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

Webinar 2: Information Evaluation Considerations

OCTOBER 18, 2022

Agenda

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- Overview of Engineering Assessment
  - Typical Environmental Releases and Worker Exposures
  - Hierarchy of Approaches Used For Estimating Release and Exposure Assessments
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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:
  - Information on material balance parameters, environmental releases, environmental release media, and engineering controls cause nearly 80% of all rework.
  - In most cases, companies provide additional information that deviates from EPA model defaults and assumptions.
  - Companies often lack understanding on what information is needed for a Section 5 engineering assessment, including the level of detail needed to support their statements relating to environmental release and worker exposure.
- In this webinar, EPA will discuss typical considerations when evaluating quantitative and qualitative information in TSCA Section 5 submissions.

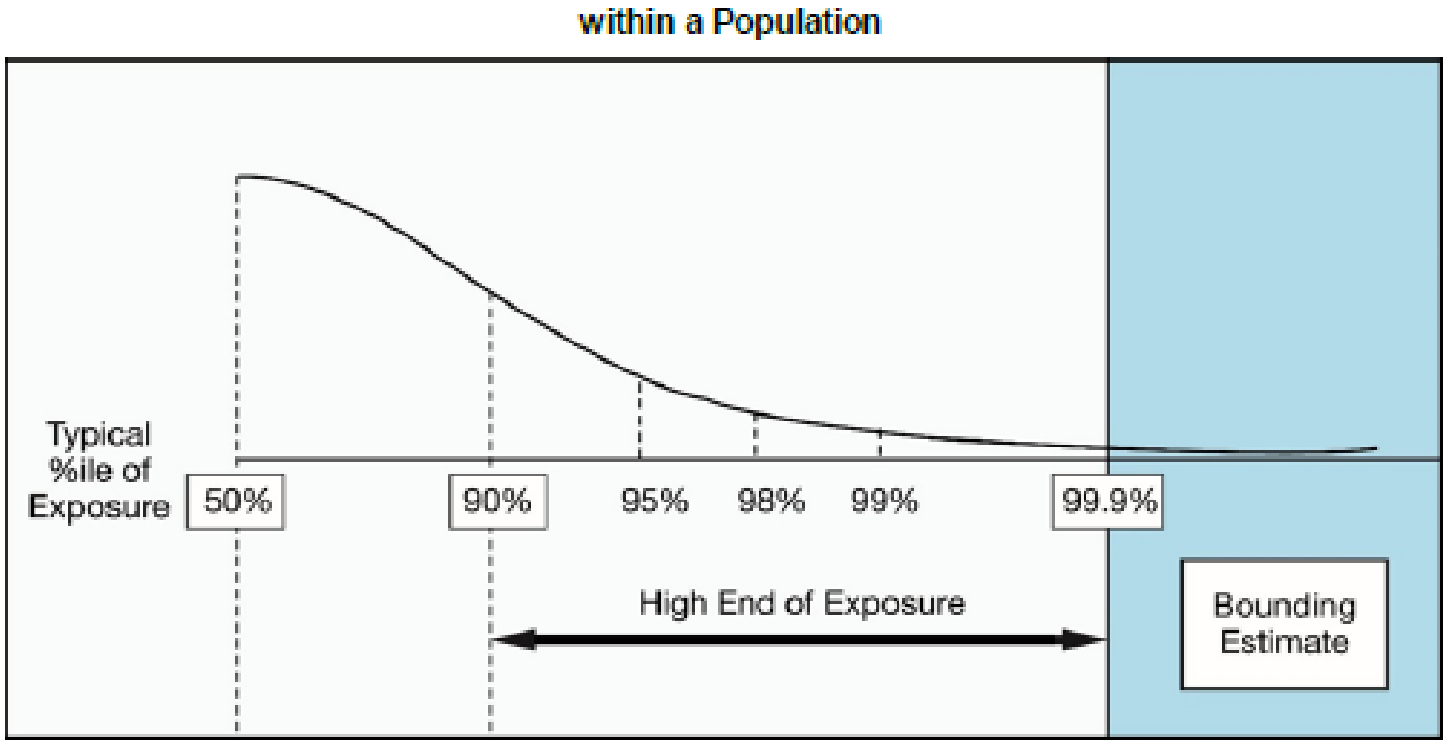
[1]Intake, review, and revision(s) to risk assessments when additional information is submitted

