

# Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes:

## Peer Review Process



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## ACKNOWLEDGMENTS

This document summarizes the results of the independent technical peer review of the EPA document *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*, EPA 744-B-98-001. The overall peer review manager was Cindy Stroup.

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The peer review was conducted by Battelle Memorial Institute under contract to EPA. Battelle was not involved in the preparation of the document undergoing peer review. The current document was prepared by Battelle under EPA Contract number 68-D5-0008 under the direction of Brandon Wood. The EPA Work Assignment Manager was Cindy Stroup.

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## 1.0 INTRODUCTION

### 1.1 BACKGROUND ON CTSA

The Cleaner Technologies Substitutes Assessment (CTSA) is a tool developed by the EPA Design for the Environment Program (DfE) for a technically-informed audience. The CTSA presents a compendium of information on existing and new technologies in a given industrial sector, compared across cost, performance, and risk parameters. The goal of the CTSA is to provide business decision-makers with sufficient information to make environmentally-sound choices. This particular CTSA, the *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes* was developed by the DfE Garment and Textile Care Program (GTCP) as part of an effort to explore opportunities for pollution prevention in the drycleaning industry. It presents information on existing drycleaning processes, such as perchloroethylene (perc) and hydrocarbons, as well as new and emerging technologies including wetcleaning and liquid carbon dioxide.

It is important to note that the focus of the fabricare CTSA is on relative risk, not absolute risk. Further, the fabricare CTSA does not attempt to resolve all uncertainties in data cited nor in methodology employed. These issues have been extensively debated by the scientific community. The fabricare CTSA is intended to demonstrate a sufficient basis for concern, to compare alternative exposure scenarios and performance information. The fabricare CTSA uses readily available information and conventional models to provide general conclusions about various cleaning technologies. It does not attempt to describe the absolute risk associated with specific clothes cleaning operations. The CTSA recognizes that evaluations and judgements for each setting need to be made individually.

The goal of the CTSA is to provide a comparative assessment of clothes cleaning technologies available to cleaners. The assessment is intended to provide cleaners information that can be used to assist them in making informed technology choices that incorporate environmental concerns along with more typical considerations of cost and performance. The CTSA is part of an effort to assist small cleaners who may have limited time or resources to compare cleaning technologies. The primary audience for the CTSA is technically informed and might consist of individuals such as environmental health and safety personnel, owners, equipment manufacturers in the clothes cleaning industry, and other decision makers. As such, the CTSA serves as a repository of information that can form the basis of a variety of user-friendly information products designed specifically for small business cleaners who are interested in choosing among cleaning technologies.

### 1.2 PEER REVIEW OBJECTIVES

In January 1993, responding to recommendations in the report Safeguarding the Future: Credible Science, Credible Decisions, Administrator William Reilly issued an Agency-wide policy for peer review. Administrator Carol Browner confirmed and reissued the policy on June 7, 1994. As a result, EPA established standard operating procedures for the organization and conduct of peer reviews. The primary objective of any peer review is to uncover technical

problems or unresolved issues for use in revising the final work product so it will reflect sound technical information and analyses. Peer review is considered a process for enhancing the scientific integrity of the end product. Peer reviews are usually conducted by a panel of independent experts in relevant scientific areas. Independent reviewers are not associated with the generation of the specific work product, either directly by substantial contribution to its development or indirectly by consultation during the development of the specific product.

The fabricare CTSA was identified as a major scientific and technical work product, and as such required an independent peer review. The technical peer review of the fabricare CTSA was conducted according to the SOP in place at the time, the Office of Prevention, Pesticides and Toxic Substances (OPPTS) “Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents, October 1, 1996 - September 30, 1997” (Appendix A). The OPPTS SOP set forth methods for: identifying work products for peer review, including the selection process and mechanisms for peer review; planning and conducting a peer review, including selecting reviewers and scheduling reviews; completing the review, including methods for evaluating comments and recommendations; the final work product; and maintaining a peer review record. The GTCF chose a balanced ad hoc panel of independent experts from outside the Agency as the mechanism to assure an objective, fair, and responsible evaluation of the work product. Information presented in the peer review was used to update and enhance the final CTSA document. All requirements in the OPPTS SOP were met or exceeded.

### **1.3 OVERVIEW OF REPORT**

The purpose of this report is to document the technical peer review of the *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*. The methods used for planning and conducting the CTSA peer review are presented in Chapter 2. The information provided in Chapter 2 summarizes recruitment and selection of the peer review panel, and discusses initiation of the peer review process. Chapter 3 integrates the results of the CTSA peer review process, providing information on the compilation of reviewer comments, complications and follow-up during the review, and an analysis of the peer review results. Chapter 4 provides discussion on the disposition of comments. The Administrative Peer Review Record (AR 199) is described in Chapter 5. A summary of the peer review process is presented in Chapter 6.

## **2.0 METHODS**

This section describes the methods undertaken in planning and conducting the peer review of the CTSA document. Section III of the OPPTS SOP document (Appendix A, pages A-17 to A-22) was used for guidance in selecting peer reviewers, scheduling the review, and developing information to provide to the peer reviewers.

### **2.1 RECRUITMENT OF PEER REVIEW PANEL**

The OPPTS SOP for peer reviews (Appendix A, pages A-17 to A-19) lists several important points of guidance to be followed when selecting a group of peer reviewers:

- Recommendations for potential peer reviewers can be identified from a number of organizations.
- Peer reviewers should be selected for independence and scientific/technical expertise.
- Peer reviewers should be free of real or perceived conflicts of interest or there should be a balancing of interests among peer reviewers.
- Each of the peer reviewers should have recognized technical expertise that bears on the subject matter under discussion.
- Taken as a whole, the peer reviewers of a work product should represent a balanced range of technically legitimate points of view.
- Generally, external peer reviewers are preferred.
- Selected experts should have views that fall to either side of the centrist position along the continuum, but not too far to either extreme.

The CTSA peer review strictly adhered to the OPPTS SOP guidance, and developed the following strategy for convening an expert panel of peer reviewers:

1. Potential candidate peer reviewers were solicited from a well established group of GTCP stakeholders.
2. A large panel of experts was convened so that all possible technical areas and points of view could be covered.
3. Potential peer reviewers were recruited through a rigorous interview and review process to ensure qualifications, independence, and timely availability.



4. To ensure independence, most peer reviewers (all reviewers who requested payment) were required to agree to a formal consulting contract which required them to immediately disclose any real, or even potential, conflict of interest.

For the past six years, the EPA DfE GTCP collaborated with a group of key stakeholders, including representatives of industry, research, environmental, labor and public interest groups. At EPA’s request, these stakeholders nominated technical peer reviewers that had expertise in one or more of the main technical areas of the CTSA: technology and economics; exposure assessment; hazard assessment; and risk assessment. Through a rigorous screening process, 40 reviewers were selected from the list. Stakeholders’ first and/or second and/or third choice nominees in each area of expertise who were available were selected for the formal peer review panel.

The group of key stakeholders who were asked to nominate peer reviewers is listed in Table 2-1. In the Spring and early Summer of 1997, stakeholders submitted candidate panelists in order of preference, in each of the following categories: technology and economics; exposure assessment; hazard assessment; and risk assessment. In addition, each proposed candidate peer reviewer was required to have training and/or experience in one or more of the following areas: (1) occupational and general exposure assessment; (2) exposure modeling techniques; (3) chemical monitoring; (4) occupational health; (5) industrial hygiene; (6) toxicology, including environmental (aquatic); (7) environmental epidemiology; (8) risk assessment; (9) economics, finance, accounting; (10) marketing; (11) comparative cleaning technologies

**Table 2-1. Stakeholders Asked for Nominations to Peer Review Panel**

Stakeholder	Company
Mr. Moon Jong Chun	Federation of Korean Drycleaning Associations
Mr. Dave DeRosa and Mr. Jack Weinberg	Greenpeace
Mr. Eric Frumin	UNITE (Union of Needletrades, Industrial and Textile Employees)
Mr. Bob Gottlieb and Ms. Jessica Goodheart	ULCA, Pollution Prevention Education & Research Center
Ms. Janet Hickman	Dow Chemical
Ms. Sylvia Hoover-Ewing and Mr. Anthony Star	Center for Neighborhood Technology
Dr. David Ozonoff	Boston University School of Public Health
Mr. Steve Risotto	Center for Emission Control
Ms. Mary Scalco and Mr. Bill Fisher	International Fabricare Institute
Dr. Judy Schreiber	New York State Department of Health
Mr. Bill Seitz	Neighborhood Cleaners Association International
Ms. Jodie Siegel	Massachusetts Toxic Use Reduction Institution
Ms. Barbara Warren and Dr. Ned Groth	Consumers Union
Dr. Manfred Wentz	Fabricare Legislative & Regulatory Education Council / AATCC

(e.g., wet methods, microwave); (12) the dry cleaning industry, including equipment and processes used, practices employed, etc.; and (13) chemistry (product, engineering, environmental fate). All stakeholders except the Federation of Korean Dry Cleaning Associations and Consumers Union nominated peer reviewers.

Candidate reviewers were asked about their availability and/or interest in reviewing the CTSA document, about their area of expertise, and whether they required payment for their review. Potential reviewers who declined to participate were asked if there was anyone they would recommend in their place. All nominated peer reviewers are listed in Table 2-2.

For each stakeholder group that nominated candidate peer reviewers, at least their first, second, and third ranked nominees in each area of expertise were contacted during June and July to determine their availability and willingness to take part in the peer review process. The CTSA peer review panel consisting of 40 peer reviewers was finalized by EPA on Monday, July 21, 1997 (Table 2-3). The panel incorporated a large and well-balanced independent panel of experts from the drycleaning industry and the environmental and scientific communities.

## **2.2 CONFLICT OF INTEREST ISSUES**

OPPTS SOP document states “Peer reviewers should be free of real or perceived conflicts of interest or there should be a balancing of interests among peer reviewers.” This was assured several ways: (1) the nominees’ resumes were reviewed to identify potential conflicts of interest, (2) preliminary screening of all nominees was conducted, (3) the panel was balanced as a whole and within each of the four key technical areas in the CTSA, and (4) each of the 28 paid reviewers was subject to a contract containing a specific conflict of interest clause.

The potential peer reviewers listed in Table 2-2 were contacted to determine their affiliation(s), qualifications, and availability. Reviewers were selected by EPA to ensure balance across the four major technical areas covered by the CTSA. During recruitment, commitments of the reviewers and their affiliations were considered to determine if significant conflicts of interest were likely. In no cases were potential conflicts deemed to be sufficiently significant to preclude the participation of any peer reviewers recommended by the GTCP stakeholders.

Of the 36 experts who ultimately reviewed the CTSA, 28 requested and received payment for their services. Of these paid reviewers, 27 became subcontractors to Battelle, the contractor who conducted the peer review for EPA, and formally agreed to the following conflict of interest clause:

Seller (peer reviewer) will avoid and immediately notify BCO (Battelle) of any activities, interests or relationships (past, present or planned) which place Seller in an actual or apparent conflict of interest with the objectives of BCO or its Client under this Contract. Seller must obtain BCO’s prior written consent before engaging in any such activities.

The other paid reviewer was a Battelle staff member, and as such, was subject to the conflict of interest clause in Battelle’s contract with EPA.

EPA applied similar requirements of independence from the work product and lack of conflict of interest when EPA contracted with Battelle Columbus Laboratories to conduct the peer review. The OPPTS SOP for peer reviews states that "...the objectivity of the peer review should not be improperly influenced or undermined by the contractor performing the review. To identify and avoid or mitigate actual or potential conflict of interest, the contract should include controls." (Appendix A, p. A-53) Battelle was well-known to EPA staff and known to be free of any conflicts of interest. They were held to standard contractual requirements which ensured their conduct of this peer review would not hinder the independence of the reviews. Battelle's Contract 68-D5-0008, under which the CTSA peer review was conducted, has a specific Organizational Conflict of Interest clause (H.2) which requires Battelle to diligently monitor all work assignments under the contract and immediately inform EPA if an actual or potential conflict of interest develops between the EPA work and other work Battelle is performing. No conflicts of interest existed at any time while Battelle conducted the CTSA peer review, compiled peer reviewer's comments, and delivered the comments to EPA.

### **2.3 CONDUCTING THE REVIEW**

Battelle prepared two separate packets of documentation for each of the peer reviewers (Appendix B). Packet B-1 included a confirmation letter, contractual statement, and non-disclosure agreement, and Packet B-2 included a confirmation letter and non-disclosure agreement. Contractual agreements were sent only to those reviewers requesting to be paid for their review. Packets were sent to all 40 peer reviewers by Federal Express on Monday, July 21, 1997. All reviewers were requested to fax their signed non-disclosure agreements to Battelle by COB Thursday, July 24, 1997. Those reviewers requesting payment were also asked to submit a proposed hourly rate which is the lowest rate they charge any client.

The official peer review period began at 11:00 am on July 24, 1997, with a conference call notifying stakeholders (Table 2-4) that the panel had been finalized and the CTSA work products were being sent out for review. In the call, EPA announced that a well-balanced panel was chosen and all of the stakeholders' first and/or second and/or third choice nominees in each area of expertise were chosen for the review. The reviewers were to be given four weeks to complete their review and return comments to Battelle by August 25, 1997.

On Thursday, July 24, 1997, the CTSA was sent to peer reviewers by Federal Express. Enclosed in each package sent to the peer reviewer was a letter of transmittal and a reminder to return their signed non-disclosure agreement to Battelle (Appendix B, Packet B-3), a charge to peer reviewers (Appendix C), and an alphabetized list of CTSA references (Appendix D). The peer review charge document attempted to properly focus the efforts of the peer reviewers and to assist them in their review. Table 2-5 presents for each peer reviewer, the copy number and date on which the CTSA was sent, and the date on which Battelle received each reviewer's comments. Although only 40 peer reviewers were selected for the review, three copies of the CTSA were sent to D. Votaw, bringing the total number of copies distributed to 42.

**Table 2-2. All Nominated Candidate Reviewers**

Elden Dickinson Michigan Department of Environmental Quality	Mr. Rory Connelly Chemical Industry Institute of Technology	Jim Ahearn Polaroid
Kathleen Wolf, Ph.D. Institute for Research and Technical Assistance	Joe McLaughlin, Ph.D. International Epidemiology Institute	Ed Olmstead NYCOSH (NY Committee for Occup Safety & Health)
Paul Dugard, Ph.D. ICI Americas, Inc.	Dr. John Graham Harvard University/School of Public Health	Dr. John Froines UCLA
Charles Riggs, Ph.D. Texas Women's University, Department of Fashion & Textiles	Dr. John Doull Kansas University Medical Center Joel Tickner MSC/U Massachusetts Lowell	Henry Anderson, M.D. Chief Medical Officer for Occupational and Environmental Health Div of Health Dept of Health and Social Services
Dr. Josef Kurz Schloss Hohenstein	Pamela Christenson Wisconsin Dept of Dev	Nancy Kim NYSHD/Div. Of Environmental Health
Mike Tatch Tatch Technical Services	Ellen Kirrane Hunter College Center for Occup & Envir Health	Dr. David Kriebel Umass-Lowell, Dept. Of Work Environment
Noel Weiss, M.D., Dr. P.H. University of Washington, School of Health & Comm. Med.	David Ozonoff, M.D., M.P.H. Boston University School of Public Health Dept of Environmental Health	Dr. Margaret Quinn Umass-Lowell, Dept. Of Work Environment
Kenneth Mundt, Ph.D. Umass, Dept. Of Biostatistics & Epidemiology School of Public Health & Health Sciences	Dick Clapp, Sc.D., M.P.H. Boston University School of Public Health Dept of Environmental Health	Philip Landrigan, M.D. EPA Children's Health Initiative
Tom Starr, Ph. D. Environ Corp.	James Melius, M.D., Ph.D. Director NY State Laborer's Health & Safety Trust Fund	Ethel H. Wise Professor of Community Medicine Chairman and Professor of Pediatric, Dept of Community Medicine Mount Sinai School of Medicine
D. Warner North, Ph.D. Decision Focus Inc.	Ms. Chris Hayes Greater Chicago P2 Program, MWRD	Thomas Eggert Wisconsin DNR Off Pollution Prev
Rudolf Jaeger, Ph.D. Environmental Medicine, Incorporated	Peter Orris, M.D. Div. Of Occup. Med/Cook County Hospital	George Alexeeff, Ph.D., D.A.B.T. Chief, Air Toxicology & Environ Toxicology Off of Environ Health Hazard Assessment California Env. Protection Agency
Dr. Robert Squire	Frank Mirer, Ph.D. Director, Health & Safety Dept., UAW	Avima Ruder, Ph.D. NIOSH/CDC, Chief, Industrywise Studies Branch Epidemiology 2 Section
Mr. Todd S. Wong Manager, Central Division State of California Air Research Board	Diane Echeverria Battelle Seattle Operations	Anne Marie Desmarais Tufts Univ., Dept. Of Civil & Envir. Engineering
James Wilkin, Ph.D.	Dale Hattis, Ph.D. Center for Technology, Environment, & Development (CENTED) Clark University	Dr. Rafael Moure-Eraso Umass-Lowell, Dept. of Work Environment
Mr. Richard H. Reitz RHR Toxicology Consulting	Donald P. Gallo Michael Best & Friedrich	David Rall former director, NIEHS
Dr. Tom Armstrong Univ. Of Michigan, School of Public Health	Diane Weiser Ecomat	Aaron Blair National Cancer Institute
Scott Earnest NIOSH/Engineering Control Technology Branch	Irv Markus Kingsgard Cleaners	Ken Geiser Massachusetts Toxic Use Reduction Inst
Dr. Salvatore DiNardi Umass/Environmental Health Sciences	Amelia Gooding DCCA, Small Bus Environ Asst Progam	
Dr. Baruch Fischhoff/Dr. Mitchell Smalls Carnegie Mellon University		

**Table 2-2. All Nominated Candidate Reviewers (Continued)**

Dr. John Peters/USC Dept. of Occup. & Environmental Medicine	Mr. Ken C. Adamson, General Manager Langley Parisian	Paul Liroy, Ph.D. Robert Wood Johnson Medical School
Mark K. Enstrom DCAA/Small Business Environ. Assn. Program	Manfred Wentz, Ph.D. Chairperson, AATCC Research Committee RA43: Dry Cleaning	Deborah Wallace Consumers Union Technical Division
Dennis F. Lekan Cuyahoga Community College	Denny Hjeresen, Ph.D. Los Alamos National Labs	Marilyn Black Air Quality Sciences
Ron Kantor Leather-Rich, Inc.	Frank Arnold, Ph.D.	John Girman Indoor Environments Division
Ann Hacker Northside Laundry & Cleaners	Andrew Persily, Ph.D. NIST	Les Sparks ORD, RTP
Rebecca Head, PhD Washtenaw Co. Dept. Of Environment	Greg Traynor T. Marshall Associates	Betsy Howard ORD, RTP
Joanna Hoelscher Citizens for a Better Environment	Charlene Bayer, Ph.D. Georgia Tech Research Institute	Dr. Ron Melnick
Stanley Liu Environment Canada, P&Y Region	Clifford Weisel, Ph.D.	Linda Sheldon RTI
Jim Orlin Morrison Suede & Leather Works	James Cone, M.D., M.P.H.	Kevin Teichman ORD
Jackie Peterson International Acad. Of Merch. And Design	George Gray, Ph.D. Harvard School of Public Health	Lance Wallace, Ph.D. US Environmental Protection Agency
Merry Bering M.I.L.D. Michigan	Arthur Upton, M.D. Environmental & Occupational Health Sciences Inst.	Eula Bingham, Ph.D. University of Cincinnati
Tony Sasson Ohio EPA Office of P2	Duncan Thomas Univ. Of Southern California Div. Of Preventative Medicine	Bernard Goldstein, M.D. Director, Env & Occup Health Sciences Inst Chairman, Dept of Community Medicine University of Medicine and Dentistry of NJ Robert Wood Johnson Medical School
Richard Simon Business Habits (Ecoclean)	Thomas Goldsworthy, M.D.	Robert Taylor, M.D., Ph.D. Howard University School of Medicine
Ken Vandersnick Wagners/Brix Cleaners	Claudia Miller, M.D. Univ. Of Texas Health Sciences Center	Louise Ryan, Ph.D. Dana Farber Cancer Institute
Dong Whang HiTech Engineering	Judy Schreiber, Ph.D. NY Dept of Health	Adolfo Correa, M.D. Johns Hopkins University School of Public Health
Allen L. White, PhD Director, Risk Anal. Group	Kimberly Thompson, Sc.D. Consultant	Joel Mattsson, M.D. Senior Associate Scientist Health & Envir. Sciences Dow Chemical Co.
Adam Finkel, Ph.D. Director, OSHA Health Standards Directorate US Department of Labor	Arnold Brown. M.D.	
Marthe Kent, Ph.D. Office of Regulatory Analysis/Directorate of Policy DOL OSHA	Routt Reigart, M.D. Medical University of South Carolina	
David Votaw Education and Information Division National Institute for Occupational Safety and Health	Dan Krewski, Ph.D., MHA Bureau of Chemical Hazards Health Canada	
Jack Lauber 53 Fairlawn Dr.	Gary Carlson, Ph.D. School of Health Sciences Purdue	
	Ron Miller	
	Brad Leinhart, Ph.D. MiCELL	
	Scott Lutz Supervisor, Air Quality Engineer Bay Area Air Quality Management District	

**Table 2-3. Final CTSA Peer Review Panel**

Ken C. Adamson General Manager Langley Parisian	Rudolf Jaeger, Ph.D. Environmental Medicine, Incorporated	Tom Starr, Ph. D. Environ Corp.
Frank Arnold, Ph.D. Consulting Economist	Ellen Kirrane Hunter College Center for Occupational & Environmental Health	Mike Tatch Tatch Technical Services
Charlene Bayer, Ph.D. Georgia Tech Research Institute	Josef Kurz, Ph.D. Schloss Hohenstein	Kimberly Thompson, Sc.D. Consultant Harvard Center for Risk Analysis
Arnold Brown., M.D. - Retired Professor Emeritus of Pathology and Universal Medicine Univ. of Wisconsin, Madison	Jack Lauber, P.E.-D.A.A.E.E. Consulting Engineer	Joel Tickner MSC/University of Massachusetts Lowell
Pamela Christenson Wisconsin Dept. of Dev.	James Melius, M.D., Ph.D. Director NY State Laborer's Health & Safety Trust Fund	Greg Traynor T. Marshall Associates
Dick Clapp, Sc.D., M.P.H. Boston University School of Public Health Dept of Environmental Health	Frank Mirer, Ph.D. Director Health & Safety Dept., UAW	Arthur Upton, M.D. Clinical Professor Environmental & Occupational Health Sciences Institute
James Cone, M.D., M.P.H.	Kenneth Mundt, Ph.D. University of Massachusetts Department of Biostatistics & Epidemiology School of Public Health & Health Sciences	David Votaw Education and Information Division (C15) National Institute for Occupational Safety and Health
Elden Dickinson Michigan Department of Environmental Quality	D. Warner North, Ph.D. Decision Focus Inc.	Clifford Weisel, Ph.D. Associate Professor Deputy Director Exposure Measurement and Assessment Division Environmental and Occupational Health Sciences Institute
Paul Dugard, Ph.D. Senior Vice President ICI Americas, Inc.	Peter Orris, M.D. Division of Occupational Medicine Cook County Hospital	Noel Weiss, M.D., Dr. P.H. Professor University of Washington School of Health & Community Medicine Department Of Epidemiology
Diane Echeverria, Ph.D. Battelle Seattle Operations	David Ozonoff, M.D., M.P.H. Boston University School of Public Health Department of Environmental Health	Manfred Wentz, Ph.D. Chairperson, AATCC Research Committee RA43: Dry Cleaning
Adam Finkel, Ph.D. Director OSHA Health Standards Directorate U.S. Department of Labor	Andrew Persily, Ph.D. NIST	Kathleen Wolf, Ph.D. Institute for Research and Technical Assistance
George Gray, Ph.D. Harvard Center for Risk Analysis Harvard School of Public Health	Routt Reigart, M.D. Medical University of South Carolina	
Dale Hattis, Ph.D. Research Associate Professor Center for Technology, Environment, & Development (CENTED) Clark University	Charles Riggs, Ph.D. Texas Women's University, Department of Fashion & Textiles	
Ms. Chris Hayes Greater Chicago P2 Program, MWRD	Judy Schreiber, Ph.D. NY State Department of Health	
Denny Hjeresen, Ph.D. Los Alamos National Labs		

Note: No known conflicts of interest existed with any peer reviewers.

**Table 2-4. Attendees at July 24, 1997 Teleconference Announcing CTSA Peer Review**

Name	Affiliation/Address
Mary Scalco, Bill Fisher	International Fabricare Institute
Bill Seitz	Neighborhood Cleaners Association, International
Ross Beard	Fabricare Legislative & Regulatory
Steve Risotto	Centers for Emission Control
Gary Baise	Baise & Miller
Eric Frumin	Union of Needletrades, Industrial and Textile Employees (UNITE)
David DeRosa, Jack Weinberg	Greenpeace
Moon Jong Chun	Federation of Korean Drycleaning Association
Cindy Stroup, Lynne Blake-Hedges, Mary Ellen Weber	U.S. Environmental Protection Agency
Melinda Armbruster, Brandon Wood	Battelle Memorial Institute

**Table 2-5. Record of CTSA Copy Numbers, Date Sent and Date Comments Received**

Copy No.	Date Copy Sent	Date Comments Received	Reviewer	Copy No.	Date Copy Sent	Date Comments Received	Reviewer
1	7/24/97	8/27/97	E. Dickinson	22	7/26/97	8/15/97	R. Jaeger
2	7/24/97	Dropped	P. Dugard	23	7/26/97	8/19/97	K. Thompson
3	7/24/97	8/27/97	P. Christenson	24	7/26/97	8/25/97	C. Hayes
4	7/24/97	9/2/97 & 9/8/97	K. Adamson	25	7/26/97	8/7/97	N. Weiss
5	7/24/97	8/12/97	A. Upton	26	7/28/97	8/27/97	G. Traynor
6	7/24/97	8/27/97	D. Votaw	27	7/26/97	9/11/97	D. Echeverria
7	7/24/97	8/27/97	D. Votaw	28	7/26/97	8/25/97	J. Cone
8	7/24/97	8/28/97	D. Votaw	29	7/26/97	8/27/97	C. Weisel
9	7/25/97	Withdrew	A. Persily	30	7/28/97	8/6/97	F. Arnold
10	7/25/97	9/3/97	J. Schreiber	31	7/26/97	8/25/97	C. Bayer
11	7/25/97	8/25/97	C. Riggs	32	7/28/97	9/3/97	P. Orris
12	7/25/97	8/18/97	J. Lauber	33	7/28/97	8/22/97	D. Clapp
13	7/25/97	8/25/97	J. Tickner	34	7/28/97	9/2/97	F. Mirer
14	7/25/97	Withdrew	J. Kurz	35	7/29/97	9/17/97	A. Finkle
15	7/25/97	8/25/97	K. Wolf	36	7/29/97	8/25/97	D. Hjeresen
16	7/25/97	8/25/97	J. Melius	37	7/29/97	8/22/97	A. Brown
17	7/25/97	8/21/97 & 9/3/97	M. Wentz	38	7/29/97	8/26/97	K. Mundt
18	7/25/97	9/2/97 & 9/3/97	M. Tatch	39	7/29/97	9/4/97	T. Starr
19	7/25/97	8/18/97	D. Ozonoff	40	7/29/97	9/5/97	G. Gray
20	7/25/97	8/25/97	E. Kirrane	41	8/1/97	8/25/97	W. North
21	7/26/97	8/20/97	D. Hattis	42	8/1/97	Withdrew	R. Reigart



## **3.0 RESULTS**

### **3.1 COMPILATION OF COMMENTS**

Thirty-six reviewers provided comments on the draft CTSA. In the course of the review, three reviewers withdrew from the panel. Reasons for withdrawal from the peer review process included not having enough time available to complete the review, and a mismatch between their interests and the material presented in the CTSA. A fourth reviewer promised to but simply never submitted comments, despite being granted an extension of the review period.

Battelle collected and compiled review comments and provided the EPA workgroup with a list of comments for their consideration and response. Comments from peer reviewers were compiled and sorted by reviewer and by CTSA chapter to which they referred. Attribution of each reviewer's comments was kept anonymous. In a few cases, text was omitted from the original comment (as indicated by "...") in order to ensure reviewer anonymity. Where a comment cited a reference that was not complete, the reference was listed in square brackets following the comment. In total, 1,855 comments were submitted which comprised 340 typewritten pages. The EPA Fabricare CTSA Workgroup reviewed all comments, determined the appropriate changes in the CTSA as a result of the comments, and prepared the Agency's Response to Comments document. That document, *Cleaner Technologies Substitute Assessment for Professional Fabricare Processes: Response to Peer Review Comments*, EPA 744-P-98-001, will be published as an EPA Report and included in the Peer Review Administrative Record #199.

In order to ensure accurate, verbatim transcription of all comments, Battelle enlisted the proof-reading services of Key Office Services, an independent company. After the comments were compiled, Key Office Services checked each comment against the original reviewer's submission to ensure that the text remained unchanged, then returned the "proofed" list of comments to Battelle for any necessary corrections.

Comments from 34 of the 36 reviewers were conveyed, without attribution, to EPA in a report dated September 12, 1997. Any additional references or information that the reviewers provided with their comments were also transmitted to EPA with the comments. An addendum to the original report which included comments from the last two reviewers was submitted October 2, 1997.

