

TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework

WEBINAR SERIES: PART 3
COMMONLY MISSED INFORMATION
FEBRUARY 28, 2023

Agenda

- Background
- Commonly missed information in TSCA Section 5 submissions
- How EPA evaluates sites not controlled by the submitter
- Q&A from 2nd webinar: “Information Evaluation Considerations”
- Q&A Session

Background

- EPA is looking for ways to improve efficiency in the new chemical review process. Reducing “rework”¹ is one area for potential efficiency improvement.
- On July 27, 2022, EPA presented an analysis of common rework issues that cause EPA to have to rework engineering assessments. EPA’s analysis shows that companies often lack understanding of what information is needed for a Section 5 engineering assessment.
- On October 18, 2022, EPA presented how it evaluates qualitative and quantitative engineering information included in the submissions, including multiple case studies with specific rationale on why EPA did or did not accept the submitted data.
- In this webinar, EPA will discuss:
 - Commonly missed information in TSCA Section 5 submissions
 - How EPA evaluates environmental release information when the operation occurs at a non-submitter site

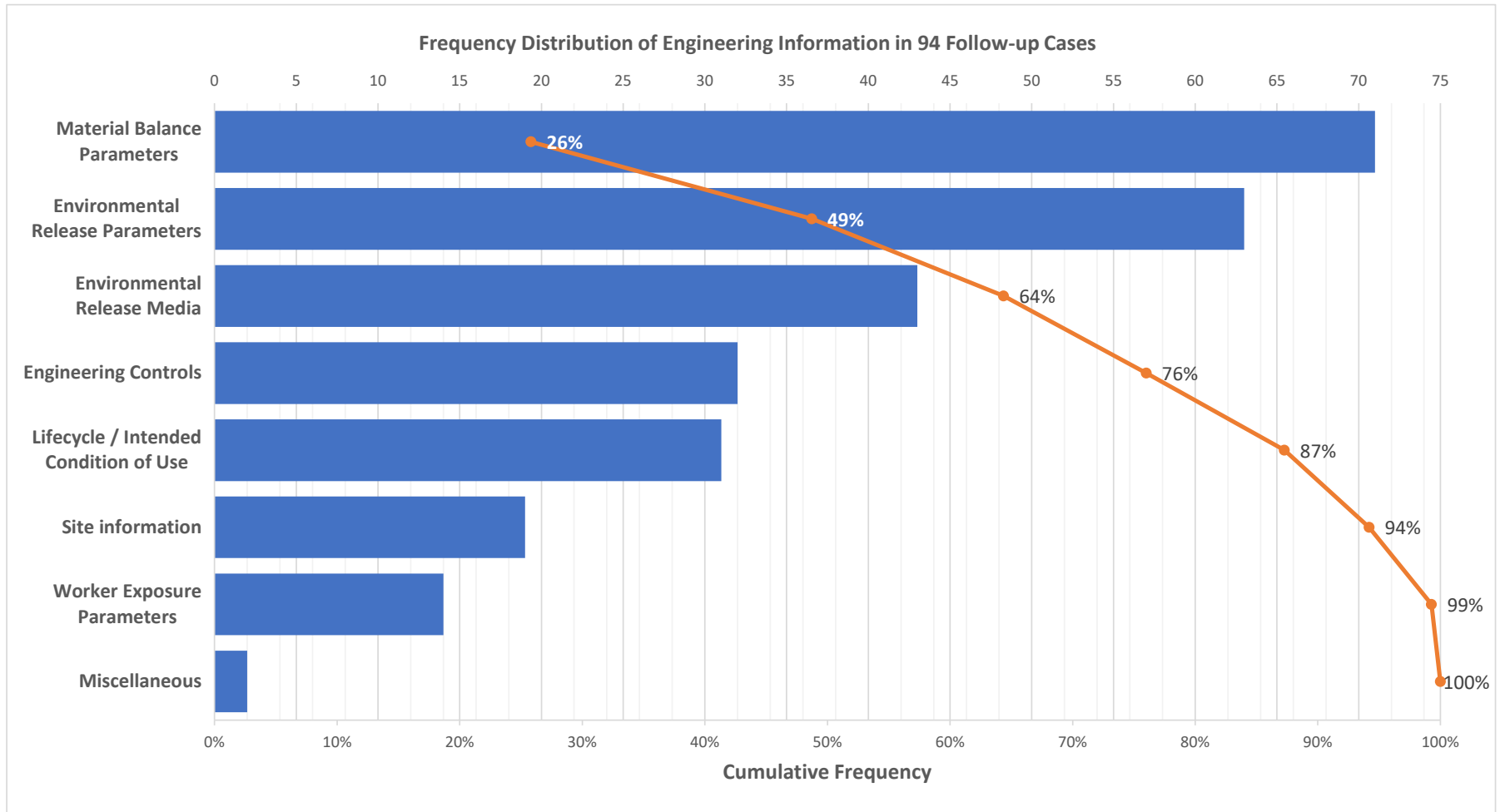
¹ Intake, review, and revision(s) to risk assessments when additional information is submitted