Overview of Engineering Assessment

- Scope of the assessment covers the entire industrial/commercial lifecycle of the new chemical substance (NCS) from cradle-to-grave:
  - Manufacturing (including import)
  - Processing
  - Industrial and Commercial Use (until NCS is no longer available for release and exposure)
- The initial review engineering report (IRER) estimates environmental releases of and occupational exposures to the NCS during each lifecycle stage:
  - Environmental releases to air, water, incineration, and/or landfill
  - Worker exposure via inhalation and dermal routes

Overview of Engineering Assessment

- New chemical assessments are intended to be screening-level[1,2] and representative of a high-end exposure scenario (90th percentile or above of the expected distribution)[3].

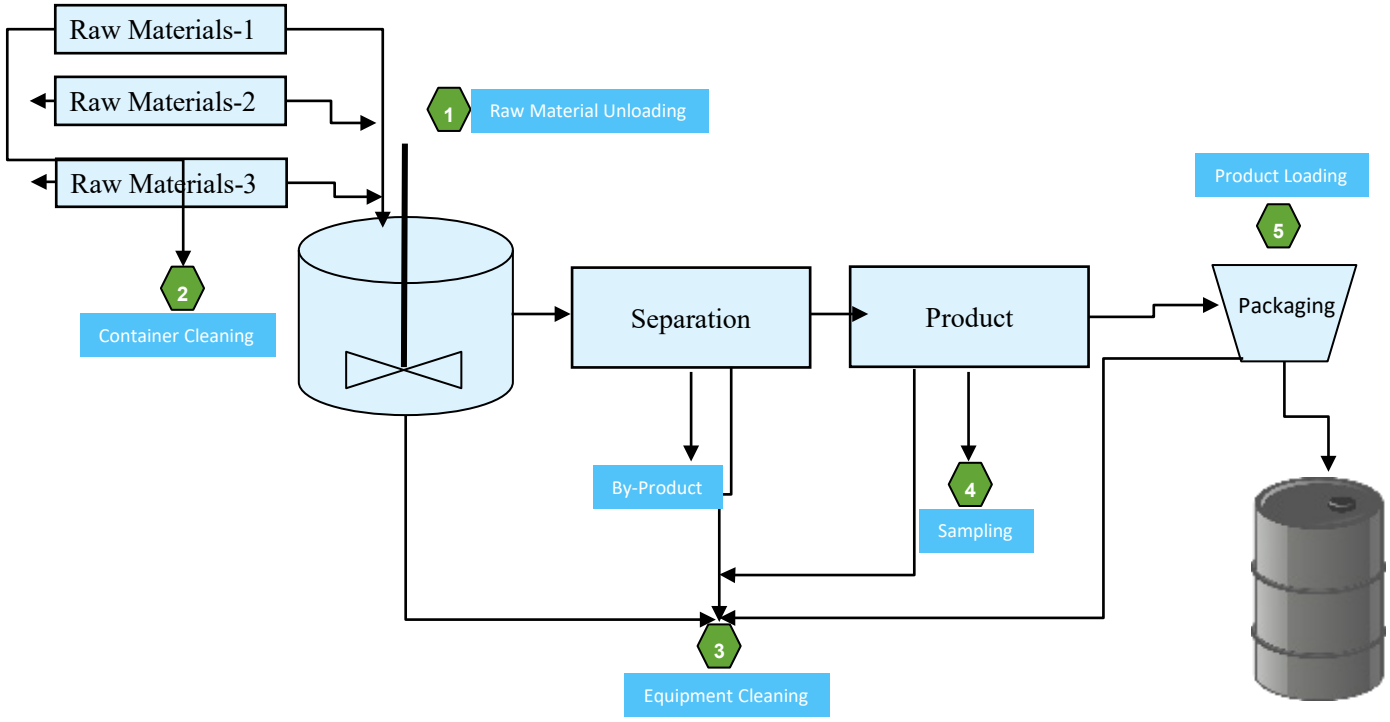


[1]ChemSTEER User Guide, May 2015,
[2]Point to Consider When Preparing TSCA New Chemical Notification, June 2018
[3] EPA's 2019 Guidelines for Human Exposure Assessment, October 2019