### **3.2 COMPLICATIONS AND FOLLOW-UP**

In the course of the review, three reviewers withdrew from the panel. Dr. Routt Reigart withdrew from the peer review process on August 1, 1997; Dr. Andrew Persily withdrew on August 22, 1997; and Dr. Josef Kurz withdrew on August 28, 1997. Reasons for withdrawal from the peer review process included not having enough time available for a complete review, in spite of initially agreeing to be on the panel. Two reviewers felt they were not qualified to review the CTSA after they saw it. Dr. Paul Dugard was dropped on January 1, 1998, because he failed to provide any comments on the CTSA. As Dr. Dugard was a key reviewer in the hazard

assessment area, he was given an extra four months to complete his review, but had to be dropped from the panel to avoid delaying the overall CTSA schedule. In all cases it was too late to replace the reviewers.

During the review, one fax was sent out to the peer reviewers as clarification on different issues. The fax was sent out to all peer reviewers on August 6, 1997 (Appendix B, Packet B-4). This was a clarification of EPA's evaluation of the carcinogenic potential of perchloroethylene. The language in the peer review copy of the CTSA was revised, as per the fax, as part of the peer review comment integration process.

During the review, one peer reviewer requested several of the papers referenced in the peer review copy of the CTSA. These references were supplied to this reviewer on August 14, 1997.

### **3.3 ANALYSIS OF RESULTS**

Table 3-1 presents summary statistics on the number of comments and number of pages of comments received by Battelle. These statistics are separated into the following categories: general comments on CTSA document, comments on the executive summary, Chapters 1-8, and Appendices A-D. There were a total of 1,855 comments submitted comprising a typed list of 340 pages. Of these 1,855 comments, there were a total 208 editorial comments. The editorial comments included spelling changes and other minor structural modifications to the document.

**Table 3-1. Summary Statistics on CTSA Comments from CTSA Peer Review Panel**

Section	Complete Set of Comments	
	# of Pages of Comments	# of Comments
General	49	181
Executive Summary	12	67
Chapter 1	56	328
Chapter 2	32	194
Chapter 3	60	357
Chapter 4	61	375
Chapter 5	12	61
Chapter 6	17	82
Chapter 7	10	50
Chapter 8	12	71
Appendix A	13	62
Appendix B	1	6
Appendix C	4	20
Appendix D	1	1
Total	340	1855

#### **4.0 DISPOSITION OF COMMENTS**

Peer review comments were compiled and sent, without attribution, to the EPA Workgroup in charge of the disposition of comments. This workgroup drafted responses to every peer review comment. The peer review comments and responses are included in a separate document (*Cleaner Technologies Substitute Assessment for Professional Fabricare Processes: Response to Peer Review Comments*, EPA 744-P-98-001). Based on the peer review comments, significant revisions were made to the CTSA document (as per the OPPTS SOP, Appendix A, Sections IV.A, and IV.B, pages A-22 to A-23).

#### **5.0 ADMINISTRATIVE PEER REVIEW RECORD**

As required in the OPPT Peer Review SOP, a public CTSA Peer Review Administrative Record was established. AR-199 contains all the documentation and major products of the CTSA technical peer review. The Index to Administrative Record #199 is included as Appendix E. Administrative Record #199 was created and is maintained in accordance with Section IV.C of the OPPTS SOP (Appendix A, p. A-23).

#### **6.0 SUMMARY**

As a major scientific and technical work product, the CTSA required an independent peer review. The technical peer review of the fabricare CTSA was conducted according to the OPPTS SOP, the Office of Prevention, Pesticides and Pollution Prevention “Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents, October 1, 1996 - September 30, 1997”. The GTCP chose a balanced ad hoc panel of independent experts from outside the Agency as the mechanism to assure an objective, fair, and responsible evaluation of the work product. As seen in Table 2-3, the peer review panel encompassed a large, balanced independent panel of experts from the drycleaning industry and the environmental and scientific communities. The peer review panel was not only balanced by the reviewers’ areas of expertise, but also by the stakeholder groups who nominated reviewers for the panel. None of the reviewers had any conflict of interest or other problems that may have hindered their fair and objective review of the document.

The attrition of four reviewers during the review process did not affect the balance of the panel nor the integrity of the review. Information presented in the peer review was used to significantly update and enhance the final CTSA document. A response to comments document has been prepared which addresses every comment provided by every peer reviewer. All requirements in the OPPTS SOP were either met or exceeded.

## **APPENDIX A**

**Office of Prevention, Pesticides and Toxic Substances  
“Standard Operating Procedures for Peer Review  
of Major Scientific and Technical Documents,  
October 1, 1996 – September 30, 1997”**

Office Of Prevention, Pesticides and Toxic Substances

STANDARD OPERATING PROCEDURES

FOR PEER REVIEW OF MAJOR

SCIENTIFIC AND TECHNICAL DOCUMENTS

OCTOBER 1, 1996 - SEPTEMBER 30, 1997

## PREFACE

### Overview

These Standard Operating Procedures (SOPs) provide guidance to all staff and managers in OPPTS on the organization and conduct of peer reviews pursuant to the Administrator's June 7, 1994 Peer Review Policy statement (Appendix A).

The guidance provides information and outlines procedures in several different areas:

- ▶ basic principles and definitions, including distinctions between peer review and public comment, and between peer involvement and peer review;
- ▶ preparing for peer review, including identifying work products, identifying appropriate peer review mechanisms, and identifying qualified experts; and,
- ▶ conducting and completing peer reviews, including materials required for peer review, creating a peer review record, and utilizing peer review comments.

In addition, appendices provide information on OPPTS staff and management responsible for peer review activities and resources for the upcoming fiscal year, work products selected for peer review during the upcoming fiscal year, and detailed information on budget, procurement, and legal considerations.

This SOP does not address, nor does it supersede, established peer review practices or procedures of the selected peer review mechanism. In fact, the SOP seeks to incorporate existing mechanisms (e.g., professional journals for research papers, Science Advisory Board and FIFRA Scientific Advisory Panel, and research grant applications) as well as instituting new ones.

### Background

Peer review at the USEPA takes many different forms depending on the nature of the work product, relevant statutory requirements, and office-specific policies and practices, among other things. In January 1993, responding to recommendations in the report Safeguarding the Future: Credible Science, Credible

Decisions, Administrator William Reilly issued an Agency-wide policy for peer review. Administrator Carol Browner confirmed and reissued the policy on June 7, 1994 and instituted an Agency-wide implementation program. These SOPs constitute implementation guidance for OPPTS.

These procedures are based on the central themes set forth in the Administrator's policy statement:

*Major scientifically and technically based work products related to Agency decisions normally should be peer reviewed. Agency managers within Headquarters, Regions, laboratories, and field components determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made in conformance with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial.*

As seen in the policy statement, one important task in implementing the Peer Review Policy entails the identification of "major scientific and technical work products." This decision is based on several considerations and is discussed in Section II. Another important task is using a peer review mechanism that is suitable for the work product under review.

The goal of the Peer Review Policy is to ensure that scientific and technical work products receive appropriate levels of critical scrutiny from scientific and technical experts as part of the overall decision making process. Generally, this technical review will precede the customary, more broadly based public review of the total decision.

### **OPPTS Peer Review Policy Overview**

OPPTS recognizes that science and social science form the basis for protection of the environment and public health. The purpose of this SOP is to ensure that peer review is used appropriately to enhance the credibility of OPPTS' decisions while ensuring that OPPTS' peer review policies are in conformity with Agency guidance. In general, OPPTS has traditionally utilized peer review as well as peer involvement procedures with much emphasis placed upon involving experts and interested parties early and often in the development of a scientific or technical work product. This allows an open exchange of data, insights, and ideas throughout the life of a project, working toward building consensus on the technical aspects of the work.

Peer review mechanisms are typically selected based upon the nature of the scientific or technical work product. In general, scientific or technical work products will undergo an internal peer review. However, for work products that are "major", potentially costly, controversial, novel approaches, or have cross-Agency implications, external peer review is recommended.



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## I. GUIDING PRINCIPLES OF PEER REVIEW

This section offers some guiding principles for peer review, defining certain terms, with emphasis on distinguishing between several closely related concepts. In particular, this section discusses the interrelationship between the broader concept of peer involvement and its components: peer input and peer review.

### **A. General Principles**

The purpose of peer review is to uncover any technical problems or unresolved issues for use in revising a preliminary product so that the final work product will reflect sound technical information and analyses. It should be noted that peer review is a process for enhancing the scientific or technical work product.

Peer involvement occurs at different stages, involving several related but different activities in the overall decision-making process (e.g., an initial research protocol or work plan, a preliminary review of an interim draft, and/or a later review of a draft final work product). Peer involvement refers to both peer input (ongoing discussions during the development of the work product) and peer review (the critical, and usually, final evaluation of the work product). Peer review can occur during the early stages of project or methods selection, or as usually defined, as part of the culmination of the work product, ensuring that the final product is technically sound.

Subject matter experts who participate in the overall peer involvement process can be expected to undertake one of three related but different roles. First, they may work as paid or unpaid consultants with a significant role as author or advisor in developing a work product. Second, OPPTS may ask independent experts to provide peer input by participating in early developmental reviews or discussions of well-developed but unfinished work products. In this case, the agency is inviting and expecting expert suggestions that could lead to substantial changes based on reviewer recommendations in the final product. Third, experts may be asked to serve as peer reviewers, providing critical evaluation and comments on work products nearing completion.

Depending on the situation, peer review can be an iterative process or a single event. Subject matter experts may review several revisions of the same document, or they may comment only

once on the document. Agency managers need to be aware of the role a subject matter expert has played in earlier reviews and make a determination -- on a case by case basis -- as to that expert's independence for any further reviews.

The importance of the peer reviewer's independence and technical expertise cannot be overemphasized as factors influencing the value and credibility of any peer review. Independence -- freedom from institutional, ideological, or technical bias -- as to the issues under review is necessary for objective, fair, and responsible evaluation of the work product under review. However, if reviewers are selected to represent any particular institution or technical perspective, balancing the review with representatives of other institutions or perspectives becomes a critical objective for the peer review. Such perspectives and/or potential conflicts-of-interest (real or perceived) should be fully identified to ensure a balanced and credible peer review. Technical bias should also be considered. An expert who serves as an author/advisor or early participant in developmental reviews or discussions may also not be considered independent and unbiased for a given work product.

The importance of scientific and technical expertise in the subject matter is obvious, but there are several dimensions. Knowledge in the subject matter is not equivalent to expertise in the subject matter. For agency decisions, a multi-disciplinary group of experts corresponding to the disciplines that contribute to complex agency decisions is often necessary for a full and complete peer review. For example, a risk assessment that relies on both animal and human data often requires experts in both areas for a complete review.

Peer review and public comment are not synonymous. Public comment solicited from the general public through the Federal Register or by other means is often required by the Administrative Procedures Act, relevant statutes or both. Public comment can also be solicited for policy purposes. The USEPA takes public comment on some strictly scientific products and almost all regulatory decisions. Public commentators usually include a broad array of people with an interest in the technical analysis or the regulatory decision; some are scientific experts, some are experts in other areas, and some are interested non-experts. The critical distinction is that public comment does not necessarily draw the kind of independent, expert information and analyses expected from the peer review process. Public comment is open to all issues, whereas, the peer review process is limited to consideration of technical issues. While an important component of the review process, public comment does not substitute for peer review.

As part of each peer review, OPPTS must formulate a clear, focused charge that identifies recognized problem areas and invites comments or assistance. This request signals the Agency's awareness of potential problems and its receptivity to expert recommendations. The charge to peer reviewers usually makes two general requests. First, it focuses the review by presenting specific questions and concerns that the Agency expects the reviewers to address. Secondly, it invites general comments on the entire work product. Focused questions also greatly simplify the task of collating, analyzing and synthesizing peer review comments on a topical basis. Moreover, written responses to these questions by peer reviewers help the Agency create a peer review record.

Careful attention to all of these elements, singly and together, assures a credible peer review process. Conversely, inattention can nullify the peer review attempt. A well-planned peer review applied to a reasonable quality starting work product, followed by responsible, visible utilization of peer review suggestions in the final product assures a credible product for use in Agency decision-making.

## **B. Definitions**

1. Peer Involvement - Peer involvement refers to independent expert participation in the development and/or review of a scientific and technical work product. Peer involvement constitutes active outreach to and participation of the broad scientific, engineering, and economics communities beyond the USEPA (external) as well as within the USEPA (internal). Typically, peer involvement takes two general forms, peer input and peer review:

a. Peer Input - Peer input generally connotes an interaction during the development of an evolving Agency work product, providing an open exchange of data, insights, and ideas. Peer input is characterized by a continued and iterative interaction with scientific experts during the early stages of peer involvement.

b. Peer Review - Peer review is an objective, critical review of a specific Agency major scientific and technical work product by an independent peer reviewer or reviewers. Peer review can occur at several discrete points during the peer involvement process. It is characterized by a one-time interaction or a limited number of interactions by independent peer reviewers.

2. Independent Peer Reviewer - An independent peer reviewer is an expert who was not associated with the generation of the specific work product either directly by substantial contribution to its development or indirectly by consultation during the development of the specific product. The independent peer reviewer, thus, can be objectively judgmental. This individual has expertise in the subject matter required for the review function.

3. Major Scientific and Technical Work Product - Scientific, engineering, and economic documents or positions that are used to support a research agenda, regulatory program, policy position or other Agency decision that meet one or more of the criteria found in Table 1 (in Section II.).

4. Peer Review Leader - A person who organizes and oversees the peer review process for individual, specific work products. Sometimes this individual is also the Project Manager for the work product.

5. Peer Review Coordinator - The individual designated by the AA to coordinate and monitor peer review activities.

6. Peer Review Group - The individuals who form the working group that supports the Peer Review Coordinator.

## **II. IDENTIFYING WORK PRODUCTS FOR PEER REVIEW**

The principle underlying the Peer Review Policy is that all major scientific and technical work products (MSTWPs) normally should be peer reviewed. The process for identifying major products for review and then determining the mechanism of review will take into account various criteria. The decision maker(s) for peer review should consider the full field of possible work products that could benefit from peer review as well as the full spectrum of peer review mechanisms for each product.

### **A. The Selection Process**

#### **1. Major Scientific and Technical Work Product (MSTWP)**

a) The determination that a scientific or technical product is a "major" work product is based upon a thorough consideration of a series of criteria. Work products that are used to support a regulatory program or policy position and that meet one or more of the criteria found in Table 1 are candidates for peer review:

<p style="text-align: center;"><b>TABLE 1.</b></p> <p style="text-align: center;"><b>SOME CRITERIA FOR IDENTIFYING MAJOR SCIENTIFIC AND TECHNICAL WORK PRODUCTS</b></p>	
1.	Supports major regulatory decisions or policy/guidance of major impact
2.	Establishes a significant precedent, model, or methodology
3.	Addresses controversial issues
4.	Focuses on significant emerging issues
5.	Has significant cross-Agency/inter-agency implications
6.	Involves a significant investment of Agency resources
7.	Considers an innovative approach for a previously defined problem/ process/methodology
8.	Satisfies a statutory or other legal mandate for peer review

There are two specific circumstances when there does not appear to be a rationale for improving the work product with peer review. First, additional peer review is not required for a particular product that has a known peer review record by a recognized expert or expert body. For example, a cancer risk assessment methodology or an exposure modeling technique that had been the subject of earlier peer review, would not require additional review, even if the product supported a significant Agency decision. Second, additional review is not required if a new application of an adequately peer reviewed work product does not depart significantly from its scientific or technical approach.

b) Scientific or technical work products that do not meet these criteria for "major" may be also considered candidates for peer review depending upon the nature of these products, specific program needs/goals, and potential benefits of the peer review process (i.e., is value added to the work product?).

c) The need for and timing of peer review at various stages in the development of the work product may greatly benefit that product. The criteria in Table 1 may be used to help determine if peer review is appropriate at a particular stage of work product development (e.g., help an office/region decide which direction/ methodology/technique is most appropriate from two or more choices).

d) Appendix D lists scientific/technical activities/products identified in each category by OPPTS as candidates for peer review for the upcoming fiscal year. Also listed is the projected mechanism of peer review for each work product.

2. **Special Circumstances Which May Constrain the Use of Peer Review**

a) Exploratory Analyses and Voluntary Risk Reduction: OPPTS is involved with a number of activities that involve exploratory scientific and technical analyses. For example, the Pollution Prevention Program may collaborate with stakeholders, including chemical manufacturers, formulators, users and others to characterize the hazards, uses, exposure(s) and risks of a substance, as well as economic considerations, to identify pollution prevention opportunities. In other cases, alternative chemicals or use practices (i.e., OPP's Special Review process) may be considered that present lower risks or exploratory analyses may be used to set priorities for additional testing or information gathering. When such scientific and technical work products are developed in anticipation of collaborative activities with stakeholders, these scientific and technical work products would not usually require peer review. If, however, OPPTS were to determine that unilateral action is appropriate, scientific and technical work products supporting such action would be candidates for peer review.

b) Constraints: Statutory and court ordered deadlines and other time constraints may limit or preclude peer review. Rarely, resource availability may also limit peer review. OPPTS will evaluate these circumstances on a case by case basis; decisions will be based on consultations involving line management and the Peer Review Coordinator. If no peer review is conducted, then written justification to the peer review archive is needed to explain the circumstance. The AA will notify the Science Policy Council of the decision.

**B. Mechanisms for Peer Review**

1. **Mechanisms List**

Peer review for OPPTS takes many different forms. In OPPTS, the most commonly used mechanisms are the FIFRA Scientific Advisory Panel, the Biotechnology Science Advisory Committee, workshops or symposia, outside experts, and the Science Advisory Board. Table 2 lists 13 different types of peer review, ranging from a single Agency expert to a twenty-person panel of external experts. Familiarity with the method, advantages, resource requirements, and logistics of the different forms, and their variations, is an important aspect of peer review planning.



**TABLE 2**

**SOME MECHANISMS FOR OBTAINING PEER REVIEW  
OF SCIENTIFIC AND TECHNICAL WORK PRODUCTS**

<b>INTERNAL PEER REVIEW</b>
1. An independent expert from within the Agency e.g., an ORD expert on non-cancer effects reviews a draft article on benchmark dose.
2. An <u>ad hoc</u> panel of independent experts from (mostly) within the Agency e.g., a group is convened to examine the case for the classification for carcinogenicity for a chemical.
3. Office work group product reviewed for technical merit by scientist in Agency laboratory e.g., initial review of regional WTI risk assessment plan by RTP scientists.
<b>EXTERNAL PEER REVIEW</b>
1. Independent expert(s) from outside the Agency e.g., a peer reviewer for a journal to whom an Agency scientist has submitted a paper for publication; a letter review by one or more reviewers
2. An <u>ad hoc</u> panel of independent experts from (mostly) outside the Agency e.g., a group is convened to reach consensus on the carcinogenicity of formaldehyde.
3. Agency (including Risk Assessment Forum)-sponsored Peer Review Workshops e.g., review of indicators of ecosystem damage.
4. An Agency-based Federal Advisory Committee (other than SAB) e.g., the Biotechnology Science Advisory Committee (BSAC) meets to review technical aspects of the release of bioengineered organisms.
5. Agency-appointed special Board or Commission e.g., review of risk issued by the CAA Commission on Risk Assessment.
6. Agency Science Advisory Board (SAB) e.g., review of drinking water criteria document for arsenic.
7. Interagency committee e.g., review of research plans by Committee on the Environment and Natural Resources (CENR) coordinated by the White House.
8. Committee of another agency e.g., review of "dioxin" reassessment by HHS Committee to Coordinate Environmentally Related Programs (CCERP).
9. Non USEPA-based groups e.g., Society of Risk Analysis review of cancer guidelines.
10. National Academy of Science/National Research Council e.g., review of children and pesticides.

## 2. Selection of Appropriate Mechanism(s)

a) Determining an appropriate mechanism of peer review is generally subjective. Science staff are responsible for recommending and OPPTS managers for selecting peer review options based upon the importance and impact of the work product, the resources available (staff, budget, reviewers), the time investment, and previous review history. The choice of mechanism is based upon several criteria, as seen in Table 1. Also, the extent of previous peer involvement and/or peer review helps determine an appropriate mechanism of peer review.

b) Generally, the more nearly novel or complex the science or technology, the greater the cost implications of the impending decision, and the more controversial the issue, then the stronger the indication for a more extensive and involved peer review and for external peer review in particular. For example, certain work products will clearly lend themselves to extensive external peer review; generally these will be products with large impacts. Other major work products may not need a large scale external peer review and may utilize a less involved, less resource intensive review. The peer review of some products may be better served with some form of internal peer review or a combination of internal and external peer review. Again, the choice is subjective and will generally be dependent upon the experience and assessment of the decision maker(s) dealing with peer review issues. It is important to make this choice at the time that the work is planned so that peer review costs and time can be budgeted into the work plan.

### **C. Categories of Office Products**

OPPTS is involved in a wide variety of activities that have strong scientific and technical components. These activities include hazard, dose-response, exposure, and risk assessments, economic analyses and valuations, development of new assessment methods, and surveys. Some activities (e.g., evaluations of new chemical substances) are performed routinely using standardized assessment methodologies.

Other activities involve breaking new ground or the use of novel techniques or analyses (e.g., formaldehyde risk assessment, acute dietary risk assessment methodology, assessment of biological control agents). All OPPTS scientific and technical activities benefit from peer involvement. The level of peer involvement will differ depending on the scope of the effort, and the significance of the potential outcome, among other factors.

For purposes of discussion, major OPPTS scientific and technical activities can be grouped into several categories.

**Category #1: Products that support major regulatory decisions.**

- 1) Risk assessments (including associated hazard, dose-response and exposure analyses)
- 2) Benefits and cost (economic) assessments relevant to some unreasonable risk determination under TSCA or FIFRA
- 3) Data requirements for pesticide registration
- 4) Technical guidance documents for the regulated community

**Category #2: New approaches to the assessment of chemicals or products of biotechnology. Issues having a major national impact on public health and or ecosystem protection. Examples include:**

- 1) issues associated with release of genetically engineered organisms into the environment
- 2) application of new scientific principles in risk assessment, e.g., the consideration of biological mechanisms for induction of cancer in risk assessment
- 3) risk assessment methods development, e.g., risk assessment methods concerning children exposed to pesticide residues
- 4) risk mitigation proposals for eco-risk reduction
- 5) efficacy testing procedures for hospital disinfectants and sterilants

**Category #3: Products that result in generation of large quantities of data or unusual data. Examples include**

- 1) major surveys, e.g.,:
  - \* national survey of lead-based paint in housing
  - \* survey of pesticides in drinking water wells
  - \* national food consumption survey
- 2) monitoring of chemicals in environmental components

Category #4: **New predictive tools or models of significance, generic assessment methodologies to be used routinely in risk assessment, novel approaches to economic valuation.** Examples include:

- 1) expert systems and quantitative techniques designed to help predict hazards, chemical fate, etc., from chemical structure, use, or toxicity/exposure data
- 2) significant models and other techniques designed to predict exposure, simulate transport, etc.
- 3) precedent-setting methods for economic valuation
- 4) priority-setting tools, e.g., OPPT Use Cluster Scoring System

Appendix C lists completed peer reviews initially listed in prior Appendices D plus representative scientific/technical activities/work products peer reviewed prior to FY-95.

### **III. PLANNING AND CONDUCTING A PEER REVIEW**

The success and usefulness of any peer review depends on the quality of the peer review draft, the care given to the statement of the issues or "charge", the match between the peer review draft and the form of peer review, the match between the peer review draft and the scientific/technical expertise of the reviewers, and Agency use of peer review comments in the final product. It is not enough simply to conduct a peer review; each of the foregoing elements requires serious attention.

#### **A. Selecting Peer Reviewers**

##### **1. Sources for Peer Reviewers**

a) Recommendations for potential peer reviewers can be identified from a number of organizations. These include external groups such as the affected party(ies); special interest groups; public interest groups; environmental groups; trade or business associations; state organizations or agencies; the National Research Council; and other Federal agencies with an involvement in or familiarity with the issue. Internal groups include the staff of the Science Advisory Board (SAB), BSAC, or the Scientific Advisory Panel (SAP); relevant ORD scientific staff; and other Program or Regional experts.

b) In certain circumstances, existing peer review organizations such as the SAB, BSAC or SAP may be used to conduct a peer review. These groups establish their own criteria for accepting work and coordination must be made directly with them. Both conduct formal, public, external peer reviews.

c) Occasionally, a member of the scientific community will offer his/her services for peer review during an ongoing peer review. Disposition of these offers will be handled on a case by case basis in consultation with the Peer Review Coordinator and appropriate decision makers.

## 2. Selecting Peer Reviewers

a) Peer reviewers should be selected for independence and scientific/technical expertise. The emphasis on independence and expertise applies equally to government experts and experts from the larger scientific community.

b) Ideally, peer reviewers should be free of real or perceived conflicts-of-interest or there should be a balancing of interests among peer reviewers.

c) Some peer reviews can be conducted with one or two reviewers; others involve panels of peer reviewers. In either case each of the peer reviewers should have recognized technical expertise that bears on the subject matter under discussion. Taken as a whole, the peer reviewers of a work product should represent a balanced range of technically legitimate points of view. In the face of equally qualified experts, cultural diversity and "address" (e.g., industrial, academic, or environmental community) are secondary factors that can play a role.

## 3. Internal vs. External Peer Reviewers

Generally, external peer reviewers are preferred. For some work products, either external or internal peer review may be appropriate. Selection of internal peer reviewers should be based upon technical expertise, available time and "address"; that is, they should not come from the immediate office or group producing the product or have any other connection with the product or document being peer reviewed.

## 4. Disciplinary Mix

a) A peer review panel or group can number from just a few individuals to ten or more, depending on the issue, the time and resources available and the broad spectrum of expertise required

to treat the range of issues/questions in the charge (see Section III.C. below). Naturally, experts whose understanding of the specific technical area(s) being evaluated are critical; nevertheless, it is also important to include a broad enough spectrum of other related experts to completely evaluate the relevant impacts on other less obvious concerns. For example, for health related peer reviews, experts in such fields as ecology and economics may provide very useful insights.

b) There is usually a continuum of views on any issue. To the extent possible or practicable, selected experts should have views that fall to either side of the centrist position along the continuum, but not too far to either extreme. This will help maintain a balanced viewpoint, while allowing all views to be expressed and discussed. A balanced panel will allow consensus building. As a general rule, experts who have made public pronouncements on an issue (e.g., those who have clearly "taken sides") have difficulty in reaching consensus positions and should be avoided.

#### 5. Constraints in Selecting Peer Reviewers

a) Peer review is not free. Regardless of the type of peer review chosen, there is some cost to the Agency. This cost can range from the time invested by a few Agency staff during an internal peer review, to the total costs associated with a full, formal, public external peer review; e.g., SAB review.

b) Sometimes the need for a peer review is accelerated due to a court-ordered deadline or other time-sensitive requirements. In such cases, it is difficult, if not impossible to conduct a full external peer review. It may even be impossible to conduct a small scale internal peer review using just a few individuals. Mechanisms for identifying and using a small number of peer reviewers should be included for OPPTS so that quick, effective peer review can be included for even the most rapidly moving products.

c) Care must be taken to reduce the possibility for real or apparent conflicts of interest between the reviewers and the OPPTS work product under review. Various tools are available to identify and limit conflicts of interest (e.g., attention to the employment, financial, and professional affiliations of the participants; filing Confidential Financial Disclosure Forms (SF-450) in the case of members of Federal Advisory Committees; exploring directly the issue with each of the participants before the review process takes place; and disclosing publicly at the beginning of meetings any previous involvement with the issue). The established peer review groups such as the Science Advisory

Board and the Scientific Advisory Panel provide useful models for addressing balance and conflict-of-interest issues. Assistance in determining legal conflicts of interest can be obtained through the Office of the General Counsel. In addition, additional advice can be obtained from the Designated Agency Ethics Officials. Appendix E has further discussion on conflict of interest.

d) To evaluate OPPTS-generated studies properly, some peer reviewers may need access to confidential business information (CBI). However, unless the reviewers are Federal employees, it is unlikely that the USEPA has the authority to disclose CBI to them. Therefore, whenever contemplating the use of outside peer reviewers, Agency staff should determine whether the reviewers will need access to CBI. If so, the Office of the General Counsel should be consulted on whether it is practical to obtain the consent of CBI submitters to disclose the information to peer reviewers.

e) Offices need to be aware of the requirements of the Federal Advisory Committee Act (FACA) when establishing peer review mechanisms. Federal advisory committees are subject to chartering by the General Services Administration, hold meetings that are open to the public, and have balanced membership requirements. The Office of the General Counsel should be consulted regarding the applicability of FACA to peer review panels, see appendix E for additional information.

## **B. Scheduling Peer Reviews**

The peer review schedule is a critical feature of the process. The schedule must take into account the availability of a peer review quality draft work product, availability of appropriate experts, time available for using peer review comments, deadlines for the final work product, and logistical aspects of the peer review (e.g., contracting procedures).

The schedule for peer review should take into account the overall rulemaking (or other decision-making) schedule. Peer review sometimes leads to new information and analyses, or recommendations for new research that would alter the work product and thus modify the scientific/technical basis for the action. For this reason, it is usually advisable to complete the peer review before taking public comment, or at least before the close of the public comment period.

## C. **Materials**

### 1. **Information Provided to Peer Reviewers**

a) Essential documentation for each peer reviewer includes:

1) A current copy of the work product to be peer reviewed with associated background material. The work product needs to be of the best possible scientific/technical quality to ensure an adequate and useful peer review.

2) A clear charge or statement of work seeking informed comment on identified issues to properly focus the efforts of the peer reviewers and ensure that their individual efforts can be merged.

