



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

**EPA Webinar
November 29, 2017**



Acronyms

CBI – *Confidential Business Information*

NOA – *Notice of Activity*

CDX – *Central Data Exchange*; EPA's secure, electronic reporting portal

CISS – *Chemical Information Submission System*, EPA's web-based reporting tool within CDX for preparing and submitting TSCA notices

e-NOA – EPA's software module within CISS specifically for Notice of Activity Forms A and B

NAA – *Notice of Activity Form A*; this is the record designation assigned to notices filed in the electronic application, e.g., NAA-17-0002

NAB – *Notice of Activity Form B*; this is the record designation that will be assigned to notices filed in the electronic application, e.g., NAB-19-0002

SRS – *Substance Registry System*; EPA's chemical pointer system



Agenda

- Reporting Requirements (*Who-What-When-Why-How*)
- 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)

(4) Chemical substances in commerce.—

(A) Rules.—

(i) In general.— Not later than 1 year after June 22, 2016, the Administrator, by rule, shall require manufacturers, and may require processors, subject to the limitations under subsection (a)(5)(A), to notify the Administrator, by not later than 180 days after the date on which the final rule is published in the Federal Register, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before June 22, 2016.

➤ *Retrospective reporting, Notice of Activity Form A reporting*



TSCA section 8(b)(4)(A) – cont.

(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).

(iv) Limitation.—

No chemical substance on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph, or be subject to section 2604(a)(1)(A)(i) of this title by reason of a change to active status under paragraph (5)(B).



TSCA section 8(b)(5)(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.

➤ *Future reporting, Notice of Activity Form B reporting*

(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 (NOA Form A)

- *What* is reported?
 - Chemical substances on the TSCA Inventory that were in U.S. commerce for non-exempt purpose during the 10-year period ending on the day before June 22, 2016 [6/21/2006 – 6/21/2016].
- *Who* Reports?
 - Manufacturers (including importers) are required to report, by statute.
 - Processors may report, by rule.
- *When* is the submission period?
 - Manufacturers (including importers) have, by statute, 180 days to report after publication of the rule [8/12/2017 – 2/7/2018].
 - Processors that choose to report have, by rule, 420 days to report after publication of the rule [8/12/2017 – 10/5/2018].



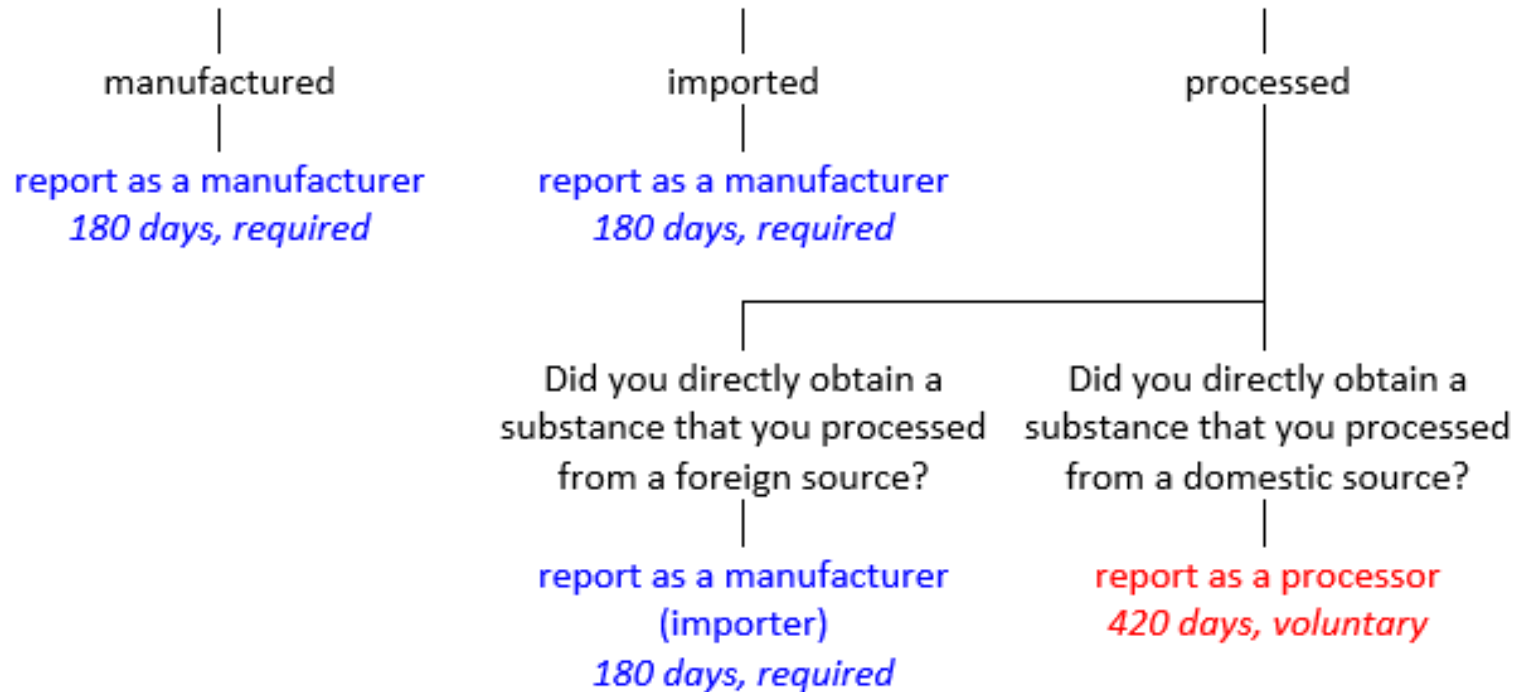
Future Reporting (NOA Form B)

