TSCA DESKBOOK 2d Edition

by Carolyne R. Hathaway, William K. Rawson, Ann Claassen, and Julia A. Hatcher

LATHAM & WATKINS LLP

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8.	U.S. EPA, The TSCA Inventory: Submitting Successful Corrections (revised, undated) (ELR Order No. AD-467)
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About the Authors



Carolyne R. Hathaway is a partner in the Washington, D.C., office of Latham & Watkins LLP. Her broad chemical regulatory practice encompasses TSCA, the OSH Act, FFDCA, FIFRA, and a variety of other environmental and health and safety issues. Ms. Hathaway has repre-

sented major chemical, petrochemical, agrichemical, and manufacturing companies in EPA enforcement proceedings alleging violations of various sections of TSCA, has provided counseling to companies on issues of TSCA compliance and interpretation, and has participated in numerous legislative and administrative proceedings concerning chemical and other environmental regulation. Ms. Hathaway received her J.D., magna cum laude, from the Georgetown University Law Center and her undergraduate degree in chemistry and biology, magna cum laude, from Salve Regina College. She also holds an MBA from Bryant College. Before entering private practice, Ms. Hathaway served as a judicial clerk to the Honorable J. Harvie Wilkinson, III of the U.S. Court of Appeals for the Fourth Circuit.



William K. Rawson is a partner in the Washington, D.C., office of Latham & Watkins LLP where he chairs the office's Environment, Land & Resources Department. He also cochairs the firm's global Chemical Regulation and Product Defense Practice Group. Mr. Rawson

maintains a broad-gauged environmental regulatory and litigation practice focusing on high-stakes chemical-related issues arising under most major environmental statutes and also in connection with congressional investigations, state legislative initiatives, and high visibility coverage by national news media. He has extensive experience dealing with complex issues pertaining to hazard, exposure, and risk assessment and risk communication. In 2006, Mr. Rawson testified before the full Senate

Committee on the Environment and Public Works on TSCA reform. Mr. Rawson received his J.D., Order of the Coif, from Stanford Law School and his undergraduate degree, magna cum laude, from Amherst College. He served as a law clerk to the Hon. Jerome J. Farris of the U.S. Court of Appeals for the Ninth Circuit.



Ann Claassen is Counsel in the Washington, D.C., office of Latham & Watkins LLP. Her practice focuses on chemical assessment and management programs administered by federal, state, and foreign regulatory agencies. She regularly advises clients on matters arising under TSCA,

FIFRA, EPCRA, CAA, CWA, RCRA, CERCLA, FFDCA, CPSA, Proposition 65, REACH, and other regulatory and voluntary programs. Much of her work involves integration of legal principles with toxicology and risk assessment science, and she is an excellent translator between lawyers and technical personnel. Ms. Claassen received her J.D., summa cum laude, Order of the Coif, from the University of New Mexico Law School and her undergraduate degree in biochemistry, magna cum laude, from Colorado College. She also completed two years of graduate work in chemistry at the University of New Mexico. Ms. Claassen served as judicial clerk to the Hon. James Sprouse of the U.S. Court of Appeals for the Fourth Circuit.



Julia A. Hatcher is a partner in the Washington, D.C., office of Latham & Watkins LLP. Ms. Hatcher is regularly recognized as a leading practitioner in Washington, D.C., by *Chambers USA* legal guide, and was selected for inclusion in The Best Lawyers in America 2012 as a rec-

ommended attorney in Environmental Law. Ms. Hatcher has extensive experience representing clients on environmental, health, safety and liability

matters ranging from compliance advice to rule-making to agency enforcement proceedings to federal court litigation managing emerging area risks. She has deep expertise in federal chemical control laws—including TSCA, RCRA, CERCLA, EPCRA, FHSA, SDWA, CAA, and CWA—and related state laws for chemical regulation and toxic

tort liability. Ms. Hatcher received her J.D., with honors, from Georgetown University Law Center and her undergraduate degree, with honors, from Mount Holyoke College. She served as a law clerk intern for the Hon. Chief Judge Harry T. Edwards of the U.S. Court of Appeals for the D.C. Circuit.

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Online Materials

To stay current of the latest TSCA-related developments, supplementary materials can be found on the Deskbook's website at www.tscadeskbook.com.

Foreword

The Environmental Law Institute is pleased to offer the second edition of the *TSCA Deskbook* as an invaluable resource to understanding an increasingly vital, yet complex area of environmental law and policy. Because the Toxic Substances Control Act governs a specialized area of environmental law, its uses and its potential are extremely important. And, because TSCA is frequently the subject of legislative reform effort, it is critical that everyone understand one of our oldest statutes. To do so, however, requires both an ambitious analytical analysis and special supplementary materials to understand the many nuances and difficulties in a statute that covers highly specialized issues of science, law, policy, and risk management.

Thanks to the skill, insight, and dedication of a determined group of the expert authors, this newest edition of *TSCA Deskbook* makes TSCA both accessible and understandable. It begins with a "Practitioner's Guide" for the Act, offering the insight and expertise of some of the most experienced TSCA practitioners. These individuals, as private practitioners and former agency officials, are intimately familiar with the operation, complexities, and nuances of this area of law. The authors describe in plain English what the Act's different sections mean and how they fit into the larger context of environmental regulation. The Deskbook also provides the full text of the Act and key EPA regulations, policies, and guidance documents.

The TSCA Deskbook is part of Environmental Law Institute's Deskbook series, which combines the invaluable experience of the top practitioners in the field with the encyclopedic coverage and keen insight provided by the staff of the Environmental Law Reporter. Deskbooks provide practicing attorneys, students, environmental professionals, and government officials an "at-the-fingertips" resource for accessing and understanding environmental law. The series covers climate change, wetlands, endangered species, NEPA, FIFRA, and many other topics by combining in-depth analysis of the topic with necessary reference materials, such as regulations, guidance documents, and forms.

The Deskbooks are natural partners to ELI's flagship resource, the *Environmental Law Reporter*. *ELR* is an attorney-edited gateway to researching and understanding environmental law and policy, with coverage since 1971 available on-line in an easily searchable format. *ELR* couples thousands of insightful articles on environmental law and policy with the most important updates, decisions, statutes, regulations, and agency documents and a cumulative index and bibliography to help you navigate this highly complex area of law. More information about the Deskbooks, *ELR*, and ELI's many other programs is available at www.eli.org.

The Environmental Law Institute makes law work for people, places, and the planet. With its non-partisan, independent approach, ELI promotes solutions to tough environmental problems. The Institute's unparalleled research, highly respected publications, and valued policy and education seminars inform the public debate and build the institutions needed to advance sustainable development. We hope the *TSCA Deskbook* proves useful in increasing understanding this important area of environmental law and regulation.

John C. Cruden President Environmental Law Institute