

CHEMICAL HERITAGE FOUNDATION

**THE TOXIC SUBSTANCES CONTROL ACT:
FROM THE PERSPECTIVE OF
CHARLES M. AUER**

Transcript of Interviews
Conducted by

Jody A. Roberts and Kavita D. Hardy

in

Washington, D.C.

on

23 April 2010

(With Subsequent Corrections and Additions)

CHEMICAL HERITAGE FOUNDATION
Oral History Program
FINAL RELEASE FORM

This document contains my understanding and agreement with the Chemical Heritage Foundation with respect to my participation in the audio- and/or video-recorded interview conducted by Jody Roberts and Kavita Hardy on 23 April 2010. I have read the transcript supplied by the Chemical Heritage Foundation.

1. The recordings, transcripts, photographs, research materials, and memorabilia (collectively called the "Work") will be maintained by the Chemical Heritage Foundation and made available in accordance with general policies for research and other scholarly purposes.
2. I hereby grant, assign, and transfer to the Chemical Heritage Foundation all right, title, and interest in the Work, including the literary rights and the copyright, except that I shall retain the right to copy, use, and publish the Work in part or in full until my death.
3. The manuscript may be read and the recording(s) heard/viewed by scholars approved by the Chemical Heritage Foundation subject to the restrictions listed below. The scholar pledges not to quote from, cite, or reproduce by any means this material except with the written permission of the Chemical Heritage Foundation. Regardless of the restrictions placed on the transcript of the interview, the Chemical Heritage Foundation retains the rights to all materials generated about my oral history interview, including the title page, abstract, table of contents, chronology, index, et cetera (collectively called the "Front Matter and Index"), all of which will be made available on the Chemical Heritage Foundation's website. Should the Chemical Heritage Foundation wish to post to the internet the content of the oral history interview, that is, direct quotations, audio clips, video clips, or other material from the oral history recordings or the transcription of the recordings, the Chemical heritage Foundation will be bound by the restrictions for use placed on the Work as detailed below.
4. I wish to place the conditions that I have checked below upon the use of this interview. I understand that the Chemical Heritage Foundation will enforce my wishes until the time of my death, when any restrictions will be removed.

Please check one:

- a. _____ **No restrictions for access.**
NOTE: Users citing this interview for purposes of publication are obliged under the terms of the Chemical Heritage Foundation Oral History Program to obtain permission from Chemical Heritage Foundation, Philadelphia, Pennsylvania.
- b. CA _____ **Semi-restricted access.** (May view the Work. My permission required to quote, cite, or reproduce.)
- c. _____ **Restricted access.** (My permission required to view the Work, quote, cite, or reproduce.)

This constitutes my entire and complete understanding.

(Signature)


Charles M. Auer

(Date)

6/29/10

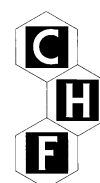
This interview has been designated as **Semi Restricted Access**.

One may view the oral history with the permission of CHF.
However, the permission of the interviewee is required to quote from, cite,
or reproduce the oral history.

Please contact CHF to request permission.



Chemical Heritage Foundation
Oral History Program
315 Chestnut Street
Philadelphia, Pennsylvania 19106



The Chemical Heritage Foundation (CHF) serves the community of the chemical and molecular sciences, and the wider public, by treasuring the past, educating the present, and inspiring the future. CHF maintains a world-class collection of materials that document the history and heritage of the chemical and molecular sciences, technologies, and industries; encourages research in CHF collections; and carries out a program of outreach and interpretation in order to advance an understanding of the role of the chemical and molecular sciences, technologies, and industries in shaping society.

CHARLES M. AUER

1952 Born in Baltimore, Maryland on 18 June

Education

1974 B.S., Biochemistry, University of Maryland, College Park

Professional Experience

U.S. Environmental Protection Agency, Washington, D.C.

