TSCA Inventory Reset

PLASTICS EHS+ Committee and FPA EHS Committee – Joint Meeting
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Earl Seibert
NA Regulatory Affairs Manager
Sun Chemical Performance Pigments
Cincinnati, OH 45232 USA
M +1 513 288-8736
earl.seibert@sunchemical.com
Key EPA Actions, Lautenberg Chemical Safety Act (LCSA)  
(June 22, 2016)

• Make affirmative safety findings for “new” chemicals entering the market
• Prioritize “active” substances systematically for risk evaluation
• Systematically evaluate risks of “high priority” chemicals (schedule)
• Regulate chemicals found to pose unreasonable risk
• Collect data where needed for decision-making
• Actively evaluate new and existing CBI claims
• "Reset" the TSCA Inventory by determining “active” substances

“This marks the first overhaul in 42 years to TSCA”
“Reset” of the Current TSCA Inventory

• As of April 2018: ~86,000 chemicals on the TSCA inventory

• Initial TSCA Inventory (~62,000): Reported to be in U.S. commerce between January 1975 and June 1979

• New chemicals added since then (~24,000): Notified via the PMN-NOC process

• Approximately 21% of all chemicals on the TSCA inventory are listed as confidential
The Revised TSCA “Reset” inventory

- Total ~ 86,000 substances on TSCA
- Active ~38,000 substances (45% of total Inventory)
- ~31,000 “public” substances, ~7,000 CBI substances
- Latest version of TSCA Inventory reflects “Active” status of chemicals as follows:
  - Reporting from 2012 and 2016 CDR reporting events
  - PMN-NOCs received by EPA since June 21, 2006
  - Notice of Activity Form A’s received by February 7, 2018
- This leaves ~48,000 substances as potentially inactive...
  (numbers may have changed since the Oct 5th deadline)
CDR Statistics from 2016

- CDR Chemicals reported: 8,707 (25,000 lbs threshold)
- 5,919 manufactured, 4,415 imported
- Manufacture/import sites: 4,917
- Companies reporting: 2,247
- Based on current Reset numbers, a significant percentage of chemicals appear to fall below the threshold
“Interim active” (IA) Substances

• Reported on the TSCA CDR as being produced if:
  – I.e., reported on the 2012 or 2016 CDRs
    (Even if on confidential Inventory)
• “Interim active” (IA) substances are not required to be reported
  – But must reported if chemical identity to be maintained as CBI
Other Substances Considered to be “Active”

• Any “naturally occurring” substance- not synthetically produced

• Any substance added to Inventory on/after June 21, 2006 due to PMN-NOC received by EPA on/after that date
Designation of Active and Inactive substances

• Reported substances => “Active”
  – According to the LCSA: EPA “shall designate …substances reported under [CDR regulations] during the reporting period that most closely preceded June 22, 2016, as the interim list of active substances…”

• Non-reported substances => “Inactive”
  – Must notify EPA prior to commencing manufacturing, importing, or processing
  – EPA cannot require a PMN for inactive to active change
  – EPA cannot delist inactive substances
Inventory Reset Rule

• Statutory requirement under the LCSA to “reset” the Inventory. EPA required to issue rule within one year of the June 22, 2016 LCSA enactment.

• August 11, 2017: EPA published final rule to “reset” TSCA Inventory

• Manufacturers and importers were then required to notify EPA within 180 days of each TSCA Inventory listed non-exempt substance produced within the 10-year “lookback period” of June 21, 2006 to June 21, 2016

• This is called “retrospective” reporting, Notice of Activity (NOA) Form A reporting. Mandatory for manufacturers and importers and voluntary for processors
Retrospective Reporting

• Companies must report Inventory-listed substances manufactured/ imported for non-exempt purposes during the 10-year “lookback period” from June 21, 2006 to June 21, 2016
  – Basic premise: “Known to or reasonably ascertainable by”
  – No exemption for low volume substances or polymers

• So-called “retrospective” reporting
  – Mandatory for manufacturers and importers, voluntary for processors

• Reports had to be made using CDX
Reset Exemptions

- Substances in processed/ imported “articles”
- Non-“chemical substances”
  - E.g., food additives, pesticides
- R&D / test marketing substances
- 40CFR 720.30(g) and (h) substances
  - Impurities, byproducts, non-isolated intermediates, end-use, etc.
- Export-only substances (unless TSCA Section12(a)(2) finding made)
Exemptions

- EPA does **NOT** believe that manufacturing or processing under a low volume (LVE), low releases/low exposures (LoREX), or polymer exemption (1984 or 1995 polymer exemption) qualify as exempt under TSCA section 8(b)

- These substances are not required to be on the Inventory, but they may be present

- However, “EPA anticipates that the presence of a substance on the confidential portion of the Inventory may be information that is not ‘known to or reasonably ascertainable by’ a person who is operating under a PMN exemption and who did not submit the confidentiality claim for the specific chemical identity of that substance.”
Retrospective Reporting Period Due Dates

