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Final TSCA Inventory Notification Rulemaking

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Toxic Substances Control Act (TSCA) Inventory Notification Rule

■ Retrospective (Form A) Reporting Requirements

- Why is reporting required?
- What is reportable?
- Who should report?
- When is reporting required?
- How will reporting occur?
- Confidential Business Information (CBI) considerations
- Helpful hints



■ Forward-Looking (Form B) Reporting Requirements

- Why, What, Who, When, and How
- CBI considerations

■ Considerations/Reminders

Roles



- **Manufacturer:** An entity that manufactures or imports a chemical substance in the U.S. A chemical supplier is probably a manufacturer
- **Processor:** An entity that blends, mixes, formulates, or otherwise processes a substance without changing the substance's identity
- **User:** An entity that uses a chemical substance for its intended purpose, after which the substance is destroyed, converted to another substance, discarded, or otherwise handled as waste
- Manufacturers and users are often also processors
- Chemical distributors may be processors if they repackage a substance

Retrospective Reporting -- Why

- Addresses issue of which chemicals on the TSCA Inventory are active in commerce
- Establishes list of active and inactive substances
 - Not an Inventory reset -- both active and inactive substances remain on Inventory
 - Going forward, only active substances may be manufactured or processed for a non-exempt commercial purpose unless a Form B notice of activity is first submitted to the U.S. Environmental Protection Agency (EPA)



Retrospective Reporting -- What

- Inventory notification applies to non-exempt chemical substances listed on the TSCA Inventory
 - Manufactured, imported, or processed during ten-year look-back period
 - Look-back period = June 21, 2006, to June 21, 2016
- Information to be reported:
 - Chemical identity
 - Indication as to whether existing CBI claim for chemical identity is sought
 - Submitter identity



Retrospective Reporting -- What

- Chemicals not within scope of final rule and therefore excluded from TSCA jurisdiction
 - Substances that are not chemical substances per TSCA Section 3(2)(B)/40 C.F.R. Section 710.3(d)
 - Any mixture
 - Although individual Inventory-listed substances present in the mixture may be subject to reporting
 - 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 nuclear source material, special nuclear material, or byproduct material,
 - Any pistol, firearm, or revolver, shells, and cartridges
 - Any food, food additive, drug, cosmetic, or medical device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or medical device



Retrospective Reporting -- What

- Chemicals not within scope of final rule and therefore exempt from reporting
 - Substances that are exempt from listing on the Inventory and exempt from premanufacture notification (PMN)
 - Substances used strictly for research and development
 - Substances imported solely as parts of articles. Note: substances contained in articles that are intended to be released are reportable
 - Impurities or byproducts with no subsequent commercial purpose
 - Substances manufactured for export only



Retrospective Reporting -- What

- Substances that are not listed on the Inventory and are manufactured based on an existing exemption
 - Substances meeting the polymer exemption
 - Substance manufactured or imported solely under a TSCA Section 5(h) exemption
 - Low release and low exposure exemption
 - Low volume exemption (LVE)
 - Substances manufactured or imported under a test marketing exemption

- NOTE: If a substance is manufactured under an exemption and nevertheless is listed on the Inventory, an active notice is required

Retrospective Reporting -- What

- Other chemicals exempt from reporting
 - Naturally occurring chemical substances as defined by 40 C.F.R. Section 710.27(b)
 - EPA will designate the category of “Naturally Occurring Chemical Substances” as active substances, thereby excluding them from reporting
 - A substance that could be naturally occurring, but is manufactured in a manner not meeting the criteria, is not exempt from reporting



Retrospective Reporting -- What

- Other chemicals excluded from reporting because EPA already has equivalent notice
 - Substances on interim list of active substances
 - Chemical substances reported under 2012 and 2016 Chemical Data Reporting (CDR) rules
 - See <https://www.epa.gov/tsca-inventory>
 - Substances added to Inventory pursuant to Notice of Commencement (NOC) during the look-back period



