

BERGESON & CAMPBELL PC



TUTOR®

CURRICULUM



Bergeson & Campbell, P.C. (B&C®) is pleased to offer TSCA Tutor® online, on-demand training developed and are presented by members of B&C's renowned TSCA practice group to provide expert, efficient, and essential TSCA training.

B&C developed TSCA Tutor in recognition that Toxic Substances Control Act (TSCA) awareness is a critically important element in the 21st century work environment for any business that involves industrial chemicals. The new normal requires awareness of TSCA's application to a company's operations to ensure consistent compliance with TSCA regulations and, importantly, to understand and anticipate how the U.S. Environmental Protection Agency's (EPA) ongoing implementation of TSCA will impact a company's industrial chemical selection and use processes.

Courses can be completed at the learner's own pace, and enrollment is valid for one full year. Registrants receive detailed handout materials, including copies of all presentations and relevant materials from EPA, which are theirs to keep. Interested professionals should visit www.TSCAtutor.com to view sample course segments and enroll in the training.

The full TSCA Tutor program includes approximately 17 hours of training.

TSCA Tutor -- Curriculum

ONE HOUR SESSIONS:

T101 - Overview of TSCA: This module provides a general overview of TSCA -- its legislative intent, key components, and role in the management of industrial chemicals. This module is especially useful for anyone who is engaged in commercial activities, any component of which is regulated by TSCA -- chemical manufactures, processors, distributors, importers, and end users of chemical substances.

T103 - Import Requirements, TSCA Section 13: This module focuses on TSCA import requirements, including discussions on how to work with foreign suppliers in preparing joint submissions to EPA.

T104 - Export Requirements, TSCA Section 12: This module focuses on TSCA export requirements, including timelines associated with reporting sunset provisions and the application of the *de minimis* concentration exemption.

T105 - Confidential Business Information (CBI): Protecting a company's confidential and proprietary ingredients and/or processes and related confidential information is commercially critical. The rules of the game have changed dramatically, however, and the stakes have never been higher in understanding what is presumptively CBI, what is not, how the process works, for how long, and what your rights are when challenged. This module focuses on all these important aspects of TSCA.



T106 – Reporting and Retention of Information, Section 8: TSCA, especially new TSCA, is data- and information-driven and stakeholders are required to generate and maintain copious amounts of information, some of which must be shared with EPA and the public through a much reviewed EPA electronic database. Curating this information is critically important for both compliance purposes and in terms of managing a narrative for your commercial partners, neighbors, competitors, and shareholders. This module reviews these critically important requirements. It also covers **Adverse Effects Identification and Reporting**. Being able to pick an adverse effect out of the TSCA line-up is crucially important at several levels. Violations of this “TSCA 8(e)” provision have proven to attract record-setting EPA penalties in the multiple million-dollar range, as EPA considers it one of the most important obligations under TSCA. Failure to identify an adverse effect can invite commercially devastating consequences in terms of product and toxic tort liability. This module instructs on how to identify an adverse effect and how to develop a TSCA 8(e) reporting process that is legally sufficient and effective.

TWO HOUR SESSIONS:

T201 - TSCA and EPA Inspections:

Preparing for a TSCA Audit: Any commercial entity engaged in the manufacture, import, process, and/or use of chemicals regulated under TSCA is subject to EPA enforcement and compliance inspection authority. When EPA elects to conduct such inspections, it does not typically give facility operators much time to prepare. Knowing what EPA will ask for before it sends a formal letter is critically important in determining how well a company will fare under the audit.

TSCA Penalties/Overview of Self-Confession Policy: The penalties that can be assessed under TSCA are not trivial -- up to \$37,500 per violation, per day. While no one intends to be found in non-compliance with TSCA, it is possible that it could occur; knowing how EPA calculates potential penalties is important in negotiating with EPA. This module covers these areas and EPA penalty policies related to those circumstances in which a company finds non-compliance during internal review processes and elects to self-report to EPA.

T202 - TSCA Section 5, Part 1 (TSCA Chemical Inventory, Exemptions):

Definitions: Understanding the language of TSCA is critical, as key terms and new concepts added by new TSCA are heavily nuanced and in some cases evolving. “Conditions of use,” “potentially exposed and susceptible subpopulations,” and “significant new use” are but three of the many terms unique to TSCA and upon which the complex regulation of industrial chemicals rests.

