

Centredale
17.07
204627

October 29, 2003



SDMS DocID 000204627

Dr. Bruce M. Alberts
President, National Academy of Sciences
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Alberts:

Dioxins are formed as a result of combustion processes such as commercial or municipal waste incineration and from burning fuels. Scientists and health experts are concerned because studies have shown exposure to dioxins at high enough dosages may cause a number of adverse health effects. One of the main health effects in question for dioxins is the potential risk of cancer in adults. There are differing interpretations of the science associated with the impact on human health from environmental exposure to dioxins. The National Science and Technology Council's Interagency Working Group (IWG) on Dioxin is requesting a review by the National Academy of Sciences (NAS) to help ensure that the risk estimates contained in the draft reassessment (2003 version) are scientifically robust and that there is a clear delineation of all associated uncertainties.

EPA and the other sponsoring agencies are both willing and eager to meet with the review panel once it is established and to provide whatever information the review panel may need. Because of the priority that has been given to the dioxin reassessment and the crucial role of the NAS review, we would appreciate a timely, rigorous and thorough review. Enclosed please find our Statement of Work. We look forward to receiving your proposal for addressing these needs and to assisting and facilitating your efforts in any appropriate way.

Sincerely yours,

/SIGNED/

Paul Gilman, Ph.D.
EPA Science Advisor and
Assistant Administrator for
Research and Development

Enclosure

EPA Desk Statement:
Draft Dioxin Reassessment (2003 Version) Sent to the NAS for Review

On October 29, 2003, the EPA, working in consultation with the National Science and Technology Council's Interagency Working Group on Dioxin (IWG), asked the National Academy of Sciences (NAS) to review the 2003 version of EPA's draft dioxin reassessment. This action was taken based on the recommendation of the IWG on dioxin.

The NAS has been asked to review the draft reassessment (2003 version) as quickly as possible. The NAS will characterize the scientific uncertainties associated with the draft report. The review will also evaluate the methods EPA used in the draft assessment to calculate levels of potential risk to humans from exposure to dioxin.

Despite previous changes, the findings of the draft reassessment (2003 version) are not significantly different from that of the 2000 draft. The current draft differs from the 2000 EPA Science Advisory Board (SAB) review draft by including changes requested by the SAB, such as:

- Using more advanced scientific methods of calculating the potential risk to humans from exposure to dioxin;
- Expanding analysis of background exposure, which is intended to provide a more current estimate of background exposure from diet; and
- Containing expanded analysis of data on whether dioxin's non-cancer effects might occur at or near doses to which we are exposed. Previous studies have focused mostly on the possible carcinogenicity of dioxin – not whether other adverse health effects are possible.

While the NAS review is conducted, EPA will not use the draft reassessment (2003 version or other versions) as the basis or rationale for regulatory and other policy action. However, EPA will continue its work to reduce human exposure to dioxin, using the best available data.

EPA will continue its current practice to utilize the best available data published from a variety of sources that meet the Information Quality Guidelines (including the requirements articulated in the draft OMB Bulletin on Peer Review and Information Quality). The Agency will consider all such data and associated uncertainty to determine the strength of the evidence in proposing regulatory actions related to dioxin and dioxin-like compounds.

Statements of Reassurance

- When fully implemented over the next few years, EPA regulations already in place will reduce quantifiable dioxin releases by 90 percent, using 1987 as a baseline.
- The U.S. food supply continues to be among the safest and most nutritious in the world, and the best dietary advice is to follow the well-known federal dietary guidelines.
- Over the past 12 years, the federal government, in partnership with the states, has taken significant action to identify and reduce known sources of dioxin exposure. For example:

- EPA's air and solid wastes programs issued stringent regulations governing air releases from several important sources of dioxin, including municipal, medical and hazardous waste incinerators, and cement kilns that burn hazardous waste.
- EPA's water quality program issued stringent regulations reducing dioxin releases from pulp and paper facilities that rely on chlorine bleaching.
- FDA and FSIS have expanded monitoring of foods for dioxin and are working with EPA to identify, and where possible, close off the pathways by which dioxin enters the food supply.

- While the dioxin reassessment is underway, federal agencies that protect health, food, and the environment are working together to ensure a coordinated approach to activities that reduce dioxin exposures.

- We will continue to identify and act on opportunities for further significant exposure reductions while the reassessment is in review using the best available data that meet the information quality guidelines.

October 29, 2003

TASK ORDER # 5

STATEMENT OF WORK

Assessment of the Health Implications of Exposure to Dioxins

Purpose

The purpose of this statement of work is to task the National Academy of Sciences (NAS) to develop a report in keeping with the Charge to the Expert Panel as written below. The U.S. Environmental Protection Agency, the U.S. Department of Agriculture, the Department of Health and Human Services, and potentially other member agencies of the National Science and Technology Council Interagency Working Group on Dioxin are cosponsoring this study.

Background

Dioxins are formed as a result of combustion processes such as commercial or municipal waste incineration and from burning fuels. Scientists and health experts are concerned because studies have shown exposure to dioxins at high enough dosages may cause a number of adverse health effects. One of the main health effects in question for dioxins is the potential risk of cancer in adults. There are differing interpretations of the science associated with the impact on human health from environmental exposure to dioxins.

For the past 12 years, EPA has been conducting a reassessment of the human health risks associated with dioxin and dioxin-like compounds. This reassessment has been reviewed by non-EPA scientists, EPA's Science Advisory Board, and by the Interagency Working Group on Dioxin. Once finalized, the dioxin reassessment will serve as the basis for many key decisions related to the further management and control of dioxin exposure at EPA and will have a clear effect upon dioxin decisions made at federal, state and local agencies engaged in dioxin.

