

**TSCA Reform: Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (Lautenberg Act)  
UL Prospector Webinar August 17, 2016  
Questions & Answers**

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**Similar Questions Concerning Jurisdiction of the Lautenberg Act (1-3):**

1. Understanding that Personal Care industry might be required to provide information on ingredients use, still will be cosmetics considered as TSCA exempt as a whole?
2. Are wound care and EPA-registered disinfectants in commerce in the US subject this TSCA reform?

Under the Lautenberg Section 3 definition for “chemical substance”, per Section 3 (2)(B)(vi) of the Act, cosmetics, drugs, or devices which meet the definition of “cosmetic”, “drug” or “device” under the Federal Food, Drug & Cosmetic Act are excluded from the definition of “chemical substance” under Lautenberg. However, a cosmetic, drug, or device manufacturer may source their ingredient chemicals from a supplier who also manufactures those same chemicals for TSCA-regulated uses. EPA may seek information on conditions of use for those chemicals, so your upstream supplier may approach you as a customer for information on your use as well as further distribution downstream in the supply chain, including information concerning potentially exposed populations. Additionally, should EPA conclude that a chemical presents an unreasonable risk and subsequently regulate the chemical, your ability to obtain that chemical from upstream suppliers in your supply chain may be impacted.

3. To be clear, a cosmetic manufacturer who works with a domestic supplier, may be required to provide information, be it safety data or consumer exposure or the like, to the EPA even though cosmetics are exempt due to the new "Conditions of Use" definition?

The definition of “Conditions of Use” under Lautenberg is as follows:

*“The term “conditions of use” means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”*

The “Conditions of Use” definition itself does not exempt cosmetics. Rather, it extends the circumstances for which EPA may require information on chemicals to include those intended, known, or reasonably foreseeable as regards manufacturing, processing, distribution, use, and disposal. Therefore by including processing, distribution, use and disposal, for chemicals used in the cosmetics industry that are also used in TSCA-regulated uses you may be required to provide such supply chain information.

**Similar Questions Concerning Sourcing Chemicals from a Distributor (4-5):**

4. If you are obtaining an ingredient from non-domestic companies through a distributor, would your distributor be ultimately responsible as the "manufacturer/importer?"
5. If you order imported chemicals from a distributor in the U.S., are you still considered "an importer" of that chemical?

In this scenario, it depends on the structure of your contract with the distributor regarding who is the “Importer of Record”. The importer of record is the responsible entity under Lautenberg.

6. I'm from Brazil and exporting raw materials - cold pressed oils and butters to over 40 countries including the US. What will change in particular for me and my business?

Your direct customers in the U.S., which are the Importers of Record (and thus considered the manufacturers under Lautenberg), may have reporting obligations concerning these chemicals. Depending on the nature of the information being required by the EPA, your direct U.S. customer may contact you for more specific information regarding your chemical.

7. This looks a lot like the California Green Chemistry requirements - what effect does the preemption clause in the Lautenberg bill have on such state rules?

Lautenberg preserves State statutes and regulations existing prior to April 22, 2016, and any actions taken under laws that were in effect as of August 31, 2003. State action on a specific chemical is preempted once EPA makes an affirmative finding of no unreasonable risk, or initiates regulation to address identified risks. During the evaluation process for a chemical, any further state action on the chemical is temporarily paused, and during this time States can apply for a waiver from the pause if they still wish to pursue their own regulation.

8. Could this potentially override California-type chemical regulations such as Proposition 65?

No, Lautenberg will not preempt California Proposition 65. Lautenberg preserves statutes and regulations existing prior to April 22, 2016, and any actions taken under laws that were in effect as of August 31, 2003. Preemption includes only chemical-specific restrictions and also does not extend to state laws that require reporting or monitoring, or address local environmental concerns related to air, water, waste treatment and disposal.

9. Could you provide examples of what an article could be in personal care? Any cosmetic formulation?

An example of an article in personal care that would be considered a consumer good would be the "tools" in a manicure set.

10. FDA has mostly exempted oxidative hair dyes for permanent salon type color. Will this open those dyes to be reviewed/regulated now like the EU did?

If the chemical ingredients used in such dyes are also subject to other uses which are regulated under TSCA, then under Lautenberg these chemicals may be subject to prioritization and evaluation.

11. Understanding that the actual TSCA inventory seems not to be very reliable, how can be prepared about possible concerns on certain ingredients?

The EPA publishes all actions as Notices, Proposed Rules or Final Rules in the Federal Register. The following resources will assist with keeping abreast of activities concerning chemicals under Lautenberg:

- a. US Federal Register Information site:  
<https://www.federalregister.gov/>
- b. US Federal Register:  
<https://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR>
- c. Federal Register daily Table of Contents email subscription (all TSCA-related actions are listed under the "Environmental Protection Agency"):  
<https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>

- d. EPA TSCA Reform Lautenberg Page:  
<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>

12. What are some of the first actions that formulators may be required to perform?

Within one year, EPA must issue a Final Rule to establish the reporting period and criteria to reset the TSCA Inventory to the “Active” TSCA Inventory. Formulators and/or their upstream suppliers may need to notify chemicals that were manufactured or imported within the ten years preceding enactment of Lautenberg (June 22, 2016). Chemicals must be notified to the Active inventory in order to continue commercial activity, and any confidentiality claims must be re-substantiated.

13. Could processors of a chemical be required to conduct testing?

Yes, in some cases, for example as regards potential exposure, processors may be required to conduct testing.

14. Will EPA solicit stakeholder input on implementation activities?

Yes, EPA has already begun to seek stakeholder input and will continue to do so. EPA recently held two public meetings on August 9<sup>th</sup> and 10<sup>th</sup> to solicit input on the processes that will be used to prioritize and evaluate chemicals under Lautenberg. The input obtained during these meetings will be considered as EPA develops its proposed procedural regulations for chemical prioritization and risk evaluation. Public meetings as well as other stakeholder input opportunities are announced in the EPA Federal Register. Please see Question 11 for access information for the Federal Register.