Overview of Engineering Assessment (continued)

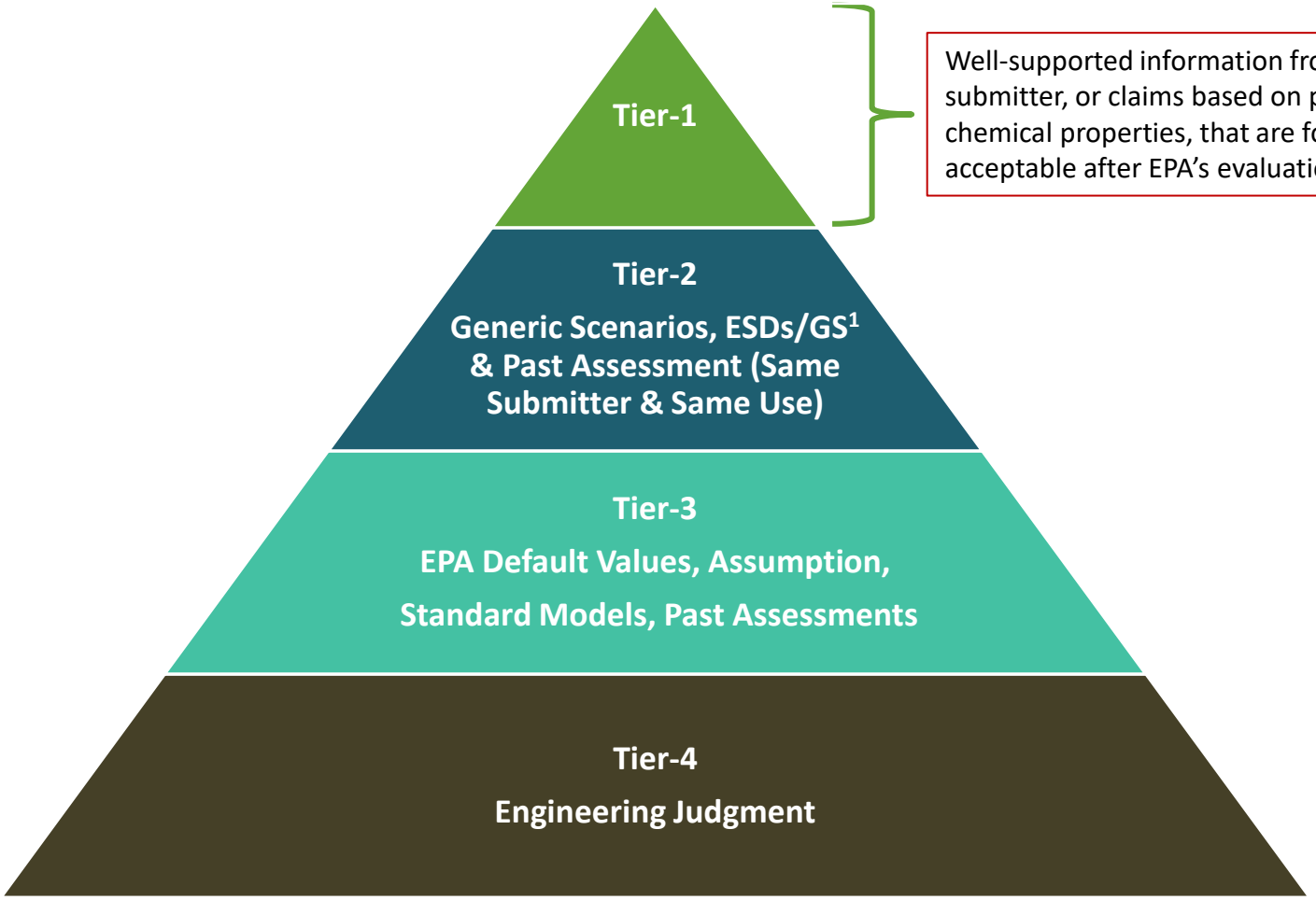
Typical Environmental Releases and Workplace Exposures

