ATTACHMENT 4

Copy of Public Comment on ICR Renewal and EPA's Response

February 23, 2009

Document Control Office (7407M)
Office of Pollution Prevention & Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: EPA-HQ-OPPT-2008-0816

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) is pleased to comment on a proposed Information Collection Request (ICR) renewal that the Environmental Protection Agency (EPA) intends to submit to the Office of Management & Budget. 73 *Fed. Reg.* 79086, (December 24, 2008). The subject of the ICR is the Voluntary Children's Chemical Evaluation Program (VCCEP), the pilot of which was announced at 65 *Fed. Reg.* 81700 (December 26, 2000).

By letter dated June 22, 2001, HSIA committed to sponsor trichloroethylene (TCE) and perchloroethylene (perc) in the VCCEP pilot, and indicated that this would be done in two stages. The first stage was to consist of execution and implementation of memoranda of understanding (MOUs) with the Agency for Toxic Substances and Disease Registry (ATSDR) to satisfy priority data needs identified by ATSDR for TCE and perc (70 *Fed. Reg.* 73749 (December 13, 2005)(as updated)), a project which had been the subject of previous discussions between HSIA and ATSDR. The testing to satisfy these data needs would be conducted pursuant to voluntary research procedures adopted by ATSDR at 57 *Fed. Reg.* 54160 (Nov. 16, 1992). The specific testing obligations undertaken by HSIA are identified in the attached Agreement Between ATSDR and HSIA for Testing and Modeling to Meet Priority Data Needs, effective July 1, 2002.

At the second stage, HSIA committed to develop hazard, exposure, risk, and data needs assessments of Tier 1 and existing higher-tier studies of TCE and perc, including the studies to be conducted for ATSDR under the MOUs. HSIA committed to submit these assessments and Peer Consultation Documents to EPA in a timely fashion following completion of the toxicity testing and acceptance of the test results by ATSDR. In this way, EPA's objective that "[e]xisting upper tier test data will be integrated into the program by having them submitted with Tier 1 information" (65 Fed. Reg. at 81707) would be achieved; indeed, TCE and perc would be among only a handful of chemicals whose VCCEP Peer Consultation would address a *complete set* of all Tier 1, 2, and 3 data specified under VCCEP (65 Fed. Reg. at 81706).

All testing and most of the related physiologically-based pharmacokinetic (PBPK) modeling that HSIA committed to do in the first stage has now been completed and submitted to ATSDR, with the exception of the oral developmental neurotoxicity studies. Because of the complexity of these studies, developing and obtaining ATSDR approval of the test protocols (as required under its voluntary research procedures) has taken longer than expected. Moreover, once a range-finding protocol had been agreed for TCE, and a range-finding study completed, the laboratory which had conducted the study (Syngenta CTL) announced in September 2006 that it would shortly close. As the AP Wistar-derived rats used by this laboratory were not available elsewhere, HSIA had to sponsor a new range-finding study at a different laboratory (Bayer CropScience LP), at significant further cost. The results of the second range-finding study became available in late 2008, and HSIA has now signed a contract with the laboratory to conduct the main TCE study, completion and acceptance of which by ATSDR is expected in early 2010. The perc developmental neurotoxicity study is expected to be completed and accepted by early 2011.

While the first stage testing was under way, EPA requested comment on the implementation of the pilot phase of VCCEP. 71 *Fed. Reg.* 67121 (November 20, 2006). In this notice, EPA expressed a desire for all Tier 1 Peer Consultations in the pilot program to be completed as soon as possible. Following comments and correspondence between HSIA, ATSDR, and EPA, it was agreed that HSIA would move directly to the Peer Consultation despite the developmental neurotoxicity studies remaining outstanding. Based on this understanding, HSIA has committed over $600,000 to develop hazard, exposure, risk, and data needs assessments and Peer Consultation documents for TCE and perc, in the expectation that these documents will be ready for submission to a Peer Consultation panel for perc by the end of Summer and for TCE by the end of Autumn 2009, thus allowing for review of the former by FY 2009 4Q and the latter by FY 2010 1Q.

