



**MEMORANDUM OF UNDERSTANDING**  
**ON COOPERATION AND COMMUNICATION IN THE DEVELOPMENT OF**  
**RISK ASSESSMENT METHODS AND TOXICOLOGIC ASSESSMENTS**  
**BETWEEN THE**  
**U.S. ENVIRONMENTAL PROTECTION AGENCY**  
**NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT**  
**AND THE**  
**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY**  
**OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**I. PURPOSE/OBJECTIVES/GOALS**

This Memorandum of Understanding (MOU) serves as a mechanism for increased communication and cooperation in the development of risk assessment methods and toxicologic assessments. Specifically, it provides agreements on the types of information that can be shared at an early, pre-public release time-point and a mechanism by which the sharing can be accomplished.

**II. BACKGROUND**

Health risk assessment is the technical analysis of the nature and magnitude of the human health and environmental risks posed by exposures to environmental contaminants. The Office of Environmental Health Hazard Assessment (OEHHA) within the California Environmental Protection Agency (Cal/EPA) and the National Center for Environmental Assessment (NCEA) within the U.S. Environmental Protection Agency (U.S. EPA) develop methods and risk estimates for chemical contaminants. Although our mandates to protect public health are very similar, our governmental organizations operate under different statutes. Similarly, the controlling laws for each office may not require identical approaches, and in some cases specify slightly different methods. Nevertheless, the two offices would benefit from a commitment to minimize differences in risk assessment methodologies, where allowed by law, and to work together to foster harmonization of risk assessment methods, share data and evaluations, and provide mutual peer review of similar work products. Such harmonization of the efforts of NCEA with OEHHA will help ensure efficient use of state and federal resources. In addition, we hope that the cooperation between NCEA and OEHHA

will facilitate timely cross-agency peer reviews of our work products, promote peer involvement in the development of risk assessment methods, and help eliminate duplication of effort.

### **III. AUTHORITIES**

EPA enters into this MOU pursuant to Section 103 of the Clean Air Act, 42 USC 7403 and Section 104 of the Clean Water Act, 33 USC 1254, both of which encourage cooperative research investigation, training, and information sharing.

OEHHA enters into this MOU pursuant to Section 59017 of the California Health and Safety Code, which similarly provides for cooperative agreements covering health risk assessment activities.

We understand that this agreement is not a funding instrument and is not intended to provide justification for sole source funding authorizations. All actions undertaken pursuant to this MOU shall be consistent with Cal/EPA and U.S. EPA applicable laws, policies, and management directives.

### **IV. ROLES AND RESPONSIBILITIES**

OEHHA and NCEA mutually agree to share workplans and schedules, and to involve the other office in discussions and evaluations of ongoing projects and draft documents, as much as is feasible. This coordination may involve:

1. Sharing proposals as well as final decisions on prioritization and scheduling of chemicals for review;
2. Exchanging reports of progress on risk assessment reviews or method development;
3. Exchanging information on emerging problems and chemicals of concern;
4. Joint evaluation of data and sharing of statistical and epidemiological expertise;
5. Providing draft documents on chemical reviews and proposed new methods to each other's scientific staff, for technical discussion on work in progress as well as for peer review of completed drafts;
6. Maintaining confidentiality of information being shared as requested or in accordance with the standard procedures of both offices;
7. Sharing the results of literature searches, including electronic and paper copies of critical documents;
8. Promotion of regular discussions at the staff level, both formal and informal, aimed towards harmonization of methods and results;
9. Joint development of risk assessment methods; and
10. Support for attendance of scientific staff, when possible, at each other's major risk assessment symposia and conferences.

#### **A. RESOLUTION OF DISAGREEMENTS AND CONFLICTS**

Insofar as NCEA and OEHHA are subject to different statutes, mandates, and directives, some methodological differences are inherent, and must be accepted as beyond the scope of this agreement. Other disagreements or differences should be discussed in a mutually supportive and respectful manner. Satisfactory resolution of such differences will improve efficiency and consistency between the two organizations, and is a major reason for development of the present MOU. Therefore be it resolved that NCEA and OEHHA shall:

1. Agree to acknowledge the requirements of all applicable statutes, mandates, and executive directives, and the extent to which these may result in different approaches;
2. Respect the opinions and scientific integrity of all staff from both organizations, despite any major differences of opinions;
3. Work to clarify or explain differences in risk assessment methods or data interpretations in a respectful manner, and similarly respond respectfully to questions about preconceptions and conclusions;
4. Work toward resolution of differences in methods and conclusions by all available consensus-building techniques, including personal telephone calls, teleconferences, videoconferences, development of position papers, or joint discussions in person, with written follow-up on the discussion results, communicated to both organizations; and
5. Agree that some conflicts or disagreements can best be settled by a joint management decision (such as the decision to use 2/3 or 3/4 body weight scaling), participated in by both organizations.

