation of Any Payment or Gift to Respondents

All respondents in the focus groups will receive a token of appreciation following their participation in focus groups. Previous research indicates providing monetary incentives can increase participation (Kreuger, 1994). As stated by Kreuger, "the incentive is not a reward…[but] serves as a stimulus to attend the session." The token of appreciation will be $75 per respondent and will be provided directly to participants by the focus group facilities.

A.10 Assurance of Confidentiality Provided to Respondents

This submission has been reviewed and determined that the Privacy Act does not apply. Westat will hire a professional focus group facility to screen and schedule respondents. The only IIF that will be obtained are the participants' name and phone numbers for setting up interview appointments, which will be maintained at the focus group facility in its proprietary files. These personal identifiers will not be linked to data. During the focus groups, only first names will be used. Focus groups will be audio taped and transcribed for use by the Westat research team in developing a report. The audio tapes will be stored in a locked file cabinet, accessible only to project staff. The recording will be destroyed at the end of the study, which is currently May, 2011.

Westat's Institutional Review Board (IRB) reviewed the study instruments and granted expedited approval for the study due to minimal risk (see Attachment 7). CDC/ATSDR is not engaged in the research.

Privacy Impact Assessment Information

10-A. The Privacy Act does not apply.

10-B. Focus groups will be audio taped and transcribed for use by the research team in developing a report. Transcripts of focus groups will only record participants first name. The audio tapes will be secured in a locked file cabinet, accessible only to project staff. The recording will be destroyed at the end of the study, which is currently May, 2011. Respondents will be informed of study data collection procedures and securing of data in the consent form (see Attachment 6).

10-C. Respondents will provide their consent to participate in the study by reading and signing the consent form. Respondents will be informed that findings from this research will be used by CDC to identify messages that will lead to the development of a framework for communicating risk information about environmental chemicals to attentive public audiences such as women interested in their young children's health risks. (See Attachment 6).

10-D. Respondents will be informed that participation in the study is purely voluntary and no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions in the consent form. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Data security procedures will be described to respondents in the informed consent form (See Attachment 6).

A.11 Justification for Sensitive Questions

The proposed research is voluntary, and no persons are required to participate. This voluntary aspect of the focus group is clearly stated in the informed consent and will be stressed by the moderator during the focus groups. There are no items considered to be sensitive for respondents.

A.12 Estimates of Annualized Burden of Hours and Costs

Estimated response burden hours are shown in Table A.12A. The estimated time for the recruitment screener is based on past experience with similar studies. The focus groups will last no longer than 2 hours. The mean hourly wage rate is based on the most recent National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is $20.90. We have revised it slightly and rounded this number to $21.00. The annualized cost burden is shown in Table A.12B.

Table A.12A: Estimates of Hour Burden

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Recruitment screener	252	1	5/60	21
Exploratory Focus Groups	72	1	2	144
Message Testing Focus Groups	54	1	2	108
Total	378	---	---	273

Table A.12B: Annualized cost to respondents

Respondents	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
Recruitment screener	21	$21.00	$441.00
Exploratory Focus Groups	144	$21.00	$3,024.00
Message Testing Focus Groups	108	$21.00	$2,268.00
Total	273	--	$5,733.00

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents beyond those presented in section A.12. There are no operating, maintenance, or capital costs associated with the collection.

A.14 Annualized Cost to the Federal Government

The total annual cost to the Federal Government will not exceed $144,000. This estimate is based on eight exploratory focus groups, at $10,000 each ($80,000 total) and six message testing focus groups at $10,000 each ($60,000 total), and cost of the Federal Project Officer ($4000). These figures include the costs of study design, materials development, facility rental, participant incentives, data collection, analysis, and report writing. Federal employees will be involved in oversight and/or analysis.

A.15 Explanation for Program Changes or Adjustments

This is a new request for approval of a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Recruitment for the focus groups will begin within one week of OMB approval and the entire study will be completed within 6 months. This includes conducting 14 focus groups, analysis and report writing. The table below outlines the project time schedule, by activity:

Table A-16: Project Time Schedule

Activity	Time Schedule
Recruit participant for exploratory focus groups	1-3 weeks after OMB approval
Conduct 8 exploratory focus groups	4–8 weeks after OMB approval
Prepare topline report	9-11 weeks after OMB approval
Develop messaging and draft materials	12-14 weeks after OMB approval
Finalize protocols for message testing	15-17 weeks after OMB approval
Recruit participants for message testing focus groups	18-20 weeks after OMB approval
Conduct 6 message testing focus groups	21-23 weeks after OMB approval
Prepare final report for focus group study	24-27 weeks after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This is a qualitative data collection. Statistical methods will not be used.

B.1 Respondent Universe and Sampling Methods

Participants for the study will be recruited from the areas where the focus groups are held (i.e., East, West, and Midwest). These participants will include women who are pregnant or have children under the age of five. In addition, these women will have a college education, are regular news readers and do not have a great deal of environmental knowledge. To ensure that nine participants are in each of the 14 focus groups (8 exploratory, 6 message testing), 12 participants will be recruited per group. Participants will be recruited using standard focus group recruitment methods, by calling their household and administering a screening questionnaire to pre-qualify them (see Attachment 3). Most will come from an existing database (or list) of potential participants, owned and maintained by each focus group facility.

B.2 Procedures for the Collection of Information

After arriving at the focus group facility, the respondents will be given information on the study and a consent form to sign (See Attachment 6). Then the respondents in each group will be gathered in a room with a trained moderator and a one-way mirror, behind which CDC and Westat staff will be seated. The moderator will explain the study, inform the group of taping and observation, and lead a discussion using a guide. Each focus group will last approximately 2 hours. The focus group discussion guides are provided in Attachment 4 (exploratory) and Attachment 5 (message testing). Responses will be collected by audio tape, and observers will take notes. After the group, the tapes will be transcribed for qualitative analysis.

B.3 Methods to Maximize Response Rates and Address Non-Response

This is not applicable. A convenience sample need not be representative to indicate a need for further message refinement or other attitudinal information.

B.4 Test of Procedures or Methods to be Undertaken

This is qualitative data collection. Statistical methods will not be used. Standard focus group discussion procedures and analysis of findings will be used.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The persons who designed the data collection and who will analyze the data are:

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