- *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.



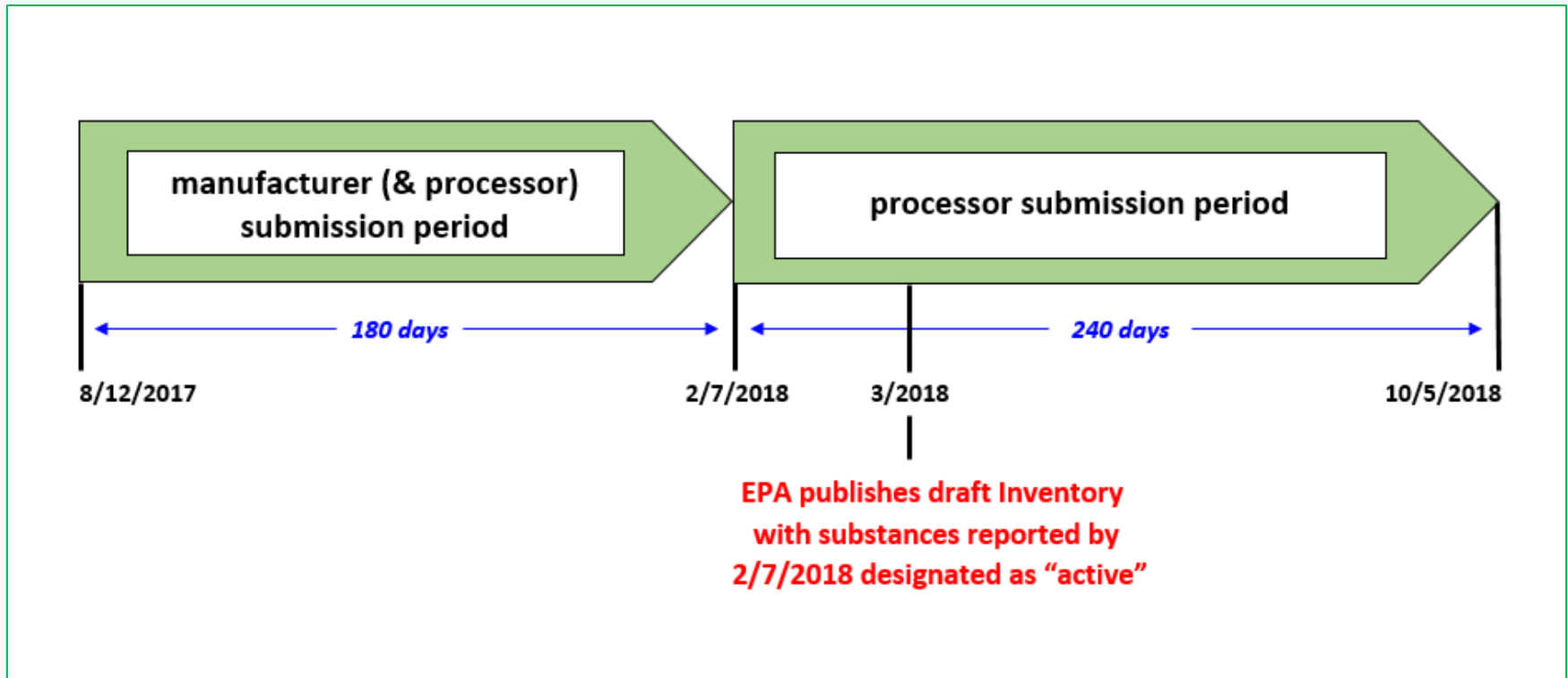
More on Who Reports - Retrospective

If you manufactured, imported, or processed 1) a TSCA Inventory listed chemical substance 2) for non-exempt commercial purpose 3) at any time during the 10-year reporting period (June 21, 2006 - June 21, 2016):