Commonly Missed Information



Missing information in the original submission often results in delays in review or EPA having to apply conservative assumptions to fill in the information gap.

Commonly Missed Information (continued)



Commonly Missed Information (continued)

- Information that must be included in the TSCA Section 5 submission is specified under §720.45.
 - *Each person who submits a notice must include the information specified in the notice form to the extent it is **known to or reasonably ascertainable** by the submitter.*

Commonly Missed Information (continued)

- **Physical form of the new chemical substance (NCS)** throughout its industrial and commercial lifecycle from manufacturing (including import), processing, and use
 - Physical form of the NCS (including % concentration) should be completed for each lifecycle stage and worker activity in both Part II, Section A (sites controlled by submitter) and Section B (sites controlled by others, below)
 - If the information is provided as a narrative, specify the physical form and concentration of the NCS in the formulation and/or final products
 - Solids are assumed to have the potential to be airborne unless supporting information is provided
 - Other related data, such as particle size distribution, should be provided if available

2. Worker Exposure/Environmental Release

(1) – From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.

(2) – Estimate the number of workers exposed for all sites combined.

(4) – Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.

(6) – Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.

(7) – Estimate the percent of the new substance as formulated when packaged or used as a final product.

(9) – From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.

(10) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).

(12) – Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.

(14) – Identify byproducts which may result from the operation.

(3), (5), (8), (11), (13) and (15) – Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity	# of Workers Exposed	CBI	Duration of Exposure		CBI	Protective Equip./Engineering Controls/Physical Form	% new substance	% in Formulation	CBI
			(4a)	(4b)					
(1)	(2)	(3)	(4a)	(4b)	(5)	(6)	(6)	(7)	(8)

Commonly Missed Information (continued)

- **Number of Sites** associated with manufacturing (including import), processing, and industrial/commercial use
 - If the exact number of processing/use sites is not known at the time of application, provide an estimate or range if reasonably known or ascertainable (e.g., 1-5 sites v. 100-500 sites)
 - Provide identity (including location) of sites if known

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued	
Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS	
The information on pages 10 and 10a refer to consolidated chemical number(s): <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6	
Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. Complete a separate section B for each type of processing, or use operation involving the new chemical substance. If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.	
<p>1(a). Operation Description -- To claim information in this section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.</p> <p>(1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify - e.g. 5 gallon pails, 55 gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity.</p> <p>(2) -- Either in the diagram or in the text field 1(b) below, provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch).</p> <p>(3) -- Either in the diagram or in the text field 1(b) below, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.</p> <p>(4) -- Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet).</p>	
Number of Sites	Confidential <input type="checkbox"/>

Commonly Missed Information (continued)

- For low-volume exemption cases, review and consider the **binding option** for the maximum 12-month production volume (PV) in Part I, Section C.
 - If the PV is not bound, EPA will review the NCS at the maximum PV of 10,000 kg/yr
 - If you choose not to bind this volume, and your stated maximum 12-month production is substantially lower than 10,000 kg/yr, indicate how the operation, release, and exposure information is likely to change if the production of the NCS is scaled up:
 - Increase in production batch size or number of batches
 - Number of manufacturing, processing, and use sites
 - Release/exposure information

