TSCA Inventory Notification (Active-Inactive) Requirements and Reporting Application –

Notice of Activity Form B

EPA Webinar March 13, 2019



Agenda

- Notice of Activity Form B
 - Reporting Requirements
 - Reporting Timeline
 - Confidential Business Information
- Electronic Reporting Application
- Questions and Answers



Overview

- The Frank R. Lautenberg Chemical Safety for the 21st
 Century Act [15 U.S. Code Chapter 53]
 - Enacted June 22, 2016
 - Primarily: TSCA section 8(b)(4), TSCA section 8(b)(5)
- TSCA Inventory Notification (Active-Inactive)
 Requirements Rule [40 CFR 710]
 - Published August 11, 2017
 - Primarily: 40 CFR 710 Subpart B Commercial activity notification
 - https://www.federalregister.gov/documents/2017/08/11/2017 15736/tsca-inventory-notification-active-inactive-requirements



TSCA section 8(b)(4)(A)

- Retrospective reporting, Notice of Activity Form A
- ➤ (4) Chemical substances in commerce.—
 - (A) Rules.—
 - (ii) Active substances.—

The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(iii) Inactive substances.—

The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

Initial TSCA Inventory posted on February 19, 2019



TSCA section 8(b)(5)(B)

- Forward-looking reporting, Notice of Activity Form B
- (5) Active and Inactive substances.—
 - (B) Change to active status.—
 - (i) In general.— Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.
 - (iii) Active status.—On receiving a notification under clause (i), the Administrator shall—(I) designate the applicable chemical substance as an active substance



Implementing Regulations

- 40 CFR 710 Subpart B Commercial activity notification
 - 710.23 Definitions.
 - 710.25 Persons subject to the notification requirement.
 - 710.27 Activities for which notification is not required.
 - 710.29 Information required in the notification.
 - 710.30 When to submit notifications.
 - 710.33 Co-manufacturers and co-processors.
 - 710.35 Recordkeeping requirements.
 - 710.37 Confidentiality claims.
 - 710.39 Electronic filing.



Retrospective Reporting Summary (Form A)

Schedule

- August 2017 reporting began (immediately after rule publication)
- February 7, 2018 deadline for required reporting by manufacturers
- October 5, 2018 deadline for voluntary reporting by processors

Reporting Statistics

>90,000 individual notices received

Initial Inventory Statistics

	ON INVENTORY	ACTIVE	INACTIVE
NON-CBI CHEMICALS	68,008	32,898	35,110
CBI CHEMICALS	18,220	7,757	10,463
TOTAL	86,228	40,655	45,573

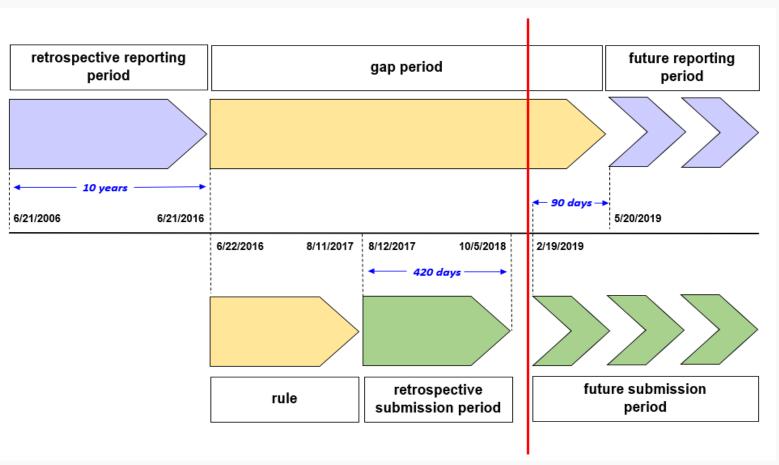


Forward-looking Reporting (Form B)

- What is reported?
 - Chemical substances designated as "inactive" on the TSCA Inventory that are anticipated to be re-introduced into U.S. commerce for non-exempt purpose.
- Who Reports?
 - Manufacturers (including importers) and processors are required to report, by statute.
- When is the submission period?
 - Manufacturers (including importers) and processors must report an inactive substance prior to re-introduction into U.S. commerce, by statute, but not more than 90 days prior, by rule.