Scope: Manufacturing, Processing, and Use



Overview of Engineering Assessment (continued)

Hierarchy of Approaches Used For Estimating Release and Exposure Assessments



[1]Emission Scenario Documents: https://www.oecd.org/env/ehs/risk-assessment/emissionscenariodocuments.htm

[1]Generic Scenarios: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases#genericscenarios

Types of Engineering Information

Submitted information may fall under one of two types:

- **Quantitative Information:** This type of information is numerical in nature. Common examples include quantity of chemical released from a source activity, duration and frequency of release and exposure.

  Example-1 : *Loss Fraction (LF) from Container Cleaning is 0.1%.*

- **Qualitative Information:** This type of information is descriptive in nature. Common examples include general statements regarding release/exposure potential of NCS, description of engineering control, and media of release.

  Example-2: *There is no worker inhalation exposure to NCS during drum loading due to presence of local exhaust ventilation.*

Gross Inadequacies

Examples of information (quantitative or qualitative) that are unlikely to be accepted for engineering assessment:

- Information less conservative than standard EPA models, Generic Scenarios, or ESD's **without substantiation or supporting documents.**
- Claims for a site not-controlled by the submitter without substantiation and supporting documentation **from the third-party.**
- Claims for large number of unknown customer sites not under submitter control.
- A single data point provided, or multiple data points provided without supporting details (*e.g.*, sampling/test method, equipment description, worker activity description, etc.).
- Claims based on engineering control to be installed in the future.

Information Evaluation Considerations

- **Quantitative Evaluation Considerations:**
  - Data Reliability
  - Representativeness
  - Accessibility / Clarity
  - Variability and Uncertainty
- **Qualitative Evaluation Criterions:** Qualitative descriptions/claims are unlikely to be to be accepted when not substantiated with supporting evidence. Some helpful example supporting documents include:
  - **For site controlled by submitter:** Visuals, site operation documents, and claims based on NCS physical-chemical properties with supporting test data detail.
  - **For site NOT controlled by submitter:** Third-party visuals, operation documents, customer notification, and claims based on physical-chemical properties with supporting test data details.
    - **Customer Notification:** It is unlikely for EPA to accept claims/statements on waste disposal methods at customer facilities if the submitter does not provide supporting documents such as how it will notify customers about how wastes containing the NCS need to be managed.

Information Evaluation Considerations (continued)

- **EPA's defaults, assumptions, and standard models:** Where relevant information is not included or included without adequate substantiation, EPA applies conservative assumptions and estimates releases and exposures using ChemSTEER models, OECD Emission Scenario Documents (ESD), and/or EPA Generic Scenarios (GS).
- GS/ESD provide conservative, screening-level estimates of environmental releases and worker exposures for specific industry sectors or exposure scenarios.
  - Some estimates may result in release/exposure amounts that are likely to be higher, or at least higher than average, than amounts that actually occur in real world practice.
- EPA also conducts a search of prior new chemical submissions (*i.e.*, PMNs/LVEs) and may use relevant information from similar past assessments.

Clarifying Common Misconceptions

- EPA's assessment covers the entire life cycle of NCS, beyond manufacturing and import.
- Engineering assessment focuses on the NCS and not on the bulk material[1].

  For example, if 1 kg of bulk material containing 5% NCS is sampled and then incinerated, the quantity of interest to EPA is the 0.05 kg NCS released to incineration.