• **February 7, 2018**
  – Mandatory reporting for manufacturers and importers

• **October 5, 2018**
  – Voluntary reporting by processors
Reset “Form A” used for Retrospective Reporting

- “Notice of Activity” (NOA) “Form A” used by manufacturers, importers, and processors during the retrospective reporting period
- Based on TSCA-NOC form
- Contained basic information such as:
  - Company identification
  - Technical contact
  - CASRN
  - CA Index name
  - Accession No.
  - Required certification statements
Timeline - Retrospective Reporting (Form A)

- **manufacturer (\& processor) submission period**
  - 8/12/2017 - 2/7/2018
  - 180 days

- **processor submission period**
  - 2/7/2018 - 10/5/2018
  - 240 days

EPA publishes draft Inventory with substances reported by 2/7/2018 designated as “active”

EPA TSCA Inventory Notification TSCA Inventory Notification (Active \- Inactive) Requirements and Reporting Application and Webinar November 29, 2017
Reset “Form B” and Forward-Looking reporting

- NOA “Form B” to be used by manufacturers, importers, and processors for **forward-looking** reporting
- Must contain same information as Form A; and
- “Anticipated” date by which substance to be manufactured or processed in the U.S.
Forward-looking Reporting Period

- Once designated “inactive,” substance cannot be manufactured, imported, or processed unless EPA notified in advance (“forward-looking reporting”)

- Substance not formally designated as “inactive” until 90 days after EPA identifies substance as such, which addresses the “resumption” issue

- Reports must be made using CDX
Timeline - Future Reporting (Form B)

EPA publishes initial Inventory with substances reported by 10/5/2018 designated as either “active” or “inactive”

Manufacturer & processor reporting

90 days

11/2018

2/2019
date when substances designated as “inactive” become effectively “inactive”

EPA TSCA Inventory Notification TSCA Inventory Notification (Active -Inactive) Requirements and Reporting Application and Webinar November 29, 2017
Transition Period

- EPA intends to issue the initial TSCA Inventory with all substances designated as “active” or “inactive” in November 2018 and a final inventory in February 2019.

- During the transition period of 90 days before the inventory is finalized, manufacturers and processors can respond to any potential inactive designations using a NOA Form B.
Timeline – All Reporting (Forms A&B)

- Retrospective reporting period
  - 6/21/2006 to 6/21/2016
  - 10 years

- Gap period
  - 6/22/2017 to 8/11/2017
  - 8/12/2017 to 10/5/2018
  - 420 days

- Future reporting period
  - 11/2018 to 2/2019
  - 90 days

- Rule

- Retrospective submission period

- Future submission period

EPA TSCA Inventory Notification TSCA Inventory Notification (Active - Inactive) Requirements and Reporting Application and Webinar November 29, 2017
Who Must Report (Form B)

• Any person who intends to manufacture, import, or process an inactive substance, for non-exempt purposes, after the effective date EPA designates the substance as inactive

• **Unless** the inactive substance listing on confidential portion of Inventory is not known to or reasonably ascertainable by the person
When Must a “Form B” be Submitted?

- Before the actual, but not more than 90 days prior to the anticipated date of manufacture, import, or processing
  - May also be submitted during 90-day period between the identification and effective dates for inactive designation, by the person currently manufacturing/processing or who anticipates doing so within 90 days following submission
  - If EPA receives submitter request to withdraw Form B and EPA has not moved substance to active or public Inventory, EPA can grant request
What If a Required Form A was not submitted?

• What if the required substance Form A was not submitted as a manufacturer/ importer during the retrospective period

• Submit Form B as required otherwise
  – Does not impact liability for failure to file Form A
  – Even if reported by one or more other companies and now “active”

• While late submissions are potential violations, EPA’s primary objective has been accurate and complete reporting.

• Late NOA Form A submissions were allowed in CDX (presumably done under the EPA Audit Policy)
Handling an “Inactive” Substance?

- This means that processors are strictly liable for handling inactive substances once so designated.

- It would be very wise to have request supplier assurances as to whether materials have been activated or are exempt to avoid the “inactive” handling scenario.
Confidential Business Information (CBI)

- Retrospective reporting (NOA Form A)
  - CBI claims allowed, but only if substance listed on confidential portion of Inventory when the notice was submitted
  - CBI claim made at the time the information is submitted even if one is the not original claimant
  - If no person requested CBI claim be maintained, EPA will move the substance to the public Inventory
  - CBI claim for “ACTIVE” chemical substance required an NOA Form A submission

- Future reporting (NOA Form B)
  - Chemical identity: Substantiation must be provided by EPA within 30 days of submission of the notice or may be provided with the notice.
  - All other data elements: Substantiation must be provided with the notice when the information is submitted

- Estimated date for publishing CBI Review Plan: November or December, 2019