The foregoing is a lengthy but necessary explanation of the reasons that HSIA supports the proposed information collection, as long as there will be in place a procedure for review of these documents by an “independent third party contractor”/ “external, third party scientific organization” to conduct the Peer Consultations, compile the results for EPA, and assess the accuracy of the documents being developed, as was always envisioned under VCCEP (*see* 65 *Fed. Reg.* at 81713-714). In the absence of such a third party contractor-driven Peer Consultation, the information being requested would have little or no “practical utility” for purposes of § 3506(c)(2)(A) of the Paperwork Reduction Act, as EPA has identified no other review process that would enable it to meet the objectives of VCCEP.

HSIA understands that, given current EPA budget priorities, it now appears that funding for VCCEP pilot Peer Consultations will not be available in FY 2009 or 2010. This is disappointing, as many commenters, including EPA’s Children’s Health Protection Advisory Committee, have expressed concern that industry funding of the Peer Consultations would taint their outcome. And HSIA, having expended some $2.5 million on the combined ATSDR/ VCCEP program for TCE and perc, does not have in place any mechanism to fund the Peer Consultations.

In the circumstances, HSIA has met with EPA to review options that would permit independent Peer Consultations for TCE and perc to take place within the next 12 -18 months. One possibility discussed was the Chemicals Assessment and Management Program (ChAMP). It was considered that this approach could permit Peer Consultations to take place by early 2010. On this basis, HSIA invited the Agency to consider introducing TCE and perc into ChAMP at its earliest opportunity. We believe that they could serve as models for future data-rich cases where timely review and assessment of the available data is important to several EPA program offices.

In conclusion, HSIA urges EPA to put in place a satisfactory review procedure for the information that is the subject of the ICR, so that it will have "practical utility" for purposes of § 3506(c)(2)(A) of the Paperwork Reduction Act.

Respectfully submitted,

Steve Risotto

Stephen P. Risotto
Executive Director

Enclosure

AGREEMENT BETWEEN THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY AND THE HALOGENATED SOLVENTS INDUSTRY ALLIANCE, INC. FOR TESTING AND MODELING TO MEET PRIORITY DATA NEEDS

I. INTRODUCTION

As part of its implementation of Section 104(i)(5) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), 42 U.S.C. § 9604(i)(5), the Agency for Toxic Substances and Disease Registry (ATSDR) enters into this Agreement with the Halogenated Solvents Industry Alliance, Inc. (HSIA). This Agreement is intended to satisfy priority data needs identified for trichloroethylene ("tri") and tetrachloroethylene ("perc") by ATSDR.

This Agreement is also intended to develop data that will satisfy commitments made by HSIA in connection with the Voluntary Children's Chemical Evaluation Program (VCCEP) announced by the Environmental Protection Agency (EPA) in 2000. 65 Fed. Reg. 81700-708 (Dec 26, 2000). EPA requested manufacturers of 23 pilot chemicals to volunteer to sponsor them in Tier I of the VCCEP program. Tri and perc manufacturers, through HSIA, agreed to sponsor tri and perc in Tier I of the VCCEP pilot in a letter of commitment to EPA dated June 22, 2001. This correspondence is available in the EPA OPPTS docket 00247D.

In its commitment letter, HSIA agreed to prepare and submit to EPA hazard, exposure, risk, and data needs assessments and prepare peer consultation documents for tri and perc. HSIA indicated that these will be prepared and submitted in a timely fashion following completion of the toxicity testing and acceptance of the test results by ATSDR. In this way, results from the ATSDR testing program will feed back into consideration of data needs for the VCCEP and may avert overlap in testing requirements between the two initiatives.

II. CHEMICALS SUBJECT TO AGREEMENT

This Agreement covers testing and data development for the chemical substances trichloroethylene (CAS No. 79-01-6) and tetrachloroethylene (CAS No. 127-18-4).