- EPA considers process activities conducted at elevated temperature, that may lead to releases and exposures not otherwise anticipated.
- EPA considers whether solid materials that are not typically airborne as manufactured would present inhalation exposure potential due to attrition (generation of smaller particles) during transportation.
- When supporting information is provided, EPA evaluates the information for acceptability before applying to the assessment.

[1] ChemSTEER Use Guide: https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases

Engineering Pre-screen Process

- Engineering Pre-screening[1] of PMN submission is performed to determine if submission is complete with regards to engineering information as per the **40 CFR § 720.65(c)(1)(vi):**

  A submission is not complete, and the notification period does not begin, if the submitter does not provide information required on the notice form and by § 720.45 or indicate that it is not known to or reasonably ascertainable by the submitter.

- Pre-screening review is limited to whether information that is required per the **40 CFR § 720.45,** such as process description, identity of sites, worker exposure, environmental releases, and controls, is included in the submission or not.

- Pre-screening review does **NOT** involve confirming whether supporting information/documentation is provided NOR any evaluation to determine, if information/documentation is acceptable. This more detailed review is performed during the engineering assessment of the case.

[1] Engineering prescreening is independent of prescreening performed by Industrial Chemistry Branch

Case Studies

Case Studies presented in the subsequent section are *representative scenarios* from past TSCA Section 5 submissions. Details were edited to:

- Redact CBI information.
- Visually present how certain information are typically provided in the PMN submission form.
- Discuss how EPA evaluates submitted information and makes determination on acceptability for engineering assessment.

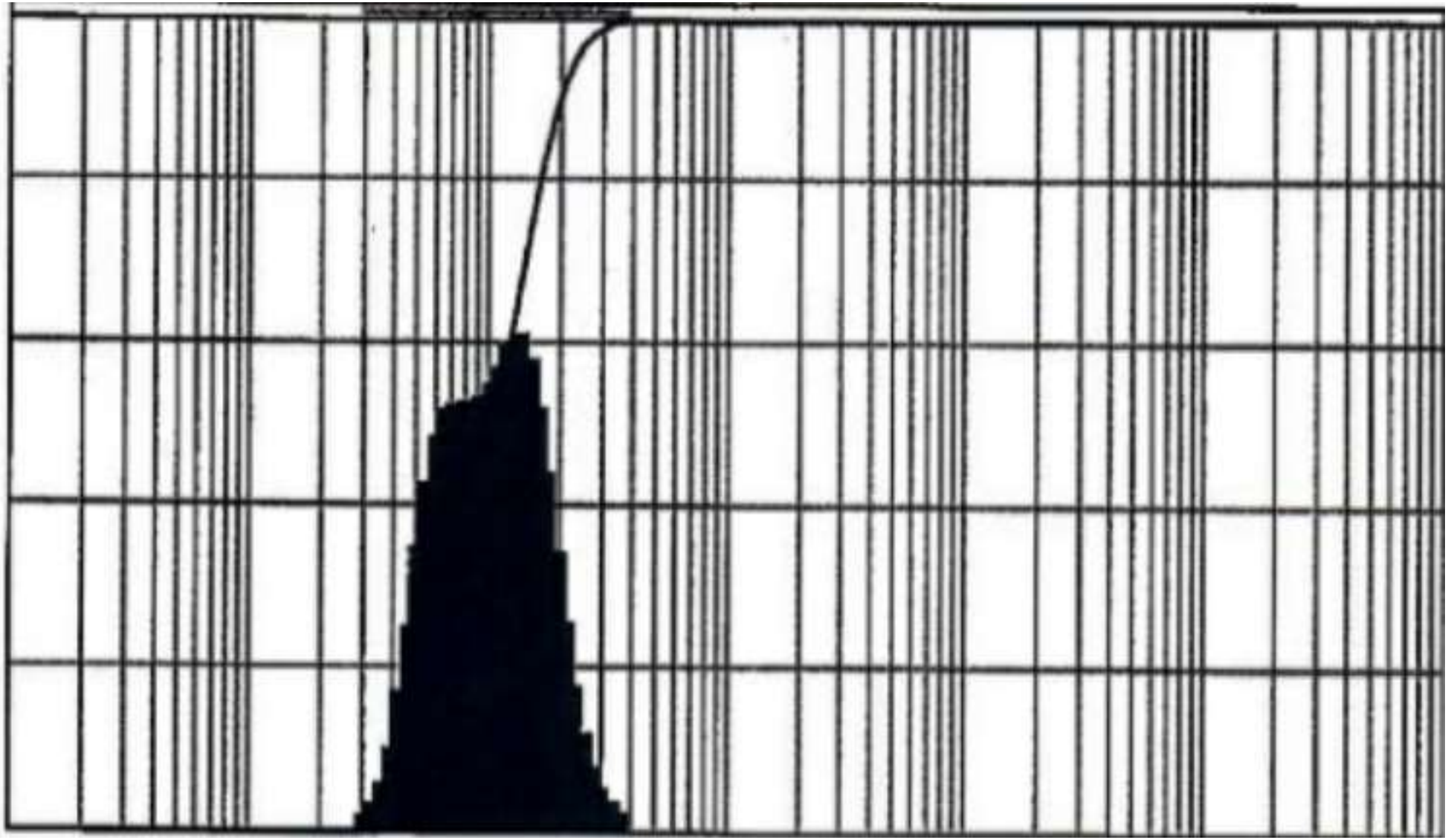
Case Studies (continued)

