

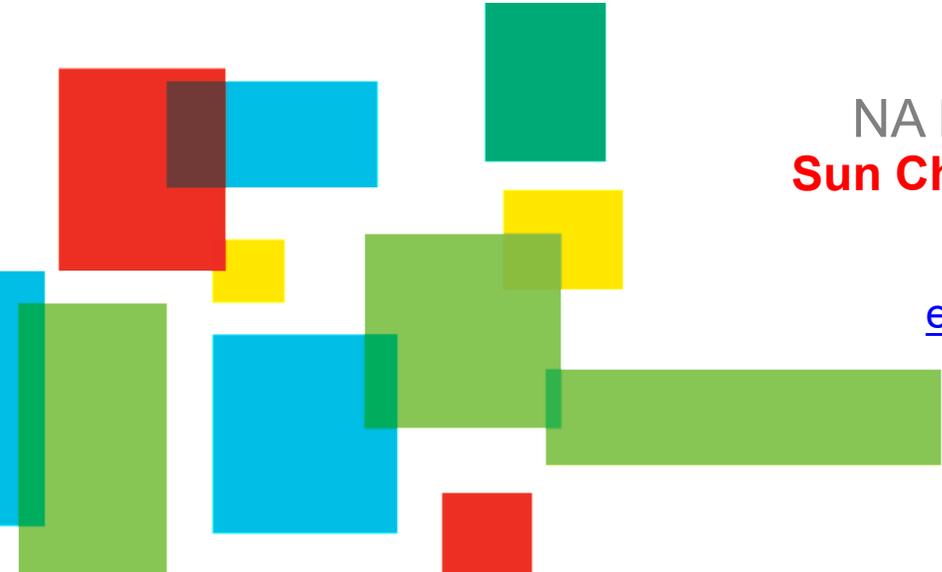


# TSCA Inventory **Reset**

## PLASTICS EHS+ Committee and FPA EHS Committee – Joint Meeting

October 16, 2018

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# 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 5<sup>th</sup> 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 Section 12(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.”

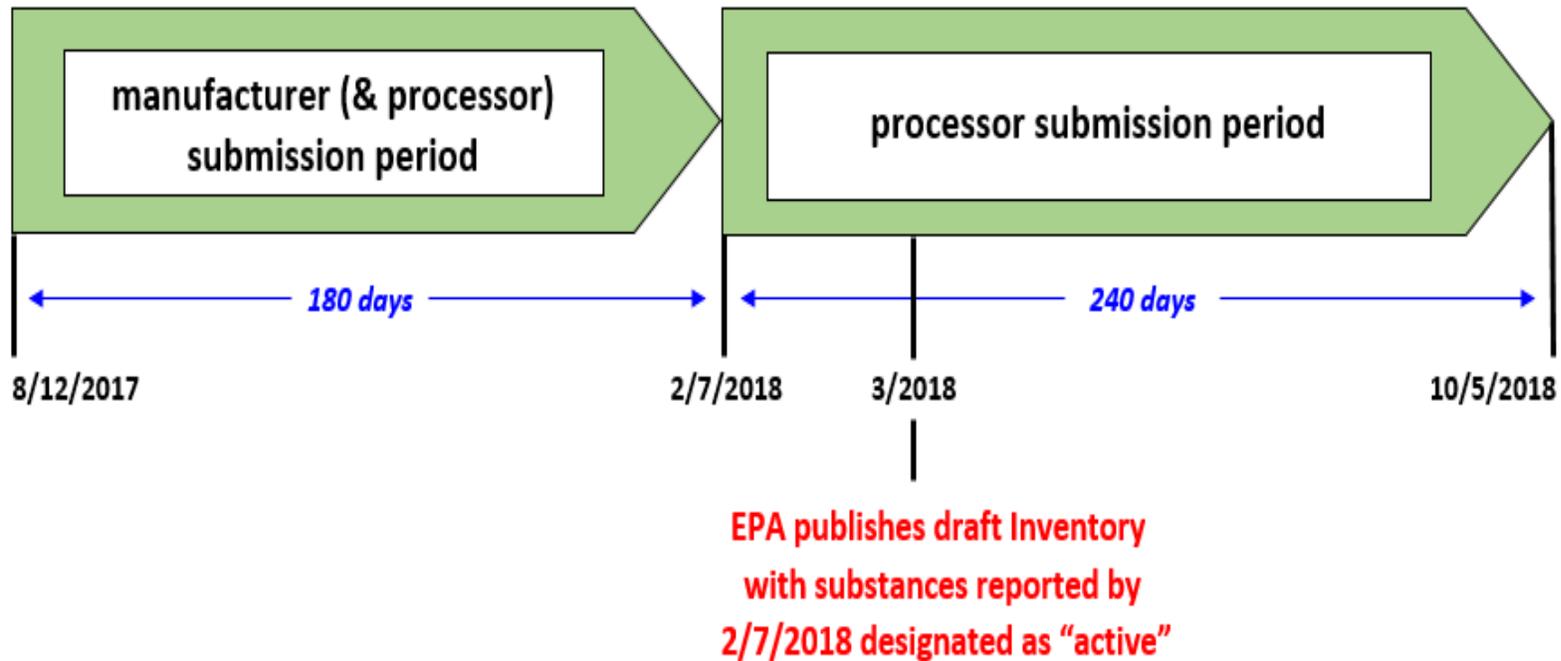
# Retrospective Reporting Period Due Dates

