

The New TSCA – What Every Company Should Know

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“LCSA” or the “Lautenberg Act”).¹ This legislation, which capped several years of difficult negotiations on Capitol Hill, is intended to modernize the 40-year-old Toxic Substances Control Act (“TSCA”) and completely overhaul how chemical products are regulated in the United States. In this paper we examine some of the most significant changes that have been made to TSCA, and we explore the practical implications of those changes for companies that manufacture, import or process chemical substances. Before diving into the changes that have been made to TSCA by LCSA, we begin with a brief summary of some of the basic features of the law.

The Basics of TSCA

Despite the law’s name, the “Toxic Substances Control Act” is not limited in its scope to just “toxic” substances; rather, the law applies to virtually all chemical products in the U.S. Indeed, only a very few specific types of chemical products – such as pesticides, foods, drugs and cosmetics – are excluded from regulation under the law. In addition, TSCA does not only apply to “chemical companies.” Any company that incorporates a chemical substance into an article (such as a lubricant or coating) is subject to regulation as a “processor” of chemical substances; and any company that imports or exports chemical products is also subject to regulation under TSCA.²

The central organizing feature of TSCA is the Chemical Substances Inventory (the “TSCA Inventory”), which is essentially a list of all chemical substances that are known to have been in commerce in the US. This list, which was created under Section 8(b) of TSCA, serves as the dividing line between “existing” chemical substances and “new” chemical substances. A substance that is listed on the Inventory is considered to be an “existing” chemical; and a substance that is *not* listed on the Inventory is considered “new.” This distinction is important because “new” and “existing” substances are regulated differently under TSCA. Generally speaking, before a “new” substance can be manufactured in or imported into the US, the manufacturer or importer must notify the U.S. Environmental Protection Agency (“EPA” or the “Agency”) through a premanufacture notification (“PMN”) and EPA must conduct a premarket

¹ Public Law No: 114-182

² Under TSCA, a “processor” is someone who prepares a substance or mixture, after its manufacture, for distribution in commerce either (a) in the same form or physical state or in a different form or physical state, or (b) as part of an article containing the chemical substance or mixture. *See* 15 USC § 2602(13). Also, importers are subject to regulation as “manufacturers” under TSCA. *See* 15 USC § 2602(9)

review of the substance.³ Once EPA’s review of the PMN is successfully completed and commercial manufacture or import of the substance commences, the substance is added to the Inventory and becomes an “existing” chemical substance. Existing substances are subject to EPA’s continuing jurisdiction under TSCA, and, as discussed in greater detail below, the new law provides the Agency with broad powers to regulate such existing substances.

It is important to recognize that the basic architecture of the TSCA statute, as highlighted above, has not changed significantly under the New TSCA. However, what *has* changed is how EPA exercises its expansive authorities within this broad architecture. The next sections of this paper describe several of the most significant changes, starting with the way in which EPA conducts premarket reviews of new chemicals.

Changes to New Chemical Review

The mechanics of the premanufacture review process remain essentially the same as when TSCA was first enacted: any person who intends to manufacture or import a “new” chemical substance must submit a PMN to EPA at least 90 days prior to initiating manufacture or import of the substance.⁴ What has changed under the new law is the standard that EPA must apply when reviewing a PMN to assess whether the substance can be commercialized. Specifically, the Lautenberg Act, directs EPA, when evaluating a new substance, to determine whether the substance presents an “unreasonable risk of harm to health or the environment” under “conditions of use” including consideration of risks to potentially exposed or susceptible subpopulations (i.e., especially vulnerable groups).⁵

The term “conditions of use” is an important new addition to the TSCA standard for reviewing new chemicals. The term is defined in the new law to mean the circumstances under which a substance is intended, known or *reasonably foreseen* to be manufactured, processed, distributed, used or disposed.⁶ Previously, under the “old” TSCA, when EPA would review a PMN for a new chemical substance, the Agency would focus its risk assessment on the *intended* uses for the substance, as identified by the PMN submitter. This allowed EPA to conduct a relatively focused risk assessment, which in turn helped facilitate timely completion of the PMN review process. Now, under the new law, EPA must conduct a risk assessment that addresses all “reasonably foreseen” uses of a new chemical—which can greatly expand the scope of its PMN review, as well as the length of time needed to complete it.