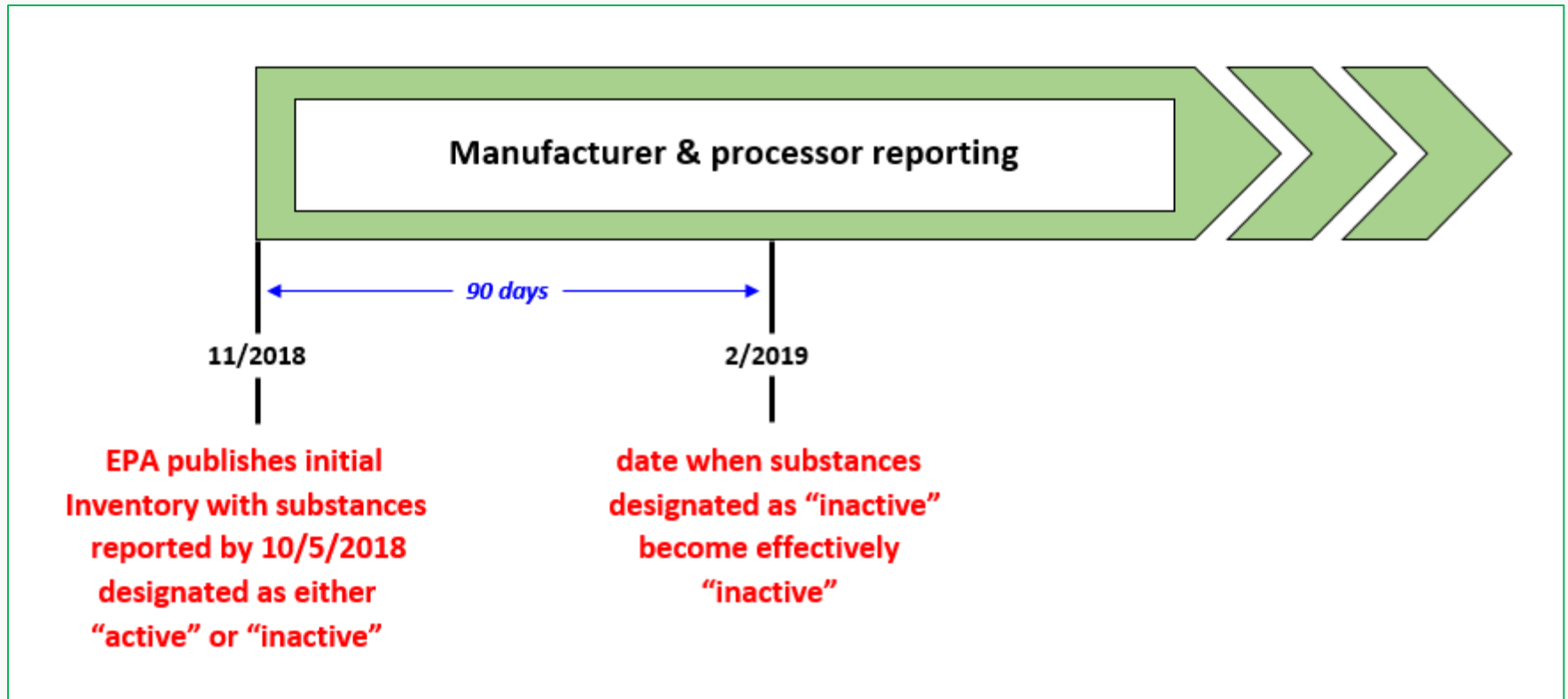


Timeline - Retrospective Reporting (Form A)