TSCA Inventory: The TSCA Chemical Inventory (TSCA Inventory) is a component that is critically important in understanding the great divide between new chemicals, for which EPA pre-market approval is required; active existing chemicals, for which commercialization is permitted, unless a TSCA Inventory flag tells us otherwise; and inactive existing chemicals. What is a TSCA Inventory flag, what is listed on the TSCA



Inventory and why, and most importantly what is not listed on the Inventory are concepts critical to TSCA compliance. This module includes an overview as to how a company can determine if chemical(s) of interest are included on the TSCA Inventory. It also covers aspects of new TSCA of which chemical stakeholders should be aware.

Exemptions: There are a number of self-executing exemptions that permit companies to manufacture or import substances that are not listed on the TSCA Inventory without notifying EPA in advance. This module examines the various exemptions and provides insight into how to ensure compliance with some of the most frequently used exemptions, including the polymer, research and development (R&D), non-isolated intermediate, export-only, and “h(7)” exemptions.

T203 - TSCA Section 5, Part 2 (New Chemicals/New Use):

New Chemicals/New Use: If a chemical is not listed on the TSCA Inventory and not otherwise exempt from Section 5 notification, EPA must review the “new” chemical and make a judgment as to whether it is likely to pose unreasonable risk. If EPA is unable to make the determination or decides that it is likely to pose unreasonable risk, the new chemical’s commercialization prospects are diminished or destroyed -- a devastating commercial consequence. This module carefully reviews the how, what, and why of EPA’s new chemical review process, how to develop a smart premanufacture notice or a “smart PMN,” and how to manage efficiently the EPA review process.

SNURs: Significant New Use Rules (SNUR) are the new normal under TSCA and a significant number of new chemical reviews result in these regulations. What are SNURs, how to decipher the rule language, why their issuance is sometimes inevitable, and how they can be averted are the focuses of this module. This module also covers required downstream communication requirements for SNURs that potentially affect all entities along the value chain -- manufacturers, importers, distributors, formulators, re-packagers, and users.

T204 - Chemical Data Reporting (CDR)

CDR Overview: Every four years, chemical manufacturers and importers are required to provide EPA with information on the chemicals they produce. The information is often not straightforward and missteps in reporting can invite enforcement and commercial liability. This module focuses on discharging these reporting obligations and successfully reporting the information electronically in EPA’s Chemical Data Exchange (CDX) system.

Byproduct Reporting under the CDR: Companies today are working toward more sustainable manufacturing processes that include opportunities to reuse or reprocess byproduct chemicals that might otherwise be disposed of as waste. Under current EPA policies, these recycled, reused, and/or reprocessed byproducts could be viewed as manufactured chemicals and, thus, subject to reporting under the CDR. This module provides an overview of the EPA byproducts’ policies and which byproduct substances are subject to reporting.



T205 – TSCA Section 4 Chemical Testing (Regulatory)/Animal Welfare:

Chemical Testing: New TSCA provides new authority to EPA to compel chemical testing. EPA is expected to exercise that new authority starting in 2019. This module focuses on what chemical stakeholders must do when confronted with a chemical testing order, and considers strategies to address chemical testing smartly and efficiently.

How to Prepare/Engage if a Chemical of Interest is Listed under TSCA Section 4: EPA has indicated its view that it expects companies to develop a coordinated response in addressing testing needs under Section 4. The creation of industry testing consortia is, thus, anticipated. Such coordination must include cost sharing for data required under the testing order, cost sharing of EPA fees, and the cost of identifying and administering needed consortia management work. Understanding EPA's expectations, coupled with today's business realities on establishing and participating in these types of groups, is essential.

T206 - Section 6 Prioritization and Risk Evaluation:

Overview of Section 6 Risk Framework -- Prioritization, Evaluation, and Management: Amended TSCA includes a rigid process and timeframe for the evaluation of chemicals under TSCA Section 6. This module reviews the steps that EPA will take to identify high priority chemicals, the evaluation process applied to high priority chemicals, and risk management approaches that are applied to chemicals found by EPA to pose unreasonable risk.

How to Prepare/Engage if a Chemical of Interest is Listed under Section 6: EPA has indicated its view that it expects companies to develop a coordinated response in information gathering under Section 6. The creation of industry testing consortia is, thus, anticipated. Such coordination must include cost sharing for data submitted, cost sharing of EPA fees, and the cost of identifying and administering needed consortia management work. Understanding EPA's expectations, coupled with today's business realities on establishing and participating in these types of groups, is essential.

Costs

Online courses are offered at \$100 for one-hour modules and \$200 for 2-hour modules. Course bundles are available at a reduced cost per course. Enrollment and payment are handled on the online training platform. Volume discounts and invoice billing are available for companies wishing to purchase courses for multiple employees.

Contact Emily Scherer, escherer@lawbc.com, for more information on volume discounts or general questions regarding TSCA Tutor.