Part I -- GENERAL INFORMATION -- Continued			
Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:			
The information on this page refers to consolidated chemical number(s): <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6			
Mark (X) the "Confidential" box next to any item you claim as confidential.			
1. Production volume -- Estimate the maximum production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume.			
Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (X)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Commonly Missed Information (continued)

- **Number of workers** – Estimate the number of workers exposed for all sites combined
 - The number of workers should include all employees who are reasonably likely to be exposed to the NCS. This would include both workers who directly handle the NCS and workers who may be exposed as “bystanders.”

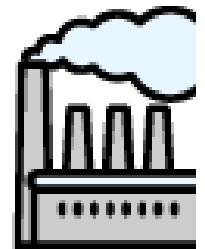
Letter of Activity	# of Workers Exposed	CBI	Duration of Exposure		CBI	Protective Equip./Engineering Controls/Physical Form
(1)	(2)	(3)	(4a)	(4b)	(5)	(6)

Commonly Missed Information (continued)

- Clearly describe the **intended use**, including uses of products containing the NCS at downstream customer sites
- If the chemical is a component of **coating, paint, or adhesive**, specify the application method/process (*e.g.*, spray coating, roll coating, roller, syringe, bead)
 - For coating products with an unknown/unidentified process, spray-application is typically assumed unless basis/supporting information is provided to rule out the possibility of spray application
- If an engineering control is present, describe the type of control and control efficiency, including documentation that supports the control efficiency estimate
- Check through the entire submission to ensure **consistency** in all information/narrative/attachments (*e.g.*, information such as physical form, release quantity, NCS concentration, and exposure duration and frequency should be consistent across the PMN submission and attachments).



Evaluating Environmental Releases for Sites not under Submitter Control



Sites not under Submitter Control

- EPA assesses environmental releases of new chemicals from manufacturing, processing, and use as part of the engineering assessment
- Submissions often make statements about the specific operation, process, and waste disposal method, including the environmental media.
- Where the operation is not under submitter control, EPA considers the following when evaluating “media of release”:
 - **Technical constraint**
 - **Administrative control**
 - **Generic Scenario, Emission Scenario Document, or other EPA guidance**

Sites not under Submitter Control (continued)

- ***Technical Constraint:***

- Constraint due to physical-chemical properties of the new chemical substance, e.g., NCS reacts with water, such that water or aqueous solution cannot be used to clean the equipment or transport containers
- Constraint related to the type of equipment/process
- Submissions should explain the constraint in writing and provide supporting technical information, such as a description of the process and equipment.

Sites not Under Submitter Control (continued)

- ***Administrative Control:***

- Company-specific Stewardship Program, such as documentation of an agreement between the submitter and its customers on how wastes containing the NCS must be managed
- Third-party (downstream sites not controlled by the submitter) documents such as Standard Operating Procedures (SOPs), Environment, Health and Safety (EHS) Policies describing site-specific waste management practices and/or requirements

- ***Generic Scenario, Emission Scenario Document, or other EPA guidance:***

- Media of release can be based on knowledge of specific industry sectors



Q&As from 2nd Webinar: “Information Evaluation Consideration”



Questions?

Additional Information

- Materials for webinar series:
 - Webinar #1: [Kick-Off Meeting](#) (July 27, 2022)
 - Webinar #2: [Information Evaluation Considerations](#) (October 18, 2022)
 - Webinar #3: Commonly Missed Information (February 28, 2023)
- Supporting materials:
 - [Summary of EPA's Analysis](#) (supplemental document)
 - [Analysis Methodology and Results](#) (supplemental document)
- EPA's webpage:
 - [TSCA New Chemicals Engineering Initiative to Increase Transparency and Reduce Rework](#)

List of Acronyms

GS = Generic Scenario

ESD = Emission Scenario Document

NCS = New Chemical Substance

SOP = Standard Operating Procedures