- **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)



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

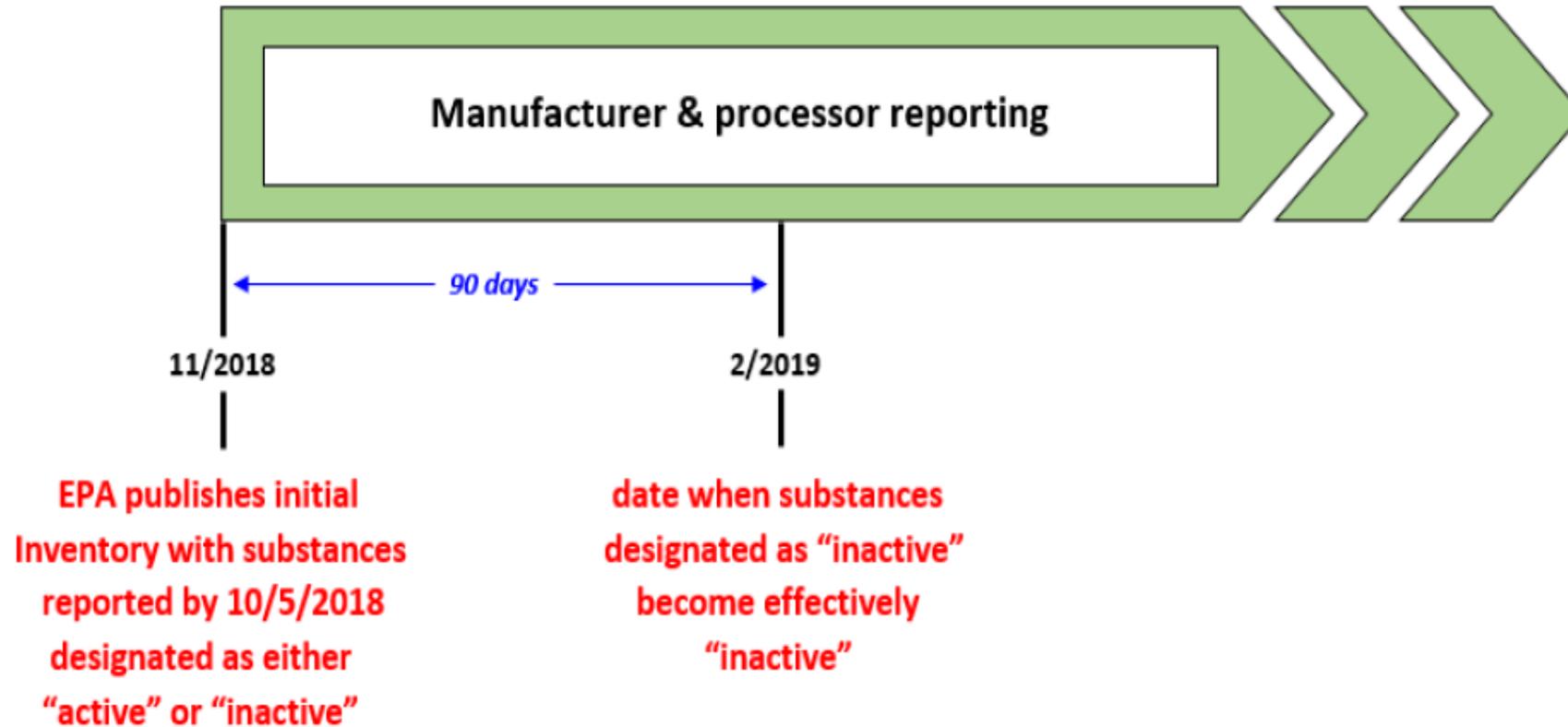
## Reset “Form B” and Forward-Looking reporting