3) Some information concerning the process that OPPTS is using for the peer review, including due date of reviewer comments and the format of those responses. Responses should be written and submitted to OPPTS by an agreed upon deadline. In certain rare cases, oral commentary may be sufficient. However, in such cases, a follow-up written response for the record is required.

4) OPPTS will make clear to the peer reviewers their responsibilities. One of the major responsibilities of peer reviewers is to ensure confidentiality of the peer reviewed work product. Each peer reviewer must be informed of the need for confidentiality with regard to the release of OPPTS products that are stamped as "DRAFT" or "DRAFT - Do Not Cite, Quote, or Release." Premature release of draft Agency products, views, or positions is inappropriate and can be damaging to the credibility of the Agency or the peer reviewer. While not having legal authority, such language will be included in the charge to the peer reviewers. Other mechanisms to use in discouraging premature release include a disclaimer that appears in a separate section at the front of the document and creating the document with watermarks clearly delineating DRAFT status (or a header or footer that states DRAFT status) on every page. In addition, in any solicitation for peer reviewers, the necessity for confidentiality and the non-release of materials shall be emphasized.

b) Useful, but not critical materials that may be sent to peer reviewers include:



1) Unless a "Delphi" type process is being undertaken, it is also useful for each peer reviewer to have the name, address, and phone, fax, and/or Internet numbers of each peer reviewer working on the specific review.

2) Any particularly relevant scientific articles from the literature;

3) It is often more practical to provide comments on a product that has line numbering added in the margin.

c) Peer Reviewers should be given what is needed to complete their task -- they should not be overburdened with excess material.

## 2. Peer Reviewer Responsibilities

The Peer Review Leader is responsible for ensuring that peer reviewers understand and comply with these responsibilities:

a) Advise the USEPA of any real or perceived conflicts-of-interest.

b) Provide written comments in specified format by the specified deadline.

c) Comply with the request for not disclosing draft work products to the public.

## IV. COMPLETING A PEER REVIEW

Performance of the formal peer review is not the final stage in the development of the work product. Rather, it is an important stage in developing the work product, with the final work product representing the true end of the peer review. As a result, the peer review process closes with three major activities: evaluating comments and recommendations, utilizing peer review comments for completing the final work product, and organizing and maintaining a record of the peer review.

### **A. Evaluating Comments and Recommendations**

1. OPPTS must carefully evaluate and analyze all peer review comments and recommendations. As discussed in Section III., a carefully crafted charge to the peer reviewers simplifies organizing and analyzing comments. Also, any other issues that are raised need to be identified and evaluated.

2. The validity and objectivity of the comments need to be evaluated. Analyses include consultation with other experts/staff within the Office and/or Agency.

3. Comments that have significant impact on time, budgetary, and/or resource requirements need to be evaluated in consultation with management. These comments may lead to allocation of additional resources and a revised schedule for the completion of the work product.

## **B. The Final Work Product**

1. OPPTS must utilize technically sound and responsible peer review comments and recommendations in completing the final work product. The major issues raised by the peer reviewers need to be identified in the front of the final work product, along with information on how they were used or not used in the final work product.

2. In the final work product, reference the location of the peer review record where all comments and related peer review information can be found. The peer review record should be placed in any associated established public docket in addition to the Office archive.

## **C. Maintaining the Peer Review Record**

1. The Peer Review Leader will collect and maintain the following materials for the peer review record, including at least:

- ▶ the draft work product submitted for peer review
- ▶ materials and information given to the peer reviewer(s)
- ▶ comments, information, and materials received from the peer reviewer(s)
- ▶ information about the peer reviewer(s) (e.g., names, affiliations, etc.)
- ▶ any logistical information (e.g., times; locations; duration, etc.)
- ▶ the final work product

2. The peer review record must be indexed and maintained in an office archive.

All peer review comments should be carefully evaluated and used to revise work products where appropriate. As discussed in III. C. (above) it is particularly useful to craft specific questions for peer reviewers so that subsequent comment will be

focussed. Focussing reviewers attention on issues of interest will facilitate comment evaluation.

In some cases, preparation of a document that responds to each comment may be appropriate. In other circumstances, comments may be addressed in a more general manner. In any case, a clear record must be maintained of the peer review process employed, as well as the specific comments received. Furthermore, the product itself must include some acknowledgment of the peer review process.

The Agency may or may not agree with comments received. However, it is important to reflect the nature of comments received and the extent to which these comments affect the scientific or technical product. In addition to revising the technical product, if appropriate, it is particularly important to communicate significant results of peer review to the decision maker(s) as well as to others who may not be versed in the technical discipline at hand. For example, a decision maker might find a peer review summary very helpful. The summary could present, in general terms, the scope of the peer review process and the thrust of the comments received. A brief statement discussing the kinds of comments received, how the comments were reflected in the work product, and the impact on the scientific or technical conclusion should be included. For example, a hypothetical summary might include language such as:

Reviewers commented that the exposure analysis assumed no chemical degradation as a result of treatment in a POTW. Reviewers felt this was overly conservative and, as a result, risks may be overestimated.

No information is available on the fate of the chemical in POTWs. However, based on analogous chemicals for which data are available, it is likely that less than 10% degradation would occur. The risk characterization has been changed to reflect risk as a range, thereby addressing the uncertainty associated with our lack of information on fate of this chemical in a POTW.

#### **V. ACCOUNTABILITY AND RESPONSIBILITY IN THE OFFICE**

Under the June 7, 1994 Peer Review Policy, the Administrator has designated the Assistant Administrators and Regional Administrators to be accountable for implementing the Policy in their respective offices. This section provides information on OPPTS' delegations of responsibility to (a) line management for

individual peer reviews, and (b) an office-wide coordination group for general assistance and advice.

## **A. Line Management**

### **1. Decision maker(s)**

a) The Assistant Administrator is accountable for the decisions regarding the identification of major scientific and technical work products and the mechanism(s) of peer review utilized for each of the products. The AA designates the OPPTS Division Directors, in conjunction with the Deputy Office Directors, as decision makers. The AA and their designee(s) are also responsible for ensuring that the peer reviews are performed and fully completed. See Appendix B for the names (or positions) of the designated decision maker(s).

b) Specific responsibilities of the decision maker(s) are:

- ▶ Designating a Peer Review Leader to organize the peer review
- ▶ Providing advice, guidance, and support to the Peer Review Leader in the preparation, conduct, and completion of the peer review
- ▶ Establishing a realistic peer review schedule (see Section III)
- ▶ Designating the stage(s) of product development where peer review is appropriate
- ▶ Ensuring that the results of peer review are carried forward in the final work product

### **2. Peer Review Leader**

a) The Peer Review Leader organizes and oversees the peer review for a specific work product. This person(s) can be the decision maker(s), but will usually be someone who is authorized by the decision maker to prepare, perform, and bring to completion the peer review. The Peer Review Leader will obtain the assistance and support of the Peer Review Coordinator and Peer Review Group (see below) as well as any others within the Agency to help perform the peer review. The Leader will be chosen on a case by case basis depending on the work product needing peer review.

b) Specific responsibilities of the Peer Review Leader are:

- ▶ Coordinating the peer review of their assigned work product with the Peer Review Coordinator and Peer Review Group
- ▶ Organizing, conducting, and completing the peer review following the procedures outlined in this SOP, particularly Sections III. and IV.
- ▶ Selecting the peer reviewers in consultation with others involved with the peer review (e.g., Peer Review Coordinator)
- ▶ Advising peer reviewers of their responsibilities

## **B. Office Coordination**

### **1. Peer Review Coordinator**

a) The Assistant Administrator for OPPTS will designate one person to coordinate or lead coordination of peer review activities for this office. The Peer Review Coordinator is listed in Appendix B.

b) Specific responsibilities of the Peer Review Coordinator are:

- ▶ Leading the Peer Review Group as well as OPPTS peer review activities
- ▶ Reporting peer review activities to the AA
- ▶ Liaison with the Science Policy Council (SPC) and Science Advisor:
  - 1) Representing OPPTS before the SPC
  - 2) Advising the SPC of any changes in SPC-reviewed list of work products and peer review mechanisms in Appendix D
  - 3) Participating in SPC peer review training, workshops, etc., as requested
  - 4) Interfacing with the Administrator's Science Advisor on peer review matters
- ▶ Submit information on OPPTS peer review candidates for each fiscal year on June 15 of the preceding year via Appendix D reporting

- ▶ Submit any SOP revisions on July 1 of each year for review for incorporation in the SOP for the next fiscal year
- ▶ Provide advice, guidance, and support to the various Peer Review Leaders for the performance of the peer reviews
- ▶ Distribute Agency-wide peer review guidance and materials to appropriate OPPTS personnel, as requested

## 2. OPPTS Peer Review Advisory Group

a) Each year, the Assistant Administrator may also designate other persons and support staff to constitute the Peer Review Advisory Group. The Group will assist the Peer Review Coordinator either as special assignments or as a designated part of their normal duties. The group members and support staff are listed in Appendix B.

b) Specific responsibilities for the Peer Review Group are:

- ▶ Assisting the Peer Review Coordinator in providing advice involving peer review activities in OPPTS
- ▶ Assisting with logistical and technical peer review needs in the office, e.g., acquisition and distribution of resources
- ▶ If needed, providing advice to decision maker(s) and/or help them with the identification of major work products and selection of appropriate peer review mechanism
- ▶ Periodic review of the SOP and how it is being implemented
- ▶ Provide advice during the planning and management of OPPTS' peer review program, e.g., integrating peer review plans into office workplans

## 3. Legal Advice

OPPTS staff and management work regularly with individual OGC staff assigned to Agency activities. Peer Review Leaders should continue to initially consult with their customary OGC advisors for legal advice or referral. Headquarters attorneys have specialties in specific areas and can be consulted as needed. Appendix B lists these contacts for OPPTS.

### **C. Budget**

Both program offices within OPPTS (OPP and OPPT) have rigorous planning processes. The planning process is the appropriate forum to ensure that peer review-related activities are appropriately budgeted, and that sufficient resources will be available to effect a completed peer review.

The planning process articulates priority activities for the coming year and provides opportunities for periodic evaluation of project status, including opportunities for redirecting program priorities. The planning process facilitates development of project plans for priority projects, including identification of scientific and technical products necessary to complete priority activities.

The project planning process provides a natural forum for discussing the nature of scientific and technical products that will be developed to support various projects. This forum provides an opportunity to discuss the mechanism of peer involvement and/or peer review needed and how these peer activities will be achieved. Discussing the scope of peer review during the planning process provides the added benefit of ensuring that timing and resource requirements associated with peer review are included in the planning process and highlighted for senior management attention.

### **D. Annual Reviews**

1. The Peer Review Coordinator will organize an annual preview of OPPTS' expected work products for the next fiscal year and submit this information to the SPC by June 15 of each year as required for Appendix D.

2. The Peer Review Coordinator will organize an annual review to assess the function of the SOP in practice. The Coordinator will consult with the SPC regarding any proposed changes by June 15 for the next fiscal year.

## APPENDIX A

### U.S. ENVIRONMENTAL PROTECTION AGENCY PEER REVIEW POLICY

#### PEER REVIEW AND PEER INVOLVEMENT AT THE U. S. ENVIRONMENTAL PROTECTION AGENCY

This document establishes the policy of the United States Environmental Protection Agency (EPA) for peer review of scientifically and technically based work products that are intended to support Agency decisions. Peer review is presented in the context of the broader concept, peer involvement.

#### BACKGROUND

The report "Safeguarding the Future: Credible Science, Credible Decisions"<sup>1</sup> focused on the state of science at EPA. The panel of experts who prepared the report emphasized the importance of peer review, especially external peer review, and the need for broader and more systematic use of it at EPA to evaluate scientific and technical work products. Their specific recommendation regarding peer review reads as follows:

"Quality assurance and peer review should be applied to the planning and results of all scientific and technical efforts to obtain data used for guidance and decisions at EPA, including such efforts in the program and regional offices. Such a requirement is essential if EPA is to be perceived as a credible, unbiased source of environmental and health information, both in the United States and throughout the world."

In response to this recommendation, then-Administrator Reilly directed staff to develop an EPA-wide policy statement, which he issued in January, 1993. The paragraphs below preserve the core of that earlier statement while updating it to specify the role of the Science Policy Council in guiding further implementation of the policy. Effective use of peer review is indispensable for fulfilling the EPA mission and therefore deserves high-priority attention from program managers and scientists within all pertinent Headquarters and Regional Offices.

#### PEER INVOLVEMENT AND PEER REVIEW

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<sup>1</sup> EPA/600/9-91/050, March 1992.



EPA strives to ensure that the scientific and technical underpinnings of its decisions meet two important criteria: they should be based upon the best current knowledge from science, engineering, and other domains of technical expertise; and they should be judged credible by those who deal with the Agency. EPA staff therefore frequently rely upon peer involvement -- that is, they augment their capabilities by inviting relevant subject-matter experts from outside the program to become involved in one or more aspects of the development of the work products that support policies and actions.

One particularly important type of peer involvement occurs when scientifically and technically based work products undergo peer review -- that is, when they are evaluated by relevant experts from outside the program who are peers of the program staff, consultants, and/or contractor personnel who prepared the product. Properly applied, peer review not only enriches the quality of work products but also adds a degree of credibility that cannot be achieved in any other way. Further, peer review early in the development of work products in some cases may conserve future resources by steering the development along the most efficacious course.

Peer review generally takes one of two forms. The review team may consist primarily of relevant experts from within EPA, albeit individuals who have no other involvement with respect to the work product that is to be evaluated (internal peer review). Or the review team may consist primarily of independent experts from outside EPA (external peer review).

#### POLICY STATEMENT

Major scientifically and technically based work products related to Agency decisions normally should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories, and field components determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made in conformance with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial.

## SCOPE

Agency managers routinely make regulatory and other decisions that necessarily involve many different considerations. This policy applies to major work products that are primarily scientific and technical in nature and may contribute to the basis for policy or regulatory decisions. By contrast, this policy does not apply to nonmajor or nontechnical matters that Agency managers consider as they make decisions. Similarly, this policy does not apply to these ultimate decisions.

This policy applies where appropriate, as determined by the National and Regional Program Managers, to major scientifically and technically based work products initiated subsequent to the date of issuance. Peer review should be employed to the extent reasonable to relevant work products that currently are under development. This policy does not apply to the bases for past decisions, unless and until the relevant scientific and technical issues are considered anew in the Agency's decision-making processes.

Except where it is required by law, formal peer review (as distinguished from the Agency's normal internal review procedures) should be conducted in a manner that will not cause EPA to miss or need extension of a statutory or court-ordered deadline. Agency managers still may undertake peer review if it can be conducted concurrently with necessary rulemaking steps.

## LEGAL EFFECT

This policy statement does not establish or affect legal rights or obligations. Rather, it confirms the importance of peer review where appropriate, outlines relevant principles, and identifies factors Agency staff should consider in implementing the policy. On a continuing basis, Agency management is expected to evaluate the policy as well as the results of its application throughout the Agency and undertake revisions as necessary. Therefore, the policy does not stand alone; nor does it establish a binding norm that is finally determinative of the issues addressed. Minor variations in its application from one instance to another are appropriate and expected; they thus are not a legitimate basis for delaying or complicating action on otherwise satisfactory scientific, technical, and regulatory products.

Except where provided otherwise by law, peer review is not a formal part of or substitute for notice and comment rulemaking or adjudicative procedures. EPA's decision whether to conduct peer review in any particular case is wholly within the Agency's discretion. Similarly, nothing in this policy creates a legal

requirement that EPA respond to peer reviewers. However, to the extent that EPA decisions rely on scientific and technical work products that have been subjected to peer review, the remarks of peer reviewers should be included in the decision record.

#### IMPLEMENTATION

The Science Policy Council is responsible for overseeing Agency-wide implementation. Its responsibilities include promoting consistent interpretation, assessing Agency-wide progress, and developing recommendations for revisions of the policy as necessary.

The Science Policy Council will oversee a peer-review work group, which will include representatives from program units throughout EPA to effect a consistent, workable implementation of the policy. The work group will assist the programs in (1) formulating and, as necessary, revising standard operating procedures (SOPs) for peer review consistent with this policy; (2) identifying work products that are subject to review; and (3) for each major work product, selecting an appropriate level and timing of peer review.

In assisting the programs, the work group will take into account statutory and court deadlines, resource implications, and availability of disinterested peer reviewers. The group will work closely with Headquarters offices and the Regional Offices toward ensuring effective, efficient uses of peer review in supporting their mission objectives. However, the Assistant Administrators and Regional Administrators remain ultimately responsible for developing SOPs, identifying work products subject to peer review, determining the type and timing of such review, documenting the process and outcome of each peer review, and otherwise implementing the policy within their organizational units.

Because peer review can be time-consuming and expensive, Agency managers within Headquarters, Regions, laboratories, and field components are expected to plan carefully with respect to its use -- taking account of program priorities, resource considerations, and any other relevant constraints as well as the policy goal of achieving high-quality, credible underpinnings for decisions. External peer reviewers should be chosen carefully to ensure an independent and objective evaluation. The affiliations of peer reviewers should be identified on the public record, so as to avoid undercutting the credibility of the peer-review process by conflicts of interest.

This policy is effective immediately. The peer-review work group mentioned above will identify the focal point to whom comments and questions should be addressed and, from time to time, will provide further information about implementation activities.

**APPENDIX B**

**KEY PERSONNEL**

**I. Individuals Involved in the Peer Review**

**A. Line Management**

1. **Decision maker(s)**: OPPTS Division Directors in conjunction with the Deputy Office Directors:

**OPP Division Directors**

Director, Program Management and Support Division  
Director, Biological and Economic Analysis Division  
Director, Biopesticides and Pollution Prevention Division  
Director, Environmental Fate and Effects Division  
Director, Field Operations Division  
Director, Health Effects Division  
Director, Registration Division  
Director, Special Review and Reregistration Division

**OPPT Division Directors**

Director, Chemical Control Division  
Director, Economics, Exposure and Technology Division  
Director, Environmental Assistance Division  
Director, Chemical Screening and Risk Assessment Division  
Director, Chemical Management Division  
Director, Health and Environmental Review Division  
Director, Information Management Division  
Director, Pollution Prevention Division

**OPPTS Deputy Office Directors**

Deputy Office Director, Office of Pesticide Programs

Deputy Office Director, Office of Pollution Prevention and Toxics

**B. Office Coordination**

2. **Peer Review Coordinator**

Name: Michael Firestone  
Position: Science Advisor/OPPTS  
Telephone: (202) 260-2897  
Term of service: continuing

3. **Peer Review Group**

Individuals serving on the Peer Review Group in FY95:

Chair: Susan H. Wayland  
Position: Deputy Assistant Administrator/  
OPPTS  
Telephone: (202) 260-2910  
Term of service: continuing

Co-chair: Penelope Fenner-Crisp  
Position: Deputy Office Director/OPP  
Telephone: (703) 305-7090  
Term of service: continuing

Co-chair: Joseph S. Carra  
Position: Deputy Office Director/OPPT  
Telephone: (202) 260-1815  
Term of service: continuing

Member: Michael Firestone  
Position: Science Advisor/OPPTS  
Telephone: (202) 260-2897  
Term of service: continuing

Member: Robert B. Jaeger  
Position: Designated Federal Official  
for FIFRA Scientific Advisory Panel  
Telephone: (703) 305-5369  
Term of service: continuing

Member: Elizabeth Milewski  
Position: Designated Federal Official for  
Biotechnology Science Advisory Committee  
Telephone: (202) 260-6900  
Term of service: continuing

Member: Amy Rispin  
Position: Senior Science Advisor/PSPS/OPP  
Telephone: (703) 308-2738  
Term of service: continuing

Member: William T. Waugh  
Position: Deputy Director  
Chemical Screening and Risk Assessment Division  
Telephone: (202) 260-3489  
Term of service: continuing

## II. Legal Advice

OPPTS works closely with OGC staff. Peer Review Leaders should continue to initially consult with their customary OGC advisers for legal advice or referral. The following individual has been identified as the OPPTS contact in OGC for matters relating to this SOP:

Robert Perlis  
Office of General Counsel

The headquarters attorneys listed below specialize in the identified areas and may be consulted, as appropriate.

Donald Sadowski  
Confidential Business Information  
Office of General Counsel

Richard Feldman  
Conflicts of Interest Disclosure  
Office of General Counsel

Hale Hawbecker  
FACA Issues  
Office of General Counsel

**APPENDIX C - Part 1 of 2**

**PRODUCTS PEER REVIEWED SINCE 1991 (Pre-1995-Initiated Items are Representative)**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Ecological Risk Assessment of Dioxins - TS9101	OPPTS	OPPT	John Bower, 260-1771	10/91	Workshop		6/91	10/91	
Reduced Protocols for Carcinogenicity Testing - TS9201	OPPTS	OPPT	David Lai, 260-6222	1/94	Workshop		9/92	12/92	
Ecological Quantitative Structure Activity - TS9401	OPPTS	OPPT	Richard Clements, 260-5270	1/95	Public Literature & Expert Panel	9/94	1/94	6/94	
Analysis of HUD National Survey Data - TS9402	OPPTS	OPPT	Manie Chen, 260-3910	9/94	Independent Experts	9/94	4/94	5/94	
Formaldehyde Risk Characterization - TS9102	OPPTS	OPPT	Vanessa Vu, 260-1245	7/92	SAB		6/91	12/91	
Design of Repair and Maintenance Study, Lead - TS9202	OPPTS	OPPT	Susan Dillman, 260-5375	4/92	Independent Experts		4/92	4/92	
Consumer Behavior Study - TS9103	OPPTS & OW	OPPT	Lynne Blake-Hedges, 260-7241	4/94	Independent Experts		9/91	12/91	Joint OW/OPPT activity. Received peer input through NACEPT. OW asked that OPPT publish study ASAP for additional feedback.
US EPA Regulatory Perspectives on the Use of QSAR for New & Existing Chemical Evaluations - TS9403	OPPTS	OPPT	Maurice Zeeman, 260-1240	5/95	Peer Review Journal	5/95	9/94	4/95	
Green Chemistry Manuscripts TS9415	OPPTS	OPPT	Tracy Williamson 260-3960	3/96	Independent Experts	9/94	3/95	3/96	Issued as ACS Publications

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**APPENDIX C - Part 1 of 2**  
**PRODUCTS PEER REVIEWED SINCE 1991 (Pre-1995-Initiated Items are Representative)**  
**(Continued)**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Lead:XRF and Test Kit Field Evaluation Study TS9411	OPPTS	OPPT	John Schwemberger 260-7195	5/95	Expert Panel	9/94	11/94	1/95	
Pilot Testing Program for Protocols for Lead-Based Paint Encapsalants TS9413	OPPTS	OPPT	Jill Hacker 260-3952	9/95	Expert Panel	9/94	6/95	8/95	Title of Work Product Revised
Pre-Intervention Data Collection from the Lead Repair and Maintenance Study TS9504	OPPTS	OPPT	Ben Lim 260-1509	10/95	Expert Panel	5/95	7/95	8/95	Title of Work Product Revised
Effects of In-Home Education on Children's Blood-Lead Levels in Milwaukee TS9505	OPPTS	OPPT	Brad Schultz (608) 265-4068	4/96	Expert Panel	5/95	8/95	10/95	Title of Work Product Revised
Environmental Toxicology/Ecological Effects Assessment by USEPA; OPPT Under TSCA TS9507	OPPTS	OPPT	Maurice Zeeman 160-1240	10/95	OTA Symposium	5/95	4/95	8/95	
Environmental Toxicology Testing & Screening Technologies TS9506	OPPTS	OPPT	Maurice Zeeman 260-1240	10/95	OTA Symposium	5/95	4/95	8/95	

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**APPENDIX C - Part 2 of 2**

**PRODUCTS PEER REVIEWED SINCE 1991 (Pre-1995-Initiated Items are Representative)**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Date Peer Review Completed	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Impact of Triazines on Water Resources - PP9301	OPPTS	OPP-EFED	Hank Jacoby 703-305-5734	10/92	Agency and outside experts		2/93	8/92	
Small scale prospective ground-water study guideline and protocol - PP9501	OPPTS	OPP-EFED	Betsey Behl 703-305-6128	4/95	workshop with outside experts	9/94	3/95	4/95	
National Survey of Pesticides in Drinking Water - PP9201	OPPTS/ OW	OPP-EFED	Elizabeth Leovey 703-305-7328	1/92	SAP/EPA experts		1/91	4/91	
Assessment of environmental release of transgenic cotton plants under an EUP - PP9202	OPPTS	OPP-BPPD	Bill Schneider 703-308-8683	4/92	SAP		2/92	3/92	
Proposed regulation of plant pesticides: scientific issues - PP9203	OPPTS	OPP-BPPD	Bernice Slutsky 202-260-6900	11/94	SAP		12/92	1/93	
Proposed regulation of plant pesticides under FFDCA: scientific issues - PP9302	OPPTS	OPP-BPPD	Bernice Slutsky 202-260-6900	11/94	BSAC	9/94	7/93	8/93	
Proposed rule for plant pesticides: scientific issues - PP9401	OPPTS	OPP-BPPD	Bernice Slutsky 202-260-6900	11/94	SAP/BSAC	9/94	1/94	2/94	
Assessment of plant pesticides containing B.t. cryIII delta endotoxin: scientific issues - PP9501	OPPTS	OPP-BPPD	W. Schneider 703-308-8683	5/95	SAP		3/95	3/95	
Two generation reproductive toxicity test guideline - PP9303	OPPTS	OPP-HED/ OPPT	Sue Makris/Jennifer Seed	proj.10/95	SAP/SAB		12/93	1/94	
Developmental toxicity test guideline and SEP - PP9304	OPPTS	OPP-HED/ OPPT	Sue Makris/Jennifer Seed	proj.10/95	SAP/SAB		12/93	1/94	
Triphenyltin hydroxide cancer assessment - PP9101	OPPTS	OPP-HED		10/91	SAP		9/91	10/91	
Triallate cancer assessment - PP9204	OPPTS	OPP-HED		7/92	SAP		6/92	7/92	
Quinclorac cancer assessment - PP9205	OPPTS	OPP-HED		9/92	SAP		6/92	7/92	

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**APPENDIX C - Part 2 of 2**  
**PRODUCTS PEER REVIEWED SINCE 1991 (Pre-1995-Initiated Items are Representative)**  
**(Continued)**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Date Peer Review Completed	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Dimethoate cancer assessment - PP9206	OPPTS	OPP-HED		9/92	SAP		6/92	7/92	
Bromoxynil cancer assessment - PP9207	OPPTS	OPP-HED		9/92	SAP		6/92	7/92	
Prodiamine cancer assessment - PP9102	OPPTS	OPP-HED		11/91	SAP		9/91	10/91	
Metolachlor cancer assessment - PP9103	OPPTS	OPP-HED		11/91	SAP		9/91	10/91	
ETU (ethylene thiourea) risk assessment - PP9104	OPPTS	OPP-SRRD	Amy Farrell 308-8054	3/92	SAP		9/91	10/91	
2,4-D weight of evidence for carcinogenicity - PP9305	OPPTS	OPP-HED	R. B. Jaeger	---	SAP/SAB		4/93	3/94	
Agency proposed cholinesterase policy - PP9208	OPPTS	OPP-HED	R.B. Jaeger 703-305-5369	5/93	SAP/SAB		11/92	4/93	
Aldicarb and sulfone - PP9209	OPPTS	OPP-HED		12/92	SAP/SAB		11/92	11/92	
Immunotoxicity test screen - PP9306	OPPTS	OPP-HED	R. Sjoblad	proj.10/95	SAP/SAB		12/93	1/94	
Inhalation guideline revisions - PP9307	OPPTS	OPP-HED	Whalen/Redden	proj.10/95	SAP/SAB		12/93	1/94	
Cholinesterase methodology - PP9308	OPPTS	OPP-HED	W. Sette 703-305-6375		SAP/SAB		12/93	1/94	
Dermal absorption test guideline - PP9309	OPPTS	OPP-HED	R. Zendzian 703-305-5495	proj.10/95	SAP/SAB		12/93	1/94	
Data requirements for pesticide registration (40CFR.Part 158): draft proposed rule - PP9402	OPPTS	OPP-PSPS	A. Rispin 703-305-5989	proj.1/96	SAP		11/94	12/94	

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**APPENDIX D - Part 1 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Estimated Date of Peer Review Initiation	Estimated Date for Receipt of Peer Review Comments	Comments
Bioremediation Risk Assessment - TS9403	OPPTS	OPPT	Phil Sayre, 260-9570	7/96	Workshop	9/94	6/93	5/96	
Use Cluster Scoring System - TS9404	OPPTS	OPPT	Dan Fort, 260-1694	10/96	SAB	9/94	10/94	11/95	
Methods for Valuing Eco Benefits - TS9404	OPPTS	OPPT	Lynne Blake-Hedges 260-7241	4/97	Expert Panel	9/94	11/96	1/97	
Economic Analysis of Lead 403 Rule - TS9406	OPPTS	OPPT	Nishkam Agarwal 260-1285	11/96	SAB	9/94	9/96	10/96	Parallel Review with TS9503
Cleaner Technology Substitutes Assessment (Case Study) - TS9407	OPPTS	OPPT	Linda Rusak, 260-5273	5/97	Expert Panel	9/94	9/96	11/96	
TRI Indicator - TS9408	OPPTS	OPPT	Nick Bouwes, 260-1662	10/97	SAB	9/94	12/96	6/97	
Source Ranking Database - TS9409	OPPTS	OPPT	Christina Cinalli, 260-3913	9/97	SAB	9/94	9/96	3/97	Title of Work Product Revised
Lead: Renovation and Remodeling Study (Phase I & II) - TS9410	OPPTS	OPPT	Darlene Watford, 260-3989	5/96	Expert Panel	9/94	2/96	4/96	Title of Work Product Revised
Assessment of Risks from Commercial Release of Engineered Microorganisms - TS9412	OPPTS	OPPT	Mark Segal, 260-3389	7/97	Expert Panel	9/94	8/94	3/95	
Ecological Tier-Testing Schemes for Biotechnology - TS9414	OPPTS	OPPT	Gwen McClung, 260-1272	8/96	Workshop	9/94	2/94	5/96	

