SUPPORTING STATEMENT
Estimating the Benefits of Reduced Risks to Health
Focus Groups
September 2016

(1) Title of the Information Collection

Estimating the Benefits of Reduced Risks of Adverse Birth and Early Life Stage Outcomes

(2) Short Characterization/Abstract

EPA is required, by statute and/or executive order, to perform benefit-cost analysis of rulemakings. For impacts on human health, a key challenge is to estimate the expected health benefits in dollar terms, largely because willingness to pay (WTP) or cost-of-illness estimates are not always available for the health effects associated with different rules. In order to provide a more comprehensive assessment of the benefits associated with rules that reduce health risks, analysts need WTP estimates for different health endpoints affected by rules. For many health endpoints, stated preference (SP) methods are a valuable method to elicit the WTP estimates needed for more complete benefits analysis.

While the literature contains many valuation estimates associated with occupational fatalities, there are fewer estimates available for a number of potentially important health endpoints affected by environmental policy. These include risk of fatal and non-fatal cancer of many types, cardiovascular outcomes such as stroke and hypertension, and cognitive effects (e.g., Alzheimer's). A key set of health effects with limited valuation data are birth and early life stage outcomes, which are associated with a wide array of environmental contaminants including lead, arsenic, mercury, and many other chemicals. The goal of the current project is to fill this gap by developing a stated preference survey instrument to elicit individuals' willingness to pay (WTP) for reduced risks of outcomes that result from exposures in utero and during early life stages, such as low birthweight, preterm birth, and neurodevelopmental effects.

EPA is particularly interested in developing willingness to pay estimates for these in utero and early life exposures for several reasons. Endpoints associated with these exposures have been identified as being particularly salient to EPA program offices because (1) they often lack valuation information; (2) they are associated with many contaminants of concern; and (3) they are likely to be encountered in one or more future rulemakings.

While the existing scientific literature is still developing, these endpoints represent an emerging area for which EPA would like to be situated to provide valuation estimates when the science is available. EPA anticipates it will take several years for the results of a stated preference study to be fully available – factoring in the time for focus groups, survey development, administration, and peer review.

The focus groups that are the subject of this ICR will enable EPA to explore the feasibility of implementing a stated preference survey for one of these endpoints. While these endpoints show promise for valuation through stated preference survey – both from the need for information as well as the emerging science –it is likely that EPA will only be able to develop a full survey for a limited subset of endpoints, and perhaps only one. The purpose of the focus

groups is to determine which endpoint(s) will be most appropriate for a stated preference survey.

This Supporting Statement provides background material for a request to conduct 12 focus groups and 24 one-on-one interviews as part of the survey development process. The results from these activities will inform the design of a survey instrument. This exercise will not produce results that can be statistically analyzed to estimate willingness to pay for any outcome for any group or set of individuals. It will produce, based on the results of these focus groups and interviews, a survey instrument for a full-scale stated preference survey. However, implementing such a survey is beyond the scope of this ICR; any request for implementing a full-scale survey will be made in a separate ICR.

(3) Need for the Collection

The developmental work being proposed under this ICR is but one component of EPA's broader initiative associated with improving its ability to monetize the health benefits associated with EPA rules by directly providing estimates of the value of reductions in risk to specific health endpoints for which little to no information currently exists. While there are well-established estimates of benefits associated with some environmental contaminant-health effect relationships (e.g., premature mortality associated with particulate matter and ozone exposure), for many other contaminant–health effect relationships there are only rudimentary approaches to evaluating the benefits of health risk reductions. Cost-of-illness (COI) measures are at times used as a proxy for willingness to pay estimates, but they are often thought to provide a lower bound on the full value of a risk reduction because such estimates typically do not include the value of any avoided pain, suffering and dread. For other health outcomes, neither WTP nor COI estimates are available, in which case the value of the risk reductions are not included in a given policy analysis.

EPA has identified two general categories of health endpoints for which (1) program offices have identified high priorities; (2) near-term developments in the science are anticipated to identify a concentration-response function; and (3) valuation information is lacking. These two categories include birth outcomes (e.g., preterm birth and low-birth weight) and neurodevelopmental outcomes (e.g., ADHD and conduct disorders). We briefly describe the science for these categories and then our plans for exploring the feasibility of conducting a stated preference study for them, beginning with the focus groups that are the subject of this ICR.