1976-1985 Staff chemist, Office of Toxic Substances

1985-1988 Section Chief, Metabolism and Structure Activity Section, Office of Toxic Substances

1985-1988 Branch Chief, New Chemicals Assessment Branch, Office of Toxic Substances

1988-1989 Deputy Director, Health and Environmental Review Division, Office of Toxic Substances

1989-1992 Director, Existing Chemical Assessment Division, Office of Pollution Prevention and Toxics

1992-2002 Director, Chemical Control Division, Office of Pollution Prevention and Toxics

2002-2009 Director, Office of Pollution Prevention and Toxics

2009-Present Charles Auer and Associates, Poolesville, Maryland
President

2009-Present Bergeson & Campbell, P.C., Washington, D.C.
Affiliate

Honors

1979 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency

1981 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency

1983 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency

1985 Dr. Joseph Seifter Memorial Award in Toxicology, U.S. Environmental Protection Agency

- 1987 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency
- 1989 Dr. Joseph Seifter Memorial Award in Regulatory Science, U.S. Environmental Protection Agency
- 1989 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency
- 1989 Lee M. Thomas Excellence in Management Award, U.S. Environmental Protection Agency
- 1991 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency
- 1994 Bronze Medal for Commendable Service, U.S. Environmental Protection Agency
- 2008 Award for Sustained Outstanding Contributions to International Environmental Protection, U.S. Environmental Protection Agency
- 2008 Presidential Rank Award, Meritorious Executive, Senior Executive Service
- 2008 Gold Medal, Distinguished Career Service Award, U.S. Environmental Protection Agency

ABSTRACT

Charles M. Auer joined the EPA's Office of Toxic Substances, before the Toxic Substances Control Act (TSCA) was passed, as an entry level chemist doing screening-level risk assessments. He was the first chair of the Structure Activity Team, which was responsible for developing structure activity relationship (SAR) analysis as a method for evaluating new chemicals. While it was clear to Auer that there was never any question that SAR satisfied the legal requirements of TSCA's Section 4 premanufacture review, he witnessed several studies to verify the validity of SAR results, including a joint effort between the EPA and European Union in the early 1990s. By this time Auer was Director of the Existing Chemical Assessment Division, where SARs were not as heavily relied upon. As a division director, Auer found it difficult to prioritize existing chemicals, primarily because Inventory Update Rules were not issued to collect changing hazard and exposure information; the EPA attempted other, more voluntary methods to collect data, to varying degrees of success.

Auer believes that the Office has been very innovating, adjusting to emerging science on toxicity and applying TSCA while staying within its legal limits, and that the key to an effective toxics program is to be as dynamic as the chemical industry.

INTERVIEWERS

Jody A. Roberts is the Associate Director for the Center for Contemporary History and Policy and the Manager of the Environmental History and Policy Program at the Chemical Heritage Foundation. Roberts received his Ph.D. and M.S. in Science and Technology Studies from Virginia Tech and holds a B.S. in Chemistry from Saint Vincent College. His research focuses on the intersections of regulation, innovation, environmental issues, and emerging technologies within the chemical sciences.

Kavita D. Hardy is a research assistant in the Environmental History and Policy Program at the Chemical Heritage Foundation. She received a B.A. in Chemistry and Economics from Swarthmore College.

TABLE OF CONTENTS

Early career	1
Bachelor's degree in biochemistry. Joining the Office of Toxic Substances. Risk assessments. Waterside Mall and Sick Building Syndrome.	
Structure activity relationship (SAR) analysis	4
Structure Activity Team and Joseph Seifter. Development of SARs. EU/US validation study. Europe's base data set requirements. Application of structure activity to existing chemicals.	
Implementation of the Toxic Substances Control Act	12
Prioritization of existing chemicals. Limited Section 4 authority. HPV Challenge. Enforceable consent agreements. Emerging science. Interagency cooperation. Confidential business information.	
Recent Challenges and Developments	18
Increasing stakeholder interest. PFOA Stewardship Program. Use of Significant New Use Rules. Corrosion Proof Fittings. Nanotechnology. Industry dynamism. Inventory Update Rules. Variety of Office responsibilities. International cooperation and standards.	
Index	27