In addition to including this new safety standard in TSCA, the Lautenberg Act also shifted the burden to EPA when applying that safety standard to a new chemical substance. Under New TSCA, before a new chemical substance can be placed on the market, EPA must make an

³ See 15 USC § 2604(a)

⁴ See 15 USC § 2604(a)(1); 40 CFR § 720.22

⁵ See 15 USC § 2604(a)(3)

⁶ See 15 USC § 2602(4)

affirmative determination that the substance satisfies the safety standard (i.e., that the new substance is not likely to cause unreasonable adverse effects under conditions of use). Previously, under “old” TSCA, the Agency was not required to make such an affirmative determination; instead, manufacture (and import) of a new chemical substance could commence following completion of a 90-day review period, **unless** EPA concluded that the substance presented an unreasonable risk. In such circumstances the Agency was empowered to impose restrictions on the new substance or require the submission of additional data as a condition of allowing commercialization of the substance.

The net effect of these changes to the new chemical review process has been to slow the Agency’s pace of new chemical reviews, as EPA evaluates all “reasonably foreseen” uses of each new substance in order to make an affirmative finding of no unreasonable risk. In early 2017 EPA acknowledged that these delays had created a large backlog of PMNs that were awaiting completion of premarket review. EPA responded to this logjam by implementing measures to help streamline the PMN review process, and by August of 2017 the Agency announced that the backlog of PMNs awaiting review had largely been eliminated.⁷ However, anecdotal evidence suggests that PMN reviews are still taking much longer than they did prior to enactment of the LCSA, and the outcomes of those reviews are much less predictable.

The Inventory Reset

The New TSCA also directs EPA to promulgate information-collection regulations that will allow the Agency to determine which substances currently listed on the TSCA Inventory are actively in commerce. On August 11, 2017, EPA published in the Federal Register the final TSCA Inventory Notification (Active-Inactive) Rule -- commonly referred to as the “Inventory Reset Rule.”⁸ The rule, which was effective immediately, creates new reporting obligations for companies that *manufacture* or *import* chemical products. Companies that *process* chemicals in order to manufacture articles or to create formulated chemical products are also affected by the new regulation.

As indicated, the main purpose of the Inventory Reset rule is to provide EPA with a clear picture of which of the tens of thousands of substances listed on the TSCA Inventory are active in commerce in the US. To accomplish this, the rule establishes both “retrospective” and “forward-looking” reporting requirements for manufacturers and importers of existing chemical substances (that are listed on the TSCA Inventory). Under the Reset regulation, substances that are reported during the “retrospective” reporting period will be designated as “active” and substances that are **not** reported during the “retrospective” reporting period will be designated as “inactive.” Once a substance has been designated as inactive it can no longer be manufactured or processed in the US until a **forward-looking** report is filed with EPA –

⁷ See <https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews>

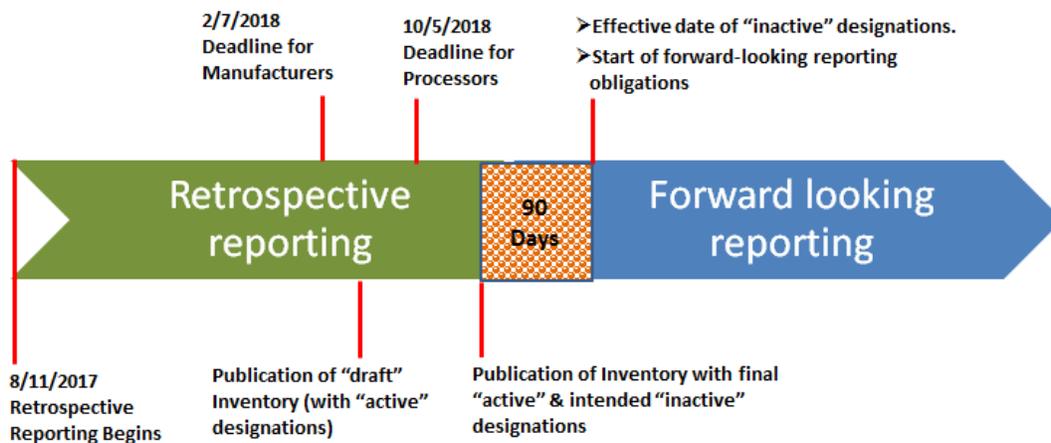
⁸ 82 Fed. Reg. 37,520 (Aug 11, 2017)

notifying the Agency that the substance is becoming “active” again. The key features of the Inventory Reset Rule are as follows:

- Retrospective Reporting** Any person who manufactured or imported an Inventory-listed substance for a non-exempt commercial purpose during the ten year period ending June 21, 2016 (referred to as the Reset “lookback period”) is required to report to EPA on those past activities. Substances that are reported in this manner will be designated as “active.” **Manufacturers** (including importers) of chemical substances must complete their retrospective reporting by **February 7, 2018**. In addition, the rule establishes a voluntary reporting period for processors of chemical substances (e.g., companies that create formulated chemical products or that incorporate chemical products such as paints or lubricants into manufactured articles). This voluntary reporting period for **processors** ends on **October 5, 2018**. All retrospective reports are filed electronically on a new “Notice of Activity Form A.”
- Forward-looking reporting** commences once EPA completes its review of the retrospective reports submitted by manufacturers (including importers) and processors. Substances that were not reported to EPA during the retrospective reporting period will be designated as “inactive” and any company that intends to manufacture, import or process a substance that has been designated as “inactive” must file a forward-looking report with EPA within 90 days of the intended date of initiating manufacture or processing of the “inactive” chemical. Forward-looking reports are filed electronically, on a new “Notice of Activity Form B.”

Figure 1, below, provides a graphic representation of the timeline for both retrospective and forward-looking reporting under the Inventory Reset Rule.

Figure 1: Timeline for retrospective and forward-looking reporting under the Reset Rule



- **Protection of Confidential Business Information (CBI)** The Reset Rule includes provisions for asserting and substantiating claims that certain reported information (in particular, chemical identity information) should be protected against public disclosure, as Confidential Business Information (CBI). However, the rule also contains several potential traps that might cause an unwary company to inadvertently lose CBI protection. Perhaps most significantly, the rule includes several exemptions from reporting – for certain chemicals that will be deemed to be “active.” For example, under the Reset rule, substances that were reported for the 2012 or 2016 Chemical Data Reporting rule (CDR) are automatically included in an “interim list of active substances” and are exempt from retrospective reporting under the Reset Rule.⁹ Companies that take advantage of this exemption and decline to file retrospective reports for a substance that is listed on the confidential portion of the Inventory (because its specific chemical identity is CBI) will forfeit the opportunity to assert CBI protection for the chemical identity of the substance, and the identity of the substance may be revealed by EPA.

Systematic Review of Existing Chemicals

Probably the biggest single change under New TSCA is the requirement, under revised Section 6 of the statute, for EPA to conduct a systematic risk review of all existing chemicals that are “active” in commerce. Prior to passage of the LCSA, one of the most common criticisms of TSCA was that the statute did not require EPA to review the safety of substances that were already listed on the Inventory (i.e., “existing” substances). The Lautenberg Act changes that dramatically, by establishing a three-step process that EPA must follow with respect to all “active” substances.

The first step of the process for reviewing active substances, referred to as “**prioritization**,” is essentially a risk screen that EPA must perform in order to ascertain whether an active substance “may present” an unreasonable risk of harm to health or the environment under conditions of use. If the Agency concludes, on the basis of available information, that an active substance “may present” an unreasonable risk, the substance is designated as “high priority” and proceeds to “Step 2” of the risk evaluation process. Conversely, if on the basis of available information, EPA concludes that the substance is “not likely to present an unreasonable risk” under conditions of use, the substance will be designated as “low priority.” Low priority substances do not proceed to the next step of the risk evaluation process unless they are subsequently re-designated as “high priority.”¹⁰

During the second step of the risk evaluation process, EPA examines all available hazard and exposure information on a substance to determine whether, based on all reasonably foreseen

⁹ The “Interim Active” list is available at the following url: <https://www.epa.gov/tsca-inventory/interim-list-active-substances>

¹⁰ See 15 USC § 2605(b)

uses of the substance, the substance presents an “unreasonable risk of adverse effects to human health or the environment.” Two aspect of this risk evaluation process are worth highlighting:

1. In determining whether a chemical substance presents an “unreasonable risk” EPA is only allowed to consider the hazards and exposures associated with that use of the chemical. Under the new law EPA is specifically prohibited from considering the costs and benefits of the chemical, the availability of suitable alternatives or any other non-risk factors. In addition, as with the PMN review process, in determining whether a chemical presents an “unreasonable risk” EPA is explicitly required to consider the risks to susceptible subpopulations, such as pregnant women and children, or workers who may receive particularly large exposures to the substance.¹¹
2. Before finalizing its risk evaluation for a substance, EPA is required to publish and receive public comments on a draft risk evaluation. If, following notice and comment, EPA determines that a substance does not present an unreasonable risk, that decision constitutes final Agency action and is subject to judicial review.