Adverse Birth Outcomes:

"Adverse birth outcomes" is a term used to describe conditions related to childbirth including birth defects, low birthweight (or reduced fetal growth), preterm birth, and fetal mortality. Low birthweight and preterm birth are associated not just with treatment and medical costs, but also with longer term effects on brain development, cardiac and renal function, and adult health, including cardiovascular disease, obesity, and metabolic disorders be (Cosmi, et al. 2011; Rinaud and Lamb, 2008). Many of these birth outcomes have been associated with environmental contaminants such as arsenic, disinfection byproducts in drinking water, N-Methylpyrrolidone (NMP), PM2.5, and lead. Causal links between lead (Pb) and adverse birth outcomes have been evaluated by EPA's Integrated Science Assessment (ISA) and the National Toxicology Program (NTP) monograph through comprehensive literature reviews (U.S. EPA 2013 and NTP 2012). The

EPA ISA reviewed studies published since the last review in 2006 of health outcomes associated with Pb exposure at all blood levels, while the NTP Monograph reviewed available literature from all years for blood Pb exposures measured at < 10mg/dL. The ISA concluded that evidence was suggestive of a causal relationship between Pb exposure and adverse birth outcomes. The NTP monograph found sufficient evidence that maternal exposures to Pb are associated with reduced fetal growth and lower birth weight. Given epidemiologic evidence for Pb and other contaminants, birth outcomes are an important set of health effects to consider for EPA benefits analysis.

Neurodevelopmental Outcomes:

"Neurodevelopmental outcomes" is a term used to describe a broad suite of health endpoints to include IQ, ADHD, autism spectrum disorders, conduct disorders, anxiety, depression, and more. We recognize that this is a broad set of outcomes which cannot all be addressed in a single valuation study. EPA's ISA and the NTP monograph provide comprehensive literature reviews and weight-of-evidence assessments for adverse developmental health effects associated with Pb (U.S. EPA 2013 and NTP 2012). Both documents assigned the strongest possible causal determination category to the association between childhood Pb exposures and attention-related problems. Impacts on IQ are regularly quantified and included in EPA benefits analyses, but other effects are generally not. Yet it appears that published literature can support quantification of some of these effects, including the association between Pb exposures and attention-deficit/hyperactivity (ADHD) outcomes. Based on these assessments and EPA's review of the literature (U.S. EPA 2016) the agency believes there is sufficient information to explore the development of valuation estimates for use in future regulatory analyses.

The results of the developmental work in this ICR are but one of several initiatives that will eventually be used to improve assessment of the benefits associated with different environmental policies. It is critical that EPA invest in developing estimates for reductions in risks that are heretofore assigned a zero value in order to provide the most accurate and up-to-date information required to make sound decisions in regulating contaminants. This survey development effort will fill an important gap in the valuation of certain health endpoints.

The focus groups and one-on-one interviews that are the subject of this ICR are an important step in determining how to frame questions and design a survey instrument that can capture the value of reduced risk of birth and neurodevelopmental outcomes for use in benefit-cost analysis. Specifically, the focus groups and interviews proposed under the generic ICR will help establish a viable survey instrument, which will later be used (under a separate ICR) to elicit and estimate the values individuals place on these reduced risks in ways that are consistent with micro-economic theory and benefit-cost analysis. The number and types of outcomes ultimately included in the survey instrument will be dependent on focus group results obtained through this effort. Key considerations for determining these specific outcomes include how salient they are to respondents, how effectively the risks can be communicated, and the acceptance of delivery mechanisms for reducing these risks.

While the scientific work associated with developing concentration-response functions is ongoing, EPA believes there is sufficient evidence to explore the feasibility of conducting a stated preference study on these endpoints. These two categories of endpoints show the most

promise for having ready scientific information in the next 1-2 years, as such they are the subject of these focus groups.

There is uncertainty regarding which endpoint(s) would be most feasible to value through stated preference methods. Because of the lack of prior stated preference research on these endpoints, we have little understanding of which aspects are most salient and how individuals view and perceive related risk information. EPA will use focus groups to explore how to effectively (1) describe scientific information regarding the endpoints, (2) communicate quantitative information regarding risks and risk changes, and (3) elicit preferences for changes in risks associated with the endpoints in an unbiased manner. The initial focus groups (2-4) are exploratory in nature and will be used to inform both the choice of which endpoint is most feasible for use in a stated preference survey and the development of draft survey questions for the selected endpoint. Subsequent focus groups and cognitive interviews requested under this generic IC will inform question format, selection of visual aids to help convey risk changes, and information treatments allowing the survey development process to evolve towards a draft stated preference survey that will ultimately be subjected to rigorous peer review and submitted for approval under a separate information collection request.