#### **B. IMPLEMENTATION PLAN**

OEHHA and NCEA agree to develop an implementation plan which will describe in detail the procedures necessary to implement this MOU and specify the respective roles of the signatory parties. The goal shall be to accomplish this implementation plan within six months from the date this MOU is signed by both signatory parties. To facilitate this effort OEHHA and NCEA propose to establish a working group that 1) will identify chemical-specific priorities of mutual interest, and 2) identify potential points of interaction between OEHHA and NCEA that will provide opportunities to leverage resources and share information.

Independent of the formal plan, staff shall be encouraged to study the list of projects underway, chemicals to be reviewed, and agency experts from both organizations, and communicate with the applicable staff when appropriate, being as respectful of the time constraints of our cross-agency counterparts.

### **C. OUTCOMES**

1. Cost reduction for both agencies may be realized through increased communication of information and work product.
2. Combining the scientific expertise within OEHHA and NCEA will improve assessments.
3. Opportunities to improve consistency or to discuss potentially divergent scientific/policy issues will be provided through increased communication afforded by the workgroup.

### **V. LIMITATIONS**

A. All commitments made in this MOU are subject to the availability of appropriated funds and each party's budget priorities. Nothing in this MOU, in and of itself, obligates OEHHA or EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or other financial obligation. OEHHA agrees not to submit a claim for compensation for services rendered to EPA or any other federal agency for activities it undertakes in carrying out this MOU.

B. This MOU is neither a fiscal nor a funds obligation document. Any endeavor involving reimbursement or contribution of funds between the parties to this MOU will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate subsidiary agreements that will be effected in writing by representatives of both parties.

C. Except as provided in Section V. paragraphs (A) and (B) and Section VII. INTELLECTUAL PROPERTY, this MOU is not legally binding and does not create any right or benefit, substantive or procedural, enforceable by law or equity against OEHHA or EPA, their officers or employees, or any other person. This MOU does not direct or apply to any person outside OEHHA and EPA.

D. OEHHA may make factual statements to the public which describe its cooperation with EPA. However, nothing in this MOU allows EPA to endorse the purchase or sale of OEHHA products or services. OEHHA agrees not to make statements to the public in news releases, product brochures, on web sites or in any media that imply EPA endorsement of OEHHA products or services.

### **VI. PROPRIETARY INFORMATION**

To carry out the joint work resulting from this MOU, the EPA and OEHHA may need to disclose proprietary information to each other. For the purpose of this MOU, proprietary information is defined as information that an affected business claims to be confidential and is not otherwise available to the public. The EPA and OEHHA each agree to clearly identify as such confidential information disclosed in writing; and to clearly memorialize in writing, within a reasonable time, any confidential information initially disclosed orally. We agree not to disclose, copy, reproduce or otherwise make available in any form whatsoever to

any other person, firm, corporation, partnership, association or other entity information designated as proprietary or confidential information without consent of (name of other party) except as such information may be subject to disclosure under the Freedom of Information Act (5 U.S.C. § 552), the California Public Records Act (Cal. Gov. Code section 6250 et seq.) and related regulations, and EPA's regulations at 40 C.F.R. Part 2, or as otherwise authorized or required by law.

## **VII. INTELLECTUAL PROPERTY**

The parties agree that any copyrightable subject matter, including but not limited to journal articles, training, educational or informational material or software, created jointly by the parties from the activities conducted under the MOU may be copyrighted by OEHHA or U.S. EPA. OEHHA and U.S. EPA mutually agree to nonexclusive, irrevocable right to reproduce, distribute, make derivative works, and publish or perform the work(s) publicly, or to authorize others to do the same on their behalf.

The parties agree that any patented invention created by OEHHA pursuant to the terms of this MOU will be jointly owned by the parties regardless of inventorship, unless an alternative agreement indicates otherwise.

## **VIII. POINTS OF CONTACT**

The following individuals are designated points of contact for the MOU:

### **U.S. Environmental Protection Agency:**

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**California Office of Environmental Health Hazard Assessment:**

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**IX. MODIFICATION/DURATION/TERMINATION**

This MOU will be effective when signed by all parties. This MOU may be amended at any time by the mutual written consent of the parties. The parties will review this MOU every 5 years to determine whether it should be revised, renewed, or cancelled. This MOU may be terminated by either party at anytime by one party notifying the other party in writing 90 days in advance of the termination date.

**X. APPROVAL**

California Office of Environmental Health  
Hazard Assessment

U.S. Environmental Protection  
Agency

Joan E. Denton, Ph.D.  
Signature

Robert Chen  
Signature

January 16, 2009  
Date

Feb. 19, 2009  
Date