

October 2nd - 3rd

INTERNATIONAL
CHEMICAL
CONFERENCE
2018

CIS Center Russia



**U.S. TOXIC SUBSTANCES CONTROL ACT REFORM:
SIGNIFICANT CHANGES AND GLOBAL IMPACTS**

Konstantin Pimenov

Senior Regulatory Specialist

UL Product Supply Chain Intelligence



AGENDA

- **Overview of TSCA Reform**
- **Section 5: New Chemical Notifications**
- **Section 8: TSCA Inventory Active-Inactive Notifications**
- **Section 6: Existing Chemical Actions**





OVERVIEW OF TSCA REFORM



OVERVIEW OF TSCA REFORM

Toxic Substances Control Act (TSCA) Reform



- Environmental Protection Agency (EPA)
- “Frank R. Lautenberg Chemical Safety for the 21st Century Act”
- Enacted 22 June, 2016
- Mandatory deadlines for specific actions and rules
- Rulemaking Process
- Administration impacts





SECTION 5: NEW CHEMICAL NOTIFICATIONS

SIGNIFICANT CHANGES AND GLOBAL IMPACTS



SECTION 5: NEW CHEMICAL NOTIFICATIONS

SIGNIFICANT CHANGES

Notifications are required to place a new chemical on the TSCA Inventory prior to commercial U.S. manufacture or import into the U.S.

EPA must review, and review criteria are now more strict: EPA must make an *affirmative finding* that New Substance

- Presents an unreasonable risk; Not likely to present an unreasonable risk; Insufficient information to assess, **or** may present an unreasonable risk
- Must consider conditions of use in which substance is intended, known, or *reasonably foreseen to be used*
- Only 15% of notifications have been allowed to commercialize without restrictions

SECTION 5: NEW CHEMICAL NOTIFICATIONS

GLOBAL IMPACTS

Export to the U.S.

- If you export a confidential chemical to the U.S. that is not on the TSCA Inventory or exempted, the U.S. importer will need to file a new chemical notification
 - The U.S. importer will ask you to file a Joint Submission to the EPA
 - You must provide the chemical identity directly to the EPA
 - You must register with the EPA Central Data Exchange (CDX) to submit this information electronically
- This impact may extend through the supply chain if you sell the chemical to a non-U.S. company who then exports it to the U.S.

SECTION 5: NEW CHEMICAL NOTIFICATIONS

GLOBAL IMPACTS

Export to the U.S.

- For any new chemical exported to the U.S.
 - The new review criteria are impacting notification outcomes: Delays, withdrawals, restrictions, testing requirements
 - This may impact your ability to sell that chemical or products containing it to the U.S.; you may be required to provide increased hazard data on the chemical; this may require testing
 - In review, EPA will assume worst case in absence of increased hazard data
- This may impact your market entry for the new chemical or new market



SECTION 8: TSCA INVENTORY

ACTIVE - INACTIVE NOTIFICATIONS

SIGNIFICANT CHANGES AND GLOBAL IMPACTS



SECTION 8: TSCA INVENTORY ACTIVE-INACTIVE NOTIFICATIONS. *SIGNIFICANT CHANGES*

- Reset of the TSCA Inventory of existing chemicals to designate “active” vs. “inactive”
- Purpose: Identify those truly still in commerce to focus EPA review
- Must notify to EPA as “active”, all chemicals on TSCA Inventory manufactured, imported or processed for commercial purposes since 21 June, 2006
- A chemical must be designated as Active to continue commercial activity
- Deadline for Manufacturers and Importers: 7 February 2018, however EPA is still accepting notifications with certain related requirements
- Deadline for Processors: 5 October 2018

SECTION 8: TSCA INVENTORY ACTIVE-INACTIVE NOTIFICATIONS. *GLOBAL IMPACTS*

- If you export a confidential chemical to the U.S. that must be designated as active by the U.S. importer:
 - The U.S. importer will ask you to file a Joint Submission to the EPA
 - You must provide the chemical identity directly to the EPA
 - You must register with the EPA Central Data Exchange (CDX) to submit this information
- This may extend through the supply chain if you sell the chemical to a non-U.S. company who then exports it to the U.S.
- If your U.S. importer fails to notify as active, they will no longer be able to import



SECTION 6: EXISTING CHEMICAL ACTIONS

SIGNIFICANT CHANGES AND GLOBAL IMPACTS



SECTION 6: EXISTING CHEMICAL ACTIONS. *SIGNIFICANT CHANGES*

Existing Chemicals are those that are listed on the TSCA Inventory:

Purpose of changes to Existing Chemical Actions under TSCA Reform:



Prioritization

Risk Evaluation

Risk Management
(Regulation)

Prioritize chemicals for review → Conduct Risk Evaluations → Apply Risk Management measures where warranted

SECTION 6: EXISTING CHEMICAL ACTIONS.

GLOBAL IMPACTS

Export to the U.S.:

- Your U.S. importer may be required to provide and submit hazard, use, and exposure information to EPA and/or to downstream customers.
- The U.S. importer may ask you for the hazard information.
- If the EPA requires additional hazard information, you may be required to generate it. This may require you to conduct testing.
- The testing may be expensive and time consuming.
- You may decide that the testing is not worth the time and cost, therefore you may elect to stop sale into the U.S.
- This may result in increased cost and/or interruption of business.

SECTION 6: EXISTING CHEMICAL ACTIONS.

GLOBAL IMPACTS

Export to the U.S.:

- The EPA risk assessment may result in restriction and regulation of chemicals that you export to the U.S.
- This may prohibit your U.S. importer from using the chemical for their desired purpose
- The U.S. importer may decide to stop importing your chemical and identify an alternative chemical
- This may disrupt your business and ability to sell into the U.S.

IN CLOSING.....

- There are many significant changes in TSCA due to the reformed legislation, that have an impact throughout the supply chain globally
- The new requirements are complex and require detailed analysis

• **UL Can Help**

- TSCA Services Team
- UL Regulatory Database (LOLI)
- UL Regulatory Compliance Software

Special thanks to *Stacie Abraham*, UL TSCA Services Team Leader

Thank you for your attention!