The set of focus groups requested here follows an emergent design approach that first uses less structured focus groups early on to better understand respondent beliefs and perceptions. Some of the questions and issues that will be addressed in initial focus groups include:

- Which birth and neurodevelopmental outcomes are of most concern?
- How are the dimensions of these outcomes (e.g., physical and neurological impacts) best communicated, and over what time frame?
- How are valuation estimates of reduced risk affected by uncertainty about risk or causality?
- Are there specific contaminants that generate particular concern?

As noted above, subsequent focus groups will become more structured as EPA evaluates which endpoints are best suited for a survey. Some of the factors EPA will use to evaluate focus group responses to inform the choice over endpoints are:

- Do respondents have an emotional response to the endpoints that make it difficult to consider tradeoffs?
- Are respondents able to describe the outcomes of concern in generally understandable terms?
- Do respondents understand essential scientific information regarding exposures to pollutants and the health outcomes?
- How do respondents react to interventions that can reduce exposure and mitigate risks?
- How do respondents interpret quantitative information about risks and risk changes, and are they willing to make choices about alternative risk reduction tradeoffs?

Once EPA has evaluated responses to these types of questions from the first few focus groups (2-4), we will choose the endpoint or endpoints that are best suited for estimating the value of risk reductions using a stated preference survey. Then EPA will focus the remaining focus groups to elicit information that will inform the design of the survey instrument, including the design of choice questions, debriefing questions, alternative information treatments and visual aids. The use of focus groups is essential for EPA to determine the feasibility, design, and

structure of stated preference survey instrument. EPA will not shift the primary focus of this effort away from valuation of developmental or adverse birth outcomes without OMB approval.

(4) Non-duplication

The selection of birth and neurodevelopmental outcomes as a set of health endpoints for this effort was informed by discussions and consultations with EPA program offices. EPA's National Center for Environmental Economics (NCEE) met with economists and policy analysts from the Offices of Air and Radiation, Water, Chemical Safety and Pollution Prevention, and Land and Emergency Management to gather information on specific health endpoints and contaminants for which EPA routinely lacks values and/or are likely to be the subject of future rulemaking efforts. Based on the results of these discussions it became apparent that birth and neurodevelopmental outcomes (1) often lack WTP estimates for valuation, (2) are associated with many contaminants of concern across program offices, and (3) are likely to be encountered in one or more future rulemakings.

Some valuation estimates for birth and neurodevelopmental outcomes are available for use in EPA benefit-cost analysis, most notably for changes in IQ and the resulting impact on lifetime earnings (e.g., USEPA 2015). While not an estimate of WTP, this effect on earnings is robust and well-established, and allows for avoided IQ impacts to be included in EPA regulatory analyses. For most other outcomes (e.g., low birthweight, pre-term birth) there are some studies that estimate cost-of-illness but very few studies that estimate WTP for risk reduction.[1]

Several studies are underway in Europe on WTP for birth and neurodevelopmental outcomes as part of an initiative by the European Chemicals Agency (ECHA). Specific birth outcomes being addressed include: IQ loss (Atherton, et al. 2016), infertility, birth defects, and very low birthweight (Scasny and Zverinova 2016).[2] It is unlikely that the values estimated in European countries would be directly applicable for US regulatory impact analysis, however the methods may be informative for the survey instrument being developed under this ICR.

Given the paucity of existing WTP estimates for birth and neurodevelopmental outcomes in the US, and that the results of the study under this ICR are designed to be unique, this study will not be duplicative of other efforts.

(5) Consultations

This is a new focus group request (not a renewal of an ongoing collection effort) so no periodic consultations with persons outside of the Agency have been conducted related to this effort.

This collection, or perhaps more likely, a potential survey instrument based on the results from these focus groups, may be of interest to other Federal, State, and Local Agencies that affect

1 One exception is von Stackelberg and Hammitt (2009) which uses contingent valuation to estimate WTP for changes in IQ and reading comprehension.

2 Recent presentations that provide more details on these and other studies sponsored by ECHA can be found at http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/expert-workshop-on-valuing-the-health-impacts-of-chemicals (accessed 3/14/16).

human health risk, as well as to the Office of Management and Budget. EPA will make a concerted effort to keep interested parties informed of progress as the survey instrument is developed, and will ensure that these parties are informed of any survey implementation.