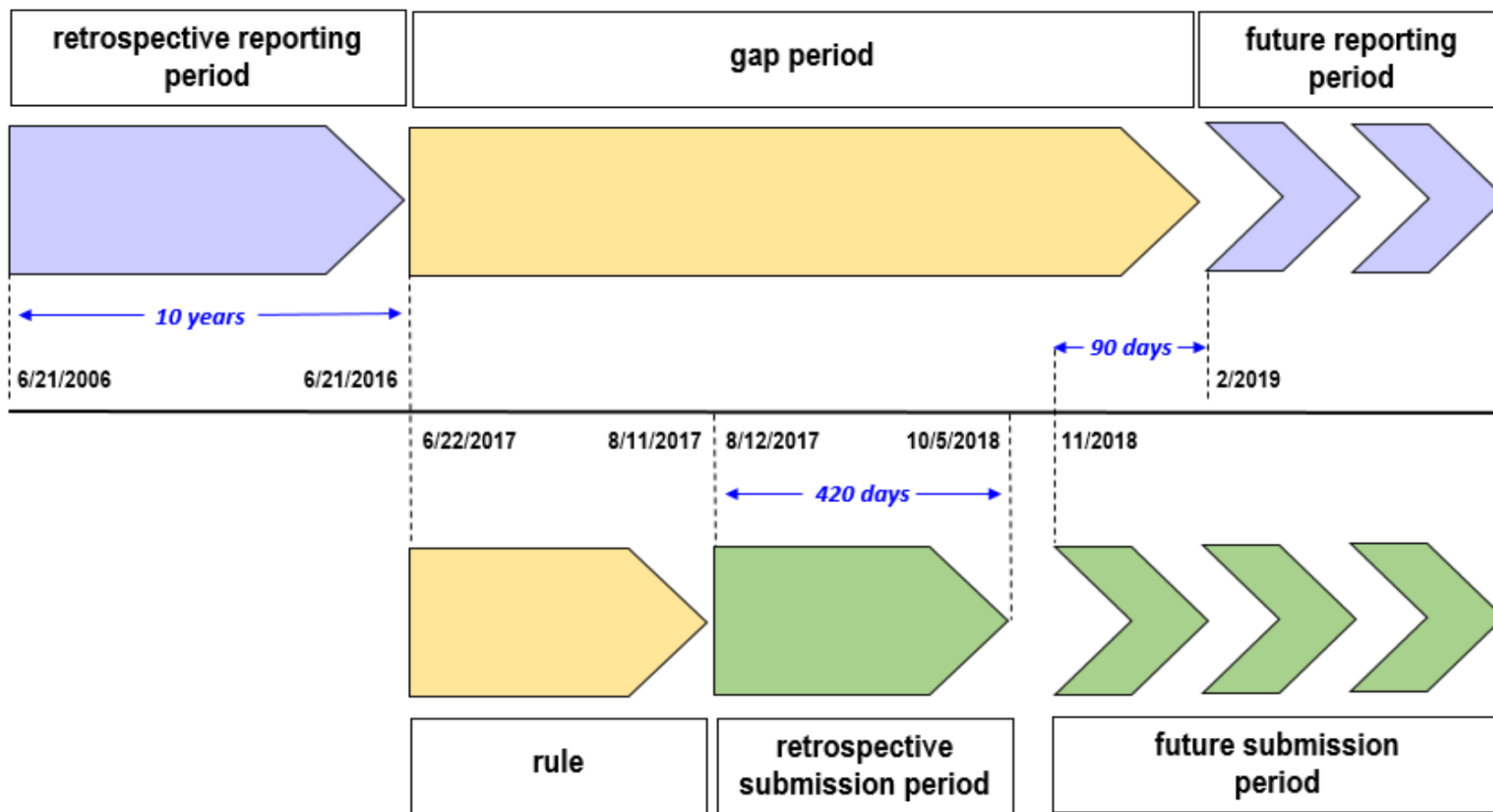


Timeline - Future Reporting (Form B)





Timeline – All Reporting (Forms A&B)





More on Reportable Chemical Substances

- Reportable substances [40 CFR 710.23 – Definitions]
 - *Chemical substance subject to commercial activity designation* means a chemical substance that requires a designation as either an active or an inactive substance. A chemical substance is subject to commercial activity designation if it is not an interim active substance, it was added to the Inventory before June 21, 2006, it is not a naturally occurring chemical substance as defined by § 710.27(b), and it has not yet been designated by the Administrator as either an active or an inactive substance.