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**APPENDIX D - Part 1 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Estimated Date of Peer Review Initiation	Estimated Date for Receipt of Peer Review Comments	Comments
Economic Incentives Study - TS9416	OPPTS	OPPT	Nishkam Agarwal, 260- 1285	12/96	Independent Experts	9/94	8/96	10/96	
Thyroid Cancer - TS9417	OPPTS	IO	Richard Hill, 260-2894	2/97	SAB	9/94	4/96	1/97	
Proposed Test Guideline for Fibrous Particles - TS9501	OPPTS	OPPT	Vanessa Vu, 260-1245	7/98	SAB	6/95	6/97	1/98	
Concise International Assessment Document (Formaldehyde) - TS9502	OPPTS	OPPT	Oscar Hernandez, 260-1832	1/97	WHO/IPCS	5/95	1/96	12/96	OPPTS Contribution to international effort
Lead 403 Rule Technical Analysis - TS9503	OPPTS	OPPT	Dave Topping, 260-7737	11/96	SAB	5/95	9/96	10/96	Parallel Review with TS9406
Estimation Programs Interface - TS9508	OPPTS	OPPT	Gary Thom, 260-3921	12/97	Independent Experts	5/95	1/97	7/97	
Dermal Exposure Assessment Methodology - TS9509	OPPTS	OPPT	Cathy Fehrenbacher, 260-0696	8/96	Independent Experts	5/95	6/94	4/95	
12-Month Report of the Lead Paint Abatement and Repair and Maintenance Study in Baltimore - TS9601	OPPTS	OPPT	Ben Lim, 260- 1509	2/97	Expert Panel	5/96	9/96	12/96	
Lead: Renovation and Remodeling Study Phase III - TS9602	OPPTS	OPPT	Dan Reinhart, 260-1585	7/97	Expert Panel	5/96	4/97	5/97	
Concise International Assessment Document - TS9603	OPPTS	OPPT	Oscar Hernandez, 260-1832	2/98	WHO/IPCS & OECD	5/96	6/97	11/97	(Potentially Isopropanol)

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**APPENDIX D - Part 1 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

Candidate Work Product	Region/ AAship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Estimated Date of Peer Review Initiation	Estimated Date for Receipt of Peer Review Comments	Comments
Cancer Expert System - TS9604	OPPTS	OPPT	Earnest V. Falke, 260-3433	2/97	Independent Experts	5/96	9/96	12/96	
Acute Exposure Guideline Levels (AEGs) - TS9605	OPPTS	OPPT	Rodger Garrett, 260- 4302	11/98	NAS	5/96	8/97	2/98	Phase I
Comparative Risk Guidance - TS9606	OPPTS	OPPT	Rodger Garrett, 260- 4302	6/98	Independent Experts	5/96	12/97	3/98	

June 13, 1996

**APPENDIX D - Part 2 of 2  
CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**

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Candidate Work Product	Region/ Aaship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Carbofuran flowable environmental risk - PP9601	OPPTS	OPP-EFED	D. Bailiff 703-305-6108	*	SAP	6/96	5/96		* Date of closure to be estimated after peer review comments are received from the SAP
TBT Monitoring - PP9602	OPPTS	OPP-EFED	Tony Maciorowski 703-305-5988	*	SAP	6/96	5/96		* Date of closure to be estimated after peer review comments are received from the SAP
Extra 10-fold safety factor - PP9603	OPPTS	OPP-HED	Jim Rowe 703-305-5664		SAP	6/96	10/96		
Small-scale Prospective Ground-water Study Guideline and Protocol (PP9405)	OPPTS	OPP	Betsy Behl 703-305-6128		SAP	6/95	12/96		Carry over from previous year. Delay from FY96 due to competing priorities not anticipated when dates originally projected
Environmental Fate and Effects Corn Cluster Risk Assessment (PP9501)	OPPTS	OPP	Ingrid Sunzenauer 703-305-5196	*	SAP	6/95	5/96		* Date of closure to be estimated after peer review comments are received from the SAP
Report from the Aquatic Effects Dialogue Group (PP9406)	OPPTS	OPP	Tony Maciorowski 703-305-5988	7/96	SAP	6/95	7/95	7/95	Closure memo in preparation

\* Peer Review Standard Operating Procedures, Office Products for Peer Review in Upcoming Fiscal Year (Appendix D).  
Science Policy Council/Peer Review Advisory Group, March 1995.

**APPENDIX D - Part 2 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

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Candidate Work Product	Region/ Aaship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Spray Drift Task Force Laboratory and Field Data (PP9503)	OPPTS	O P P - EFED/SRRD	Arnett Jones 703-305-7416 and Jay Ellenberger 703-308-8085		Internal/external review which may include a series of workshops	6/95	6/96		Internal/external review inserted prior to SAP.
Plant pesticides - final rule (PP9504)	OPPTS	OPP-BPPD	Flora Chow 703-308-8290		SAP	6/95	9/96		Waiver from SAP review will be sought because there have been no science changes since the proposal was peer reviewed
Guideline for independent laboratory validation of environmental chemistry methods (PP9505)	OPPTS	OPP- BEAD	Don Marlow 703-308-8198		SAP	6/95	5/96		
Triazine benefits assessment (PP9506)	OPPTS	OPP-BEAD	Steve Nako 703-308-8092		SAP or other external panel	6/95	12/96		Carry over from previous year. Delays in completion of PD2/3 have meant that this peer review will occur in FY97
Pesticide usage monograph (PP9407)	OPPTS	OPP- BEAD	Arnold Aspelin 703-308-8136		SAP or other external panel	9/94	12/96		Carry over from previous year. Key staff time has not been available to complete this project, but much of the report has been developed.

\* Peer Review Standard Operating Procedures, Office Products for Peer Review in Upcoming Fiscal Year (Appendix D).  
Science Policy Council/Peer Review Advisory Group, March 1995.



**APPENDIX D - Part 2 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

Candidate Work Product	Region/ Aaship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Pesticide benefit analysis guidance document (PP9507)	OPPTS	OPP-BEAD	Arnold Aspelin 703-308-8136		SAP or other external panel	6/95			Carry over from previous year. The scope of this project has been expanded to include USDA/NPIAP and stakeholder involvement, taking more time than originally planned. The need for SAP-type involvement will be reevaluated later in the process.
Physical Chemistry test guidelines (PP9508)	OPPTS	OPP-HED,RD	F. Griffith, R. Boethling	6/96	SAP/SAB	7/95	9/95	10/95	Closure memo July '96
Residue Chemistry test guidelines (PP9509)	OPPTS	OPP-HED/ OPPT	R. Loranger 703-305-6192	6/96	SAP/SAB	6/95	9/95	10/95	Closure memo June '96
Nontarget Organism test guidelines (PP9510)	OPPTS	OPP-EFED/ OPPT	L. Touart/R. Morcock 703-305-6134/202-260-1265	12/96	SAP/SAB	6/95	5/96		
Nontarget Plant test guidelines (PP9511)	OPPTS	OPP-EFED, OPPT	R. Petrie/R. Morcock 703-305-7358/202-260-1265	12/96	SAP/SAB	6/95	5/96		

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\* Peer Review Standard Operating Procedures, Office Products for Peer Review in Upcoming Fiscal Year (Appendix D). Science Policy Council/Peer Review Advisory Group, March 1995.

**APPENDIX D - Part 2 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

Candidate Work Product	Region/ Aaship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Antimicrobial Product Performance test guidelines (PP9512)	OPPTS	OPP-RD	Z. Vaitusis 703-305-7470		SAP/SAB	6/95	9 - 12/96		Scheduling of these guidelines is being adjusted in order to allow direct harmonization with Canada through CUSTA. The goal is now to issue a single set of harmonized guidelines with Canada - an expanded scope of this project.
Toxicology test guidelines (PP9513)	OPPTS	OPP-HED/ OPPT	W. Sette/L. Keifer 703-305- 6375/202-260- 1548		SAP/SAB	6/95	10/96		
Vertebrate Control test guidelines (PP9514)	OPPTS	OPP-RD	W. Jacobs 703-305-6406		SAP/SAB	6/95	12/96		Completion of residue and product chemistry guidelines was much more resource intensive than anticipated due to extensive industry input and peer involvement. Skill mix problems led to the delay in completion of the vertebrate control guidelines.

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\* Peer Review Standard Operating Procedures, Office Products for Peer Review in Upcoming Fiscal Year (Appendix D).  
 Science Policy Council/Peer Review Advisory Group, March 1995.

**APPENDIX D - Part 2 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

Candidate Work Product	Region/ Aaship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Special Review/Draft Notice of Intent to Cancel DDVP - PP9515	OPPTS	OPP-SRRD	J. Housenger 308-8010		SAP	6/95	----		Peer review of 4 special reviews did not occur in FY96. Three of the special reviews originally planned for peer review in FY96 (PP9516,7,8) were settled by negotiation with the fourth, DDVP, delayed to allow incorporation of new information.
Risk assessment for acute and subchronic endpoints: less than lifetime risk (PP9519)	OPPTS	OPP-HED	Jess Rowland 703-308-2719		SAP	6/95	FY97		Carry over from previous year because of changes in key personnel and delays due to furlough. This will be reviewed at a later meeting.
Use of In utero cancer studies (PP9520)	OPPTS	OPP-HED	Whang Phang 703-308-2723		SAP	6/95	9/96		Carry over from previous year. Too many other tox projects going to SAP in Oct/96.
Metabolism peer review process: plants and animals (PP9521)	OPPTS	OPP-HED			SAP	6/95	FY97		Carryover from previous year. Delayed because of change in personnel.

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\* Peer Review Standard Operating Procedures, Office Products for Peer Review in Upcoming Fiscal Year (Appendix D).  
 Science Policy Council/Peer Review Advisory Group, March 1995.

**APPENDIX D - Part 2 of 2**  
**CANDIDATE PRODUCTS FOR FUTURE PEER REVIEW THROUGH FY-97**  
**(Continued)**

Candidate Work Product	Region/ Aaship	Program Office	Peer Review Leader/ Phone	Estimated Date of Peer Review Completion	Review Mechanism	Date of Initial Entry	Date Peer Review Initiated	Date Peer Review Comments Received	Comments
Subdivision K: Post-application test guidelines (PP9522)	OPPTS	OPP-HED	OREB		SAP	6/95	FY97 or 98		Loss of contract funding to complete guidelines will cause a delay
Development of a sorting scheme for endocrine disruptors (PP9604)	OPPTS (ORD involvement)	OPPTS	Denise Keehner 703-3057695		To be determined	6/96	FY97		Longterm project with format to be determined.
Alachlor and vinclozilin	OPPTS	OPP	HED		SAP	6/96	TBA		
Bladder tumors (PP9523)	OPPTS	OPP	K. Baetcke 703-305-7712		RAF	6/95	FY97		Carryover from previous year due to skill mix problems.
Ocular toxicity: visual system (PP9525)	OPPTS	OPP-HED	K. Baetcke 703-305-7712		SAP	6/95	FY97		Carry over from previous year. Too many other tox projects going to SAP in Sept/96. This will be reviewed at a later meeting.
Acute dietary data requirements and methodology of risk assessment (PP9526)	OPPTS	OPP-HED		6/96	SAP	6/95	9/95		
Guidelines for anticipated residues (PP9527)	OPPTS	OPP-HED			SAP	6/95	FY 97		Carry over from previous year because of lack of funding.
Cholinesterase as a measure of toxicity (PP9528)	OPPTS	OPP-HED	K. Baetcke 703-305-7712		RAF	6/95	FY97		Data to be summarized were far more extensive than originally anticipated.

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\* Peer Review Standard Operating Procedures, Office Products for Peer Review in Upcoming Fiscal Year (Appendix D).  
 Science Policy Council/Peer Review Advisory Group, March 1995.

## APPENDIX E

### RESOURCES FOR PEER REVIEW SERVICES

#### I. ACQUISITION OF PEER REVIEW SERVICES

A range of peer review services are available to the USEPA including internal, external (voluntary, purchase order, contractor employee), and Special Government Employee (SGE). The mechanism selected is generally based on the nature of the scientific or technical work product.

##### **A. Voluntary Services**

As a general matter, the USEPA can ask outside experts to peer review Agency products without compensation. Several environmental statutes authorize the USEPA to engage in cooperative activities with "institutions, organizations, and individuals." Accordingly, such groups may cooperate with the USEPA in research and informational activities related to the following statutes: Clean Air Act at 42 U.S.C. §7402; Clean Water Act at 33 U.S.C. §1254; Resource Conservation and Recovery Act at 42 U.S.C. §6981; and Safe Drinking Water Act at 42 U.S.C. §300j-1.

However, if a person or organization wishes to cooperate with the USEPA to perform some sort of voluntary activity, program officials should ask them to sign a "Visitor/Guest Worker" agreement, currently used at USEPA laboratories. This is because the Anti-Deficiency Act at 31 U.S.C. §1342 prohibits so-called "voluntary" services that could give rise to a claim for compensation. Moreover, accepting "volunteers" to fill USEPA employee "slots" might violate the personnel statutes and might give rise to a valid claim for compensation in violation of the Anti-Deficiency Act.

##### **B. Contracts**

The USEPA may contract for peer review services. The contract may be written solely for peer reviews or be included as part of an umbrella contract, which calls for performance of other tasks as well.

For assistance in preparing the necessary pre-award documents, program officials should consult The Cookbook: How to Get Contracts Awarded in EPA and Chapter 2 of the Contracts Management Manual (CMM). The following discussion identifies

five key elements that should be considered in contracts for peer reviews: Statements of Work (SOWs), Advisory and Assistance Services (AAS) or Sensitive Activities, Management Controls, Identification of Peer Reviewers, and Federal Advisory Committees. Special considerations for small purchases are discussed in section I.C. Small Purchases.

1. **Statement of work (SOW)**

The SOW must clearly specify that the contractor is responsible for preparing peer review evaluations and set forth guidelines for the peer review of scientific or technical documents. The contractor may perform the peer review with in-house staff, subcontractors or consultants. Any guidelines for performing peer reviews to ensure soundness and defensibility must be developed by the program office and made part of the contract. The contractor would then ensure that the peer reviews adhered to the guidelines.

The SOW cannot simply define the role of the prime contractor as arranging for the services of others to perform peer reviews and logistics for meetings. Unless the prime contractor is clearly tasked with responsibility for performing peer reviews, individual peer reviewers' fees and associated travel expenses are not payable under the contract.

The USEPA may pay for the reviewer's comments or evaluation, and also for attendance at a meeting with the Agency and other reviewers to discuss the results of the peer review. If the SOW calls for the preparation of comments or an evaluation, and specifies a meeting with the Agency and other peer reviewers to discuss the results of the peer review, payment is appropriate. The peer reviewer's attendance at the meeting would then be part of contract performance.

2. **Advisory and assistance services (AAS) or sensitive activities**

Contracts that provide services that support or improve Agency decision-making or policy development are subject to special management controls. These services include: "...those services acquired from non-Governmental sources by contract or by personnel appointment to support or improve agency development, decision-making, management, and administration, or to support or improve the operation of management systems. Such services may take the form of information, advice, opinions, alternatives, conclusions, recommendations, training, and direct assistance." For additional information on advisory and assistance services

and sensitive activities, program officials should review EPA Order 1900.2, Contracting at EPA and Chapter 2 of the CMM.

New contracts for these services require management approvals prior to issuance of the solicitation. The following thresholds have been established for approval of these justifications:

<u>Contract Amount</u>	<u>Approved</u>	<u>Concurrence By</u>
\$25,000,000 and over	Both the Program Office Assistant/Associate Administrator (AA) or equivalent and the Deputy AA for Finance and Acquisition, Office of Administration and Resources Management	Program Office Senior Resource Official (SRO)
\$5,000,000 to \$24,999,999	Both the Program Office AA and Office Director Office of Acquisition Management	Program Office SRO
Under \$5,000	Program Office AA	Program Office SRO

(See the June 30, 1993, Interim Procedures for Approval and Documentation of Procurements Involving AAS.) Note, these procedures and approval levels will be changed upon implementation of Office of Federal Procurement Policy (OFPP) Policy Letter 93-1, Management Oversight of Service Contracting in Chapter 2 of the CMM.

### 3. Management controls

Contracting for peer review services is permitted. However, because of the potential for improper use of these contracts, special management controls are required.

#### a. **Inherently governmental functions (IGFs)**

OFPP Policy Letter 92-1, dated September 23, 1992, describes (a) functions that are inherently governmental and must be performed only by Government employees and (b) functions that may be contracted, but so closely support Government employees in their performance of IGFs that the contract terms and performance require close scrutiny by Federal officials.

Peer reviews represent only a contractor's recommendations, advice or analysis of a document. Agency officials must make the official Agency decision regarding acceptability of the document. To ensure that Agency officials are not improperly influenced by recommendations in the peer review, management controls must be included in the contract. One possible control would be to require the peer reviewers to submit with their evaluations or comments a description of the procedures used to arrive at their recommendations; a summary of their findings; a list of sources relied upon; and make clear the methods and considerations upon which their recommendations are based. To the extent possible, the contract should set forth any guidelines or criteria for performance of the peer review. Agency officials should document their evaluations of the quality and validity of the peer review.

**b. Conflict of interest (COI)**

Another important factor is that the objectivity of the peer review should not be improperly influenced or undermined by the contractor performing the review. To identify and avoid or mitigate actual or potential COI, the contract should include controls. Such controls might require the contractor to report on prior and current work, and prior clients that might create COI. Other controls might include Agency review and placing limits or advance approval on future work. There should also be procedures implemented to assure that the contractor does not gain an unfair advantage in future requirements as a result of their performance of peer reviews. Program officials should consult the Contracting Officer (CO) for special contract clauses.

The EPA Acquisition Regulations (EPAAR) at 48 CFR Subpart 1509.5 generally mandates conflicts of interest solicitation provisions and contract clauses for contracts over \$25,000, but makes them optional for small purchases of \$25,000 or less.

See 48 CFR 1509.508(b) & (c)  
48 CFR 1552.209-70, -71 & -72

**Contract for peer review services:** A USEPA contracting officer will include conflicts of interest solicitation provisions and contract clauses as a matter of course without involvement by the USEPA project officer, if the peer review services are obtained pursuant to a contract



over \$25,000. If the peer review services are subcontracted pursuant to a prime contract (over \$25,000), then the prime contractor is ordinarily required to include a conflicts of interest clause substantially similar to the conflicts of interest clause in the primary contract in its subcontract to the peer reviewer.

Although the USEPA contracting officer and/or prime contractor has the primary responsibility to include the required conflicts of interest provisions/clauses, the USEPA project officer may nevertheless wish to:

1. Highlight the conflict of interest requirements in the Scope of Work for the procurement of the peer review services.
2. Develop a specific conflict of interest clause regarding the peer review at issue as a substitute to the standard conflicts of interest clause.
3. Review the solicitation/contract to make sure that the required conflicts of interest clause has been included.

**Small purchase order for peer review services:** Although conflict of interests requirements are optional for small purchases, they are nevertheless a good idea. Accordingly, an USEPA project officer obtaining peer review services with a small purchase order should request the purchasing agent/contracting officer to include a conflict of interest solicitation provision and contract clause in the purchase order.

**c. Confidential business information (CBI)/Privacy Act protected information and other sensitive information**

When peer reviewers are not employees of the United States Government, it is unlikely that the USEPA will have authority to give reviewers access to confidential business information in the absence of consent for such disclosure by the CBI submitter. Therefore, all documents provided to non-Federal reviewers must be screened for information claimed as CBI. Even where business information has not been explicitly claimed as CBI, if it is of a kind where the submitter might be expected to object to its release, prior to release the submitter must be asked whether it wishes to assert a claim, unless the submitter has previously been informed that failure to assert a CBI claim may result in

disclosure without notice. Language should be included in the contract to clearly identify any required procedures or processes prior to release of any protected information, including any requirements for confidentiality agreements, as well as limits on use and disclosure of the data by contractor personnel.

**d. Personal services**

Under contracts, the USEPA may not engage the peer reviewers in any improper personal services relationships, i.e., an arrangement under which contractor personnel are subject to relatively continuous supervision and direct control by an Agency official or employee. These relationships are characterized as one where the contractor employee interacts with the Agency in a manner similar to that of a federal employee.

To avoid these improper relationships, program officials should write well-defined SOWs. The SOWs should set forth the requirements in detail for work to be performed independently, including the manner in which it will be evaluated. The SOW must set forth what work is to be performed not how the work is to be performed. Technical direction may be used to clarify ambiguous technical requirements to ensure efficient and effective contractor performance, and is not considered supervision or assignment of tasks. For additional information, program officials should consult EPA Order 1901.1A, Use of Contractor Services to Avoid Improper Contracting Relationships.

**4. Identification of peer reviewers**

Program officials cannot interfere in a contractor's ability to perform work by "selecting" who will perform the peer review. The Federal Acquisition Regulation (FAR) governs the CO's and program officials' relationship with the contractor.

However, the CO does have the ability to review and consent to subcontractors and consultants. The contract can also specify which individuals are key personnel and include peer reviewers. The FAR and Agency implementing regulations set forth rules governing the use and replacement of key personnel. Further, the contract can require workplans for approval by the Agency, wherein the contractor will propose the peer reviewers it is considering for selection.

Program officials should identify the qualifications required to perform the review work and the criteria for technical acceptability. The USEPA may identify a pool of qualified subcontractors and consultants to the prime contractor, but cannot direct the use of any particular subcontractor or consultant.

## **5. Federal Advisory Committees**

The Federal Advisory Committee Act (FACA) requires that the Agency develop a charter, maintain balanced membership, and hold open meetings when it establishes an "advisory committee." An advisory committee is any group established by the USEPA for the purpose of providing advice as a group to the Agency. It does not include advice coming from individual attendees at a meeting or groups established by a non-federal entity such as an EPA contractor. See, 41 C.F.R. §101-6.1004(i). If a contractor convened peer review panel will provide advice and recommendations to the USEPA as a group, then the group is subject to FACA chartering requirements.

## **C. Small Purchases**

The acquisition of supplies or nonpersonal services from the open market and on a sole source basis when the aggregate amount involved in any one transaction does not exceed \$25,000 constitutes a "small purchase". The USEPA has developed a guide entitled Small Purchases, A Guide for Program Offices, which provides basic information about small purchases and purchase orders. The guide should be used in preparing a procurement request (PR) for the purchase of peer review services under the small purchase limitation.

The same considerations in the preceding discussion on IGFs, COI, access to CBI, and personal services apply to small purchases. Normally, the Government issues a small purchase order directly to the individual peer reviewer, instead of to a prime contractor who may subcontract for performance of the peer review.

## **Approvals**

All small purchases for peer reviews are considered AAS. The approval level for small purchase AAS is at least one organizational level above the initiating office. When award is made during the fourth quarter of the fiscal year, approval must be received from a program official at least two organizational levels above the initiating office.

## **Competition**

The FAR requires competition for purchases in excess of \$2,500. To accomplish competition, Purchasing Agents will solicit quotes from three vendors unless a requirement is justified on a sole source basis. A sole source justification must be detailed and fully describe the circumstances supporting the justification. Program officials should refer to EPAAR Subpart 1513.170-1 for more information on preparing justifications. Poor planning does not constitute a valid basis for a sole source justification. COs will make a small purchase award to the vendor with the lowest offered price.

## **Procurement Requests**

Program Officers should include the following in all PRs for the purchase of peer reviews:

1. A fixed-price amount at or below the small purchase limitation.
2. A detailed description of the requested services, inclusive of:
  - a. Total quantity per line item;
  - b. Estimated unit price per line item;
  - c. Total cost per line item;
  - d. Specific deliverables for each line item; and
  - e. Total cost of the purchase request.
3. The name, address, and phone number of three competitive sources if the value of the request is \$2,500 or more.
  - a. Reference FAR Subpart 3.6 and Environmental Protection Agency Acquisition Regulation (EPAAR) Subpart 1503.601 regarding sources from Government employees or organizations owned and controlled by them.
  - b. Provide sources from small businesses if available.
4. If the request is a sole source purchase, justification must be provided in accordance with the EPAAR Subpart 1513.170-1.

## II. TRAVEL

### **A. Contracts and Purchase Orders**

Funds obligated on a contract or purchase order are available to pay for the costs of producing the peer review including the travel costs and fee of the peer reviewer.

The USEPA acquires peer reviews through small purchases issued directly to peer reviewers or through contracts with companies, which then acquire the services of peer reviewers. By issuing a purchase order or awarding a contract for a peer review, the USEPA may pay not only for the peer reviewer's comments, but also for his or her attendance at a meeting with the Agency and other reviewers to discuss his or her comments. The scope of work of the contract must include the organization of peer reviews and indicate whether the contractor will be required to discuss a specific peer review work product with the Agency and/or with other peer reviewers. Attendance at a meeting to discuss a peer review work product would then be part of the contract's performance. Thus, the contract may serve as the mechanism to pay for a peer reviewer's fee and associated travel expenses to provide comments to the USEPA.

### **B. Special Government Employees**

Travel and per diem expenses of experts hired as SGEs for peer review may only be paid through the issuance of invitational travel orders (5 U.S.C. §5703). These invitational travel and per diem expenses should be charged to an appropriate USEPA travel account.

Members of the SAB, SAP, and other FACA advisory committees are hired as SGEs. It is not appropriate to reimburse travel or per diem expenses of advisory committee members or other SGEs through a contract.

## **APPENDIX B**

### **Correspondence with Peer Reviewers**

**PACKET B-1**

July 21, 1997

Dear \_\_\_\_\_ :

Thank you for your interest in participating in the formal technical peer review of EPA's *Cleaner Technologies Substitutes Assessment (CTSA) for Fabricare: Including Dry and Wet Cleaning Technologies*.

Prior to receiving the CTSA review package we request that you submit a brief letter proposal with the labor rate you will charge to conduct this peer review. We are asking you to focus your review on the area(s) in which you have particular expertise (i.e., economics and technology, hazard assessment, exposure assessment, or risk assessment). Accordingly, we anticipate your review and written comment preparation will require no more than 24 labor hours. In this proposal, please include the following:

1. Your proposed labor rate, along with a statement that this is the lowest rate you currently charge any client (required by Federal government contracting regulations);
2. A signed and dated copy of the enclosed Peer Reviewer Non-Disclosure Agreement (required); and
3. A brief (one or two page) biographical sketch showing your educational training and recent professional experience (unless already sent to Melinda Armbruster of Battelle).

Please submit your proposal (Items 1, 2, 3) to me by fax (614-424-4250) by Thursday, July 24, 1997, as well as the original of all of the above documents by regular mail (use enclosed pre-addressed envelope). Please note that we cannot send you a copy of the CTSA review package until we receive all three of the above requested documents. Upon acceptance of your proposal, Battelle will issue a formal purchase order agreement; this agreement will also include the attached Terms and Conditions.

Under separate cover on July 28<sup>th</sup> or 29<sup>th</sup>, you will receive, via Federal Express, a CTSA review package including the CTSA, Charge to Peer Reviewers, and a list of available references, if needed, to assist with your review. If you are not going to be at your office address on July 28<sup>th</sup> or 29<sup>th</sup>, please inform us of the address to send the package to. Someone must be present to sign for the package or Federal Express will not deliver it. In addition to your written comments concerning the CTSA itself, we are also asking for your comments on the adequacy of the supporting documents and key studies used in the development of the CTSA associated with your area(s) of expertise. Further, if you are aware of any references or data sets that EPA has not used, please indicate so in your submitted comments; copies of any such studies would be appreciated. EPA is committed to getting this document out by September 1997 and in order to



do that we need to receive your written comments by Monday August 25<sup>th</sup>. Please plan accordingly.

Thank you again for your participation. We appreciate your interest and willingness to assist EPA with this important document. If you have any questions, please feel free to contact me at (614) 424-4547.

Sincerely,

Bruce E. Buxton, Ph.D.  
Program Manager

BEB:lnl  
Enclosures

**Cleaner Technologies Substitutes Assessment (CTSA)  
for Fabricare: Including Dry and Wet Cleaning Technologies**

**Peer Reviewer  
Non-Disclosure Agreement**

The CTSA document is an internal, preliminary work product developed by EPA. Neither Battelle nor the peer reviewers are authorized to distribute, cite, quote or in any manner release any portion of the CTSA or selected supporting material. All copies of the CTSA and supporting materials will be returned to Battelle with the written review comments.

I have read this non-disclosure statement and agree to its conditions.