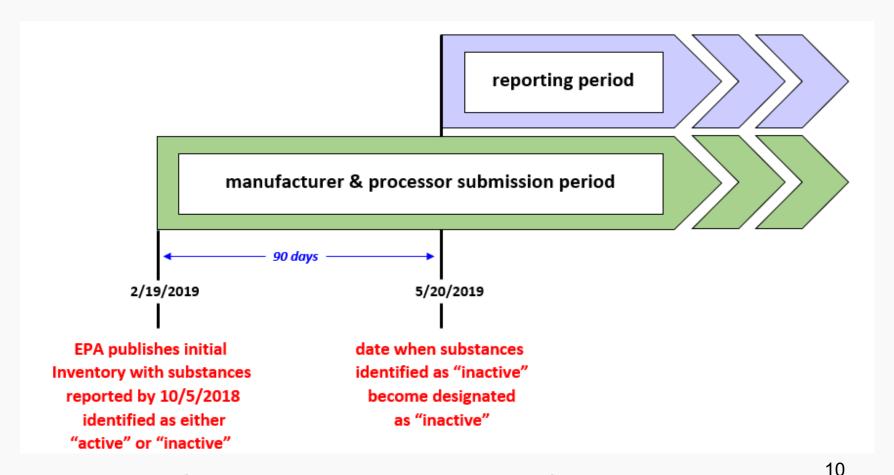


Timeline – All Reporting





Timeline – Forward-looking Reporting (Form B)





- Reporting period starts May 20, 2019
 - When substances currently identified as "inactive" are designated as "inactive"
- When is the submission period?
 - Submission period began on February 19, 2019.
 - —This is the date that the TSCA Inventory was posted and is 90 days prior to the start of the reporting period.
 - Allows certain manufacturers and processors to submit a Form B in advance of a substance being designated as "inactive," as required by the statute, without having to stop current commercial activity.



- Transitional period reporting
 - For processors (temporary scenario):
 - —that processed a substance during the retrospective reporting period and chose not to voluntarily report, and the substance is identified as inactive,
 - —and that are currently processing the substance and anticipate continuing to process the substance into the reporting period,
 - ➤ the submission period is the 90 days between posting the initial Inventory and the start of the reporting period



- Transitional period reporting
 - For manufacturers (including importers) and processors (temporary scenario):
 - —that reintroduced a substance into commerce during the transitional period, and the substance is identified as inactive,
 - —and that are currently commercializing the substance and anticipate continuing to commercialize the substance into the reporting period,
 - ➤ the submission period is the 90 days between posting the initial Inventory and the start of the reporting period



- Transitional period reporting
 - For manufacturers (including importers) and processors (steady-state):
 - —that anticipate reintroducing an inactive substance into U.S. commerce in the future,
 - ➤ the submission period is prior to commercialization but not more than 90 days prior



- Chemical substances subject to forward-looking reporting
 - Are designated as an inactive substance on the Inventory
 - Are anticipated to be reintroduced into U.S. commerce for non-exempt purpose
 - Reportable substances also:
 - Meet the 40 CFR 710.3 definition of "Chemical Substance"
 - Do not meet a 40 CFR 710.27 activity exemption



- 40 CFR 710.3 definition of "Chemical Substance"
 - Substances not included in the definition:
 - Mixture
 - A pesticide when manufactured, processed, or distributed in commerce for use as a pesticide
 - Tobacco or any tobacco product, but not including any derivative products
 - A source material, special nuclear material, or byproduct material
 - A pistol, firearm, revolver, shells, and cartridges
 - Food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device



- 40 CFR 710.3 definition of "Chemical Substance"
 - Note:
 - An excluded substance may be listed on the TSCA Inventory if, in addition to being an excluded substance (e.g., pesticide), it has another use that makes it a TSCA-reportable substance.
 - Under the TSCA Inventory Notification (Active-Inactive) rule, a TSCA Inventory-listed, inactive substance therefore:
 - Is not reportable if a person anticipates manufacturing or processing such substance as a substance that is excluded from the definition of "Chemical substance"
 - May be reportable if a person anticipates manufacturing or processing such substance as a substance that is included in the definition of "Chemical substance."