III. PURPOSE OF THE TESTING PROGRAM

The purpose of the testing program specified in this Agreement is to supplement available information in order to further characterize the potential for subchronic toxicity, neurotoxicity, immunotoxicity, developmental toxicity, reproductive toxicity, and developmental neurotoxicity effects of tri and perc. One component of this testing program will develop or refine pharmacokinetic and mechanistic (PK/MECH) data directed at characterizing the mode of action of tri and perc. Such information, along with data from health effects studies, will be used to inform route-to-route extrapolations as specified in Table 1 of this Agreement.

ATSDR believes that the PK/MECH studies designed to construct quantitative dosimetric characterization of the disposition and relevant response mechanisms with regard to tri and perc, in conjunction with the studies and route-to-route extrapolation reporting that are specified in Table 1, will generate high quality test data that will be adequate to meet its priority data needs for tri and perc. To ensure data quality, ATSDR has adopted procedures for conducting voluntary research, 57 Fed. Reg. 54160 (Nov. 16, 1992), that will apply to development of data under this Agreement. These procedures require that ATSDR and HSIA sign a memorandum of understanding (MOU) prior to initiation of research projects.

Pursuant to these procedures, HSIA will submit to ATSDR for each study identified in Table 1 a study plan that includes test protocols and a schedule with deadlines for initiation and completion of each test and submission of interim and final reports. The test protocols will be reviewed by an ATSDR-appointed peer-review panel. Consistent with CERCLA § 104(i)(13), the peer review panel will consist of no fewer than three nor more than seven peer reviewers who (a) are selected by the Administrator of ATSDR; (b) are disinterested scientific experts; (c) have a reputation for scientific objectivity; and (d) lack institutional ties with any person involved in the conduct of the study under review.

If the study plan is approved by ATSDR following review of the protocol by the peer reviewers, HSIA and ATSDR will proceed to enter into an MOU for the study. Each MOU will meet the content requirements specified at 57 Fed. Reg. 54162, including without limitation deadlines for initiation and completion of each test and submission of interim and final reports.

MODIFICATION AND BREACH

If for reasons beyond its control HSIA is unable to submit a study plan by the date identified in Table 1, it shall notify ATSDR in writing of the need for modification of Table 1 and the reasons supporting such modification. ATSDR shall respond in writing to the proposed modifications within 2 to 6 weeks either: (i) approving the modifications as proposed, (ii) approving the modifications as revised by ATSDR, or (iii) disapproving the modifications entirely. If ATSDR does not approve the modifications as proposed, HSIA will have 2 weeks within which to: (i) accept ATSDR's decision and proceed in accordance therewith, (ii) request that ATSDR reconsider its decision, or (iii) withdraw from this Agreement. ATSR will respond to a request for reconsideration within 2 weeks.

If HSIA submits a request for modification of Table 1 to ATSDR, the time schedule established for submission of a study plan shall be extended by the length of time required by ATSDR and HSIA to respond to and approve the modifications.

Failure by HSIA to submit a study plan by the date identified in Table 1 (as it may be modified) shall constitute a breach of this Agreement. In the event of a breach, ATSDR will not impose any claim to damages, but at the Agency's discretion may terminate this Agreement.

V. EFFECTIVE DATE

This Agreement shall be effective July 1, 2002.

SIGNATURES

Agency for Toxic Substances and Disease Registry

Date: 6/27/02 By: Christopher T. DeRosa

Christopher T. De Rosa, Ph.D.
Director
Division of Toxicology

Halogenated Solvents Industry Alliance, Inc.

