REQUEST FOR PROPOSALS
Human Health Exposure Assessment TIP
1/03/00

1.) RfP Title:  DEMOGRAPHICS AND DATABASES WHITE PAPER

2.) RfP Number:  HHEA 2

3.) Introduction and Description of Topic

The purpose of this project is to evaluate the "adequacy" of information currently available (or under development) on the "inputs" to exposure models. These inputs (also called exposure factors) include individual’s physiological characteristics, exposure-related behaviors, factors related to occupational exposure, residential characteristics, and data on the use of consumer and commercial products. The inputs include both those factors that determine the magnitude, or intensity, of the exposure and those which determine the frequency and patterns of exposure in the lives of the exposed individuals. The “adequacy” of the data on a specific factor will be characterized in terms of ability of the current information to provide an understanding of national patterns of inter-individual variation and intra-individual variation over time of the input.

The information provided by this project will primarily be used to inform and advise the CMA HHEA TIP in its efforts to carry out its mission:

Identification, facilitation and communication of generic research that will characterize people’s exposure to chemicals and raise the confidence and lower the uncertainty for quantitative estimates of exposure associated with potential human health effects to chemicals.

This work will summarize the literature and the current ongoing research initiatives for the subject of demographics and databases in a Critical Review Paper. The Critical Review Paper will be published in the peer-reviewed literature.

Background

The field of human exposure modeling is, at this point in time, generally underdeveloped. Currently, exposure assessors rely on models to characterize the dose rates received as the result of exposures to chemicals in the environment, diet, and indoor environments. These models require detailed and authoritative information on exposure related factors that is typically not available.

Because of these data gaps, EPA and other regulatory agencies have adopted conservative “default values” for the model inputs. These default values are often based on estimates of the upper bounds of the range of values for an input, where the range reflects the uncertainty or variation in the value of the input. The use of such default values results in estimates of dose rates that are difficult to evaluate. It is difficult to determine if the dose rates predicted based on the default values actually occur, and if they occur, what would be the frequency of occurrence. Consequently, default-based exposure estimates have been viewed as being “hypothetical” or unrelated to actual exposures.

This problem has been exacerbated by the adoption of more sophisticated probabilistic models that require information on the inter- and intra-individual variation in inputs. Consequently, there is an increasing need for a detailed understanding of the range of values that could occur for these exposure inputs.

There are three dimensions to the information that is required on most exposure inputs. The first is interindividual variation or variation between individuals in a population. This variation occurs
because individuals truly differ in their physiological characteristics, in their behaviors and in their locations in time and space. As a result, inputs to exposure models to characterize a population’s exposure behaviors will follow a distribution that reflects these interindividual differences. The second type of information is how the value of an input for an individual changes over time because of his or her changing behaviors and locations over time. This is temporal variability of an input value for an individual (or intra-individual variation). The third type of information is on the uncertainty or lack of specific knowledge of the characterizations of interindividual and temporal variation in the values of an input for an individual or a population of individuals.

There have been a number of efforts to collect, organize, and present information on exposure inputs. These include EPA’s Exposure Factors Handbook, the Residential Exposure Assessment Project, the AIHC Exposure Sourcebook, and numerous individual publications on specific inputs. In general, all of these efforts have sought to derive the best estimates of either distributions that reflect interindividual variation (and in some cases uncertainty) or upper bound estimates suitable for using as default values.

This task will review these efforts, and other ongoing research, and present an evaluation of the adequacy of the data in terms of inter and intra variation and uncertainty. This work will lay the basis for research on exposure inputs that would show how exposure predictions might be improved or what additional information might best lower the uncertainty associated with model predictions. Both occupational and general population exposures should be included, but with the predominant focus on general population exposures (a 25/75 split is recommended).

The specific origin and background for this request comes from the DEMOGRAPHICS AND DATABASE SESSION, CMA Exposure Workshop, CIIT, Research Triangle Park, NC, May 18 and 19, 1999. The summary of the proceedings from this workshop is attached to this RFP. This summary is included to provide the potential contractor with the additional background on the scope of topics discussed and considered. It is within the context of the scope of these proceedings that the critical review should be conducted.

**Project Description**

The purpose of this project is to create an evaluation of the adequacy of data on exposure inputs. *It is not intended to be a re-summary or update of the Exposure Factors Handbook.*

These inputs should include individual’s physiological characteristics, exposure-related behaviors, factors related to occupational exposure, residential characteristics, and data on the use of consumer products. The inputs also include those factors that determine the frequency and patterns of exposure in the lives of the exposed individuals. Both occupational and non-occupational population exposures should be included, but with the predominant focus on the non-occupational population exposures (a 25/75 split is recommended).