NOT REQUIRED



NOT REQUIRED

Retrospective Reporting -- What

- Substances already notified under retrospective reporting
 - Will need evidence that substance has been notified
 - Copy of a Central Data Exchange (CDX) receipt of the Notice of Activity (NOA) Form A from another manufacturer
 - CAUTION: If NOA Form A withdrawn, substance no longer active
- Note: To maintain CBI claim, Form A reporting is required, even if the substance is interim active
- Substances added to Inventory after June 22, 2016
 - CBI claims for such substances will be maintained



NOT REQUIRED



NOT REQUIRED

Retrospective Reporting -- Who and When



REQUIRED

Chemical manufacturers and importers must report no later than 180 days from publication (approximately the end of the calendar year)

- No option for extension; deadline mandated by statute
- EPA to publish draft Inventory with active designations “as soon as is practicable” following manufacturers’ reporting deadline
 - Draft Inventory based on manufacturers’ reporting will not have legal effect of actually designating any chemical substance as inactive
 - Processors can use draft Inventory based on manufacturers’ reporting in their review



Retrospective Reporting -- Who and When



- Chemical processors may report no later than 420 days after the final rulemaking
 - Processor defined as any person who processes a chemical or mixture
 - Process means preparation of a chemical substance or mixture, after its manufacture for distribution in commerce
 - In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or
 - As part of an article containing the chemical substance or mixture

Retrospective Reporting – Who and When

- Processors have the option to not report and continue processing until the effective date of EPA's designation of a chemical substance as inactive on the Inventory
 - At such time, any further processing of the substance for a non-exempt commercial purpose, without prior notification to EPA, will be prohibited
- Processor notification will allow EPA to list the substance as active
 - Processing can continue without the need for a later notification
 - Processors can use draft Inventory with active designations from manufacturer/importer reporting to identify other chemicals that should be designated as active



Retrospective Reporting -- How

- EPA CDX/Chemical Information Submission System (CISS)
- Information “known to or reasonably ascertainable” is to be reported
- Reporting to occur via NOA Form A
 - Joint submissions allowed in circumstances where chemical identity is not known due to confidentiality
 - Most useful when a confidential substance is used as a feedstock for manufacturing
 - Form A submitter may report using an Accession Number (the numeric identifier for substances with confidential identities)
 - Useful when a confidential substance is used without chemical transformation

Retrospective Reporting -- CBI

- Two types of CBI assertions expected
 - Requests to maintain existing CBI claim for chemical identity
 - Claims for CBI protection for information other than specific chemical identity



Retrospective Reporting -- CBI

- Chemical Identity CBI claims for chemicals designated as active
 - Any manufacturer or processor may seek to maintain an existing CBI claim
 - Not limited to the original claimant
 - If no request to maintain CBI received, an active substance must be moved to the non-confidential portion of the Inventory
 - CBI claim must be substantiated
 - Structurally descriptive name is required
 - Submitter must provide certification statement regarding the basis for the CBI claims

Careful consideration of chemical identity CBI critical



If CBI maintenance is not requested during retrospective reporting, EPA required to move the substance to the public portion of the Inventory

Retrospective Reporting -- CBI

- EPA CBI Review Plan
 - EPA to issue separate rulemaking to establish CBI review plan
 - To include when and what will be required for substantiation and when to provide
- No mandatory substantiation requirement for CBI chemical identity requests at time of submission of NOA Form A
- During retrospective reporting, if request received, chemical substance will remain on the confidential portion of the Inventory pending:
 - Submission of substantiation required under to-be-issued CBI review plan; and
 - EPA review of the claim
 - Substantiation will be required by a date to be established



Retrospective Reporting -- CBI

- EPA will review requests for maintenance of chemical identity CBI per TSCA Section 8(b)(4)(D) in the timeframe mandated by TSCA Section 8(b)(4)(E)
- Companies can substantiate chemical identity CBI claims when NOA Form A is filed if desired
 - If the proactive substantiation is submitted no more than five years before the due date in the to-be-issued EPA CBI review plan, company would be exempt from the requirement to submit additional substantiation under the terms of the review plan



Retrospective Reporting -- CBI

- Questions to address for pro-active substantiation
 - Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)? If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s)
 - Will disclosure of the information likely result in substantial harm to your business's competitive position? If you answered yes, describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public.
 - To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Identify the measures or internal controls your business has taken to protect the information claimed as confidential: nondisclosure agreement required prior to access; access is limited to individuals with a need-to know; information is physically secured; other internal control measure(s). If yes, explain.