More on Reportable Chemical Substances

- Reportable substances [40 CFR 710.23 – Definitions]
 - *Reportable chemical substance* means a chemical substance that is listed on the Inventory and that is either:
 - (1) A chemical substance subject to commercial activity designation for which notification is required or allowed under § 710.25(a) and § 710.25(b),
 - (2) A chemical substance that was added to the confidential portion of the Inventory before June 22, 2016, or
 - (3) an inactive substance for which notification is required under § 710.25(c).



More on Reportable Chemical Substances

- Excluded substances [40 CFR 710.3 – Definitions]
 - Substances not listed on the TSCA Inventory.
 - Substances not included in TSCA definition of “chemical substance”:
 - Any mixture. Note: A mixture is excluded from reporting under TSCA, but the components of a mixture are reportable and are listed on the TSCA Inventory.
 - E.g., Hydrates are considered a mixture of the anhydrous form and water and are reported as the anhydrous form.
 - Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide;
 - Tobacco or any tobacco product, but not including any derivative products;
 - Any source material, special nuclear material, or byproduct material.
 - Any pistol, firearm, revolver, shells, and cartridges; and
 - Any 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.



More on Reportable Chemical Substances

- Excluded substances – 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 substance therefore:
 - Is not reportable if a person manufactured or processed such substance as a substance that is excluded from the definition of “Chemical substance.”
 - May be reportable if a person manufactured or processed such substance as a substance that is included in the definition of “Chemical substance.”



More on Reportable Chemical Substances

- Exempted substances – substances for which EPA already has an equivalent notice (retrospective reporting)
 - Substance is already marked “ACTIVE” on the TSCA Inventory.
 - TSCA section 8(b)(6) – Interim list of active substances. —
 - States that EPA will designate substances reported under the CDR cycle that most closely preceded June 22, 2016, as the interim list of active substances for the purposes of TSCA section 6.
 - EPA compiled the interim list of active substances to include substances reported to the 2012 and 2016 CDR and designated these substances as “ACTIVE” on the TSCA Inventory.
 - Substances added to the TSCA Inventory on or after June 21, 2006, are designated as “ACTIVE.” This includes:
 - Substances added to the TSCA Inventory during the retrospective reporting period (6/21/2006 – 6/21/2016)
 - Substances added to the TSCA Inventory since TSCA was amended (since 6/22/2016)



More on Reportable Chemical Substances

- Exempted substances – substances for which EPA already has an equivalent notice (retrospective reporting)
 - CDX receipt exemption
 - A person is exempt from the retrospective reporting if the person has evidence, in the form of a CDX receipt, documenting EPA's receipt of an NOA Form A from another manufacturer.
 - Persons should keep in mind, however, that they bear the risk of failing to report if they rely on this CDX receipt exemption, and the Form A notice (for which they have a CDX receipt) is later withdrawn, leading to the substance being designated as inactive.



More on Reportable Chemical Substances

- Exempted substances – 40 CFR 710.27
 - The manufacturing or processing of a chemical substance in small quantities solely for research and development.
 - The manufacturing or processing of a chemical substance solely for test marketing purposes.
 - The manufacturing or processing of a chemical substance solely for 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 a chemical substance as part of an article.



More on Reportable Chemical Substances

- Exempted substances – 40 CFR 710.27
 - Manufacturing or processing naturally occurring chemical substances.
 - The manufacturing or processing of a chemical substance as described in § 720.30(g).
 - Any byproduct if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to component substances extracted from the byproduct.)



More on Reportable Chemical Substances

- Exempted substances – 40 CFR 710.27]
 - The manufacturing or processing of a chemical substance as described in § 720.30(h).
 - Any impurity.
 - Any byproduct which is not used for commercial purposes.
 - Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.
 - Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.



More on Reportable Chemical Substances

- Exempted substances – 40 CFR 710.27]
 - The manufacturing or processing of a chemical substance as described in § 720.30(h).
 - Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article.
 - Any chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance.
 - Any chemical substance which results from a chemical reaction that occurs when (1) certain substances function as intended or (2) a substance which is intended solely to impart a specific physiochemical characteristic functions as intended.
 - Any non-isolated intermediate.