Date: June 21, 2002 By: _____

Paul H. Dugard, Ph.D., Dip RCPath (tox)
Director of Scientific Programs

TABLE 1

TESTING SCHEDULE

TRICHLOROETHYLENE

Test	**Submission of Protocol (month/year)**
Developmental toxicity (rat)	
Testing by inhalation route	Study Complete
Generic PBPK model development	7/2002
Neurotoxicity	
- PBPK extrapolation of extant data	7/2002
Subchronic toxicity	
- PBPK extrapolation of extant data	7/2002
Developmental toxicity (rat)	
- PBPK route-to-route extrapolation	7/2002
Immunotoxicity (rat)	
- Testing by inhalation route	10/2002
Developmental neurotoxicity (rat)	
- Testing by oral route	10/2003
Immunotoxicity (rat)	
- PBPK route-to-route extrapolation	4/2004

TESTING SCHEDULE

PERCHLOROETHYLENE

Test	Submission of Protocol (month/year)
Developmental toxicity (rat)	
Testing by inhalation route	7/2002
Generic PBPK model development	10/2002
Neurotoxicity	
PBPK extrapolation of extant data	10/2002
Subchronic toxicity	
PBPK extrapolation of extant data	10/2002
Reproductive toxicity	
- PBPK extrapolation of extant data	10/2002
Immunotoxicity (rat)	
- Testing by inhalation route	7/2003
Developmental toxicity (rat)	
- PBPK route-to-route extrapolation	1/2004
Developmental neurotoxicity (rat)	
- Testing by oral route	7/2004
Immunotoxicity (rat)	
PBPK route-to-route extrapolation	1/2005

March 23, 2009

MEMORANDUM

SUBJECT: Response to comments on second renewal of VCCEP ICR

FROM: Jim Willis, Director
Chemical Control Division (7405M)

TO: Angela Hofmann, Director
Regulatory Coordination Staff (7101M)

One public comment on the second renewal of the VCCEP ICR was received from Stephen P. Risotto of the Halogenated Solvents Industry Alliance (HSIA). Mr. Rissotoa, on behalf of HSIA, commented that HSIA supports the ICR renewal if Peer Consultation by a third party is retained as the review procedure for chemical assessments and that the sponsor should not have to pay for Peer Consultation.

HSIA's comments on the ICR renewal did not address the accuracy of the estimated cost burden for which comment was sought, or how the estimated sponsor's burden might be minimized. Instead, HSIA's comments focused on two possible program modifications that have not been finalized nor for which cost burden estimates have been given in the ICR renewal (i.e., that Peer Consultation will not be used in the future as the review procedure for chemical assessments and that the sponsor will pay for Peer Consultation in its new role). The ICR cost burden estimate was not based on these possible program modifications, but on the original VCCEP process and, therefore, comments on these modifications are beyond the scope of the ICR renewal.

EPA solicited comments on possible modifications to the VCCEP process through two public meetings in 2008, and in a Federal Register notice (71 FR 67121, Nov 20, 2006) requesting comment on the VCCEP pilot (in particular, Peer Consultation) in 2006. Based on the comments received in response to the 2006 FR notice, possible modifications to VCCEP, including that the sponsor might have to pay for future Peer Consultations, were listed in an FR notice announcing a public meeting on that subject in July 2008 (73 FR 36512, June 27, 2008). HSIA did not attend the July 2008 public meeting or provide comments. Comments taken at the July 2008 public meeting, however, moved EPA to consider another program modification: To not use Peer Consultation as the review procedure for chemical assessments. In early October 2008, EPA

informed the public and VCCEP stakeholders, including HSIA, that EPA was seeking comment on additional possible modifications to VCCEP including the elimination of Peer Consultation as the review procedure for chemical assessments. EPA asked that any comments on the possible modifications be presented at a public meeting to be held on October 21-23, 2008. HSIA did not attend the public meeting or provide comment that it disagreed with eliminating Peer Consultation as the chemical assessment review procedure nor did anyone else.

No changes were made to the draft ICR renewal as a result of HSIA's comments objecting to two possible program modifications because these modifications have not been finalized nor included in the cost burden estimate. If the program modifications are finalized, they will be captured in the next renewal of the ICR in 2012. If the program modifications are finalized during the three-year effective period of the second renewal of the ICR, the cost burden of VCCEP will be reduced. The cost burden estimates provided in the second ICR renewal will then overestimate the true cost burden during that three-year period.

cc: Catherine Roman