---

Signature of Peer Reviewer

---

Date

**TERMS AND CONDITIONS- CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT  
(CTSA), PEER REVIEW**

Control Revision: 246226

**1. FORMATION OF THE CONTRACT**

- A) This Contract *Purchase Order Number*, dated **21 July, 1997** is Battelle Columbus Operations' (BCO) offer to Seller, and acceptance by Seller is expressly limited to the terms of this offer. BCO objects to any additional or modified terms stated in Seller's acceptance. Acceptance may be by prompt written acknowledgment or by beginning performance.
- B) **Modifications.** None of the terms and conditions of this Contract may be contradicted, modified, supplemented, explained, waived or rescinded except as provided in the Contract or in written agreement signed by both parties. Only a BCO Procurement Representative may sign on behalf of BCO.
- C) **Delegation and Subcontracting.** Without BCO's written consent, Seller will not delegate any duty of performance, or subcontract for the design, development or procurement of any substantial portion of goods or services under this Contract. This clause does not limit Seller's purchases of standard commercial supplies, services or raw materials.
- D) **Waiver and Severability.** Any action or inaction by BCO or the failure of BCO, on any occasion, to enforce any right or provision of this Contract shall not be construed to be a waiver by BCO of its rights hereunder, and shall not prevent BCO from enforcing such provision or right on any future occasion. A determination that any portion of this Contract is unenforceable or invalid shall not affect the enforceability or validity of any of the remaining portions of this Contract.
- E) **Notice of Delay.** Whenever Seller has knowledge of any delay or potential delay in the performance of work under this Contract, Seller shall immediately give notice thereof, and all relevant information with respect thereto, to the cognizant BCO Procurement Representative and shall notify the BCO representative of any material changes in the information required hereunder. Seller's notification shall include the cause or causes of such delay and Seller's plan to correct such cause(s) to recover such delay or potential delay.
- F) **Order of Precedence.** If the various parts of this Contract are inconsistent, the following order of precedence will apply: (1) special terms and conditions; (2) the terms and conditions in these General Provisions; (3) specifications; (4) all other attachments incorporated in this Contract by reference.
- G) **Applicable Law.** This Contract will be governed by and construed in accordance with the laws of the State of Ohio with no consideration given to the state's conflict of laws rules, regardless of the places of execution or performance of this Contract.
- H) **Rights and Remedies.** The rights and remedies of the parties set forth in this Contract are cumulative and in addition to any other rights or remedies that they may have at law or in equity.
- I) **Independent Contractor.** Seller is an independent contractor for all purposes. In no event shall Seller, its agents, representatives, or personnel that it supplies to BCO under this Contract be deemed to be employees of BCO. Seller's employees shall be paid exclusively by Seller for all services performed and Seller shall be responsible for and shall actually comply with all requirements and obligations relating to such employees under local, state or federal law, (or foreign law as applicable) including but not limited to minimum wage, social security, unemployment insurance, state and federal income tax, and worker's compensation. BCO has no responsibility for withholding any portion of salary or wages due employees of Seller to comply with any of the aforementioned taxes or obligations.
- J) **Notice.** Any notice or payment required to be given or made hereunder by either party to the other may be given or made by depositing the same in the U.S. Mail, postage prepaid, addressed to BCO or Seller at the addresses indicated on the face of the Purchase Order. Except where a specific notice period is provided herein, any notice shall be deemed to have been given and any payment to have been made on the date of the mailing thereof.
- K) **Successors in Interest.** This Contract shall be binding upon, inure to the benefit of, and be enforceable by and against the successors, assignees, and transferees of the parties hereto.

**2. DEVOTION OF REASONABLE TIME AND SKILL**



**TERMS AND CONDITIONS- CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT  
(CTSA), PEER REVIEW**

Control Revision 346294

- A) Seller shall provide the highest professional standard of services and devote Seller's full attention and efforts the interests of BCO during all hours charged to BCO. Seller shall comply with appropriate legal, ethical and professional standards of behavior and conduct.

**3. CONFLICT OF INTEREST**

- A) Seller will avoid and immediately notify BCO of any activities, interests or relationships (past, present or planned) which place Seller in an actual or apparent conflict of interest with the objectives of BCO or its Client under this Contract. Seller must obtain BCO's prior written consent before engaging in any such activities.

**4. INVOICE AND PAYMENT**

- A) Seller will submit invoices to the cognizant BCO Representative shown the face of this order on a monthly basis. Invoices will include the following information:
  - i) A description of the services provided during the invoice period, including: the name of the individual providing the service; dates of service; number of hours expended on that date; and the total amount being billed for that service.
- B) Reimbursable Expense. Invoices shall include only those expenses specified on the accompanying Purchase Order as reimbursable.

**5. DAMAGES**

- A) Indemnity. Seller agrees to indemnify, defend, and hold harmless BCO, its divisions, subsidiaries and affiliates, officers, trustees, agents and employees from any and all liabilities, claims, suits, demands, and all expenses and costs including reasonable attorney's fees and costs, arising out of the performance of Seller's work hereunder that are caused, in whole or in part, by Seller's negligent or wrongful act or omission or that of anyone employed by Seller for whose act Seller may be liable.
- B) Consequential Damages. In no event shall either party to this Contract be liable for any special, incidental or consequential damages of any type or nature whatsoever.

**6. DELIVERY**

- A) Delivery of all items, reports or other deliverables required under this Contract will be made FOB Destination: *Battelle Memorial Institute, Columbus Operations, 505 King Avenue, Columbus OH 43201-2693*.

**7. AUDIT**

- A) Until three years after final payment, Seller will maintain, and BCO will have the right to examine and audit, books, records, document, and accounting procedures and practices sufficient to reflect properly all direct and indirect costs of whatever nature claimed to have been incurred and anticipated to be incurred for the performance of this Contract.

**8. SELLER'S NONDISCLOSURE**

- A) Seller shall not, without the written consent of BCO, either during or after the performance of the work required hereunder, use, other than for such performance, or disclose to any person other than a duly authorized representative of BCO any information, data, material or exhibit created, developed, produced or otherwise obtained in the course of the work required hereunder, or any information contained in reports, drawings, documents, business plans or other records furnished to Seller by BCO. Seller further agrees that it will not divulge any matter, the disclosure of which would be detrimental to the interests of BCO as determined by BCO. Nothing contained herein shall prevent Seller from making proper use of its experience gained in the performance of the work required hereunder. The restrictions of this provision shall not apply to information in the prior possession of Seller or to information acquired by Seller from a source other than BCO that has the right to disclose such information to Seller, and which Seller, in turn, has the right to disclose, nor shall it limit any rights the Government may have in such information. *Seller further agrees to return to BCO all copies of any material provided to Seller.*



**TERMS AND CONDITIONS- CLEANER TECHNOLOGIES SUBSTITUTES ASSESSMENT  
(CTSA), PEER REVIEW**

Contract Revision 246226

- B) Seller further agrees to enter into a separate Peer Reviewer Non-Disclosure Agreement for the protection of such information upon request by BCO.

**9. CHANGES**

- A) BCO may, at any time, exclusively by written order signed by its authorized Procurement Representative, and without notices to sureties, make changes within the general scope of this Contract which affect, among other things, the services to be performed, and the time and place of performances thereof. If any such change causes an increase or decrease in the cost of this Contract, and equitable adjustment shall be made and the Contract shall be modified in writing accordingly. Any claim by Seller for adjustment under this Article must be asserted in writing to BCO within 30 calendar days after the date of receipt by Seller of the written change authorization, or within such extension as BCO may grant in writing. BCO may, in its sole discretion, consider any such claim regardless of when asserted. Such claim shall be in the form of a complete change proposal fully supported by factual information. Pending any such adjustment, Seller will diligently proceed with the Contract as modified. BCO shall have the right to examine any of Seller's pertinent books and records for the purpose of verifying Seller's claim.

**10. TERMINATION**

- A) Upon 30 days written notification non-terminating party, either party to this Contract may terminate this Contract in whole or in part any time and for any reason. In the event of termination, BCO shall be liable for payments to Seller only for services performed by Seller to the effective date of the termination, and then only in accordance with the payment provisions of this Contract.
- B) **Force Majeure.** Neither party is responsible to the other for nonperformance or delay in performance of the terms and conditions herein due to Acts of God, acts of Government, wars, riots, and other causes beyond the control or the performing party.

**11. EXPORT OF DATA**

- A) Without the prior written consent of BCO and the U.S. Government (Department of Commerce), Seller will not transmit directly or indirectly any technical data (as defined by Export Administration Regulations) received from BCO or developed under this Contract, any immediate product of such technical data, or any commodity produced by an immediate product of the technical data or any portion thereof to any country outside of the United States.

**12. RIGHTS AND REMEDIES**

- A) The right and remedies of the parties set forth in this Contract are cumulative and in addition to any other rights or remedies that they may have at law or in equity.

**13. COMPLIANCE WITH STATUTES AND REGULATIONS**

- A) Seller shall comply with all applicable statutes and governmental rules, regulations and orders.

**14. APPLICABLE LAW**

- A) This Contract shall be governed by and construed in accordance with the laws of the State of Ohio regardless of the place(s) of execution or performance of this Contract.

**PACKET B-2**

July 21, 1997

Dear \_\_\_\_\_ :

Thank you for your interest in participating in the formal technical peer review of EPA's *Cleaner Technologies Substitutes Assessment (CTSA) for Fabricare: Including Dry and Wetcleaning Technologies*. Under separate cover on July 28<sup>th</sup> or 29<sup>th</sup>, you will receive, via Federal Express, a CTSA review package including the CTSA, Charge to Peer Reviewers, and a list of available references, if needed, to assist with your review. If you are not going to be at your office address on July 28<sup>th</sup> or 29<sup>th</sup>, please inform us of the address to send the package to. Someone must be present to sign for the package or Federal Express will not deliver it. In addition to your written comments concerning the CTSA itself, we are also asking for your comments on the adequacy of the supporting documents and key studies used in the development of the CTSA associated with your area(s) of expertise. Further, if you are aware of any references or data sets that EPA has not used, please indicate so in your submitted comments; copies of any such studies would be appreciated. EPA is committed to getting this document out by September 1997 and in order to do that we need to receive your written comments by Monday August 25<sup>th</sup>. Please plan accordingly.

Please submit a signed and dated copy of the enclosed Peer Reviewer Non-disclosure Agreement to me by fax (614-424-4250) by Thursday, July 24, 1997, as well as the original of all the above documents by regular mail (use enclosed pre-addressed envelope). We can not send to you a copy of the CTSA until we receive your signed agreement.

Thank you again for your participation. We appreciate your interest and willingness to assist EPA with this important document. If you have any questions, please feel free to contact me at (614) 424-4547.

Sincerely,

Bruce E. Buxton, Ph.D.  
Program Manager

BEB:lnl  
Enclosure

# **Cleaner Technologies Substitutes Assessment (CTSA) for Fabricare: Including Dry and Wetcleaning Technologies**

## **Peer Reviewer Non-Disclosure Agreement**

The CTSA document is an internal, preliminary work product developed by EPA. Neither Battelle nor the peer reviewers are authorized to distribute, cite, quote or in any manner release any portion of the CTSA or selected supporting material. All copies of the CTSA and supporting materials will be returned to Battelle with the written review comments.

I have read this non-disclosure statement and agree to its conditions.

---

Signature of Peer Reviewer

---

Date



**PACKET B-3**

July 25, 1997

Dear \_\_\_\_\_ :

Thank you for agreeing to participate in the formal technical peer review of EPA's ***Cleaner Technologies Substitutes Assessment (CTSA) for Fabricare: Including Dry and Wetcleaning Technologies***. As you know, EPA has been working with the dry cleaning industry and other interested parties to evaluate current and alternative clothes cleaning technologies and controls to reduce exposures to perchloroethylene and other solvents used in dry cleaning. As part of this program, EPA has developed the CTSA. This CTSA is intended to be an analytical tool that methodically assesses the comparative performance, costs, and human and environmental risks associated with traditional and alternative chemicals, processes, and technologies in the clothes cleaning industry. The goal of the CTSA is to develop accurate information for dry cleaners that will enable the cleaning industry to make informed judgements on the products and technologies used in their facilities.

We believe we have identified a peer review panel whose excellent and unbiased technical reviews of the document will result in a high-quality final product. Every effort was made to identify technical peer reviewers who are considered experts within their respective fields of study and have specific knowledge gained through training or experience in one or more of the following areas relevant to the CTSA:

- economics and technology,
- hazard assessment,
- exposure assessment, and
- risk assessment.

Please find enclosed a copy of the CTSA along with a guidance document and a list of available references, if needed, to assist with your review. In addition to your comments on the CTSA itself, we are also asking for your comments on the adequacy of the supporting documents and key studies used in the development of the CTSA associated with your area(s) of expertise. Further, if you are aware of any references or data sets that EPA has not used, please indicate so in your submitted comments; copies of any studies would be appreciated.

We request that all your comments be summarized in a separate listing, with each comment identified by the page number, and paragraph number to which it pertains. Please do not mark up the CTSA itself with comments for EPA to consider. Due to the length of the CTSA, and the number of reviewers, we cannot go through each copy of the CTSA and pick up marginal notations. We have enclosed a detailed charge for your review and an alphabetized list of all CTSA references. If you feel you need to see a particular reference as part of your review, and you do not have access to it, please call me and we will send you a copy as soon as possible.

EPA is committed to getting this document out by September 1997 and in order to do that we need to receive your written comments no later than Monday August 25th. If you anticipate any problem with this deadline, please let us know immediately.

Thank you once again for your participation. Please return to Battelle the entire CTSA review package, including the CTSA, along with your comments. For your convenience, we have enclosed a pre-paid pre-addressed Federal Express return package. You only need to enclose all the materials and drop the package at any Federal Express drop box no later than Friday August 22nd. If you have any questions, please feel free to contact me at (614) 424-4547, or Brandon Wood at (614) 424-7285.

Sincerely,

Bruce Buxton, Ph.D.  
Program Manager

BEB:lnl  
Enclosure

# **REMINDER**

**Before beginning your review of the CTSA, fax a signed and dated copy of the Non-disclosure Agreement to Dr. Bruce Buxton of Battelle at fax (614)424-4250.**

**If you cannot locate your copy of the Non-Disclosure Agreement, please call Dr. Buxton immediately at (614)424-4547.**

**PACKET B-4**

August 6, 1997

CTSA Peer Reviewer  
Sent via fax

Dear Peer Reviewer:

**Clarification of Language on Carcinogenic Potential**

EPA has asked us to provide you with the attached clarification of EPA's evaluation of the carcinogenic potential of Perchloroethylene. The language currently in the CTSA will be revised, as per the attached, as part of the peer review comment integration process. This applies to statements on page 3 of the Executive Summary, on page 7 of Chapter 4, and on pages A-1 and A-13 in Appendix A.

If you have any questions on this, please call me on 614-424-4547.

Sincerely,

Bruce E. Buxton, Ph.D.  
Program Manager  
Statistics and Data  
Analysis Systems

BEB:lnl  
Enclosures

### **Clarification for CTSA Peer Reviewers of EPA's Position on the Carcinogenic Potential of Perchloroethylene (Perc)**

The carcinogenic potential of Perc has been extensively investigated. Perc has been shown to cause cancer in laboratory studies in rats and mice when given by ingestion or inhalation. There is also evidence from several studies of workers in the laundry and dry cleaning industry suggesting a possible causal association between exposure to Perc and elevated risk of cancer. The potential for an increased risk of cancer depends on several factors, including the dose (how much), the frequency (how often), the duration (how long), and how one comes in contact with it, as well as the state of health, age, lifestyle, family traits etc. of the exposed individuals. Most people are likely to have a very low risk of getting cancer from breathing air, drinking water, or eating food containing Perc. Workers and residents working and living near dry cleaning establishments that send clothes to another location for cleaning are likely to be at low risk. There is concern, however, for people working and living near dry cleaners that do use Perc on premises located in an apartment building. Any potential increased health risk depends on the type of machine used, what precautions are being properly employed, and conditions inside the facility.

The CTSA reflects scientific evaluations by the International Agency for Research on Cancer (IARC) and the EPA regarding the human carcinogenic potential of Perc. In 1987, IARC reviewed the available studies and concluded that Perc is "possibly carcinogenic to humans". Using the same body of data and its own classification scheme, EPA's Office of Research and Development (ORD) concluded that Perc is "a probable human carcinogen" primarily on the basis of sufficient evidence of carcinogenicity in laboratory animals. This position was also taken by the EPA's Carcinogen Risk Assessment Verification Enterprise (CRAVE) in December 1990. The EPA's Science Advisory Board (SAB), on the other hand, recommended in 1991, that the human carcinogenicity of Perc lies between probable and possible. Subsequently, EPA-ORD published its 1991 review on Perc and maintained its conclusion that Perc is a probable human carcinogen (published in March 1995). Since then, new health effects information has become available. IARC, in mid 1995, reevaluated the carcinogenicity of Perc and concluded that Perc is "probably carcinogenic to humans", based on limited evidence of carcinogenicity in humans and sufficient evidence in animals. At this time, the Agency plans to incorporate new information, finalize its evaluation, and formally include the health effects assessment of Perc on its consensus database known as the Integrated Risk Information System (IRIS).

The CTSA document itself is not intended to resolve all uncertainties in data cited nor in methodology employed. These issues have been extensively debated by the scientific community. The document is intended to demonstrate a sufficient basis for concern, to compare alternative exposure scenarios and to provide alternative approaches in communicating risks. It uses readily available information, simplifying assumptions, and conventional models to provide general conclusions about various cleaning technologies. It cannot be used to describe the absolute risk associated with specific clothes cleaning operations, only to permit evaluations, and judgments for each setting need to be made individually.

## **APPENDIX C**

### **Charge to Peer Reviewers**



**Cleaner Technologies  
Substitutes Assessment for Fabricare:  
Including Wet and Dry Cleaning Technologies**

**CHARGE TO PEER REVIEWERS**

July 1997

***TECHNICAL PEER REVIEW: Cleaner Technologies Substitutes Assessment (CTSA) for Fabricare: Including Dry and Wetcleaning Technologies***

**Charge to CTSA Peer Reviewers**

The following is intended to provide structure for your review and to enable the EPA to address your comments directly in the final revision of the CTSA.

The CTSA document is intended to provide a flexible format for systematically comparing the technical and economic tradeoff issues associated with traditional and alternate products, processes, and technologies. The goal of the CTSA is to offer a detailed picture of the environmental impacts, cost and performance issues associated with each option to assist users to make informed decisions about which alternatives are best for a particular situation. The CTSA document is not intended to resolve all uncertainties in data cited nor in methodology employed. For example, this document is not intended to resolve the controversy on the carcinogenic potential of perchloroethylene, nor on the appropriate slope factor. These issues have been extensively debated by the scientific community. Rather, the document is intended to demonstrate a sufficient basis for concern, to compare alternative exposure scenarios and to provide alternative approaches in communicating risks. The EPA is seeking comment on the presentations of science, technology and economic considerations in the document. Issues related to policy considerations are beyond the scope of this peer review.

The information contained in the human health hazard sections was gleaned from existing summaries, by the agency, its sister agencies or from professional groups taking positions in accepted published sources, as well as supplemented by primary sources. They do not represent primary research or a position based solely on primary sources. A summary appears in Chapter 2, with more technical presentation in Appendix B.

As you review the document, if you wish to comment or suggest specific changes, please annotate directly in the text where the change or additional work is needed. If the provided space is insufficient, please continue on a separate sheet of paper. After reviewing the document, prepare a summary report that addresses your major issues. Please present your comments constructively, be specific about the issues/changes suggested, and cite the page number where the change should occur. If an issue has been omitted or addressed improperly, please give specific information on how it should be addressed. **If you are citing a new reference (that has not been previously provided by the EPA), please provide a copy and indicate where in the text it should be included.**

The Office of Pollution, Prevention and Toxics of the EPA has prepared a series of issues and questions relevant to each section and topic area. These items are deemed by EPA as areas of concern to be considered and will aid in guiding your peer review. You may address these issues along with any other concerns in your report. After you have completed your review,

***DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE***

please return both the document and your comments, along with a copy of any new reference(s) to the contractor (Battelle).

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**I. GENERAL CTSA DOCUMENT CONCERNS**

The following are several areas of concern that are applicable to the entire CTSA document. These issues pertain to content, format, and presentation. Are you aware of any enhancements which would improve the general presentation of information pertaining to the following issues.

**Chapters 1 through 8**

1. Does each of these chapters clearly explain its purpose? If the chapter purpose is not clearly articulated, indicate what you believe the purpose of the chapter was.
2. Is the text clear and well presented? Can you suggest other ways to present the information to enhance its clarity?
3. Do tables/figures enhance understanding of the information presented in these chapters? If not, how should the information be presented? Please provide an example.
4. Are there any inconsistencies between the data presented in the tables and text? Can you suggest other ways to present the information? Please provide an example.
5. Are relevant references provided for the information contained in each of these chapters?

**II. ECONOMIC ASSESSMENT**

The Economic elements of the CTSA are found in Chapters 1, 6, 7, and 8.

**A. Chapter 1, Overview of Drycleaning**

1. Does this chapter help set the stage for the comparative evaluation you understand will follow?

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2. Are you aware of any specific sources where information is more current or different from that quoted in this chapter?

**B. Quantities where we would particularly appreciate your knowledge of newer or higher quality data include:**

1. Solvent mileage (solvent use per unit of clothes cleaned), by technology.
2. Maintenance costs for machines in use.
3. Volume of clothes cleaned, by technology.
4. Permitting costs, are these factored in to the trade off issues correctly?
5. Projected demand, by technology.
- 6a. Average site releases to H<sub>2</sub>O, each technology, total U.S. releases.
- 6b. Average site releases to air, each technology, total U.S. releases.

**III. ENGINEERING ASSESSMENT**

**A. Process Descriptions**

1. Are the proper primary equipment and operations included? If not, what has been omitted?
2. Do the technologies appear to have been properly categorized? If not, what categorization would be more appropriate?
3. Are the descriptions accurate and adequate?

**B. Environmental Release Estimates**

1. Are release estimates reasonably accurate, keeping in mind that the relative differences between technologies for a given solvent are the primary purpose for the estimates? If not, please provide enough information, including bases, to calculate new estimates.
2. Are these release estimates adequate to properly distinguish the important differences between the various technologies for each solvent?

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3. Have any important equipment or operational factors been omitted? If so, please provide a basis for each new factor, if available, for quantification.
4. Are the assumptions reasonable? If not, please provide a basis for any new assumption.
5. Are the exposure characterizations in Chapters 3 and 4 consistent with one another? Do they help the reader understand the context for evaluating risk?
6. Perc occupational and residential exposures have been measured in a number of disparate settings by various protocols. Do the summarization measures and descriptions adequately convey the variety and the contribution it has to the estimates of exposure and risk in different scenarios? Should anything specifically be added to the text in Chapters 3, 4, and 8?

**C. Environmental Release Assessments**

1. Are the estimates reasonable? If not, what other estimates could be used? In providing other estimates, please include the basis for each estimate and an example.
2. Are the data sets used for estimations reasonably representative of the industry as a whole? If not, what data would be?

**D. Exposure Estimates**

1. Are the data sets used for inhalation exposure concentrations or potential dose rates reasonably representative of the industry as a whole? If not, what data would be? Are the data appropriate for the type and magnitude of exposure the EPA is trying to estimate?
2. Is the number of samples taken, in the case of the monitoring studies used in the assessment, statistically significant [although a rigorous statistical analysis was not performed]? If not, how should this be characterized in the text?
3. Are the assumptions reasonable? If not, what assumptions should replace them? Please include a basis to support assumptions.

**E. Pollution Prevention, Best Management Practices, and Control Options**

1. Are there any other options for operational improvements? If so, what options are omitted? Please provide relevant details.
2. Are there any errors/omissions in process substitutes provided?
3. Are the improvements presented clearly?

#### **IV. GENERAL POPULATION EXPOSURE ASSESSMENT**

1. Is the information presented clearly?
2. Are the exposure scenarios realistic?
3. Have the exposed populations been adequately characterized?

#### **V. HUMAN HEALTH HAZARD ASSESSMENT**

The hazard information for the CTSA is found in Chapters 3 and 4. The health and environmental hazards of Perc, one of the chemicals covered in the CTSA, have been studied extensively. EPA's assessment of the hazards of Perc has been the subject of rigorous peer review, including a review by EPA's Science Advisory Board. The hazards of Perc shall not be a principle focus of this peer review.

##### **A. Chapters 3 and 4, Perchloroethylene and Petroleum Processes, respectively**

1. Is the discussion of perchloroethylene dose-response modeling straightforward? Are its sources clear (for readers who want more detail)?
2. Are you aware of human health effects information pertaining to relevant exposures reported on any substance in one of the described technologies that should have been included in the summaries.

#### **VI. RISK ASSESSMENTS**

The Risk Assessments for the CTSA are found in Chapters 3 and 4 and Appendix G.

##### **A. Chapters 3 and 4, Perchloroethylene and Petroleum Processes, respectively**

The Agency is aware that other quantified assessments of perchloroethylene exist, and that there is debate within the scientific community on the interpretation of several metabolic and animal/human extrapolation issues, and these are pointed out in the text. However, the EPA has not updated its earlier dose/response assessment of perchloroethylene, and such a revision is beyond the scope of the CTSA. Also, an updated risk assessment is not considered essential for the purpose of this document, which is to indicate ways users can make decisions about relative risk, and alternative exposure reduction technologies.

1. Does the risk assessment accomplish the objective of highlighting which sorts of situations pose greatest risk of experiencing adverse effects from exposure to each cleaning process? If not, please suggest ways that this objective could be accomplished.
2. Are the effects characterizations in chapter 2 and chapter 4 consistent with one another? Do they help the reader understand the circumstances under which there may be risk?
3. Are the risk tables clear? If not, how might they be improved?
4. Are sources of uncertainty sufficiently covered in the Risk Assessment sections? If not, what other uncertainties should be included?
5. Does the risk assessment for the petroleum solvents clearly convey the fact that there was a disproportionate amount of information, specifically, toxicity information, that was available for most of the cleaning processes in comparison to that available for perchloroethylene? Is there a hidden bias in the assessment that could be corrected with clearer language as to the respective amounts of information we were dealing with?
6. Recently the EPA's Science Policy Council released a final draft (1/6/95) of "Guidance for Risk Characterization." All Agency risk assessments are supposed to adhere to the principles detailed in this guidance document. Do the risk-related sections of the CTSA adhere to the principles discussed in the guidance document? If not, what should be done to improve the CTSA in this regard?