More on Reportable Chemical Substances

- Exempted substances – Note:
 - An exempted substance may be listed on the TSCA Inventory if, in addition to being an exempted substance in one chemical process (e.g., impurity), it is also a TSCA-reportable substance in another chemical process.
 - Under the TSCA Inventory Notification (Active-Inactive) rule, a TSCA Inventory-listed substance therefore:
 - Is not reportable if a person manufactured or processed such substance solely as an exempted substance.
 - May be reportable if a person manufactured or processed such substance for non-exempt purpose.
 - Note about TSCA section 5(h)(4): A substance that was the subject of a TSCA section 5(h)(4) exemption (e.g., LVE, LOREX, polymer) and that was subsequently listed on the TSCA Inventory via a commenced PMN is not exempt from reporting under the TSCA Inventory Active-Inactive rule.



More on Reportable Chemical Substances

- Summary of reportable substances
 - Chemical substances on the TSCA Inventory are reportable if they were or are anticipated to be in U.S. commerce for non-exempt purpose during the reporting period specified in the rule.
 - A reportable substance:
 - Is listed on the TSCA Inventory.
 - Meets the 40 CFR 710.3 definition of “Chemical Substance.”
 - Has not already been reported in an equivalent notice (retrospective reporting).
 - Is not already designated as “ACTIVE” on the TSCA Inventory.*
 - Has not been documented as reported in an NOA Form A (via a CDX receipt).
 - Does not meet a 40 CFR 710.27 activity exemption.
 - Does not meet the 40 CFR 710.27 exemption for manufacturing or processing naturally occurring chemical substances.

* See June 2017 TSCA Inventory publication or the Exemption List.



Confidential Business Information

- General point regarding retrospective reporting and substances whose chemical identities are CBI
 - If a person seeks to maintain an existing CBI claim for a chemical substance that is already designated as “ACTIVE” on the TSCA Inventory, an NOA Form A must be filed that includes such a request.



Confidential Business Information

- Procedures for the submission of information claimed as CBI [40 CFR 710.37]
 - Retrospective reporting (NOA Form A)
 - Chemical identity: Substantiation may be provided with the notice or may be submitted pursuant to requirements of the CBI review plan described in TSCA section 8(b)(4)(C)–(D). Substantiation will be reviewed per the CBI review plan.
 - All other data elements: Substantiation must be provided with the notice. Substantiation will be reviewed per TSCA section 14(g) requirements.
 - Future reporting (NOA Form B)
 - Chemical identity: 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.



Confidential Business Information

- CBI Review Plan [TSCA section 8(b)(4)(C)–(D)]
 - “Not later than 1 year after the date on which the Administrator compiles the initial list of active substances ... the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion (of the Inventory).”
 - Timeline for completion of reviews: “Not later than 5 years after the date on which the Administrator compiles the initial list of active substances.”
 - Estimated date for compilation of initial list of active substances: November or December, 2018.
 - Estimated date for publishing CBI Review Plan: November or December, 2019.



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 A is available for retrospective reporting, and NOA Form B will be available for future reporting.
- <https://cdx.epa.gov/> , <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn>

**Retrospective
Reporting
[8(b)(4)A]

How to
Report?**

EPA	U.S. Environmental Protection Agency NOTICE OF ACTIVITY OF MANUFACTURE, IMPORT, OR PROCESSING – FORM A		Submission Date:	
			Revised Date:	
Part I – Submitter Identification				
Manufacturer, Importer, Processor (in U.S.)	Name of Authorized Official		Mailing Address (street, city, zip code)	CBI*
	(first)	(last)		
	Company Name		Mailing Address (street, city, zip code)	
Technical Contact (in U.S.)	Name		Telephone Number	
	(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)			
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 – 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 manufactured, imported, or processed the above chemical substance between the dates of June 21, 2006 and June 21, 2016. 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:	31

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

How to
Report?

EPA		U.S. Environmental Protection Agency		Submission Date:	
		NOTICE OF ACTIVITY OF MANUFACTURE, IMPORT, OR PROCESSING – FORM B		Revised Date:	
Part I – Submitter Identification					
Manufacturer, Importer, Processor (in U.S.)	Name of Authorized Official		Mailing Address (street, city, zip code)		CBI*
	(first)	(last)			
	Company Name		Mailing Address (street, city, zip code)		
Technical Contact (in U.S.)	Name		Telephone Number		
	(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)				
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:					
** 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.					
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		



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.
 - Non-CBI substances already designated as “ACTIVE” on the TSCA Inventory are not included on the pick list. CBI substances already designated as “ACTIVE” on the TSCA Inventory are included on the pick list.
 - Substances uploaded from an Excel spreadsheet will be checked against the pick list.
 - A company can submit any number of notices with any number of chemicals from any number of sites or organizational units.



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>
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Questions & Answers