Retrospective Reporting -- CBI

- Questions to address for pro-active substantiation (cont'd)
 - Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential.
 - Is the claim of confidentiality intended to last less than 10 years? If so, indicate the number of years (between 1-10 years) or the specific date/occurrence after which the claim is withdrawn.
 - Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If you answered yes, explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

Retrospective Reporting -- CBI

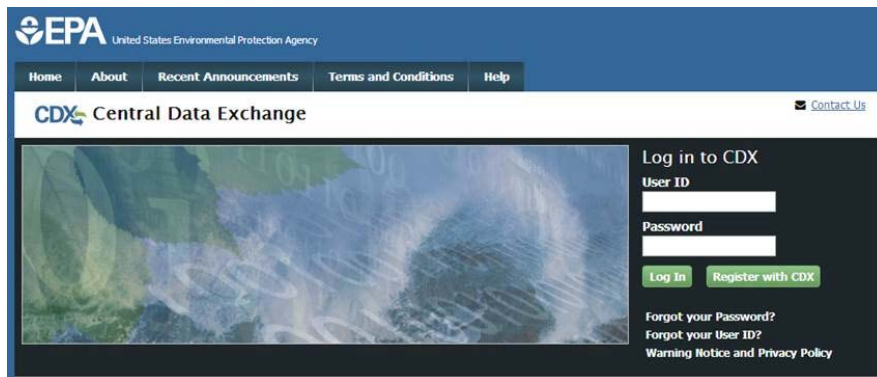
- CBI requests for information other than chemical identity
 - Company must provide certification statement regarding the basis for the CBI claims
 - Claims must be substantiated at the time of submission
 - EPA to review 25 percent of these claims per TSCA Section 14(g)(1)



REQUIRED

Retrospective Reporting -- Helpful Hints

- If your company is not already signed up for EPA CDX, do so now
 - If your company is signed up, verify user name(s) and password(s)



Retrospective Reporting -- Helpful Hints



- Gather records to document what chemicals your company manufactures, imports, or processes by Chemical Abstracts Service Registry Number (CAS RN) or Accession Number
 - Keep documentation for both exempt and non-exempt chemicals
- Identify chemicals that need maintenance of chemical identity CBI
- Search Inventory and identify those chemicals listed on the EPA interim active list
- Identify those chemicals NOCed during look-back period (may be indicated as interim active on an updated version of the Inventory)

Retrospective Reporting -- Helpful Hints

- To reduce reporting burden, consider working within trade groups to share NOA Form A submission receipts
- Focus on manufactured/imported chemicals first due to shorter reporting period; processed chemicals have longer timeframe
 - Processor should only have to report if it has been using a very long-term stock of substance -- otherwise the manufacturer or importer should have reported activity in the past ten years
 - Processors should review the draft active/inactive list to be sure their supply chains are listed as active



**FIRST
THINGS FIRST**

Forward-Looking Reporting -- Why



- Allows chemicals designated as inactive during retrospective reporting process to resume manufacturing or processing for non-exempt commercial purposes
 - Substance is not considered inactive until 90 days after EPA designates it as inactive
 - To occur with first issuance of Inventory with active and inactive listings
- Upon receiving forward-looking notification, EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active

Forward-Looking Reporting -- Who, What, When, and How

- Who
 - Persons that intend to manufacture, import, or process inactive substance for non-exempt commercial purpose (other than R&D, impurities, byproducts, exports-only)
- What
 - Chemical identity
 - Intent to maintain chemical identity CBI
 - Anticipated date of manufacture, import, or process
- When
 - *Not more than 90 days prior to the anticipated date of commercial activity*
- How
 - EPA CDX
 - NOA Form B
 - Joint submissions allowed in circumstances where chemical identity is not known due to confidentiality