(6) Peer Review Plans

Interim products such as focus group scripts and draft survey questions developed during this project will be subject to routine internal review by the EPA staff. The final product from these focus group efforts is a survey instrument to elicit individuals' willingness-to-pay for reductions in health risks – the precise nature of which will be informed in part by the focus groups. A report summarizing the main findings from the focus groups and one-on-one interviews will accompany the survey draft. External peer review is beyond the scope of this initial effort, but both the survey instrument and focus group report will be externally reviewed prior to any full-scale study.

(7) Confidentiality

The survey instrument will fully conform to federal regulations – specifically the Privacy Act of 1974 (5 U.S.C. 552a), the Hawkins-Stafford Amendments of 1988 (P.L 100-297), and the Computer Security Act of 1987. Each prospective respondent will be informed that their participation in the exercise is voluntary. The identities of the individuals will be kept confidential by the investigators and not associated with their responses in any report.

(8) Sensitive Questions

There are no questions included in the survey materials on sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private or sensitive materials.

(9) Respondents

Respondents will be members of the general public who volunteer to participate in focus groups and interviews. Participants will be recruited by the focus group facility so as to provide adequate representation of the target population and are typically compensated for their time by the facility. The compensation amount may vary by facility depending on typical compensation in each geographic location, but will not exceed $75 per participant. See section 11 for more information on areas of focus.

(10) Collection Schedule

The project timeline depends on the results of the focus groups, as well as external constraints. The expected timeline for the data collection is as follows. Please note that these tasks may partially overlap; in particular, we allow for the possibility of some one-on-one interviews to be conducted prior to the completion of all the focus groups. Initial focus groups will likely be used to scope participants' understanding of concepts, explore the use of different risk communication tools, and to gauge the relative importance of certain health outcomes. While results from the initial focus groups will serve as inputs to the survey drafting process, later focus group participants will help gauge the effectiveness of draft materials.

Task:	Expected Completion Date:
Contact potential respondents	Start 2 Weeks from ICR approval (on a rolling basis)
Conduct Focus Groups	15-20 Weeks from ICR approval
One on one interviews with draft survey instrument	15 to 19 Weeks from ICR approval

(11) Respondent Burden

Participants for focus groups and individual interviews will consist of residents in several metropolitan areas across the U.S. likely to include Washington, D.C., Baltimore, MD, Richmond, VA, and Boston, MA. Respondents may also be recruited from more rural areas surrounding these locations. We plan to conduct a maximum of 12 two-hour voluntary focus groups of approximately 10 individuals each. The respondent burden for focus groups is 240 hours. We also plan to conduct 24 two-hour one-on-one interviews to test draft survey instruments. The respondent burden for interviews is 48 hours. The total burden under this ICR is therefore 288 hours.

In summary, the total burden for voluntary respondents consists of:
Focus groups: 12 groups * 10 people/group * 2 hrs per person = 240 hours.
One-one interviews: 24 people * 2 hours per person = 48 hours.

For a total burden of 288 hours.

References

Atherton J, Atkinson G, Georgiou S, Mourato S. 2016. The Value of Reducing Children's Exposure to Lead (Pb), A stated preference approach. Presentation at ECHA Workshop on Valuing the Health Impacts of Chemicals, Helsinki.

Cosmi, E, T Fanelli, S Visentin, D Trevisanuto, V Zanardo. 2011. Consequences in Infants that Were Intrauterine Growth Restricted. Journal of Pregnancy, v2011, Article ID 364381.

Rinaudo, P F, and J Lamb. 2008. Fetal Origins of Perinatal Morbidity and/or Adult Disease. Seminars in Reproductive Medicine, 26(5): 436-445.

Scasny M, Zverinova I. 2016. The ECHA Study on Fertility, Birth Defects, and Developmental Toxicity: How Much are Improving Fertility and Reducing Risk of Birth Defects Worth. Presentation at ECHA Workshop on Valuing the Health Impacts of Chemicals, Helsinki.

US EPA. 2015. *Benefit and Cost Analysis for the Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category*. EPA-821-R-15-005.

Von Stackelberg K, Hammitt J. 2009. Use of Contingent Valuation to Elicit Willingness-to-Pay for the Benefits of Developmental Health Risk Reductions. *Environmental and Resource Economics* 43:45-61.