- Worker inhalation exposure from particulates is a frequent area of rework. As such, several case studies are selected to cover situations where submitter claims were either accepted v. not accepted, with rationales for each type of determination.
- **Typical Particulate Inhalation Exposure Activities:** Manufacturing, Processing and Use operations involving handling, transferring, unloading, or loading of NCS in solid forms are expected to present potential for workers exposure to total and respirable particles.
- **Typical Engineering Assessment Approach:** In the absence of specific and substantiated information from the submitter, EPA assesses inhalation exposure to total and respirable particulates using either the applicable ESD or the OSHA Particulates Not Otherwise Regulated (PNOR) Total and Respirable Dust, Permissible Exposure Limit (PEL) Model.

Case Study 1

Scenarios	NCS was present in solid form (100% concentration) when unloaded from super sacks to process equipment. Inhalation exposure to total and respirable particulates was expected.
Type of Information	Quantitative: Particle Size Distribution Histogram.
Substantiation	A Particle Size Analysis Report was provided (see next slide).
Determination	Not accepted.
Rationales for Determination	• Submitted test results were in foreign language, no English translation was provided. • Only contained histogram of particle size distribution. Graph quality was poor, it was difficult to read data. • No other detail on **Sample Size, Test Method, Equipment capability and suitability** was provided. • No information was provided to assess **Representativeness, Uncertainty, Variability in the data.**
Impact on Case	Inhalation exposures to both total and respirable particulates were assessed using the OSHA Particulates Not Otherwise Regulated (PNOR) Total and Respirable Dust, Permissible Exposure Limit (PEL) Model.

Case Study 1 (continued)



Values of Axis are redacted to protect CBI.

Case Study 2

Scenarios	NCS was present in solid form (100% concentration) when unloaded from super sacks to process equipment. Inhalation exposure to total and respirable particulates was expected.
Type of Information	Quantitative: Particle Size Distribution Data. Statement was made that there are no respirable particles present during unloading, based on data.
Substantiation	A Particle Size Analysis Report was provided.
Determination	Accepted.
Rationales for Determination / Evaluation Considerations	Submitted test Report contained sufficient details for EPA's evaluation, including: **Sample Size:** 10 Samples tested by two independent laboratories. **Test Method:** Test method description, including sample preparation. **Equipment:** Details on equipment capability and suitability for the particle size of interest, along with performance verification certificate. **Test Results**: Raw data with meta data, including description of the data and acronyms used **Reliability:** Data collection methodology is provided. **Representativeness:** Sampled collected during the activity of interest to represent worker exposure under typical process conditions. **Variability:** Variability in data was well within needed to measure the response variable **Accessibility/Clarity:** Relevant testing detail were clear, well documented and made accessible to EPA.
Impact on Case	Empirical data submitted were found to have acceptable quality after EPA's evaluation. Based on the evaluation of data, respirable particles were not expected. Engineering assessment was revised to eliminate worker inhalation exposure to respirable particles.