- **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)



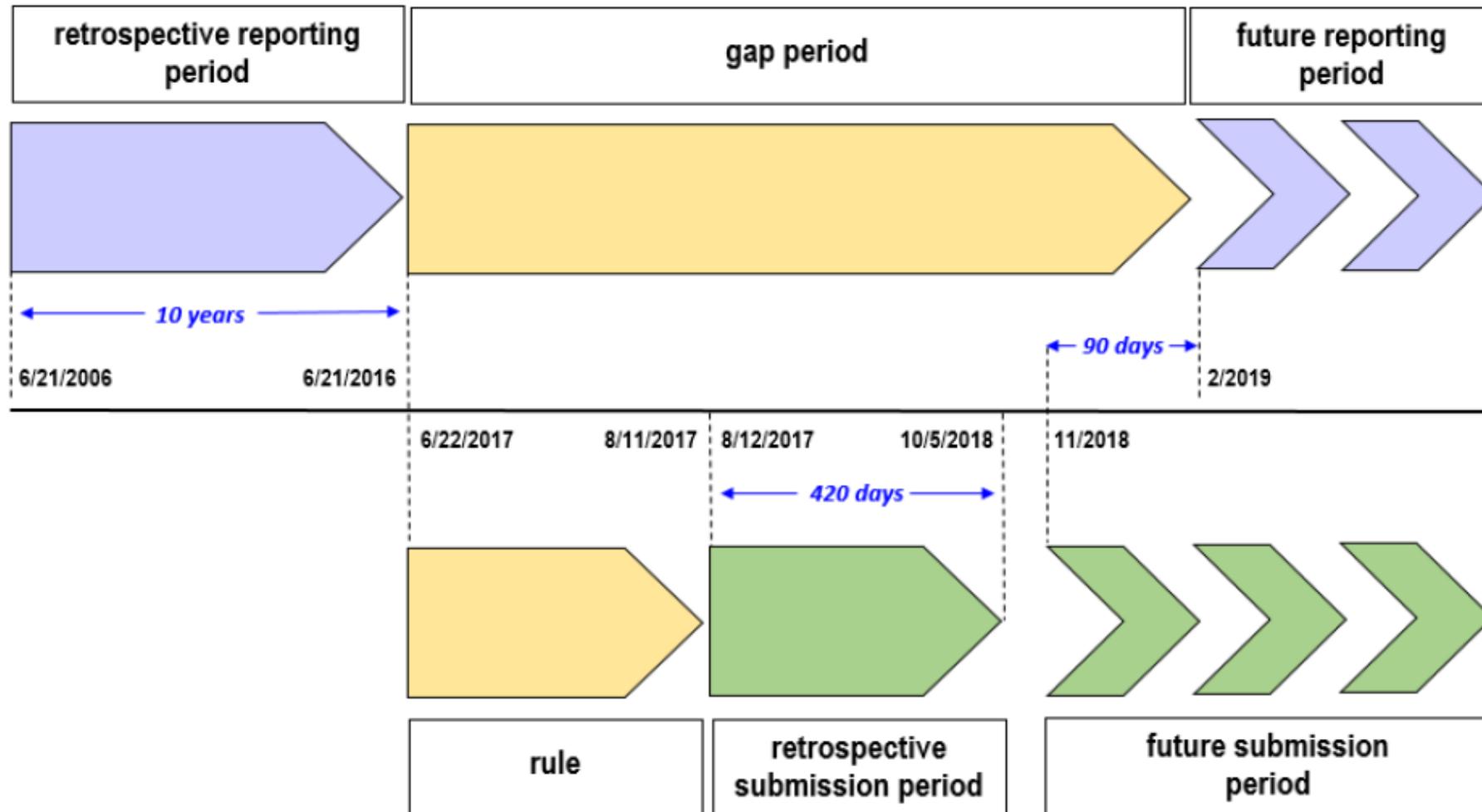
EPA TSCA Inventory Notification TSCA Inventory Notification (Active -Inactive) Requirements and Reporting Application and Webinar November 29, 2017

# 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)



## 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