At least three phases of this project are anticipated,

1. Information gathering – a search and review of published and unpublished (or gray) Literature. This includes contacting, interviewing, and networking with workers in the field.

2. Synthesis of the available information to identify the current knowledge base, and any planned or in-progress studies, and the gaps in the available data or knowledge base that are not sufficiently addressed by current research related to these two topics.

3. Submission of findings and conclusions to a peer-reviewed publication as a Critical Review Paper.

**Scope**
This work should determine the following types of information:

1. A list of the specific model inputs and related factors and their relative importance to the uncertainty and variation in estimates of individuals dose rates,
2. The adequacy of the available data (in both published and gray literature an currently under development) for supporting:
   - A default value,
   - Distribution(s) that characterizes the uncertainty in the factor (assuming the factor has no variation),
   - Distribution(s) that characterizes inter-individual variation (assuming the factor has no intra-individual variation and minimal uncertainty) for the general population and other sub populations of interest,
   - Distributions that jointly characterize inter- and intra- individual variation,
   - Distributions that jointly characterize variation and (if appropriate) uncertainty.
3. Ongoing research efforts on model inputs,
4. A sense of whether the current default value for a factor is a substantial overestimate of the actual range of values of the input,
5. A description of the data gaps that prevent a complete understanding of inter-and intra-individual variation.

Milestones

Milestone 1. The respondent shall submit a report presenting the results of work on phase 1 and 2 above. Where data gaps exist they will be identified and characterized in some detail by the respondent; however, the respondent shall NOT propose research to address them as part of this project.

Milestone 2. The respondent shall present a paper that has been submitted to a peer-reviewed publication.

Partnership Opportunities

The final report to CMA should indicate who is doing research in these areas along with available operational details of the work and the organizational and historical opportunities that might exist to allow for collaboration with the CMA Long Range Research Initiative.

5.) Special Requirements

All proposals should include costs for preparing manuscripts for submission of results to peer-reviewed journals. Semi-annual status reports and annual financial reports are required for all funded research projects.

6.) Eligibility

Proposals may be submitted by any domestic or foreign for-profit or non-profit organization, public or private, such as universities, colleges, hospitals, laboratories, or units of State and local governments.

7.) Funds Available

Total Timing: 6 months from date of award

Funding $50,000-70,000

8.) Review of Proposals

All proposals received in response to this RFP will be reviewed for completeness, responsiveness and merit by the CMA Human Health Exposure Assessment Technical Implementation Panel (HHEA TIP).
Incomplete or non-responsive proposals will be returned to applicants without further review. The HHEA TIP is composed of scientists from industry, government, academia, and private sector consultants. CMA’s Strategic Science Team will approve award recommendations.

9.) Review Criteria

The following criteria will be used by the HHEA TIP to evaluate proposals.

- Consistency with TIP research plan
- Proven competency of institution/investigator in the specific field
- Quality of proposed milestones/timeline
- Cost effectiveness
- Use of external collaborator/leveraging/networking

11.) Award Criteria

The criteria that will be used in making awards include receipt of a sufficient number of proposals of adequate scientific merit, as determined by peer reviewers; relevance of proposals to the priorities outlined; availability of funds; and program balance.

12.) Submission of Full Proposals

Proposals must be received by CMA by February 15, 2000. All proposals must be prepared using the Full Project Proposal Form (attached). The proposal must be signed by an individual who is authorized to sign on behalf of and bind the organization to the proposed rates (including indirect costs) and identified Principal Investigators. *Curricula Vitae* for the Principal Investigators and all other key personnel, including subcontractors and consultants, should also be submitted. Ten copies of the proposal should be sent to the following address.

*Cheryl O. Morton*
Chemical Manufacturers Association
1300 Wilson Blvd.
Arlington, VA 22209

13.) Proposal Procedures

Each applicant will receive a copy of the Full Project Proposal Evaluation Form and Final Project Proposal Selection Form. Successful applicants will receive an award letter from CMA in March 2000.

14.) Inquiries

CMA’s web site cmahq.com contains general information about the Health and Environmental Effects Research Initiative. Questions regarding this RFP should be directed to Cheryl O. Morton at 703-741-5220 or Cheryl_Morton@cmahq.com.

Summary of Timeline for Proposal Submission, Award and Project Completion

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<thead>
<tr>
<th>Event</th>
<th>Timing</th>
</tr>
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<tbody>
<tr>
<td>Full proposals due to CMA</td>
<td>February 15, 2000</td>
</tr>
<tr>
<td>Award Notification</td>
<td>March 17, 2000</td>
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<tr>
<td>Final Report</td>
<td>September 18, 2000</td>
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