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TSCA: Old and New

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1.1 Introduction

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-128 (Lautenberg), which makes important changes to the Toxic Substances Control Act (TSCA). TSCA was enacted in 1976 and over the following almost four decades, the provisions in Title 1 had never been amended. Lautenberg results in fundamental shifts in the requirements and approach under TSCA, while introducing important new concepts and approaches (new TSCA). It is our view that the body of changes, including the balancing of competing needs and interests and the careful drafting, yield a statute that has been greatly strengthened in a way that addresses all or virtually all of the deficiencies and problems that have plagued TSCA over the years.

Lautenberg amended a number of TSCA provisions, including those relating to:

- Definitions (Section 3), which introduced a number of important new terms such as conditions of use (COU) and potentially exposed and susceptible subpopulations (PESS);
The meaning of “unreasonable risk” that was clarified, wherever it appeared in new TSCA, as not involving consideration of costs or other nonrisk factors;

- Testing (Section 4), where the U.S. Environmental Protection Agency (EPA) received additional new authority to use rules, orders, or consent agreements to require testing;

- Review and regulation of new chemicals (Section 5) that now requires an affirmative EPA determination on all new chemicals and EPA action depending on the determination made;

- Review and regulation of existing chemicals (Section 6) that was revised to include sequential prioritization, risk evaluation, and risk management steps;

- Information reporting (Section 8), including the need for EPA to undertake an “Inventory reset” process to distinguish TSCA Inventory chemicals that were active versus inactive in commerce;

- Confidential business information (CBI) (Section 14) that now requires assertion and substantiation of CBI claims, with additional requirements in the case of confidential chemical identities, but also expanded CBI access to state and tribal government authorities, among others;

- Preemption (Section 18), one of the most difficult areas to resolve in reaching Congressional agreement;

- Fees (Section 26), including expanded authority to collect fees and establishment of a fund to hold the fees that are then to be used, subject to appropriations, to defray the costs of administering certain EPA activities under Sections 4, 5, 6, and 14 of new TSCA; and

- Numerous and often tight timelines and deadlines for completion of actions.

The new program, not surprisingly, will face a variety of implementation hurdles due to the challenge of deadlines, resources, and only a short (if any) honeymoon period. It might take a significant length of time before regulations, policies, and new procedures are “up and running” to implement fully the new legislation. That said, we join with others in applauding not only the legislative crafting that went into the full text but also the ability of this Congress, often unable to bridge partisan divides, to come to agreement on such an ambitious and important undertaking.
1.2 SAMPLING OF LEGISLATIVE CONCEPTS

CONSIDERED BUT NOT INCLUDED IN NEW TSCA

A number of concepts were raised over the protracted period that was required for Congress to reach agreement on new TSCA. While many new concepts found their way into the new law (including those noted in the preceding section and others discussed in subsequent chapters), other concepts, for whatever reason, did not. We offer a sampling of such concepts as a reminder of what was considered along the way. The references go back to analyses of TSCA reform legislative texts that are available at www.lawbc.com. Note that a given concept may be discussed in several different legislative texts/analyses:

- Additional regulatory requirements for new chemicals that were found to meet persistence and bioaccumulation triggers.¹
- Sustainable Chemistry.²
- Explicit protection for confidential chemical identities and retaining “old TSCA” (Pub. L. No. 94-469) Sections 5 and 8 unchanged.³
- Use of a periodic “hard” Inventory reset that would have changed the status of chemicals found not to be in commerce.⁴
- Definitions for and use of the terms safety assessment, safety determination, and safety standard.⁵
- Requirement that EPA consult with the Occupational Safety and Health Administration (OSHA) before taking action under Section 6 concerning occupational exposure.⁶

². Id.
⁶. Id.
• A modification to Section 8(e) that would have allowed any person to submit information reasonably supporting the conclusion that a chemical “does not present a substantial risk.”

• Expansion of Section 12(b) export notice requirements to include notices needed to meet U.S. treaty obligations (e.g., under Stockholm or Rotterdam Conventions).

• Requirements to ban asbestos and to implement an effort on “disease clusters.”

• Explicit reference to a role for “accumulation of chemicals” in humans in considering additional testing under Section 4.

• Explicit requirement for a “Notice of Commencement” (NOC) in Section 5.

• Provision allowing a state governor/agency or the public to petition/recommend that EPA make a prioritization decision on a chemical.

• Requirement that EPA make a second, more rigorous determination on new chemical “may present” cases before those chemicals could enter commerce, including consideration of aggregate risk issues.

• Deletion of old TSCA Section 5(h)(4) (used for new chemical exemptions such as the Low Volume Exemption (LVE) and Polymer Exemptions).
• Requirement that EPA conduct risk evaluations on all Inventory chemicals and to conduct reevaluations every 15 years, including consideration of aggregate exposures.\(^ {15}\)

• Application of the “arbitrary and capricious” standard for judicial review in lieu of the old TSCA “substantial evidence” standard.\(^ {16}\)

• A requirement that EPA promulgate a Section 8(a) rule on manufacturers and processors of active chemicals to report use and exposure information on such chemicals.\(^ {17}\)

• Replacement of old TSCA Section 2 on Findings, Policy, and Intent with a new set of provisions and including concepts such as innovation, building public confidence in federal oversight, minimizing undue burden on commerce, and others.\(^ {18}\)

• Deletion of old TSCA Section 5(b)(4) concerning the “chemicals of concern list.”\(^ {19}\)

• Inclusion of a “goal” in Section 2 to review all chemicals in commerce for safety and identify the highest priority chemicals for expedited review.\(^ {20}\)

• Definitions and use of the concepts of aggregate and cumulative exposure in assessment and management of chemicals.\(^ {21}\)

• Defining chemical substance to include articles and allowing EPA to determine, notwithstanding molecular identity, that a “variant” of a chemical substance is a new chemical; defining a new term special substance characteristic.\(^ {22}\)

• Defining environment to include “ambient and indoor air.”\(^ {23}\)

• Requirement to establish “minimum information sets” for new and existing chemicals and to require submission of such information from manufacturers and processors.\(^ {24}\)

\(^{15}\) Id.

\(^{16}\) Id.


\(^{18}\) Id.

\(^{19}\) Id.


\(^{21}\) Id.

\(^{22}\) Id.

\(^{23}\) Id.

\(^{24}\) Id.
• Requirement that any person manufacturing or processing a new chemical submit a notification to EPA.25
• Requirement on EPA to create decisional “categories” of new chemicals and that new chemicals falling into the “insufficient information” category must submit additional information and are out of commerce until the testing has been satisfied and the chemical has been recategorized.26
• New Section 5(h) exemption for new chemicals that are “intrinsically safe substances.”27
• Broad order authority for risk management of existing chemicals under Section 6 and for submission of information under Section 8.28
• Requirement on EPA to identify, assess, and develop actions plans to address any “disproportionate exposures” of residential populations to chemicals or mixtures. The shorthand for this concept was “hot spots.”29
• Authority to implement the Stockholm and Rotterdam Conventions, and the Aarhus Convention (Persistent Organic Pollutants Protocol).30
• Explicit authority to regulate occupational exposure under Section 6 provided the requirement “reflect[s] the industrial hygiene hierarchy of controls.”31
• Use of a “reasonable certainty of no harm” safety standard under Section 6.32
• Section 4 authority to require companies to conduct human biomonitoring studies.33

The remainder of this book analyzes new TSCA in detail. While the concepts outlined above are not explicitly found in new TSCA, readers will see variations on some themes in the new law.

25. Id.
26. Id.
27. Id.
28. Id.
29. Id.
30. Id.
32. Id.
33. Id.