- 40 CFR 710.27 activity exemptions
 - The manufacturing or processing of an inactive substance solely for:
 - research and development (small quantities)
 - test marketing purposes
 - export from the United States as described in § 720.30(e) or § 721.3, except where the Administrator has made a finding described in TSCA section 12(a)(2)
 - The import or processing of an inactive substance as part of an article
 - Manufacturing or processing naturally occurring chemical substances
 - The manufacturing or processing of an inactive substance as described in § 720.30(g) or § 720.30(h)



- 40 CFR 710.27 activity exemptions
 - Note:
 - An exempted substance may be listed on the TSCA Inventory if, in addition to being an exempted substance in one process (e.g., impurity), it is also a TSCA-reportable substance in another process.
 - Under the TSCA Inventory Notification (Active-Inactive) rule, a TSCA Inventory-listed, inactive substance therefore:
 - Is not reportable if a person anticipates manufacturing or processing such substance solely as an exempted substance
 - May be reportable if a person anticipates manufacturing or processing such substance for non-exempt purpose



Confidential Business Information

- Procedures for the submission of information claimed as CBI [40 CFR 710.37]
 - Forward-looking reporting (NOA Form B)
 - <u>Chemical identity</u>: Substantiation must be provided within 30 days of submission of the notice or may be provided with the notice. Substantiation will be reviewed per TSCA section 14(g) requirements.
 - All other data elements: Substantiation must be provided with the notice. Substantiation will be reviewed per TSCA section 14(g) requirements.



How to Report

- Electronic filing [40 CFR 710.39]
 - Report using EPA's Chemical Data Exchange (CDX)
 - Registration required
 - Select your user role for the "CSPP: Submissions for Chemical Safety and Pesticides Programs", then within "Chemical Information Submission System" (CISS) choose the software: "TSCA Section 8(b) – e-NOA"
 - NOA Form B is available for forward-looking reporting.
- https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn">https://cdx.epa.gov/, https://cdx.epa.gov/, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn

Future	
Reporting	
8(b)(5)(B)]	

How to Report?

EPA

U.S. Environmental Protection Agency NOTICE OF ACTIVITY OF MANUFACTURE, IMPORT, OR PROCESSING – FORM B

Submission Date:	
Revised Date:	

Part	l – Sub	mitter lo	dentitio	cation

	Name of Authorized Official	Mailing Address (street, city, zip code)	CBI*
Manufacturer,	(first) (last)		
Importer, Processor (in U.S.)	Company Name	Mailing Address (street, city, zip code)	
Technical Contact	Name	Telephone Number	
(in U.S.)	(first) (last)		

^{*} CBI refers to the term "Confidential Business Information." Mark (X) in the CBI box(es) if the submitter information is to be held confidential.

Part II - Chemical Substance Identity

CASRN	TSCA Inventory Chemical Name (if specific chemical identity is not CBI)		
Accession Number	Generic Chemical Name (if specific chemical identity is CBI)		
			10000

Part III - Status of Confidential Chemical Substance Identity

I am seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory.

I am not seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory.

Part IV - Anticipated Date** of Reintroduction of Chemical Substance in U.S. Commerce***

Date:

Part V - Certification

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge, is true, accurate, and complete. I also certify that I have intent to manufacture, import, or process the above chemical within 90 days of submission. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

Signature of authorized official		Date	22
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^{**}__if the notice is filed prior to the effective date of the chemical substance's inactive designation, the most recent date of manufacture or processing may be provided in lieu of an anticipated date.

^{***} Mark (X) in the CBI box if the date is to be held confidential.



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How to Report

- Electronic filing [40 CFR 710.39]
 - Notices can be submitted by a corporate office and/or by a site or other organizational unit within a company.
 - Substances can be selected from a pick list in the application, or substances can be uploaded into the application from an Excel spreadsheet.
 - Only substances identified as "inactive" on the TSCA Inventory are included on the pick list at this time.
 - Substances uploaded from an Excel spreadsheet will be checked against the pick list.



Electronic Reporting Application Demonstration



Thank you!

- https://www.federalregister.gov/documents/2017/08/11/2017-15736/tsca-inventory-notification-active-inactive-requirements
- https://www.epa.gov/tsca-inventory
- Tracy Williamson, Chief, Industrial Chemistry Branch williamson.tracy@epa.gov, tscainventory@epa.gov 202-564-8569 (direct), 202-564-8740 (branch)
- Myrta Christian, Associate Chief, Industrial Chemistry Branch <u>christian.myrta@epa.gov</u>, <u>tscainventory@epa.gov</u>
 202-564-8498 (direct), 202-564-8740 (branch)



Questions & Answers