Forward-Looking Reporting -- CBI

- As with Form A reporting, only chemicals on the confidential portion of the Inventory may be claimed as CBI
- TSCA Section 8(b)(5)(B) stipulates that CBI requests be substantiated not later than 30 days after submitting NOA Form B
 - See 40 C.F.R. Section 710.37(a)(2)
 - Companies can provide substantiation with NOA Form B submission
 - EPA suggests it may be more efficient to substantiate chemical identity CBI claims at time of filing

Considerations/Reminders

■ Definition of manufacturer under TSCA

- For purposes of TSCA rules, manufacturer refers to chemical manufacture.
 - It does not relate to aircraft or other type of manufacturer. An aircraft manufacturer is probably a processor of a TSCA substance
- Keep in mind that under TSCA, manufacturer does include importer. A company importing a chemical or chemical mixture to the U.S. would be considered a manufacturer for TSCA purposes
- A company that imports a mixture is a manufacturer of each component in the mixture



Considerations/Reminders

- Reporting period/order of reporting for retrospective reporting
 - Look-back period of ten years prior to new TSCA enactment (June 21, 2006, to June 21, 2016)
 - Manufacturers and importers must report with 180 days from promulgation of the final rule
 - Processors (formulators) may report, but are not required to do so
 - If they choose to report, processors (formulators) have an additional 360 days after the first final active/inactive list based on manufacturers' reporting is published
 - Users (not importers) of chemical products (*e.g.*, aircraft manufacturers) likely meet definition of processor and will have the same reporting option (360 days after the first list based on manufacturers' reporting is published)

Considerations/Reminders

- Information to be reported
 - Chemical identity and CBI claims must be submitted
 - Submitter identity is automatically captured upon submission via CDX
 - A technical contact is required
- Protecting CBI
 - At least one company seeking to maintain CBI identity must submit a Form A, even if the substance is identified as interim active
 - Each company seeking to maintain CBI identity should probably submit a Form A -- if relying on another's CBI claim, confidentiality may be lost if the other claimant withdraws the claim or allows it to sunset

Considerations/Reminders

- How to address chemical components in multiple formulations or differences in formulation purchase history over the ten-year look-back
 - Each component (by chemical identity) must be notified, but only once
 - For example, only one Form A is required for acetone, even if it is used in 25 different formulations
 - No requirement to report on dates or activity
- Reporters with many substances to report may want to use EPA's XML template to upload reports in batches

Considerations/Reminders

- How should aircraft manufacturers and formulators work together to identify list of chemicals to notify as active?
 - An end-user of a formulation should work with the formulation supplier
 - Formulator should work with individual substance manufacturers
 - Keep documentation on what processors/formulators agree to do
 - Request copies of Form A CDX receipts on chemicals notified as active
 - Processors and users should check the initial active/inactive list (after manufacturer reporting)

Considerations/Reminders

- Will aircraft manufacturers need to consider reporting substances used by suppliers on their behalf? (Suppliers inside and outside the U.S.?)
 - Aircraft manufacturers should work with all suppliers to identify those chemicals that should be notified as active
 - Anticipate that most chemical manufacturers will report substances that they manufacture or import, essentially “covering” the supply chain
 - As users, U.S. aircraft manufacturers can submit active chemical notifications during the processor review period
 - Non-U.S. entities cannot report

Considerations/Reminders

- What documentation is required?
 - A company must submit NOAs based on information that is known or reasonably ascertainable
 - Defined as all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know
 - Information is in the possession or control of a person if it is: (1) in the person's own files, including files maintained by employees of the person in the course of their employment; (2) in commercially available databases to which the person has purchased access; or (3) maintained in the files in the course of employment by other agents of the person who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question

Questions?



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Thank You

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