



®

BERGESON & CAMPBELL, P.C.

1203 Nineteenth Street, NW | Suite 300 | Washington, DC | 20036-2401 | tel 202.557.3800 | fax 202.557.3836 | web www.lawbc.com

BERGESON & CAMPBELL, P.C.***TSCA Practice***

This document is intended to introduce you to Bergeson & Campbell, P.C.'s (B&C) Toxic Substances Control Act (TSCA) practice. B&C's legal and business professionals are highly skilled in various aspects of chemical-specific regulatory, legislative, and enforcement-related matters arising under TSCA.

TSCA is among the oldest of environmental statutes, but it presents continually new and challenging issues, as seen most recently in the Nanoscale Materials Stewardship Program (NMSP), on which the United States Environmental Protection Agency (EPA) is working, the High Production Volume (HPV) Chemical Challenge Program, and the Voluntary Children's Chemical Evaluation Program (VCCEP). B&C has a thorough understanding of TSCA, its implementing regulations, and the general principles underlying the federal system for managing TSCA-related products. B&C is well suited to assist chemical manufacturers, producers, importers, and exporters with EPA's management of regulated chemical products; the review and approval, as appropriate, of existing and/or new engineered nanoscale chemical substances; the scope of activities subject to TSCA requirements, including the process by which EPA requires new data for existing chemicals, reporting obligations relevant to both new and existing chemicals, and the often thorny issues involved in importing and exporting chemicals; and the process by which new chemical products are permitted on the market, including the many complex issues arising from the often substantial requirements TSCA allows EPA to impose on these new chemicals.

B&C has substantial experience in assisting clients on a wide array of issues arising under TSCA, including the regulation of products of biotechnology. B&C is a long standing sponsor of the American Chemistry Council/Synthetic Organic Chemical Manufacturers Association Global Chemical Regulations Conference. All of our attorneys have considerable experience in assisting clients with TSCA regulatory and litigation matters. In addition, many of our attorneys and other professionals have scientific and regulatory backgrounds that make them uniquely qualified to address the science-based legal issues that arise under TSCA.

We are especially pleased that Jim Aidala, former EPA Assistant Administrator for Toxics under the Clinton Administration, is on our team. Jim has a technical background, having attended Brown University, Harvard, and MIT before joining the government. Jim has been intimately involved with TSCA legislative reauthorization and key regulatory matters for over two decades, and offers significant value in addressing chemical policy and related issues.



®

BERGESON & CAMPBELL, P.C.

TSCA Practice
Page 2

Dr. Joseph Plamondon, who has a Ph.D. in organic chemistry from the University of California at Davis, brings a unique perspective to TSCA issues, as he has spent over 25 years as part of the regulated community at the Rohm and Haas Company and Akzo Nobel. Dr. Plamondon has had a long and distinguished career, and is well known in the industrial chemical community. In addition to his work within the chemical industry, he has spent over ten years consulting with chemical companies on a broad range of TSCA issues. These have included providing strategic preparation and submission of premanufacture notifications (PMN) designed to avoid TSCA Section 5(e) consent orders and other adverse regulations, as well as offering guidance to companies in the determination of whether certain health and safety information is reportable under TSCA Section 8(e). Dr. Plamondon has presented at many conferences and professional meetings, *e.g.*, the American Chemistry Council's Global Chemical Regulations Conference (Living with TSCA), among others, and has written extensively on chemical regulatory matters.

Additionally, Susan Hunter Youngren, who has a Ph.D. in environmental biology, has more than 18 years of experience in the field of risk assessment, with particular emphasis on exposure assessment. She has served as the project manager/senior scientist for a diverse range of risk assessments required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including residential, dietary, and microbial exposure assessments; under Proposition 65, including Maximum Allowable Dose Level (MADL) and No Significant Risk Level (NSRL) development; and under the Resource Conservation and Recovery Act (RCRA), including Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)/RCRA hazardous waste site assessment. Dr. Youngren is well versed in the preparation of individual, aggregate, and cumulative residential and consumer product exposure assessments using deterministic and Monte Carlo techniques. Dr. Youngren has managed and conducted numerous residential and occupational exposure assessments and is well suited to assist clients before EPA when exposure issues are raised in the context of PMN reviews.

B&C's TSCA experience includes:

- TSCA compliance audits, assessing compliance with all TSCA provisions;
- Section 4 test rules and related Organization for Economic Cooperation and Development (OECD), EPA, and Interagency Testing Committee (ITC) testing issues;
- HPV Chemical Challenge Program, Extended HPV Program, and International Council of Chemical Associations (ICCA) testing, including testing coalition formation and representation;



®

BERGESON & CAMPBELL, P.C.

TSCA Practice
Page 3

- VCCEP;
- Section 8(a), (d), and (e) recordkeeping and reporting requirements Standard Operating Procedures (SOP), and systems development issues;
- PMN/Microbial Commercial Activity Notice requirements;
- PMN requirements pertinent to products of nanotechnology and engineered nanoscale materials;
- Section 5 Significant New Use Rules (SNUR);
- Section 6 chemical restrictions, including bans;
- Export issues;
- Inventory issues;
- Polychlorinated biphenyl (PCB) issues;
- Approval and regulation of nanotechnology and biotechnology products; and
- Defense advocacy.

B&C published in 2001 a book on TSCA, published by the American Bar Association Section of Environment, Energy, and Resources. For more information on the book and how to order it, visit http://www.lawbc.com/other_pdfs/tscaprac2.pdf.

We also often work closely with clients on ensuring that their facilities have the expertise and tools necessary to avoid TSCA compliance problems. We prepare TSCA compliance manuals and SOPs, and regularly conduct in-house training seminars for clients.

In addition, we work on many chemical-specific issues that cut across EPA programs. For example, we are now representing manufacturers of several chemicals in connection with EPA's notices announcing the Integrated Risk Information System (IRIS) review of certain chemicals. Both cancer and non-cancer endpoints are being assessed.



BERGESON & CAMPBELL, P.C.

TSCA Practice
Page 4

As skilled and experienced professionals, B&C attorneys and non-attorneys offer assistance in these and many other areas. We offer our skills as both attorneys and business counselors because to offer less will not provide value to our clients.

Value is also offered in a more quantitative form -- as a small and highly specialized business, B&C is able to offer its professionals' legal skills, business judgment, and years of experience at rates below those of our competitors. Because we do not need to carry hundreds of attorneys throughout the world, we offer fixed, flat-fee, risk-sharing pay-for results, or other competitive business arrangements. Moreover, the professionals with whom you begin a project are the same ones with whom you close it. Efficiencies are maintained and maximized by having a core group of professionals devoted to projects from start to finish. You will not be paying to train inexperienced or new attorneys. Indeed, none of our professionals has less than six years of experience in these areas. Senior professionals have over two decades of experience in these areas.

What we cannot as easily share in this communication is the value we offer to your business and the enthusiasm and creativity with which we approach all representations. We invite you to experience both. Additionally, we invite you to speak with us about our diverse billing arrangements. All are intended to enhance the value of our representation and your business.

For further information, please call Lynn Bergeson at (202) 557-3801 or Lisa Campbell at (202) 557-3802.

January 2009