Finally, if, based on its risk evaluation, EPA determines that a chemical substance does present an unreasonable risk to health or the environment, the Agency must proceed to “risk management” rulemaking, to impose restrictions or prohibitions on the continued use of the chemical as needed to assure that the substance will no longer present an unreasonable risk.¹² It is only during this “risk management” step – when deciding what restrictions to impose on a chemical -- that EPA can consider non-risk factors such as costs, benefits, feasibility, the availability of alternatives and other similar factors.¹³

This aspect of New TSCA has the potential to cause significant disruption for manufacturers and other companies that utilize chemical products in their operations, because EPA is required to conduct risk reviews of all “active” chemicals, including products that have been available on the market for years – or decades. Moreover, if EPA determines that a chemical substance presents an unreasonable risk, the new law requires EPA to act quickly to impose restrictions. Generally, under the new law, the Agency must issue proposed risk management regulations within one year of determining that a chemical presents an unreasonable risk, and EPA must finalize the proposed restrictions within two years of making the unreasonable risk determination. So companies that rely on these chemical products could easily be caught flat-footed if they are not vigilant in monitoring EPA’s risk evaluations.

It is worth noting that, as directed by the LSCA, EPA has promulgated regulations governing how the Agency will implement the prioritization and risk evaluation processes.¹⁴

¹¹ See 15 USC § 2605(b)(4)

¹² See 15 USC § 2605(a)

¹³ See 15 USC § 2605(c)

¹⁴ See 82 Fed. Reg. 33,753 (July 20, 2017) (prioritization rule) and 82 Fed. Reg. 33,726 (July 20, 2017) (risk evaluation rule)

Those regulations have been challenged in court and, as of this writing, those cases are still pending.

New Provisions Governing CBI

Under the LCSA, it has become more difficult to maintain chemical information as confidential. This increased difficulty arises in part from the Act's categorization of information that may be protected or could never be protected; but it also results from the Act's requirement that CBI claims be substantiated at the time of submission and that submitters certify that the information fits the criteria for confidentiality. Even if information qualifies as CBI, maintaining confidentiality is complicated by the limitation on the time during which a claim of confidentiality is effective, the list of situations in which CBI can be released, and the requirement for EPA review of CBI claims.

The LCSA defines completely new categories of protected, non-protected, and possibly protected information. Certain information can now never qualify as CBI. Such unprotected information includes information (other than process, formula, or mixture composition information) from health and safety studies relating to a substance that is sold in the U.S., aggregated production volumes and production ranges, general descriptions of processes or uses, and information that was previously CBI relating to a substance EPA has decided to ban or phase out. On the other end of the spectrum, certain information is now presumed to be confidential. This presumptively confidential information includes specific process information, market and sales information, supplier and customer identities, detailed formulas for mixtures, specific production volume or use information, and the chemical identity of a substance not yet sold in the U.S.¹⁵

Data submitters must substantiate any information not presumed to be confidential, at the time of CBI submission. Prior to the LCSA, EPA only asked a company to substantiate a CBI claim as needed, well after submission. In addition, under New TSCA, CBI protection is provided for a limited period, with opportunities for renewal. Thus, unless the CBI is presumed confidential, CBI protection will only last 10 years, at which time the submitter must affirmatively request renewal of the protection.¹⁶ In addition, re-substantiation of CBI claims may be required in certain situations – for example, if the substance is designated as a high-priority substance, if the substance changes from “inactive” to “active” status, or if disclosure of the information would help EPA conduct a risk evaluation or issue a rule relating to a substance that presents an unreasonable risk. Also, the LCSA requires submission of a new certification statement for all CBI claims. The submitter must certify that (s)he has protected the information, that the information is not legally required to be disclosed, that disclosure would

¹⁵ See 15 USC §§ 2613(b), (c)(2)

¹⁶ See 15 USC §§ 2613(e)

cause harm, and that the information is not reasonably discoverable. TSCA did not previously require a certification for CBI claims.¹⁷

Finally, unlike “old” TSCA, under which EPA was unlikely to ever examine the basis for a CBI claim unless the public requested the information, the LCSA requires EPA to review all claims that chemical identities are CBI and 25% of other CBI claims.



Warren Lehrenbaum

Partner

Washington, D.C.

Wlehrenbaum@crowell.com

Phone: +1 202.624.2755

1001 Pennsylvania Avenue NW

Washington, DC 20004-2595



Amy Symonds

Associate

Washington, D.C.

Asymonds@crowell.com

Phone: +1 202.624.2536

1001 Pennsylvania Avenue NW

Washington, DC 20004-2595

¹⁷ See 15 USC §§ 2613(c)