## **APPENDIX D**

### **Peer Review Reference List**



**Cleaner Technologies  
Substitutes Assessment for Fabricare:  
Including Wet and Drycleaning Technologies**

**PEER REVIEW REFERENCE LIST**

July 1997

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***TECHNICAL PEER REVIEW: Cleaner Technologies Substitutes Assessment (CTSA) for Fabricare: Including Dry and Wet Cleaning Technologies***

**CTSA REFERENCES**

1. Abt. 1994. Dry cleaning industry. Use cluster analysis. Final report. Prepared for the U.S. EPA Office of Pollution Prevention and Toxics under Contract No. 68-D2-0175. Abt Associates. April 5.
2. ACGIH. 1986. American Conference of Governmental Industrial Hygienists. Documentation of threshold limit values. ACGIH, Committee on Threshold Limit Values. Cincinnati, OH.
3. ACGIH. 1994. American Conference of Government Industrial Hygienists. 1994-1995 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, ACGIH.
4. Adamson, K. 1996a. Personal communication between Ken Adamson, Langley-Parisan Cleaners, and Jonathan Greene, Abt Associates Inc. November 25.
5. Adamson, K. 1996b. The status of wet cleaning in Canada: Exploring the boundaries of wet cleaning. Presented at Conf. on Global Experience and New Developments in Wet Cleaning Technology. Schloss Hohenstein, Boennigheim, June. p. 15-20.
6. Adamson, K. 1997. Personal communication between Ken Adamson and Alice Tome, Abt Associates Inc. January.
7. Ahlborg Jr., G. 1990. Pregnancy outcome among women working in laundries and dry-cleaning shops using tetrachloroethylene. *Am J Ind Med* 17:567-575. [As cited in ATSDR (1993).]
8. AIHA. 1990. Perchloroethylene exposure assessment among dry cleaning workers. *Am Ind Hyg Assoc J* 51. October.
9. Alden, C.L. 1986. A review of unique male rat hydrocarbon nephropathy. *Toxicol Pathol* 14:109-111. [As cited in ATSDR (1995).]
10. Amato. 1994. Personal communication between sales representative of Amato Industries and Michael Müller of Abt Associates Inc.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

11. Amoore, J.E., and E. Hautala. 1983. Odor as an aid to chemical safety: odor thresholds compared with threshold limit values and volatilities for 214 industrial chemicals in air and water dilution. *J of Appld Toxicol* 3:272-90.
12. Anderson, C., K. Sundberg, and O. Groth. 1986. Animal model for assessment of skin irritancy. *Contact Dermatitis* 15:143-151. [As cited in ATSDR (1995).]
13. Andersson, H.F., J.A. Dahlberg, and R. Wettstrom. 1975. On the formation of phosgene and trichloroacetyl chloride in the nonsensitized photooxidation of perchloroethylene in air. *Acta Chem. Scand. A.* 29:473-474. [As cited in Versar (1987).]
14. ANSI. 1982. American National Standard Safety Levels with Respect to Human Exposure to Radiofrequency Electromagnetic Fields, 300 kHz to 100 GHz. American National Standards Institute, NY. ANSI C95.1-1982. [As cited in Elder (1994).]
15. Anttila, A., E. Pukkala, M. Sallmén, S. Hernberg, and K. Hemminki. 1995. Cancer incidence among Finnish workers exposed to halogenated hydrocarbons. *J Occup Med*. In Press. [As cited in IARC (1995).]
16. Aoyama, Y. 1994. Personal communication between Y. Aoyama, Tokyo Sensen Kikai Seisakusho Co., and Cassandra De Young, Abt Associates Inc. December 29.
17. API. 1977. American Petroleum Institute. Teratology study in rats. Stoddard solvent final report. Washington, DC. [As cited in ATSDR (1995).]
18. API. 1982. American Petroleum Institute. Mutagenicity study of thirteen petroleum fractions. Project no. U-150-14 (EA-1). Washington, DC. [As cited in ATSDR (1995).]
19. API. 1987. American Petroleum Institute. Mutagenicity of API 8501, Stoddard solvent (CAS 8052-41-3) in a mouse lymphoma mutation assay. Final report. Washington, DC. [As cited in ATSDR (1995).]
20. Arlien-Söborg, P., P. Bruhn, C. Gyldensted, et al. 1979. Chronic painters' syndrome: Chronic toxic encephalopathy in house painters. *Acta Neurol Scand* 60:149-156. [As cited in ATSDR (1995).]
21. Aschengrau, A., D. Ozonoff, C. Paulu, et al. 1993. Cancer risk and tetrachloroethylene-contaminated drinking water in Massachusetts. *Arch Env Hlth* 48:284-292.
22. Ashland. 1989. Ashland Chemical Company. Material safety data sheet for Stoddard (petroleum) solvent. May.
23. Ashland. 1992. Ashland Chemical Company. Material safety data sheet for Stoddard (petroleum) solvent. March.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

24. ATSDR. 1993. Agency for Toxic Substances and Disease Registry. Toxicological profile for tetrachloroethylene. USDHHS, Agency for Toxic Substances and Disease Registry, Public Health Service. Atlanta, GA.
25. ATSDR. 1995. Agency for Toxic Substances and Disease Registry. Toxicological profile for Stoddard solvent. USDHHS, Agency for Toxic Substances and Disease Registry, Public Health Service. Atlanta, GA.
26. AWWA. 1995. American Water Works Association. Personal communication with Alice Tome, Abt Associates Inc. November 1.
27. BAAQMD. 1993. Bay Area Air Quality Management District. An Investigative Survey of Perchloroethylene in Residential Areas above Dry Cleaners in San Francisco.
28. Bagnell, P.C., and H.C. Ellenberger. 1977. Obstructive jaundice due to a chlorinated hydrocarbon in breast milk. *J Can Med Assoc* 117:1047-1048. [As cited in USEPA (1985).]
29. Bailey, W. Undated. Personal communication between W. Bailey, Blue Plains Treatment Plant, and Mary Katherine Powers, USEPA/OPPT/EETD.
30. Baker, S. 1996. Personal communication between Scott Baker, Hill Equipment Company, and Jonathan Greene, Abt Associates Inc. December.
31. Barnes and Dourson. 1988. *Regulatory Toxicology and Pharmacology* 8:471 - 486.
32. Becknell, C. 1994. Personal communications between Cary Becknell, Safety Kleen, and Cassandra De Young, Abt Associates Inc. August 22 and September 1.
33. Belluscio, J. 1996. Personal communications between Jack Belluscio, Global Technologies, LLC, and Joseph Breen, USEPA, Office of Pollution Prevention and Toxics. October 30.
34. Blackler, C., R. Denbow, W. Levine, and K. Nemsick. 1995. A Comparative Analysis of PCE Dry Cleaning and an Alternative Wet Cleaning Process. National Pollution Prevention Center for Higher Education. Ann Arbor, MI.
35. Blair, A., P. Decoutle, and D. Graumen. 1979. Causes of death among laundry and dry-cleaning workers. *Am. J. Public Health* 69(5):508-511.
36. BLS. 1996a. Bureau of Labor Statistics. Downloaded from the BLS Information Bulletin Composite File of the Producer Price Index for Capital Equipment and

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

- Chemicals and Allied Products. U.S. Department of Labor, Bureau of Labor Statistics, Office of Prices and Consumer Living Conditions.
37. BLS. 1996b. Bureau of Labor Statistics. Downloaded from the BLS Information Bulletin Composite File of the Producer Price Index for Energy. U.S. Department of Labor, Bureau of Labor Statistics, Office of Prices and Consumer Living Conditions.
  38. BLS. 1997. Bureau of Labor Statistics. Downloaded from the BLS Information Bulletin Composite File of the Producer Price Index for Capital Equipment and Chemicals and Allied Products. U.S. Department of Labor, Bureau of Labor Statistics, Office of Prices and Consumer Living Conditions.
  39. Boethling, R.S. 1993. Structure activity relationships for evaluation of biodegradability in the EPA's Office of Pollution Prevention and Toxics. Environmental Toxicology and Risk Assessment, 2nd Volume, ASTM STP 1216. J.W. Gorsuch, F.J. Dwyer, C.G. Ingersoll, and T.W. La Point, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 540-554.
  40. Bosco, M.G., I. Figa-Talamanca, and S. Salerno. 1987. Health and reproductive status of female workers in dry cleaning shops. Int Arch Occup Environ Health 52:295-301. [As cited in ATSDR (1993).]
  41. Braunstein, L.E. 1940. Subacute yellow atrophy of the liver due to solvent. J Am Med Assoc 114:136-138.
  42. Bruce, B. 1994. Personal communication between Benghkt Bruce, Unimac, and Sue Hollenbeck, SAIC. June.
  43. Bruce, B. 1995. Personal communications between Benghkt Bruce, Unimac, and Cassandra De Young, Abt Associates Inc. January.
  44. Buben Jr., O'Flaherty J. 1985. Delineation of the role of metabolism in the hepatotoxicity of trichloroethylene and perchloroethylene: A dose-effect study. Toxicol Appl Pharmacol 78:105-122. [As cited in IRIS (1993).]
  45. Busch RH, McDonald KE, Briant JK, Morris JE, Braham TM. 1983. Pathologic effects in rodents exposed to sodium combustion products. Environ Res 31:138-147.
  46. Caled. 1995. Comments submitted by Caled on CTSA Phase II drafts sent for stakeholder comments.
  47. Cameli, N., G. Tosti, N. Venturo, and A. Tosti. 1991. Eyelid dermatitis due to cocamidopropyl betaine in a hard contact lens solution. Contact Dermatitis 25:261-262.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

48. Cannon, B. 1994. Personal communications between Barry Cannon, Boewe Passat/Permac, and Cassandra De Young, Abt Associates Inc. August 11 and 16.
49. Carpenter, C.P. 1937. The chronic toxicity of tetrachloroethylene. *J Ind Hyg Toxicol* 19:323-336. [As cited in ATSDR (1993).]
50. Carpenter, C.P., E.R. Kinkead, D.L. Geary Jr., et al. 1975a. Petroleum hydrocarbon toxicity studies: I. Methodology. *Toxicol Appl Pharmacol* 32:246-262. [As cited in ATSDR (1995).]
51. Carpenter, C.P., E.R. Kinkead, D.L. Geary Jr., et al. 1975b. Petroleum hydrocarbon toxicity studies: III. Animal and human response to vapors of Stoddard solvent. *Toxicol Appl Pharmacol* 32:282-297. [As cited in ATSDR (1995).]
52. CAS. 1993. Chemical Abstracts Service. On-line search of Registry File. August.
53. CCRIS. 1995. Chemical Carcinogenesis Research Information System. Built and maintained by the National Cancer Institute; reviewed by expert consultants and qualified contractors.
54. CEC. 1992. Center for Emissions Control. Dry cleaning: An assessment of emission control options. September.
55. CEPA. 1993. California Environmental Protection Agency. Air Resources Board. Proposed airborne toxic control measure and proposed environmental training program for perchloroethylene dry cleaning operations. Staff report. August.
56. Chao, S. 1994. Personal communication between Sid Chao, Hughes Corporation, and Alice Tome, Abt Associates Inc. December.
57. Cheverria, D., R.F. White, and C. Sampaio. 1995. A behavioral evaluation of PCE exposure in patients and dry cleaners: a possible relationship between clinical and preclinical effects. *JOEM* 37(6):667-680.
58. CIR. Cosmetic Ingredient Review Expert Panel. 1983. Final report on the safety assessment of Sodium Laureth Sulfate and Ammonium Laureth Sulfate. *J. Am. Coll. Toxicol.* 2(5):1-34
59. CIR. Cosmetic Ingredient Review Expert Panel. 1984. Final report on the safety assessment of Polysorbates 20, 21, 40, 60, 61, 65, 80, 81, and 85. *J. Am. Coll. Toxicol.* 3(5):1-82.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

60. CIR. Cosmetic Ingredient Review Expert Panel. 1986. Final report on the safety assessment of hydroxyethylcellulose, hydroxypropylcellulose, methylcellulose, hydroxypropylmethylcellulose, and cellulose gum. *J. Am. Coll. Toxicol.* 5(3):1-59. Hazardous Substance Database (HSDB). 1994.
61. CIR. Cosmetic Ingredient Review Expert Panel. 1987. Final report on the safety assessment of Sodium Sesquicarbonate, Sodium Bicarbonate, and Sodium Carbonate. *J Am Coll Toxicol* 6(1):121-138.
62. CIR. Cosmetic Ingredient Review Expert Panel. 1993. CIR Cosmetic Ingredient Review: 1993 Annual Report. Washington, DC.
63. Clark, B., J.G. Henry, and D. Mackay. 1995. Fugacity analysis and model of organic chemical fate in a sewage treatment plant. *Environ Sci Technol* 29:1488-1494.
64. Clayton, G.D., and F.E. Clayton. Eds. 1982. Acetic Acid in Patty's Industrial Hygiene and Toxicology; Third revised edition: Volume 2C Toxicology. John Wiley and Sons, New York, pp. 3059-3061, 4386-4389, 4358-4359, 4909-4911, 4946-4948.
65. Clements, R.G. (Ed.). 1988. Estimating toxicity of industrial chemicals to aquatic organisms using structure activity relationships. EPA-560/6-88-001. Environmental Effects Branch, Health and Environmental Review Division (7403), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency. Washington, DC. PB89-117592. National Technical Information Services (NTIS), U.S. Department of Commerce. Springfield, VA.
66. Clements, R.G., J.V. Nabholz, D.W. Johnson, and M. Zeeman. 1993a. The use and application of QSAR's in the Office of Toxic Substances for ecological hazard assessment of new chemicals. *Environmental Toxicology and Risk Assessment*. ASTM STP 1179. W.G. Landis, J.S. Hughes, and M.A. Lewis, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 56-64.
67. Clements, R.G., J.V. Nabholz, D.W. Johnson, and M. Zeeman. 1993b. The use of quantitative structure-activity relationships (QSARs) as screening tools in environmental assessment. *Environmental Toxicology and Risk Assessment*. 2nd Volume. ASTM STP 1216. J.W. Gorsuch, J.F. Dwyer, C.G. Ingersoll, and T.W. La Point, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 555-570.
68. CNT. 1996. Center for Neighborhood Technology. Alternative clothes cleaning demonstration shop. Final report. Chicago, IL. (Chapter 2)

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

69. CNT. 1996. Center for Neighborhood Technology. Wetcleaning machines: a report by the Center for Neighborhood Technology obtained from the World Wide Web site <http://www.cnt.org>. (Chapter 1)
70. Coca, J., and R. Diaz. 1980. Extraction of furfural from aqueous solutions with chlorinated hydrocarbons. *J of Chem Engin Data* 25:80-83.
71. Coler, H.R., and H.R. Rossmiller. 1953. Tetrachloroethylene exposure in a small industry. *Ind Hyg Occupa Med* 8:227. [As cited in USEPA (1985).]
72. Collins, J. 1995. Personal communication between Jim Collins, Safety Kleen, and Cassandra De Young, Abt Associates Inc. January 13.
73. Conaway, C.C., C.A. Schreiner, and S.T. Cragg. 1984. Mutagenicity evaluation of petroleum hydrocarbons. In: *Advances in Modern Environmental Technology*. Vol. 6: Applied toxicology of petroleum hydrocarbons. H.N. MacFarland, C.E. Holdsworth, J.A. MacGregor, et al., Eds. Princeton Scientific Publishers, Inc. Princeton, NJ. pp. 89-107. [As cited in ATSDR (1995).]
74. Consumers Union. 1995. Perchloroethylene in the air in apartments above New York City dry cleaners: A special report from Consumers Union.
75. CRC. 1975. Chemical Rubber Publishing Company. *Handbook of Chemistry and Physics: 56th Edition*. CRC Press. Cleveland, OH.
76. CRC. 1984. *Handbook of Chemistry and Physics*. 65th ed. Weast, Ed. CRC Press.
77. CRWQCB. 1991. California Regional Water Quality Control Board. Cleanup and abatement order for PCE dischargers in Turlock. Staff report. CRWQCB, Central Valley Region. Summer.
78. CTFA. Cosmetic, Toiletry and Fragrance Association. 1976. Submission of unpublished data. Primary skin irritation study on 20 percent aqueous Lauramide DEA. CIR, Washington, DC. No. 2-32-82.
79. CTFA. Cosmetic, Toiletry and Fragrance Association. 1977a. Submission of unpublished data. Acute oral toxicity of a bubble bath containing 6 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-47.
80. CTFA. Cosmetic, Toiletry and Fragrance Association. 1977b. Submission of unpublished data. Primary skin irritation study on 10 percent aqueous Lauramide DEA. CIR, Washington, DC. No. 2-32-56.



**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

81. CTFA. Cosmetic, Toiletry and Fragrance Association. 1977c. Submission of unpublished data. Human primary skin irritation study on a bubble bath containing 6 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-51.
82. CTFA. Cosmetic, Toiletry and Fragrance Association. 1977d. Submission of unpublished data. Repeat insult patch test on a medicated liquid cleanser containing 5 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-63.
83. CTFA. Cosmetic, Toiletry and Fragrance Association. 1978a. Submission of unpublished data. Acute oral toxicity of 25 percent Lauramide DEA in corn oil. CIR, Washington, DC. No. 2-32-53.
84. CTFA. Cosmetic, Toiletry and Fragrance Association. 1978b. Submission of unpublished data. Acute dermal toxicity of 50 percent Lauramide DEA in corn oil. CIR, Washington, DC. No. 2-32-54.
85. CTFA. Cosmetic, Toiletry and Fragrance Association. 1979a. Submission of unpublished data. Acute oral toxicity of a noncoloring shampoo containing 8.0 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-72.
86. CTFA. Cosmetic, Toiletry and Fragrance Association. 1979b. Submission of unpublished data. Acute oral toxicity of a noncoloring shampoo containing 8.0 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-73.
87. CTFA. Cosmetic, Toiletry and Fragrance Association. 1979c. Submission of unpublished data. Acute oral toxicity of a noncoloring shampoo containing 8.0 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-74.
88. CTFA. Cosmetic, Toiletry and Fragrance Association. 1979d. Submission of unpublished data. Human primary skin irritation test on a noncoloring shampoo containing 8 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-79.
89. CTFA. Cosmetic, Toiletry and Fragrance Association. 1979f. Submission of unpublished data. Repeat insult patch test on a skin cleanser containing 4 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-32.
90. CTFA. Cosmetic, Toiletry and Fragrance Association. 1980a. Submission of unpublished data. Subchronic dermal toxicity study on a medicated liquid cleanser containing 5.0 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-64.
91. CTFA. Cosmetic, Toiletry and Fragrance Association. 1980b. Submission of unpublished data. Human soap chamber test on a liquid soap containing 10 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-104.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

92. CTFA. Cosmetic, Toiletry and Fragrance Association. 1980c. Submission of unpublished data. Repeat insult patch test on a liquid soap containing 10 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-150.
93. CTFA. Cosmetic, Toiletry and Fragrance Association. 1980d. Submission of unpublished data. Repeat insult patch test on a liquid soap containing 10 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-105.
94. CTFA. Cosmetic, Toiletry and Fragrance Association. 1981a. Submission of unpublished data. Human primary skin irritation test on a product containing 5 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-70.
95. CTFA. Cosmetic, Toiletry and Fragrance Association. 1982a. Submission of unpublished data. Subchronic dermal toxicity study on a cream cleanser containing 4.0 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-33.
96. CTFA. Cosmetic, Toiletry and Fragrance Association. 1982b. Submission of unpublished data. Human soap chamber test on a liquid soap containing 10 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-103.
97. CTFA. Cosmetic, Toiletry and Fragrance Association. 1982c. Submission of unpublished data. Human soap chamber test on a liquid soap containing 10 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-102.
98. Daniell, W.E., W.G. Couser, and L. Rosenstock. 1988. Occupational solvent exposure and glomerulonephritis: A case report and review of the literature. *J Am Med Assoc* 259:2280-2283. [As cited in ATSDR (1995).]
99. Davidson, I.W.F., and R.P. Beliles. 1991. Consideration of target organ toxicity of trichloroethylene in terms of metabolite toxicity and pharmacokinetics. *Drug Metabolism Reviews* 23:493-599.
100. Daubert, T.E. and R.P. Danner. 1985. Data compilation tables of properties of pure compounds. Vol. 4. Design Inst for Physical Property Data, Am Inst of Chem Engin. Hemisphere Publishing Corp. New York, NY.
101. DeSimone, J., and M.A. Smith. 1996. Design and application of surfactants for carbon dioxide. Nomination for the Presidential Green Chemistry Challenge Awards Program. November 29.
102. DIALOG. 1993. Search of the "Freedonia Market Research Database," July 8.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

103. Dice, W.H., G. Ward, J. Kelley, et al. 1982. Pulmonary toxicity following gastrointestinal ingestion of kerosene. *Ann Emerg Med* 11:138-142.
104. Dimitriades, B., B.W. Gay Jr., R.R. Arnts, and R.L. Seila. 1983. Photochemical reactivity of perchloroethylene. 600/3-83-001. U.S. Environmental Protection Agency, Environmental Sciences Research Laboratory. Research Triangle Park, NC. [As cited in Versar (1987).]
105. Dmitrieva, N. V. 1965. Maximum permissible concentration of tetrachloroethylene in factory air. *Hyg. Sanit.* 31:387-393. (English translation). [As cited in USEPA (1985).]
106. Dmitrieva, N.V. 1968. Bioelectric activity and electric conducting properties of muscles exposed to chlorinated hydrocarbons. *Farmakologiya i Toksikologiya* 31(2):228-230. (English translation). [As cited in USEPA (1985).]
107. Dmitrieva, N.V. 1973. Changes in the bioelectrical activity in the cerebral cortex of rats with the narcotic effect of substances with different polarization properties. *Experimentalnaya Khirurgiya i Anestezidologiya* 6:72-75. (English translation). [As cited in USEPA (1985).]
108. DOE. 1993. An environmentally conscious approach to clothes maintenance - final report. Grant Proposal to USEPA, Department of Energy Kansas City Plant. Kansas City, MO. July.
109. Dolon, C. 1996. Personal communication between Chris Dolon, AquaTex, and Jonathan Greene, Abt Associates Inc. December.
110. Du Bach, C. 1994. Personal communication between Chris Du Bach, Fibrimatic, and Cassandra De Young, Abt Associates Inc. August 17.
111. Duh, R.W., and N.R. Asal. 1984. Mortality among laundry and dry cleaning workers in Oklahoma. *Am Pub Health* 74(11):1278-1280. [As cited in USEPA (1985).]
112. Earnest, G.S. 1997. Control of perchloroethylene exposures in dry cleaning. Hard copy of overhead projector slide presentation. Presented at the American Industrial Hygiene Conference and Exposition, Dallas, Texas. May 22. Sponsored by NIOSH, Cincinnati, OH.
113. Eberhardt, H., and K.J. Freundt. 1966. Tetrachloroethylene poisoning. *Arch Toxikol* (Berlin) 21:338-351. (In German; English translation). [As cited in USEPA (1985).]
114. ECETOC, 1990. Technical Report No. 37. Tetrachloroethylene Assessment of Human Carcinogenic Hazard.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

115. Elder, J.A. 1994. Thermal, cumulative, and life span effects and cancer in mammals exposed to radiofrequency radiation. Chapter 13 in Biological effects of Electric and Magnetic Fields. DO Carpenter and S Ayrapetyan, eds, Academic Press, San Diego, CA, Volume 2, pp. 279- 295. (Appendix A)
116. Elder, J. 1994. Personal communication between J. Elder, USEPA Health Effects Research Laboratory, and Mays Swicord, Food and Drug Administration, Center for Devices and Radiological Health, Div. of Life Sciences. July. (Chapter 4)
117. Environment Canada. 1995. Final report for the Green Clean™ project. Prepared by Environment Canada and the Green Clean Project Participants. Government of Canada EN40-5-0/1995/E.
118. EPA-SAT. 1994. United States Environmental Protection Agency Structure Activity Team. Washington, DC.
119. EPRI. 1993. Electric Power Research Institute. Development of a microwave clothes dryer. Thermo Energy Corporation, Palo Alto, California; and JG Microwave, Twain Harte, California. EPRI TR-102114, Project 2034-39. Interim Report, July 1993.
120. Eskenazi, B., A.J. Wyrobek, L. Fenster, et al. 1991a. A study of the effect of perchloroethylene exposure on the reproductive outcomes of wives of dry cleaning workers. *Am J Ind Med* 20:575-691.
121. Eskenazi, B., A.J. Wyrobek, L. Fenster, et al. 1991b. A study of the effect of perchloroethylene exposure on semen quality in dry cleaning workers. *Am J Ind Med* 20:593-600.
122. Ewers, L., G. Earnest, A. Ruder, and G. Burroughs. 1997. Methods to evaluate exposure assessment in dry-cleaning. Paper presented at the American Industrial Hygiene Conference & Exposition, Dallas, TX, May 22, 1997. Sponsored by NIOSH, Cincinnati, OH.
123. Exxon. 1994. Personal communication between Exxon representative and Michael Müller, Abt Associates Inc. March.
124. Faha, T. Undated. Personal communication between T. Faha, Fairfax County Department of Public Works (FCDPW), and Mary Katherine Powers, USEPA/OPPT/EETD.
125. Faig, K. 1996. Personal communication between Ken Faig, International Fabricare Institute, and Alice Tome, Abt Associates Inc.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

126. FCC. 1988. 21 CFR 1030. Performance standards for microwave and radio frequency emitting products. Section 1310.10. 21 CFR Ch. 1, 4-1-88 edition.
127. Ferguson, M. Undated. Personal communication between M. Ferguson, Water Control Board Office of Environmental Quality, State of Virginia, and Mary Katherine Powers, USEPA/OPPT/EETD.
128. Flick, E.W. 1990. Industrial solvents handbook, 4th ed. Noyes Data Corp. Park Ridge, NJ.
129. Flodin, U., C. Edling, and O. Axelson. 1984. Clinical studies with psychoorganic syndromes among workers with exposure to solvents. *Am J Ind Med* 5:287-295. [As cited in ATSDR (1995).]
130. Fowler, J.F. 1993. Cocamidopropyl betaine: the significance of positive patch test results in twelve patients. *Cutis* 52:281-284.
131. Franchini, I., A. Cavatorta, M. Falzoi, S. Lucertini, and A. Mutti. 1983. Early indicators of renal damage in workers exposed to organic solvents. *Int Arch Occup Environ Health*. 52:1-9.
132. Friberg, L., B. Kylin, and A. Nystrom. 1953. Toxicities of trichloroethylene and tetrachloroethylene and Fujiwara's pyridine-alkali reaction. *Acta Pharmacol Toxicol* 9:303-312. [As cited in ATSDR (1993).]
133. Frost and Sullivan. 1991. The U.S. market for industrial solvents 1991/92. Frost and Sullivan, New York, NY.
134. Gamberale, F., G. Annwall, and M. Hultengren. 1975. Exposure to white spirit: II. Psychological functions. *Scand J. Work Environ Health* 1:39-39.
135. Gay Jr., B.W., P.L. Hanst, J.J. Bufalini, and R.C. Noonan. 1976. Atmospheric oxidation of chlorinated ethylenes. *Environ. Sci. Technol.* 10:58-67. [As cited in Versar (1987).]
136. Giesen, L. 1994. Personal communication between Leo Giesen, VIC Manufacturing, and Cassandra De Young, Abt Associates Inc. August 11.
137. Gochet, B., C. de Meester, A. Leonard, et al. 1984. Lack of mutagenic activity of white spirit. *Int Arch Occup Environ Health* 53:359-364. [As cited in ATSDR (1995).]
138. Gold, J.H. 1969. Chronic perchloroethylene poisoning. *Can Psychiatric Assoc J* 14:627-630. [As cited in USEPA (1985).]

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

139. Goodheart, J. 1996. Personal communication between Jessica Goodheart, UCLA Pollution Prevention Education and Research Center, and Jonathan Greene, Abt Associates Inc. December 30.
140. Gosselin, R.E., R.P. Smith, and H.C. Hodge. 1984. Clinical toxicology of commercial products. Williams and Wilkins.
141. Gottlieb, R., J. Goodheart, P. Sinsheimer, C. Tranby, and L. Bechtel. 1996. UCLA Wet Cleaning Demonstration Project. Interim Progress Report. UCLA Pollution Prevention Education and Research Center. Los Angeles, CA. November.
142. Grady, P. 1996. EPA's ORD research program on alternative technologies, part II. Presented at Conf. on Apparel Care and the Environment: Alternative Technologies and Labeling, Washington. September. pp. 49-54.
143. Green, T., J. Odum, J.A. Nash, and J.K. Foster. 1990. Perchloroethylene-induced rat kidney tumors: An investigation of the mechanisms involved and their relevance to humans. *Toxicol Appl Pharmacol* 103:77-89.
144. Greenpeace, 1997. Information on wet cleaning facilities downloaded from website <http://www.greenpeace.org/wetlist.html>.
145. Gregersen, P. 1988. Neurotoxic effects of organic solvents in exposed workers: Two controlled follow-up studies after 5.5 and 10.6 years. *Am J Ind Med* 14:681-702. [As cited in ATSDR (1995).]
146. Gregersen, P., B. Angelsoe, T.E. Nielson, et al. 1984. Neurotoxic effects of organic solvents in exposed workers: An occupational, neuropsychological, and neurological investigation. [As cited in ATSDR (1995).]
147. GSC. 1988. General Services Corporation. Exposure screening manual. Prepared for USEPA, Office of Pollution Prevention and Toxics, under Contract No. 68-02-4281.
148. GTLLC. 1996. Letter from Jack Belluscio, Global Technologies LLC, to Joseph Breen, US EPA/OPPT/DfE. September 10.
149. Hake, C.L., and R.D. Stewart. 1977. Human exposure to tetrachloroethylene: Inhalation and skin contact. *Environ Health Perspect* 21:231-238. [As cited in ATSDR (1993).]
150. Hand, T. 1994. Personal communication between Tom Hand, Allied Signal, and Sue Hollenbeck, SAIC. June.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

151. Hane, M., O. Axelson, J. Blume, et al. 1977. Psychological function changes among house painters. *Scand J Work Environ Health* 3:91-99. [As cited in ATSDR (1995).]
152. Hansch, C., and A.J. Leo. 1985. Medchem project issue no. 26. Pomona College. Claremont, CA.
153. Hanst, P.L. 1978. Part II: Halogenated pollutants. Noxious trace gases in the air. *Chemistry* 51:6-12. [As cited in Versar (1987).]
154. Hardin, B.D., G.P. Bond, M.R. Sikov, F.D. Andrew, R. Beliles, and R.W. Niemier. 1981. Testing of selected workplace chemicals for teratogenic potential.
155. Harvey, G. Undated. Personal communication between G. Harvey, Alexandria Plant, and Mary Katherine Powers, USEPA/OPPT/EETD.
156. Hastings, L., G.P. Cooper, and W. Burg. Human sensory response to selected petroleum hydrocarbons. In: *Advances in Modern Environmental Toxicology*. Vol. 6: Applied toxicology of petroleum hydrocarbons. H.N. MacFarland, C.E. Holdsworth, J.A. MacGregor, et al., Eds. Princeton Scientific Publishers, Inc. Princeton, NJ. pp. 255-270.
157. Hayes, J.R., L.W. Condie Jr., and Borzelleca Jr. 1986. The subchronic toxicity of tetrachloroethylene (perchloroethylene) administered in the drinking water of rats. *Fund Appl Toxicol* 7:119-125. [As cited in IRIS (1993).]
158. Hickman, J.C. 1992. Chlorocarbons, -hydrocarbons (CHCl=CCl<sub>2</sub>). In: *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th ed. John Wiley and Sons. New York, NY. pp. 6:50-59.
159. Hill Sr., J. 1994. Personal communication between Jim Hill Sr., Hill Equipment Company, and Michael Müller, Abt Associates Inc. March. (Chapter 1)
160. Hill, J. 1994. Personal communications between Jim Hill, Hill Equipment Company, and Sharon Dubrow, SAIC. August and September. (Chapter 3)
161. Hill Jr., J. 1994a. Personal communication between Jim Hill Jr., Hill Equipment Company, and Leland Deck, Abt Associates Inc. March. (Chapter 6)
162. Hill Jr., J. 1994b. Personal communication between Jim Hill Jr., Hill Equipment Company, and Cassandra De Young, Abt Associates Inc. June and August. (Chapter 6)
163. Hill Sr., J. 1997. Personal communication between Jim Hill Sr., Hill Equipment Company, and Alice Tome, Abt Associates Inc. January.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

164. Hiller, H., et al. 1989. Gas production. In: Ullmann's Encyclopedia of Industrial Chemistry, 5th ed. VCH Publishers. New York, NY. pp. A10:188-9.
165. Hinrichs, B. 1993. Personal communication between Bob Hinrichs, Unocal, and Karl Kuellmer, Abt Associates Inc. July.
166. Hoffman, H.L. 1982. Petroleum products. In: Kirk-Othmer Encyclopedia of Chemical Technology, 3rd ed. John Wiley and Sons. New York, NY. pp. 17:261-71.
167. Hohenstein. Undated. Forschungsinstitut Hohenstein. The importance of wet-cleaning for the textile care industry: options for organizational expansion and/or rationalization. Methods for Management, Inc.
168. Hohenstein. 1996. Forschungsinstitut Hohenstein. International survey on regulations, machine data and general data of the textile dry cleaning industry. June.
169. Hope, B. 1994. Personal communications between Bruce Hope, Pros Equipment, and Cassandra De Young, Abt Associates Inc. July.
170. Howard, P.H., and M. Neal. 1992. Dictionary of chemical names and synonyms. Lewis Publishers. Ann Arbor, MI. pp. I 318-19.
171. Hughes. 1994. Carbon dioxide dry cleaning technology. Mariana Purrer. Hughes Environmental Systems, Inc. El Segundo, CA. March. (Chapter 3)
172. Hughes. 1994. Personal communication between Mariana Purrer, Hughes Environmental Systems, Inc., and Sue Hollenbeck, SAIC. July. (Chapter 1)
173. Hughes. 1996. Report on site visit to Hughes liquid CO<sub>2</sub> process development and fabrication locations by Scott Prothero, US EPA. February.
174. HSDB. 1994. Hazardous Substance Data Bank. Developed and maintained by the National Library of Medicine, Washington, DC.
175. IARC. 1995. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 63, Dry cleaning, Some Chlorinated Solvents and Other Industrial Chemicals. Tetrachloroethylene, pp. 159-221.
176. IEEE. 1992. IEEE Standard for Safety Levels with Respect to Human Exposure to Radiofrequency Electromagnetic Fields, kHz to 3.00 GHz. [As cited in Elder (1994).]
177. IFI. 1989. International Fabricare Institute. Equipment and plant operations survey. Focus on Dry Cleaning. Vol 13(1). March.