Task

The National Science and Technology Council's Interagency Working Group on Dioxin is requesting a review by the NAS to help ensure that the risk estimates contained in the draft reassessment (2003 version) are scientifically robust and that there is a clear delineation of all associated uncertainties. It is recognized that a review by the NAS as articulated in the Charge to the Expert Panel would be beneficial and informative as the Agency moves toward the finalization of the dioxin reassessment.

Charge to the Expert Panel

To the extent possible, the NAS analysis should characterize the breadth of the uncertainties and variability associated with risk assessment decisions and numerical choices, including, for example, modeling assumptions, including those associated with the dose response curve and

points of departure. To the degree feasible, this characterization should include dose-ranges and associated likelihood estimates for identified human health outcomes. It is important that the Academy's review identify gaps in our scientific knowledge that are critical to understanding the reassessment and identify any significant new research or data that should be reflected in the reassessment. Furthermore, the study should be a quantitative uncertainty analysis where appropriate, including quantification through expert elicitation or other estimation means where necessary.

While we would encourage a broad review that includes looking at uncertainty and variability, the NAS shall address the following: 1) the scientific evidence for the appropriate classification of dioxin as to its potential human carcinogenicity; 2) the validity of the non-threshold linear dose-response model in light of epidemiological studies and the corresponding cancer slope factor calculated by the Agency through the use of this model; 3) the scientific evidence supporting the calculation and use of Toxicity Equivalence Factors; and 4) the appropriateness of including 'dioxin-like' chemicals in the risk assessment without individual empirical review of their effects.¹ Uncertainty associated with the reassessment's approach toward the analysis of food sampling and human dietary intake data and, therefore, human exposures, are also of particular concern.

We hope that the NAS can provide advice on innovative ways to make the implications of the uncertainties underlying the reassessment more easily understood by the decision maker. We expect that the approach used by the NAS will be of value for future risk assessments other than dioxin, thereby advancing the field of risk assessment. An accessible approach to present the uncertainty inherent in complex assessments would improve not only the individual risk assessment, but also communication and risk management needs for diverse categories of environmental contaminants.

Required Expertise

The following are examples of expertise that are considered essential:

- Exposure Assessment
- Pharmacokinetics (PK) and PK Modeling
- Molecular and cellular aspects of receptor-mediated responses
- Toxicology with specialties in cancer, reproduction, development, immune function, and toxicity equivalence factors (TEFs)
- Epidemiology, both cancer and non-cancer
- Reproductive physiology/medicine
- Pediatric biology/medicine
- Dose-response modeling
- Statistics/Probabilistic methods

¹ From Title IV of Division K of the Conference Report for the Consolidated Appropriations Resolution, 2003.

Risk Assessment
Risk Communication
Uncertainty Analysis

The IWG will establish a project advisory group (PAG) that will include representatives from the sponsoring agencies. All interactions concerning charge, scope and expertise shall include the PAG and the Task Order Manager. The Task Order Manager and the PAG will meet with the review panel once it is established and provide whatever background information the review panel may need.

Deliverables:

The products of this task order shall be as follows:

- 1) A project milestone chart shall be provided to the EPA Task Order Manager (TOM) and the PAG within 30 days of task initiation. This project milestone chart shall detail the significant efforts of the task, as well as expected progression of the report deliverable.
- 2) Written progress reports shall be provided to the EPA TOM monthly, as well as at major review milestones. The written progress reports shall include an update of the project milestone chart and a summary of the activities taken during the period covered by the report and the activities anticipated during the next month. The report shall include financial information which summarizes the expenditures during the period. The written progress reports shall be delivered via email to the PAG, followed by a mailed hard copy of the progress report.
- 3) The primary product of this study shall be a report with appropriate external review in accordance with applicable NAS and National Research Council (NRC) review procedures. Expected audiences include the sponsoring agencies and a wide variety of individuals concerned with the potential risks associated with dioxins. A pre-publication version of the report shall be delivered to the sponsoring agencies within 12 months of project initiation. Expert panel representatives shall brief the sponsoring agencies on its report and study conclusions. The remaining three months are for publication and dissemination of the report. The primary products of this review will be coordinated in accordance with NRC procedures. Sufficient copies of the report will be produced for distribution to the sponsors, the Committee members and major interested parties. Copies of the report summary will be produced for broader distribution and made available on the Internet through the National Academy Press.
- 4) Where public meetings are required in the performance of this task, the EPA TOM shall be informed via email of the time, location and agenda of the meeting at least seven days prior to the meeting. A brief synopsis of the meeting shall be provided via email to the sponsoring agencies within 14 days after the meeting. When public meetings occur, EPA TOM and the cosponsoring agencies shall be provided with the ability to participate

through conferencing equipment that allows attendance through phone and/or videoconferencing technologies.

5) If public web sites or similar means are used to disseminate information to the public during the course of this task, the EPA TOM will be notified of the location of such web sites, as well as relevant changes to them.

6) The NAS has developed interim policies and procedures to implement Section 15 of the Federal Advisory Committee Act (FACA), 5 USC App. Sec. 15. Section 15 includes certain requirements regarding public access and conflicts of interest that are applicable to agreements under which the Academy, using a committee, provides advice or recommendations to a Federal agency. In accordance with Section 15 of FACA, the Academy shall submit to the government sponsor(s) following delivery of each applicable report a certification that the policies and procedures of the Academy that implement Section 15 of FACA have been substantively complied with in the performance of the contract/grant/cooperative agreement with respect to the applicable report.

Acceptance: By the EPA Task Order Manager, in consultation with the cosponsoring agencies' representatives to the Project Advisory Committee.

Acceptance Criteria: Technical accuracy, completeness, timeliness, grammatically correct, free of typographical errors, and conformance with the specific task, charge, expertise and deliverables of this Statement of Work.