INDEX

- 3**
3M Company, 19
- 4**
4-PCH (4-phenylcyclohexene), 2, 3
- A**
Agnew, Spiro T., 2
Albert, Adrien, 5
asbestos, 20, 24
- B**
Berlin, Germany, 8
- C**
CBI. *See* Toxic Substances Control Act (TSCA): confidential business information
CDC. *See* Centers for Disease Control and Protection
Centers for Disease Control and Protection (CDC), 18
Chemical Hazard Information Profiles (CHIP) documents, 1
CHIP. *See* Chemical Hazard Information Profiles
Congress, 1, 4, 7, 13, 16, 20, 21
Corrosion Proof Fittings v. EPA, 20
Court of Appeals for the Fifth Circuit, 20
- E**
EDF. *See* Environmental Defense Fund
Elkins, Charles L., 18
Environmental Defense Fund (EDF), 18
Environmental Working Group, 18
EPA. *See* U.S. Environmental Protection Agency
EU. *See* European Union
European Union (EU), 7, 8, 9, 10, 19
- F**
Freedom of Information Act, 8
- G**
Greenwood, Mark A., 18
- H**
High Production Volume (HPV) Challenge Program, 13, 25
- J**
Japan, 19, 26
- M**
Moore, John A., 7
Muir, Warren R., 24
- N**
nanotechnology, 20, 21, 22, 24, 25, 26
National Academy of Sciences, 15
National Environmental Effects Research Laboratory, 15, 16
National Toxicology Program, 7
Natural Resources Defense Council (NRDC), 13, 18
NRDC. *See* Natural Resources Defense Council
- O**
Organisation for Economic Co-operation and Development (OECD), 7, 25, 26
- P**
PCB. *See* polychlorinated biphenyl perfluorooctanesulfonic acid (PFOS), 14, 15, 19
perfluorooctanoic acid (PFOA), 14, 15, 19
Pew Charitable Trusts, 18
PFOA. *See* perfluorooctanoic acid

PFOS. *See* perfluorooctanesulfonic acid
PMN. *See* Toxic Substances Control Act
(TSCA): premanufacture notice
polychlorinated biphenyl (PCB), 24

R

Registration, Evaluation, Authorisation, and
Restriction of Chemicals (REACH), 19

S

Scotchgard, 19
Seifter, Joseph, 4, 5
Stockholm Convention on Persistent
Organic Pollutants, 19
Structure Activity Team. *See* Toxic
Substances Control Act (TSCA):
Structure Activity Team
Sustainable Futures Initiative, 6

T

Toxic Substances Control Act (TSCA), 1, 2,
3, 4, 5, 7, 12, 13, 15, 18, 20, 21, 22
base data set, 4, 7, 8, 9, 10
confidential business information, 8, 16
definition of chemical, 20, 21, 22
enforceable consent agreements, 13, 14
existing chemicals, 1, 2, 9, 11, 12, 20, 21,
24
inventory update rule, 12, 23, 24
new chemicals, 1, 4, 5, 6, 7, 8, 9, 11, 12,
16, 20, 21, 22, 24, 25
premanufacture notice, 5, 10, 11, 12, 22
risk assessment, 1, 5, 10, 14, 15
Section 21, 3
Section 4, 11, 12, 18

Section 5, 21
Section 5(e), 10, 12
Section 6, 12, 19, 20
Section 8(e), 5, 10, 12
significant new use rule, 19, 20, 22
structure activity relationships, 4, 5, 6, 7,
9, 10, 11, 12, 15
Structure Activity Team, 4, 5, 6, 8
substantial risk notice. *See* TSCA,
Section 8(e)
testing rule, 7, 12, 13, 18, 25
TSCA Inventory. *See* TSCA, Section 8

U

U.S. Department of Commerce, 8
U.S. Department of State, 8
U.S. Environmental Protection Agency
(EPA), 1, 2, 3, 4, 6, 7, 8, 9, 10, 11, 12, 13,
14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24
Office of Pesticide Programs, 24
Office of Pollution Prevention and
Toxics, 1, 14, 15, 18, 23, 24, 25
Office of Research and Development, 14,
15
Office of Toxic Substances, 2
U.S. Supreme Court, 20
University of Maryland, 1

V

Veith, Gilman D., 16

W

Washington, D. C., 1, 2, 15
Waterside Mall, 2