**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

178. Immanuel Jr., F. 1994. Personal communication between Frank Immanuel Jr., District Cleaners Equipment, and Cassandra De Young, Abt Associates Inc. August 11.
179. IRIS. 1993. Integrated Risk Information Database. Chemical files. Available through TOXNET on line. Washington, DC. (Appendix A)
180. IRIS. 1993. Integrated Risk Information Database. Chemical files. Background document 1A. Washington, D.C. Available through TOXNET on line. (Appendix C)
181. IRIS. 1997. Integrated Risk Information Database. Chemical files. Washington, DC. Available through TOXNET on line.
182. IRIS. 1997. Integrated Risk Information Database. Chemical files. Background document 1A. Washington, D.C. Available through TOXNET on line. (Appendix C)
183. IT. 1991 (Feb). IT Corporation. Chemical engineering branch manual for the preparation of engineering assessments. Prepared for USEPA, Office of Toxic Substances, Chemical Engineering Branch. Washington, DC. November.
184. Jenkins, L. 1994. Personal communication between Lauri Jenkins, Four State Machinery, and Cassandra De Young, Abt Associates Inc. August 18.
185. Jones, E. Undated. Personal communication between E. Jones, Fairfax County Department of Public Works (FCDPW), and Mary Katherine Powers, USEPA/OPPT/EETD.
186. Jungers, R.H., and S.J. Howie. PEDCO Environmental Inc. 1980. Exposure to perchloroethylene associated with the use of coin type dry cleaning machines. USEPA. Research Triangle Park, NC. [As cited in Versar (1987).]
187. Kaplan, S.D. 1980. Dry-cleaners workers exposed to perchloroethylene: a retrospective cohort mortality study. Contract No. 210-77-0094. U.S. Department of Health, Education, and Welfare, National Institute for Occupational Safety and Health. Washington, DC. [As cited in USEPA (1985).]
188. Katz, R.M., and D. Jowett. 1981. Female laundry and dry-cleaning workers in Wisconsin: a mortality analysis. *Am J Pub Health* 71:305-307. [As cited in USEPA (1985).]
189. Katzman, H. 1997. Personal communication between Howard Katzman, Metropolitan Machinery, and Jonathan Greene, Abt Associates Inc. January 17.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

190. King, P. 1994. Personal communication between Pat King, Hoyt Corporation, and Cassandra De Young, Abt Associates Inc. August 22.
191. Kinsman, R. 1997. Personal communication between Richard Kinsman, Global Technologies, and Jonathan Greene, Abt Associates Inc. February.
192. Kirk-Othmer. 1981. Microwave technology. Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley & Sons.
193. Korting, H.C., Parsch, E.-M., Enders, F., Przybilla, B. 1992. Allergic contact dermatitis to cocamidopropyl betaine in shampoo. *Journal of the American Academy of Dermatology*: 27:1013-1015.
194. Kurz, J. 1995. Personal communication between Josef Kurz, Hohenstein Institute, and Michael Müller, Abt Associates Inc. February.
195. Kyyroenen, P., H. Taskinen, M.L. Lindbohm, et al. 1989. Spontaneous abortions and congenital malformations among women exposed to tetrachloroethylene in dry cleaning. *J Epidemiol Community Health* 43:346-351. [As cited in ATSDR (1993).]
196. Lage, A. 1994. Personal communications between Al Lage, Columbia-Ilsa, and Cassandra De Young, Abt Associates Inc. August 17 and 18.
197. Lane, J.C. 1980. Gasoline and other motor fuels. In: Kirk-Othmer Encyclopedia of Chemical Technology, 3rd ed. John Wiley and Sons. New York, NY. pp. 11:660-61.
198. Lauwerys, R., J. Herbrand, J.P. Buchet, A. Bernard, and J. Gaussin. 1983. Health surveillance of workers exposed to tetrachloroethylene in dry-cleaning shops. *Int Arch Occup Environ Health* 52:69-77.
199. Leo, A., and D. Weininger. 1985. CLOGP vers 3.3: Estimation of the n-octanol water partition coefficient for organics in the TSCA inventory. Pomona College. Claremont, CA.
200. Levelton, B.H. 1995. The Canadian dry cleaning sector. Prepared for Environment Canada, Commercial Chemicals Division, Environmental Protection Branch. File: 495-059. October.
201. Levine, B., M.F. Fierro, S.W. Goza, et al. 1981. A tetrachloroethylene fatality. *J Forensic Sci* 26:206-209. [As cited in ATSDR (1993).]
202. Levine, J. 1997. Personal communication between Jerry Levine, Neighborhood Cleaners Association International, and Alice Tome, Abt Associates Inc. January.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

203. Lienhart, R. 1997. Personal communication between R. Bradley Lienhart, MiCell Technologies, and Lynne Blake-Hedges, USEPA. May 27.
204. Lin, R.S., and I.I. Kessler. 1981. A multifactorial model for pancreatic cancer in man. *J Am Med Assoc* 245:147-152. [As cited in USEPA (1985).]
205. Lipnick, R.L. 1993. Baseline toxicity QSAR models: A means to assess mechanism of toxicity for aquatic organisms and mammals. *Environmental Toxicology and Risk Assessment*. 2nd Volume. ASTM STP 1216. J.W. Gorsuch, F.J. Dwyer, C.G. Ingersoll, and T.W. La Point, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 610-619.
206. Litovitz, T., and A.E. Greene. 1988. Health implications of petroleum distillate ingestion. *State Art Rev Occup Med* 3:555-567.
207. Little. 1980. Arthur D. Little. Engineering control technology assessment of the dry cleaning industry. U.S. Dept. of Health, Education, and Welfare, NIOSH. Cincinnati, OH. October.
208. Lob, M. 1957. Dangers of perchloroethylene. *Arch Gewerbepath Gewerbehyg* 16:45-52. (In German; English translation). [As cited in USEPA (1985).]
209. Lowenheim, F.A., and M.K. Moran. 1975. Faith, Keyes, and Clark's Industrial Chemicals, 4th ed. Wiley-Interscience. New York, NY. pp 604-611.
210. Lukaszewski, T. 1979. Acute tetrachloroethylene fatality. *Clin Toxicol* 15:411-415. [As cited in ATSDR (1993).]
211. Lummis, D. 1996. Personal communication between Dennis Lummis, NIE Insurance, and Alice Tome, Abt Associates Inc.
212. Lyman, W.J., W.F. Reehl, and D.H. Rosenblatt (Eds). 1982. Solubility in water. In: *Handbook of Chemical Property Estimation Methods*. McGraw-Hill Book Company. New York, NY. pp 2-1 to 2-52, Equation 2-2.
213. Mains, H. 1996. Personal communication between Harold Mains, Fabritek International, and Jonathan Greene, Abt Associates Inc.
214. Mann, M.D., D.J. Pirie, and J. Wolfsdorf. 1977. Kerosene absorption in primates. *J Pediatr* 91(3):495-498.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

215. Mannsville. 1995. Mannsville Chemical Products Corporation. Mannsville Chemical Products Synopsis. Asbury Park, NJ.
216. Materna, B.L. 1985. Occupational exposure to perchloroethylene in dry cleaning industry. *American Industrial Hygiene Association Journal* 46:268-273. [As cited in ATSDR 1995.]
217. McDonald, A.D., B. Armstrong, N.M. Cherry, et al. 1986. Spontaneous abortion and occupation. *J Occup Med* 28:1232-1238. [As cited in ATSDR (1993).]
218. McGaughy, R. 1994. Personal communication between Dr. Robert McGaughy, USEPA, Office of Health and Environmental Assessment, Human Health Assessment Group, and Jill Gendelman, USEPA. July.
219. Mellan, I. 1977. *Industrial Solvents Handbook*, 2nd ed. Noyes Data Corporation. Park Ridge, NJ.
220. Mergler, D., S. Belanger, S. de Grosbois, et al. 1988. Chromal focus of acquired chromatic discrimination loss and solvent exposure among printshop workers. *Toxicology* 49:341-348. [As cited in ATSDR (1995).]
221. Meylan, W.M., and P.H. Howard. 1991. Bond contribution method for estimating Henry's Law constants. *Environ Toxicol Chem* 10:1283-1293.
222. Meylan, W.M., and P.H. Howard. 1995. Atom/fragment contribution method for estimating octanol-water partition coefficients. *J Pharm Sci* 84:83-92.
223. Meylan, W.M., P.H. Howard, and R.S. Boethling. 1992. Molecular topology/fragment contribution method for predicting soil sorption coefficients. *Environ Sci Technol* 26:1560-1567.
224. Meylan, W.M., P.H. Howard, and R.S. Boethling. 1996. Improved method for estimating water solubility from octanol/water coefficient. *Environ Toxicol Chem* 15(2):100-106.
225. MHS. 1993. Municipal Health Service. Exposure to perchloroethylene in homes nearby drycleaners using closed systems and the effect of remedial actions. *Proceedings of Indoor Air '93*, Vol. 2. Amsterdam, the Netherlands.
226. MiCELL Technologies. 1997. Providing cleaner solutions. April 10.
227. MiCELL Technologies. Undated. The MiCare™ garment care system. Questions and answers.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

228. Mikkelsen, S., M. Jorgensen, E. Browne, et al. 1988. Kerosene “burns”: A new case. *Contact Dermatitis* 19(4):314-315. [As cited in ATSDR (1995).]
229. Milch, N. 1994. Personal communication between Neal Milch, Electrolux, USA, and Sue Hollenbeck, SAIC. June and July.
230. Miller, M. 1997. Personal communication between Michael Miller, U.S. Department of Labor Unemployment Insurance Service, and Jonathan Greene, Abt Associates Inc. January 6.
231. Misuishi, Y. 1995. Personal communication between Yoshmichi Misuishi, Director, All Japan Laundry and Dry Cleaning Association, and Alice Tome, Abt Associates Inc. February.
232. Mirza, A. Undated. Personal communication between A. Mirza, New York State Department of Environmental Conservation (NYSDEC), and Mary Katherine Powers, USEPA/OPPT/EETD.
233. Morgan, B. 1969. Dangers of perchloroethylene (Letter). *Br Med J* 2:513. [As cited in ATSDR (1993).]
234. Moser, J. 1994. Personal communication between Joe Moser, Fluormatic, and Cassandra De Young, Abt Associates Inc. August 22.
235. Munz, E., and P.V. Roberts. 1987. Air-water phase equilibria of volatile organic solutes. *J of the Am Water Works Assoc* 79:62-9.
236. Murphy, M. 1994. Personal communication between Mike Murphy, Unimac, and Cassandra De Young, Abt Associates Inc. August 26. (Chapter 6)
237. Murphy, T. 1994. Personal communication between Tom Murphy, Kleen Rite, and Sharon Dubrow, SAIC. September. (Chapter 1)
238. Nabholz, J.V. 1991. Environmental hazard and risk assessment under the United States Toxic Substances Control Act. *The Science of the Total Environment*. Vol. 109/110, pp. 649-665.
239. Nabholz, J.V., P. Miller, and M. Zeeman. 1993a. Environmental risk assessment of new chemicals under the Toxic Substances Control Act (TSCA) Section Five. *Environmental Toxicology and Risk Assessment*. ASTM STP 1179. W.G. Landis, J.S. Hughes, and M.A. Lewis, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 40-55.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

240. Nabholz, J.V., R.G. Clements, M.G. Zeeman, K.C. Osborn, and R. Wedge. 1993b. Validation of structure activity relationships used by the USEPA's Office of Pollution Prevention and Toxics for the environmental hazard assessment of industrial chemicals. Environmental Toxicology and Risk Assessment. 2nd Volume. ASTM STP 1216. J.W. Gorsuch, F.J. Dwyer, C.G. Ingersoll, and T.W. La Point, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 571-590.
241. Narotsky, M.G., and R.J. Kavlock. 1995. A multi-disciplinary approach to toxicological screening: developmental toxicity. J of Env Tox and Env Health 45:145-171.
242. NCI. 1977. National Cancer Institute. Bioassay of tetrachloroethylene for possible carcinogenicity. U.S. Department of Health, Education, and Welfare Pub. NIH 77-813. Washington, DC. [As cited in USEPA (1985).]
243. NCRP. 1986. National Council on Radiation Protection and Measurements. Biological effects and exposure criteria for radiofrequency electromagnetic fields. Report No. 67. Bethesda, MD.
244. NESCAUM. 1986. Health Evaluation Document for Tetrachloroethylene.
245. NESCAUM. 1989. Northeast States for Coordinated Air Use Management. Evaluation of the health effects from exposure to gasoline and gasoline vapors. Final report.
246. Nethercott, J., J.M. Pierce, G. Likwornik, et al. 1980. Genital ulceration due to Stoddard solvent. J Occup Med 22:549-552. [As cited in ATSDR (1995).]
247. Newman, R. Undated. Personal communication between R. Newman, New York State Department of Environmental Conservation (NYSDEC), Regional Office, and Mary Katherine Powers, USEPA/OPPT/EETD.
248. Newsome, L.D., D.E. Johnson, and J.V. Nabholz. 1993. Quantitative structure-activity predictions for amine toxicity algae and daphnids. Environmental Toxicology and Risk Assessment. 2nd Volume. ASTM STP 1216. J.W. Gorsuch, F.J. Dwyer, C.G. Ingersoll, and T.W. La Point, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 591-609.
249. NIOSH. 1982. National Institute for Occupational Safety and Health. National occupational exposure survey of 1982. U.S. Dept. of Health, Education, and Welfare, Public Health Service, Centers for Disease Control, NIOSH. Washington, DC.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

250. NIOSH. 1990. National Institute for Occupational Safety & Health. Pocket guide to chemical hazards. DHHS-90-118. NIOSH, U.S. Department of Health and Human Services. Washington, DC.
251. NTP. 1986. National Toxicology Program. NTP technical report on the toxicology and carcinogenesis studies of tetrachloroethylene (perchloroethylene). Publ. No. 86-2567. U.S. Department of Health and Human Services, NIH.
252. NTP. 1986. National Toxicology Program. Toxicology and carcinogenesis of tetrachloroethylene (perchloroethylene) (CAS No. 127-18-4) in F344/N rats and B6C3F<sub>1</sub> mice (inhalation studies). NIH pub. 86-2567. NTP TR 311. National Institutes of Health. Bethesda, MD. [As cited in ATSDR (1993).] (Appendices A, C)
253. NTP. 1994. National Toxicology Program. Division of Toxicology Research and Testing; Management Status Report; 07/07/94, p.18, ref 8.
254. NYSDEC. 1992. Descriptive data of Sewage Treatment Systems in New York State. New York State Department of Environmental Conservation.
255. NYSDEC. 1993. New York State Department of Environmental Conservation. Regulating PCE emissions from dry cleaning machines: An economic and public health impact analysis. Office of Policy and Program Analysis and Division of Air. Albany, NY. March.
256. NYSDOH. 1993. New York State Department of Health. An investigation of indoor air contamination in residences above dry cleaners. Risk Analysis. Vol. 13, No. 3. (Chapter 4)
257. NYSDOH. 1993a. New York State Department of Health. An investigation of indoor air contamination in residences above dry cleaners. Risk Analysis, Vol. 13, No. 3. (Chapters 3, 7 & Appendix B)
258. NYSDOH. 1993b. New York State Department of Health. Survey of dry cleaning facilities in Capital District, New York and New York City. October.
259. NYSDOH. 1994. New York State Department of Health. Investigation of tetrachloroethylene in the vicinity of two dry cleaners: An assessment of remedial measures. Draft report.
260. OCIS. 1994. OSHA Computerized Information System. Set of 3 data reports generated by OCIS staff for USEPA. January.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

261. Odum, J., T. Carean, J.R. Foster, and P.M. Hext. 1988. The role of trichloroacetic acid and peroxisome proliferation in differences in carcinogenicity of perchloroethylene in the mouse and rat. *Toxicol Appl Pharmacol* 92:103-112.
262. Olsen, J., K. Hemminki, G. Ahlborg, et al. 1990. Low birthweight, congenital malformations, and spontaneous abortions among dry-cleaning workers in Scandinavia. *Scand J Work Environ Health* 16:163-168.
263. Olson, B.A. 1982. Effects of organic solvents on behavioral performance of workers in the paint industry. *Neurobehav Toxicol Teratol* 4:703-708.
264. OPD. 1992. 1993 OPD Chemical Buyers Directory. 80th annual ed. Schnell Publishing Co., New York, NY.
265. OSHA. 1989. Occupational Safety and Health Administration. US Code of Federal Regulations, Title 29, Part 1910, Section 1910.95. Occupational noise exposure. 29 CFR Ch. XVII (7-1-89 ed.)
266. OTEC. 1993. OTEC leaders in hydrocarbon drycleaning. Product literature. OTEC (MSG) Ltd. Rotherdam.
267. Otter, W. 1996. Report on the European Wet Cleaning Committee. Presented at Conf. on Apparel Care and the Environment: Alternative Technologies and Labeling, Washington. September. p. 107-114.
268. Patton, J. 1996. Results and conclusions from wet cleaning demonstration projects. Presented at Conf. on Apparel Care and the Environment: Alternative Technologies and Labeling, Washington. September. p. 129-136.
269. Pedersen, L.M., K. Larsen, and C-H Cohr. 1984. Kinetics of white spirits in human fat and blood during short-term experimental exposure. *Acta Pharmacol Toxicol* 55:308-316. [As cited in ATSDR (1995).]
270. Pedersen, L.M., S. Rasmussen, and C-H Cohr. 1987. Further evaluation of the kinetics of white spirits in human volunteers. *Pharmacol Toxicol* 60: 135-139. [As cited in ATSDR (1995).]
271. PEI. 1985. PEI Assoc., Inc. Occupational exposure and environmental release assessment of tetrachloroethylene. Prepared for the U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances. Washington, DC. December.



**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

272. Perry, R., and C. Chilton. 1973. Chemical Engineers Handbook, 5th edition. McGraw-Hill Inc.
273. Peter, C. and Hoting, E. 1992. Contact allergy to cocamidopropyl betaine (CAPB). Contact Dermatitis 26:282-283.
274. Pfaffli, P., H. Harkonen, and H. Savolainen. 1985. Urinary dimethylbenzoic-acid excretion as an indicator of occupational exposure to white spirit. J Chromatography, Biomedical Applications 337:146-150.
275. Phillips, R.D. 1983. Effect of Stoddard solvent on kidney function and structure of Fischer 344 and Sprague-Dawley rats. In: Proceedings of the 13th Conference on Environmental Toxicology, Wright-Patterson Air Force Base, November 16-18, 1982. Air Force Aerospace Medical Research Laboratory, Aerospace Medical Division, Air Force Systems Command. Springfield, VA. pp. 328-336. [As cited in ATSDR (1995).]
276. Phillips, R.D., and G.F. Egan. 1981. Teratogenic and dominant lethal investigation of two hydrocarbon solvents. Abstract. Toxicologist 1:15.
277. Pindyck, R.S., and D.L. Rubinfeld. 1989. Microeconomics. Macmillan Publishing Company. New York, NY.
278. Plog, B.A., Ed. 1988. Fundamentals of Industrial Hygiene. Appendix C. 3rd ed. National Safety Council.
279. Porter, D., et al. 1995. An environmentally conscious approach to clothes maintenance. Final report. Prepared for the U.S. Department of Energy under contract DE-ACO4-76-DP00613. December.
280. Prager, D., and C. Peters. 1970. Development of aplastic anemia and the exposure to Stoddard solvent. Blood 35:286-287.
281. Pynn, J. Undated. Personal communication between J. Pynn, Newtown Creek Plant Superintendent, and Mary Katherine Powers, USEPA/OPPT/EETD.
282. Radian. 1993. Radian Corporation. Memorandum from Amigo et al. of Radian Corp. to the Dry Cleaning NESHAP Project File (USEPA Air Docket A-88-11). Summary of findings from a well investigation project conducted by the California Water Quality Control Board. August.
283. Regulatory Toxicology and Pharmacology. 1994. Interpretive rev. of the potential adverse effects of chlorinated organic chemicals on human health and the environment. Report of an expert panel. Reg Tox & Pharm, 94: August.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

284. Reich, D.A., and C.L. Cormany. 1979. Drycleaning and laundering. In: Kirk-Othmer Encyclopedia of Chemical Technology, 3rd ed. John Wiley and Sons. New York, NY. pp. 8:50-68.
285. Riddick, J.A., W.B. Bunger, and T.K. Sakano. 1986. Organic solvents: physical properties and methods of purification. Techniques of Chemistry, 4th ed. Vol. II. A. Weissburger, Ed. John Wiley & Sons. New York, NY.
286. Riggs, C. 1996. EPA's ORD research program on alternative textile care technologies, part I. Presented at Conf. on Apparel Care and the Environment: Alternative Technologies and Labeling, Washington, September. p. 37-49.
287. Riley, A.J., A.J. Collings, N.A. Browne, et al. 1984. Responses of the upper respiratory tract of the rat to white spirits vapor. Toxicol Lett 22:125-132. [As cited in ATSDR (1995).]
288. Rom WN, Greaves W, Bang KM, Holthouser M, Campbell D, Bernstein R. 1983. An epidemiologic study of the respiratory effects of trona dust. Arch Environ Health 38:86-92.
289. Risotto, S. 1996. Presentation by Steve Risotto, Center for Emissions Control. Charlotte, NC.
290. Ross, J.S. and White, I.R. 1991. Eyelid dermatitis due to cocamidopropyl betaine in an eye make-up remover. Contact Dermatitis 25:64.
291. Rossberg, et al. 1986. Chlorinated hydrocarbons. In: Ullmann's Encyclopedia of Industrial Chemistry, 5th ed. VCH Publishers. New York, NY. pp. A-6:233-307.
292. Rothman, N., and E.A. Emmett. 1988. The carcinogenic potential of selected petroleum-derived products. State Art Rev Occup Med 3:475-494. [As cited in ATSDR (1995).]
293. Rowe, V.K., D.D. McCollister, H.C. Spencer, E.M. Adams, and D.D. Irish. 1952. Vapor toxicity of tetrachloroethylene for laboratory animals and human subjects. Arch Ind Hyg Occup Med 5:566-579. [As cited in ATSDR (1993).]
294. RTL. 1978. Research Testing Laboratories. Submission of unpublished data. Repeat insult patch test on a bubble bath containing 6 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-52.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

295. RTL. 1980. Research Testing Laboratories. Submission of unpublished data. Repeat insult patch test on a noncoloring shampoo containing 8 percent Lauramide DEA. CIR, Washington, DC. No. 2-32-71.
296. Ruder, A.M., E.M. Ward, and D. Brown. 1994. Cancer mortality in female and male dry-cleaning workers. Accepted for publication, *J of Occ Med*, and presented at the Women and Health: Occupation and Cancer Conference in Baltimore, MD, November 1993.
297. Safety Kleen. 1986. Dry cleaning waste market analysis. Materials from Safety Kleen presentation to USEPA. November 12.
298. Sax, N.I., and R.J. Lewis. 1987. *Hawley's Condensed Chemical Dictionary*, 11th ed. Van Nostrand Reinhold Company. New York, NY.
299. Schaefer H, Zesch A, Stuetzgen G. 1982. *Skin permeability*. London: Springer-Verlag.
300. Schreiber, J. (NYSDOH). 1992. An assessment of tetrachloroethane in human breast milk. *Journal of Exposure Analysis and Environmental Epidemiology*, Vol. 2, Suppl. 2.
301. Schreiber, J. 1993. Predicted infant exposure to tetrachloroethylene in human breast milk. *Risk Analysis* 13:515-524.
302. Schreiner, J. 1996. Personal communication between James Schreiner, Exxon Chemical Company, and Alice Tome, Abt Associates Inc.
303. Schumann, A.M., T.F. Quast, and P.G. Watanabe. 1980. The pharmacokinetics of perchloroethylene in mice and rats as related to oncogenicity. *Toxicol Appl Pharmacol* 55:207-219. [As cited in IRIS (1993).]
304. Schwetz, B.A., B.K. Leong, and P.J. Gehring. 1975. The effect of maternally inhaled trichloroethylene, perchloroethylene, methyl chloroform, and methylene chloride on embryonal and fetal development in mice and rats. *Toxicol Appl Pharmacol* 32:84-96.
305. Scott, J.L., G.E. Cartwright, and M.M. Wintrobe. 1959. Acquired aplastic anemia - an analysis of thirty-nine cases and review of the pertinent literature. *Medicine* 38:119-172. [As cited in ATSDR (1995).]
306. Seitz, W. 1995. Statement by William Seitz, Neighborhood Cleaners Association at the December 5 Phase II Stakeholders Meeting Washington, DC.
307. Seitz, W. 1996. Personal communication between William Seitz, National Cleaners Association, and Jonathan Greene, Abt Associates Inc. December 19.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

308. Setala K. 1960. Progress in carcinogenesis, tumor enhancing factors. A bio-assay of skin tumor formation. *Progr. Exp. Tumor Res.* 1:225- 278, as cited in CIR 1984.
309. Shaffer, W. 1995. Letter to Joseph Breen, USEPA, from William B. Shaffer Jr. on behalf of the Martinizing Environmental Group. September 22.
310. Sheldon, L., R. Handy, T. Hartwell, C. Leininger, and H. Zelon. 1985. Human exposure assessment to environmental chemicals - nursing mothers study. Prepared for USEPA by Research Triangle Institute. Research Triangle Park, NC.
311. Shell. 1994. Personal communication between a representative of Shell Chemicals and Michael Müller, Abt Associates Inc. March.
312. Siemiatycki, J., R. Dewar, L. Nadon, et al. 1987. Associations between several sites of cancer and twelve petroleum-derived liquids: Results from a case-referent study in Montreal. *Scand J Work Environ Health* 13:493-504.
313. Silva, L. 1993. Cleaning with carbon dioxide to eliminate waste. Pacific Northwest Laboratory, Innovative Concepts Program 392240. Richland, WA.
314. Singh, H.B., L.J. Salas, H. Shigeishi, A.J. Smith, E. Scribner, et al. 1979. Atmospheric distributions, sources and sinks of selected halocarbons, hydrocarbons, SF<sub>6</sub>, and N<sub>2</sub>O. EPA 600/3-79-107. U.S. Environmental Protection Agency. Research Triangle Park, NC. [As cited in Dimitriades et al. (1983).]
315. Singh, H.B., L.J. Salas, R. Stiles, and H. Shigeishi. 1981a. Measurements of hazardous organic chemicals in the ambient atmosphere. SRI Project 7774. Report prepared by Stanford Research Institute for the U.S. Environmental Protection Agency. Menlo Park, CA. [As cited in Dimitriades et al. (1983).]
316. Singh, H.B., L.J. Salas, and R. Stiles. 1981b. Trace chemicals in the clean atmosphere. EPA 600/3-81-055. U.S. Environmental Protection Agency. Research Triangle Park, NC. [As cited in Dimitriades et al. (1983).]
317. Smith, M.K., J.L. Randall, E.J. Read, and J.A. Stober. 1989. Teratogenic activity of trichloroacetic acid. *Teratology* 40:445-451. [As cited in Davidson and Beliles (1991).]
318. Smith, R. 1994. Personal communication between Richard Smith, Thermo- Energy, and Sue Hollenbeck, SAIC. June.
319. Smith, R. 1994. Personal communication between Richard Smith, Thermo- Energy Corporation, Palo Alto, California, and Jill Gendelman, USEPA. July 19. (Appendix A)

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

320. Smith, D. 1994. Personal communication between Dick Smith, Thermo-Energy Corp., and Alice Tome, Abt Associates Inc. December 14. (Chapter 6)
321. Smith, D. 1995. Personal communication between Dick Smith, Thermo-Energy Corp., and Cassandra De Young, Abt Associates Inc. January 3.
322. Solet, D., and T.G. Robins. 1991. Renal function in dry cleaning workers exposed to perchloroethylene. *Am J Ind Med* 20:601-614.
323. SRC. 1993a. Syracuse Research Corporation. National center for manufacturing sciences solvents database. Syracuse, NY. Version 1.5. July 1.
324. SRC. 1993b. Syracuse Research Corporation. LogKow Program. Version 1.10a. Syracuse, NY. July 18.
325. SRC. 1993c. Syracuse Research Corporation. Henry (estimation of Henry's law constant) program. Version 2.2. Syracuse, NY.
326. SRRP. 1992. Source Reduction Research Partnership. Source reduction and recycling of halogenated solvents in the dry cleaning industry. Technical support document. Metropolitan Water District of Southern California and the Environmental Defense Fund. Pasadena, CA.
327. Stanley, M. 1994. Personal communication between Mary Stanley, Cissell Manufacturing, and Cassandra De Young, Abt Associates Inc. August 23.
328. Starr, A. 1997. Personal communication between Anthony Starr, Center for Neighborhood Technologies, and Alice Tome, Abt Associates Inc. May.
329. State Environmental Protection Agency. 1992. The measurements of tetrachloroethylene concentrations in the work rooms of dry cleaning establishments and in rooms adjacent to dry cleaners in the German state of Baden-Wurtemberg. Final report. Translated by Abt Associates Inc. for USEPA. Hertzstrasse, Germany.
330. Stewart, R.D. 1969. Acute tetrachloroethylene intoxication. *J Am Med Assoc* 208(8):1490-1492. [As cited in USEPA (1985).]
331. Stewart, R.D., C.L. Hake, H.V. Forster, et al. 1981. Tetrachloroethylene: Development of a biologic standard for the industrial worker by breath analysis. Contract no. HSM 99-72-84. PB82-152166. National Institute for Occupational Safety and Health. Cincinnati, OH.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

332. Stork, B. 1994. Personal communication between Bill Stork, ArtiChill, and Cassandra De Young, Abt Associates Inc. August 15.
333. Suissa, S. 1996. Personal communication between Sam Suissa, Omega Cleaning Systems, and Alice Tome, Abt Associates Inc. August 4.
334. Sullivan, G. 1996. Personal communication between Gail Sullivan, Abt Associates Inc., and Jonathan Greene, Abt Associates Inc. December 19.
335. Szmigielski, S., A. Szymdzinski, A. Pietraszek, M. Bielec, M. Janiak, and J.K. Wrembel. 1982. Accelerated development of spontaneous and benzopyrene-induced skin cancer in mice exposed to 2450-MHz microwave radiation. *Bioelectromagnetics* 3:179-191. [As cited in Elder (1994).]
336. Taniguchi, S., Katoh, J., Hisa, T., Tabata, M., Hamada, T. 1992. Shampoo dermatitis due to cocamidopropyl betaine. *Contact Dermatitis* 26:139.
337. Tchobanoglous, G., and F. Burton. 1991. *Wastewater Engineering: Treatment, Disposal, and Reuse*. 3rd ed. McGraw-Hill, Inc. New York, NY. pp. 71-82.
338. Tepe, S.J., M.K. Dorfmueller, R.G. York, and J.M. Manson. 1982. Teratogenic evaluation of perchloroethylene in rats. Unpublished. [As cited in USEPA (1985).]
339. Till, J. 1994. Personal communication between Jamie Till and Tom Abbott, Dynaclean, and Sharon Dubrow, SAIC. September.
340. Tirell, D.C. 1989. Dry cleaning. In: *Ullmann's Encyclopedia of Industrial Chemistry*, 5th ed. VCH Publishers. New York, NY. pp. A9:49-53.
341. Tolley, G.S. et al. 1986. Valuation of reduction in human health symptoms and risks. Final report. Prepared by the University of Chicago for USEPA. January. [As cited in Unsworth and Neumann (1993).]
342. Tuohimaa P, and Wichmann L. 1981. Sperm production of men working under heavy-metal or organic solvent exposure. In: Hemminki K, Sorsa M, Vainio H, eds. *Occupational hazards and reproduction*. Washington DC: Hemisphere Publishing Corp., 73-79. [As cited in ATSDR(1993).]
343. TURI. 1996. Toxic Use Reduction Institute. Training curriculum for alternative clothes cleaning. Draft final report. Lowell, MA.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

344. Turner R. and S. Lutz. 1979. Application of carbon adsorption to petroleum dry cleaning emissions. Paper presented at APCA/WPCF Control of Specific (Toxic) Pollutants Conference, Florida, February 13-16. p. 263.
345. UCD. Undated. Unocal Chemicals Division. 140 solvent 66/3 product description. Schaumburg, IL.
346. Unimac. 1994. Unimac Wet Cleaning Models UF160W and UFF230W. Commercial Laundry Equipment. Marion, FL.
347. Unsworth, R.E., and J.E. Neumann. 1993. Industrial Economics, Incorporated. Review of existing value of morbidity avoidance estimates: Draft valuation document. Memorandum to Jim DeMocker, USEPA Office of Policy Analysis and Review. September 30.
348. Unsworth, A. 1994. Personal communication between Allan Unsworth, Department of Commerce, International Trade Administration, Office of Trade and Economic Analysis, and Rob Funk, Abt Associates Inc. December 19.
349. USEPA. 1975. U.S. Environmental Protection Agency. Report on the problem of halogenated air pollutants and stratospheric ozone. EPA 600/9-75-008. USEPA, Office of Research and Development. Research Triangle Park, NC. (Chapter 2)
350. USEPA. 1982. U.S. Environmental Protection Agency. Petroleum dry cleaners: background information for proposed standards. Draft EIS. Office of Air Quality, Planning and Standards. Research Triangle Park, NC. (Chapters 1, 8 & Appendix B)
351. USEPA. 1982a. U.S. Environmental Protection Agency. Guideline series: Control of volatile organic compound emissions from large petroleum dry cleaners. EPA-450/3-82-009. USEPA, Office of Air Quality Planning and Standards. Research Triangle Park, NC. (Chapter 3)
352. USEPA. 1982b. U.S. Environmental Protection Agency. Petroleum dry cleaners: Background information for proposed standards. Draft environmental impact statement. USEPA, Office of Air Quality Standards. Research Triangle Park, NC. (Chapter 3)
353. USEPA. 1984. U.S. Environmental Protection Agency. Estimating concern levels for concentrations of chemical substances in the environment. USEPA, Office of Pollution Prevention and Toxics, Health and Environmental Review Division (7403), Environmental Effects Branch. Washington, DC. (Chapter 2)
354. USEPA. 1984a. U.S. Environmental Protection Agency. Summary of histopathology findings for dermal carcinogenesis lifetime skin painting study of solvent-cutback type

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

- rust preventative. Document no. 88-8400629. USEPA, Office of Toxic Substances. Washington, DC. (Appendix A)
355. USEPA. 1984b. U.S. Environmental Protection Agency. Biological Effects of Radiofrequency Radiation. J. Elder and D. Cahill, Eds. EPA-600/8-83-026F. Health Effects Research Laboratory. Research Triangle Park, NC. (Appendix A)
356. USEPA. 1985. U.S. Environmental Protection Agency. Health assessment document for tetrachloroethylene (perchloroethylene). EPA/600/8-82/005F. PB-85-249704/AS. USEPA, Office of Health and Environmental Assessment. Washington, DC. (Chapter 4, Appendices A, B, C)
357. USEPA. 1986. U.S. Environmental Protection Agency. The Total Exposure Assessment Methodology (TEAM) Study: Summary and analysis. USEPA, Office of Acid Deposition, Environmental Monitoring and Quality Assurance. (Chapters 3 & 4)
358. USEPA. 1986. U.S. Environmental Protection Agency. Addendum to the health assessment document for tetrachloroethylene (perchloroethylene). Updated carcinogenicity assessment for tetrachloroethylene (Perchloroethylene, PERC, PCE). Review Draft. EPA/600/8-82/005FA. (Appendix A)
359. USEPA. 1986a. U.S. Environmental Protection Agency. Addendum to the health assessment document for tetrachloroethylene (perchloroethylene). Updated carcinogenicity assessment for tetrachloroethylene (perchloroethylene, PERC, PCE). Review draft. EPA /600/8-82/005FA. (Appendix C)
360. USEPA. 1986b. U.S. Environmental Protection Agency. Risk assessment guidelines. EPA/600/8-87/045. Washington, DC. (Appendix C)
361. USEPA. 1987. U.S. Environmental Protection Agency. A reassessment of the biological effects of radiofrequency radiation non-cancer effects. USEPA, Office of Radiation Programs, Health Effects Research Laboratory. Research Triangle Park, NC. July 21. (Appendix A)
362. USEPA. 1988. U.S. Environmental Protection Agency. Health effects assessment for tetrachloroethylene. EPA/600/8-89/096. USEPA, Office of Research and Development, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. Cincinnati, OH. (Appendix A)
363. USEPA. 1988. U.S. Environmental Protection Agency. Evaluation of perchloroethylene emissions from dry cleaned fabrics. EPA 600/2-88-061. USEPA, Air and Energy Engineering Research Laboratory. Research Triangle Park, NC. October. (Chapters 3, 4, Appendix B)



**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

364. USEPA. 1988. U.S. Environmental Protection Agency. Options for regulating PCE emissions in the dry cleaning industry: a cost-benefit analysis. Draft report. Office of Pesticides and Toxic Substances. Washington, DC. (Chapter 6)
365. USEPA. 1989. U.S. Environmental Protection Agency. Exposure Factors Handbook. USEPA, Office of Health and Environmental Assessment, Exposure Assessment Group. (Chapter 3)
366. USEPA. 1989. Exposure Factors Handbook. Office of Health and Environmental Assessment, Exposure Assessment Group. (Appendix B)
367. USEPA. 1990. U.S. Environmental Protection Agency. Drycleaning and laundry plants, RCRA/Superfund fact sheet. EPA/530-SW-90-027b. Draft environmental impact statement. EPA-450/3-91-020a. Office of Air Quality, Planning and Standards. Washington, DC. (Chapter 6)
368. USEPA. 1991. U.S. Environmental Protection Agency. Dry cleaning facilities - background information for proposed facilities. Draft environmental impact statement. EPA-450/3-91-020a. USEPA, Office of Air Quality, Planning and Standards. Washington, DC. November. (Chapter 3)
369. USEPA. 1991. U.S. Environmental Protection Agency. Response to issues and data submissions on the carcinogenicity of tetrachloroethylene (perchloroethylene). EPA/600/6-91/002F. USEPA. 1991. (Executive Summary, Appendix C)
370. USEPA. 1991. U.S. Environmental Protection Agency. Response to issues and data submissions on the carcinogenicity of tetrachloroethylene (perchloroethylene). EPA/6006-91/002R. (Chapter 4)
371. USEPA. 1991a. U.S. Environmental Protection Agency. Dry cleaning facilities - background information for proposed facilities. Draft EIS. EPA-450/3-91-020a. Office of Air Quality, Planning and Standards. November. (Chapter 1)
372. USEPA. 1991a. U.S. Environmental Protection Agency. Dry cleaning facilities - background information for proposed facilities. Draft environmental impact statement. EPA-450/3-91-020a. Office of Air Quality, Planning and Standards. Washington, DC. November. (Chapter 6)
373. USEPA. 1991a. U.S. Environmental Protection Agency. Response to issues and data submissions on the carcinogenicity of tetrachloroethylene (perchloroethylene). EPA/600/6-91/002F. (Appendix A)

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

374. USEPA. 1991b. U.S. Environmental Protection Agency. Economic impact analysis of regulatory controls in the dry cleaning industry. Final. EPA-450/3-91-021. Office of Air Quality, Planning and Standards. October. (Chapters 1 & 6)
375. USEPA. 1991b. U.S. Environmental Protection Agency. Guidelines for developmental toxicity risk assessment. Notice. 56(234) FR 63798. (Appendix A)
376. USEPA. 1992. U.S. Environmental Protection Agency. Protection of Stratospheric Ozone: Final Rule. (57 FR 33754). (Chapter 2)
377. USEPA. 1992. U.S. Environmental Protection Agency. Preliminary economic assessment of transfer enclosure requirements in the dry cleaning industry. USEPA, Office of Air Quality Planning and Standards. Research Triangle Park, NC. August. (Chapter 4)
378. USEPA. 1992. U.S. Environmental Protection Agency. EMF in your environment: Magnetic measurements of everyday electrical devices. Office of Radiation and Indoor Air. Washington, DC, 20460. EPA 402-R-92-008. (Appendix A)
379. USEPA. 1992. U.S. Environmental Protection Agency. A cross-species scaling factor for carcinogen risk-assessment based on equivalence of  $\text{mg/kg}^{3/4}/\text{day}$ . Draft report. (57(109) FR 24152-24). (Appendix C)
380. USEPA. 1992a. U.S. Environmental Protection Agency. Preliminary economic assessment of transfer enclosure requirements in the dry cleaning industry. Office of Air Quality Planning and Standards. Research Triangle Park, NC. August. (Chapter 1)
381. USEPA. 1992a. U.S. Environmental Protection Agency. USEPA proceedings: international round table on pollution prevention and control in the dry cleaning industry. May 27-28. (Chapter 3)
382. USEPA. 1992b. U.S. Environmental Protection Agency. International roundtable on pollution prevention and control in the dry cleaning industry. EPA/774/R-92/002. Office of Pollution Prevention and Toxics. Washington, DC. (Chapter 1, Appendix B)
383. USEPA. 1992b. U.S. Environmental Protection Agency. Preliminary economic assessment of transfer enclosure requirements in the dry cleaning industry. USEPA, Office of Air Quality Planning and Standards. Research Triangle Park, NC. August. (Chapter 3)
384. USEPA. 1992c. U.S. Environmental Protection Agency. Guidelines for exposure assessment. (57 FR 22932). (Chapter 3)

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

385. USEPA. 1993. U.S. Environmental Protection Agency. Economic analysis of air pollution regulations: dry cleaning industry. RTI Project Number 5428-33 DR. Office of Air Quality, Planning and Standards. Research Triangle Park, NC. September. (Chapter 8)
386. USEPA. 1993. U.S. Environmental Protection Agency. Dry cleaning industry MACT standard. Briefing for the Deputy Administrator. USEPA, Office of Air and Radiation. May 24. (Appendix A)
387. USEPA. 1993a. U.S. Environmental Protection Agency. Dry cleaning facilities - Background information for promulgated standards. Final EIS. EPA 450/3-91-020b. Office of Air Quality Planning and Standards. Research Triangle Park, NC. September. (Chapter 1)
388. USEPA. 1993a. U.S. Environmental Protection Agency. Dry cleaning industry MACT standard. Briefing for the Deputy Administrator. USEPA, Office of Air and Radiation. May 24. (Chapter 3)
389. USEPA. 1993a. Dermal Model User's Guide. Prepared by Versar for the Office of Pollution Prevention and Toxics. (Appendix B)
390. USEPA. 1993a. U.S. Environmental Protection Agency. Multiprocess wet cleaning cost and performance comparison of conventional dry cleaning and an alternative process. EPA 744-R-93-004. Office of Pollution Prevention and Toxics. Washington, DC. (Chapter 6)
391. USEPA. 1993b. U.S. Environmental Protection Agency. Economic impact analysis of regulatory controls in the dry cleaning industry. EPA450/3-91-021b. Office of Air Quality Planning and Standards. Research Triangle Park, NC. (Chapter 1)
392. USEPA. 1993b. U.S. Environmental Protection Agency. National emission standards for hazardous air pollutants for source categories: Perchloroethylene dry cleaning facilities. Final Rule. (58 FR 49354). (Chapter 3)
393. USEPA. 1993b. U.S. Environmental Protection Agency. Economic analysis of air pollution regulations: dry cleaning industry. RTI Project Number 5428-33 DR. Office of Air Quality, Planning and Standards. Research Triangle Park, NC. September. (Chapter 6)
394. USEPA. 1993b. Exposure Assessment Branch revised exposure report for the TRI listing of phosphine. (Appendix B)

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

395. USEPA. 1993c. U.S. Environmental Protection Agency. Multiprocess wet cleaning cost and performance comparison of conventional dry cleaning and an alternative process. EPA 744-R-93-004. USEPA, Office of Pollution Prevention and Toxics. Washington, DC. (Chapter 3)
396. USEPA. 1993d. U.S. Environmental Protection Agency. Dermal Model User's Guide. Prepared by Versar for the Office of Pollution Prevention and Toxics. (Chapter 3)
397. USEPA. 1994. U.S. Environmental Protection Agency. AQUIRE (Aquatic toxicity information retrieval database). USEPA, Office of Research and Development, Environmental Res. Labs., Scientific Outreach Program. Duluth, MN. (Chapters 2 & 4)
398. USEPA. 1994. U.S. Environmental Protection Agency. External review draft: Aqueous and terpene cleaning: Interim report. USEPA, Office of Toxic Substances. Washington, DC. September 16. (Appendix A)
399. USEPA. 1994a. U.S. Environmental Protection Agency. Dry cleaning - cleaner technologies substitutes assessment - phase I. Draft. Office of Pollution Prevention and Toxics, Design for the Environment. December. (Chapter 6)
400. USEPA. 1994b. U.S. Environmental Protection Agency. Dry cleaning - phase II clean technology substitutes assessment. Draft. Office of Pollution Prevention and Toxics, Chemical Engineering Branch. Washington, DC. August. (Chapter 6)
401. USEPA. 1995. U.S. Environmental Protection Agency. Profile of the dry cleaning industry. EPA 310-R-95-001. USEPA, OECA. Washington, DC. (Chapter 2)
402. USEPA. 1995. Draft guidelines for completing the initial review exposure report. (Chapter 3, Appendix B)
403. USEPA. 1996. U.S. Environmental Protection Agency. Proposed guidelines for carcinogen risk assessment. EPA/600/p-92/003Ca. April. (Chapter 4, Appendix C)
404. USEPA. 1996a. U.S. Environmental Protection Agency. Plain English guide for perc dry cleaners: a step by step approach to understanding federal environmental regulations. EPA 305-B-96-002. USEPA, OECA. Washington, DC. (Chapter 2)
405. USEPA. 1996b. U.S. Environmental Protection Agency. Cleaner Technologies Substitute Assessment: Lithographic Blanket Washes. EPA 744-R-95-008. USEPA, OPPT. Washington, DC. (Chapter 2)
406. Van Waters and Rogers. 1994. Personal communication between customer service representative of Van Waters and Rogers and Michael Müller, Abt Associates Inc.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

407. Vecellio, C. 1996. FTC care labeling revisions. EPA 744-R-96-002. Presented at Conference on Apparel Care and the Environment: Alternative Technologies and Labeling, Washington. September. pp. 147-153.
408. Verkkala, E., P. Pfaffi, and H. Savolainen. 1984. Comparison of local neurotoxicity of three white spirit formulations by percutaneous exposure of rat tail nerve. *Toxicol Lett* 21:293-299.
409. Vernot, E.H., R.T. Drew, and M.L. Kane. 1990. Acute toxicologic evaluation of unleaded motor gasoline. Abstract. *Acute Toxic Data* 1:28. [As cited in ATSDR (1995).]
410. Versar. 1986. Versar, Inc. Standard scenarios for estimating exposure use of consumer products. Vol. 1. Prepared under EPA Contract No. 68-02-3968. September.
411. Versar. 1987. Versar, Inc. Physical/chemical properties, environmental fate and mobility, and monitoring data for six halogenated solvents. Prepared by VERSAR, Inc. under Contract No. 68-02-4254, Task 43. USEPA, Office of Pollution Prevention and Toxics. July 31.
412. Vilaplana, J., Mascaro, J.M., Trullas, C., Coll, J., Romaguera, C., Zemba, C., Pelejero, C. 1992. Human irritant response to different qualities and concentrations of cocoamidopropyl-betaines: a possible model of paradoxical irritant response. *Contact Dermatitis* 26:289-294.
413. Villareal, J. 1994. Personal communications between Joe Villareal, Marvel, and Cassandra De Young, Abt Associates Inc. August 11 and 22.
414. Vu, V. 1997. Memorandum titled "Provisional RfC for perchloroethylene." From Vanessa Vu, Acting Director, Health and Environmental Review Division, to William Waugh, Acting Director, Chemical Screening and Risk Assessment Division, OPPT, USEPA.
415. Weishaar, R. 1997. Personal communications between Ray Weishaar, Raytheon Corporation Commercial Products Division, and Jonathan Greene, Abt Associates Inc. February 19.
416. Weissler, B. 1994. Personal communications between Bill Weissler, Diversitron, and Cassandra De Young, Abt Associates Inc. August 16 and 22.
417. Wentz, M., and W. Fisher. 1973. Perchloroethylene vapor in dry cleaning plants. Special report. International Fabric Institute. pp. 1-14. [As cited in Versar (1987).]

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

418. Wentz, M. 1993. Personal communication between Manfred Wentz, R.R. Street & Co., and Michael Müller, Abt Associates Inc. August/September.
419. Wentz, M. 1995. Personal communication between Manfred Wentz, R.R. Street & Co., and Alice Tome, Abt Associates Inc. January.
420. Wentz, M. 1996. The status of wet cleaning in Canada: the concept of textile care process spectra. Presented at Conf. on Global Experience and New Developments in Wet Cleaning Technology. Schloss Hohenstein, Boennigheim. June. p. 20-25.
421. Wessler, B. 1994. Personal communication between Bill Wessler, Diversitron, and Sharon Dubrow, SAIC. September.
422. Westat. 1987. Westat, Inc. Household solvent products: A national usage survey. Prepared for USEPA, Office of Pollution Prevention and Toxics, under Contract No. 68-02-4243. July.
423. Wieser, D. 1997. Personal communication between Diane Wieser, Ecomat Franchises Inc., and Jonathan Greene, Abt Associates Inc. January 7.
424. Wilcock, A. 1996. Personal communication between Anne Wilcock, University of Guelph - Textile Science Group, and Jonathan Greene, Abt Associates Inc. November 12.
425. Wittels, E., J.W. Hay, and A.M. Gotto. 1990. Medical costs of coronary artery disease in the United States. *The American Journal of Cardiology* 65:432-440.
426. Wolf, K. 1992. Case study: Pollution prevention in the dry cleaning industry: A small business challenge for the 1990s. *Pollution Prevention Review*. Summer.
427. Wolfsdorf, J., and H. Kundig. 1972. Kerosene poisoning in primates. *S Afr Med J* 46(20):619-621.
428. Zaqeski, F. Undated. Personal communication between F. Zaqeski, New York State Department of Environmental Conservation (NYSDEC), and Mary Katherine Powers, USEPA/OPPT/EETD.
429. Zeeman, M.G., and J. Gilford. 1993. Ecological hazard evaluation and risk assessment under EPA's Toxic Substances Control Act (TSCA): An introduction. *Environmental Toxicology and Risk Assessment*. ASTM STP 1179. W.G. Landis, J.S. Hughes, and M.A. Lewis, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 7-21.

**DO NOT CITE, QUOTE, DISTRIBUTE OR RELEASE**

430. Zeeman MG, Nabholz JV, Clements RG. 1993b. The development of SAR/QSAR for use under EPA's Toxic Substances Control Act (TSCA): An introduction. Environmental Toxicology and Risk Assessment. 2nd Volume. ASTM STP 1216. J.W. Gorsuch, F.J. Dwyer, C.G. Ingersoll, and T.W. La Point, Eds. American Society for Testing and Materials. Philadelphia, PA. pp. 523-539.
431. Zielhuis, GA, Gijssen R, Van Der Gulden JWJ. 1989. Menstrual disorders among dry-cleaning workers. Scand J Work Environ Health 15:238. [As cited in ATSDR (1995).]
432. Zwicker GM, Allen MD, Stevens DL. 1979. Toxicity of aerosols of sodium reaction products. J Environ Pathol Toxicol 2:1139-1150; as cited in Busch et al. 1983.

## **APPENDIX E**

### **Index to Administrative Record #199**



**INDEX to Administrative Record #199**

of the  
Technical Peer Review of the US EPA Report:  
*Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*  
EPA 744-B-98-001, June 1998

- A. **Office of Prevention, Pesticides and Toxic Substances STANDARD OPERATING PROCEDURES FOR PEER REVIEW OF MAJOR SCIENTIFIC AND TECHNICAL DOCUMENTS, October 1, 1996 - September 30, 1997**, under which this technical peer review was conducted.
- B. **The official technical peer review version of the *Cleaner Technologies Substitutes Assessment for Fabricare: Including Wet and Dry Cleaning Technologies, (CTSA) July 1997***. (NOTE: After the peer review was completed, the final document title was changed to: *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*).
- C. **Materials and information sent to peer reviewers during course of peer review**
1. July 21, 1997 letter from Bruce E. Buxton, Ph.D., Battelle Program Manager, mailed to 29 peer reviewers who were to be paid for their review, requesting information and transmitting a non-disclosure agreement and contracts information. With enclosures:
    - a. *Peer Reviewer Non-Disclosure Agreement*
    - b. *Battelle's Special and General Provisions Technical Services for Government Time and Material, Labor Hour Contracts*
  2. July 21, 1997 letter from Bruce E. Buxton, Ph.D., Battelle Program Manager, mailed to 11 peer reviewers who were not to be paid for their review, requesting information and transmitting a non-disclosure agreement. With enclosure:
    - a. *Peer Reviewer Non-Disclosure Agreement*
  3. July 25, 1997 letter from Bruce Buxton, Ph.D., Battelle Program Manager, mailed to 40 peer reviewers and transmitting the official peer review version of the fabricare CTSA. Specific guidance to the reviewers and a list of references cited in the CTSA were bound into each official peer review copy of the CTSA:
    - a. Reminder page to return signed non-disclosure agreement to Battelle
    - b. Bound in the front of each peer review copy: **July 1977 Charge to CTSA Peer Reviewers**
    - c. Bound at the end of each peer review copy: **July 1997 Peer Review Reference List** of all references that were cited in the peer review version of the fabricare CTSA.

4. August 6, 1997 letter from Bruce Buxton, Ph.D., Battelle Program Manager, faxed to 40 peer reviewers, clarifying carcinogenic potential of perchloroethylene. With enclosure:
  - a. August 6, 1997 *Clarification for CTSA Peer Reviewers of EPA's Position on the Carcinogenic Potential of Perchloroethylene (Perc)*
5. August 14, 1997, letter from Brandon Wood, Battelle CTSA Task Leader, to Kimberly Thompson, Dr.S., transmitting requested references from peer review version of CTSA. With the following list of enclosures (see AR Section C3c for actual references):
  - a. List of references sent to K. Thompson

**D. Comments, information, and materials received from the peer reviewers**

1. Signed Non-Disclosure Agreements from 40 peer review panelists
2. Proposals from panelists that were to be paid for their review
3. Invoices submitted to Battelle from panelists that were to be paid for their review
4. Original comments and additional materials as submitted by the 36 peer reviewers that responded
5. List of additional materials submitted by each peer reviewer

**E. Information about the peer reviewers**

1. List of 40 technical peer reviewers on the panel and their affiliations
2. Biosketches submitted by peer reviewers
3. Table of the 113 nominated candidate reviewers and detailed information on their technical expertise, who nominated them, and why they were or were not on the panel.

- F. Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Peer Review Process, EPA 744-S-98-002, June 1998.** (NOTE: This EPA report summarizes the entire process that was followed for the technical peer review of the fabricare CTSA, how the panel was selected, all logistical information, and the results. This report was prepared for stakeholders and other interested parties, and to document the peer review process from start to finish as part of this Administrative Record.)

- G. Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Response to Peer Review Comments, EPA 744-P-98-001, June 1998**

**H. Final CTSA and related documents**

1. *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*, EPA 744-B-98-001, June 1998 (final CTSA)
2. *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: SUMMARY*, EPA 744-S-98-001, June 1998 (summary version abstracted directly from the full CTSA)
3. **Federal Register Notice of Availability of CTSA and Summary CTSA**
4. *Fact Sheet: Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*, EPA 744-F-98-011, June 1998

5. *Frequently Asked Questions About Drycleaning*, EPA 744-K-98-002, June 1998

- I. **Indexed list and a copy of each of the 404 references cited in the final published report: *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes***, EPA 744-B-98-001, June 1998

REPORT DOCUMENTATION PAGE	1. REPORT NO. EPA 744-S-98-002	2.	3. Recipient's Accession No.
4. Title and Subtitle  Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes: Peer Review Process		5. Report Date: June 1998	
7. Author(s) Brandon J. Wood, Melinda Armbruster		6.	
8. Performing Organization Rept. No.		9. Performing Organization Name and Address  Battelle Memorial Institute 505 King Avenue Columbus, Ohio 43201-2693	
10. Project/Task/Work Unit No. G003470-0108		11. Contract(C) or Grant(G) No.  (C) 68-D5-0008  (G)	
12. Sponsoring Organization Name and Address  U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics (7401) 401 M Street, S.W. Washington, D.C. 20460		13. Type of Report & Period Covered Final Report	
14.		15. Supplementary Notes	
16. Abstract (Limit 200 words)  This report presents the general approach and considerations taken into account for conducting the peer review of the <i>Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes</i> , EPA 744-B-98-001. The objective of the peer review was conducted to uncover any technical problems or unresolved issues for use in revising the preliminary work product so that the final work product reflects sound technical information and analyses and enhance the scientific technical work product. The review process began with a conference call between CTSA stakeholders and EPA on July 24, 1998. The peer review panel consisted 40 reviewers, each of whom was specialized in at least one of the four following categories: Technology and Economics, Exposure Assessment, Hazard Assessment, and Risk Assessment. The panel encompasses a large, balanced independent panel of experts from the dry cleaning industry and the environmental and scientific communities. Peer reviewers of the CTSA document submitted a total of 1,855 comments comprising 340 pages. The EPA Technical Workgroup in charge of developing and revising the CTSA document based on reviewers' comments drafted responses to every peer review comment. Additional investigations and revisions were made to the CTSA document based on the peer review comments.			
17. Document Analysis  a. Descriptors: drycleaning, wetcleaning, perchloroethylene, PCE ? b. Identifiers/Open-Ended Terms: Possible carcinogens, pollution prevention ? c. COSATI Field/Group: Not applicable			
18. Availability Statement EPA Docket AR-199 NCEPI: (800) 490-9198		19. Security Class (This Report) Unclassified	21. No. of Pages 146
		20. Security Class (This Page) Unclassified	22. Price