Case Study 3

Scenarios	NCS was present in solid form (100% concentration) when charged to the reactor at a non-submitter site. Inhalation exposure to particulates was expected.
Type of Information	Qualitative: There is no exposure to workers (see next slide).
Substantiation	None. The submission did not describe the charging process or provide information on engineering controls.
Determination	Not accepted.
Rationales for Determination	No substantiation is provided for the claims.
Impact on Case	Inhalation exposures to both total and respirable particulates were assessed using OSHA Particulates Not Otherwise Regulated (PNOR) Total and Respirable Dust, Permissible Exposure Limit (PEL) Model.

Case Study 3 (continued)

Example screen shot from the Section A- Industrial Sites Controlled by Submitter.

c. Amount and Duration -- Complete 1 or 2 as appropriate				Confi-dential
1. Batch	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year	☐
2. Continuous	Maximum kg/day (100% new chemical substance)	Hours/day	Days/year	☒
	null	[redacted]	[redacted]	

d. Process description	Mark (X) to indicate your willingness to have your process description binding. → ☐

(1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.).
(2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

☐ New Chemical Substance is processed at the site identified on this submission, which is controlled by the submitter. There is no exposure to workers.

Case Study 3 (continued): Rework

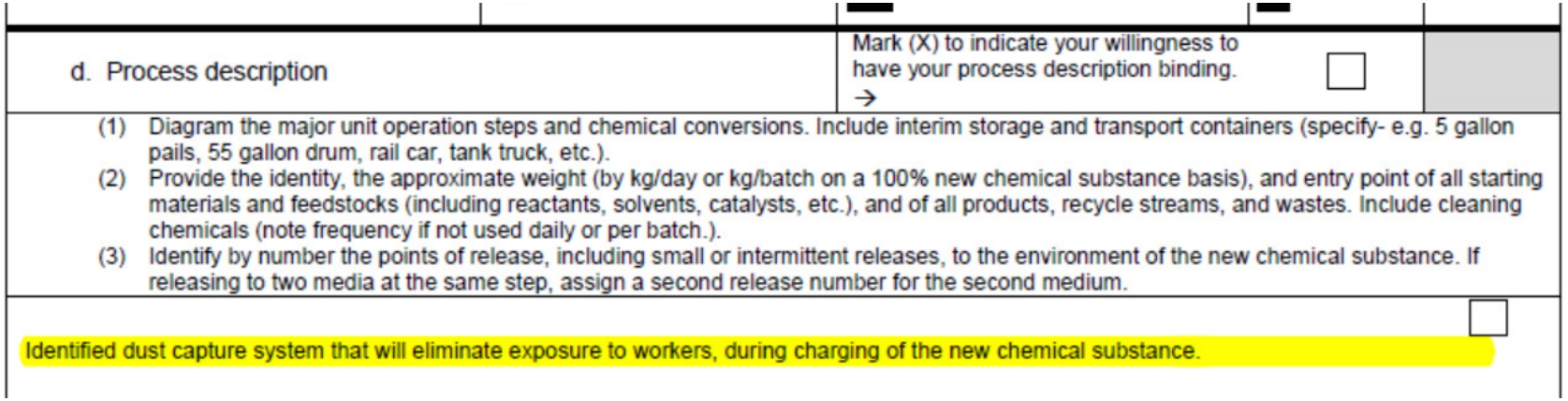
Scenarios	NCS was present in solid form (100% concentration) when charged to the reactor at a non-submitter site. Inhalation exposure to particulates was expected.
Type of Information	Qualitative: There is no particulate exposure, since NCS is transferred to reactor under closed system.
Substantiation	Visuals of actual process set up.
Determination	Accepted.
Rationales for Determination	Detailed description of the closed-system transfer demonstrating each step of unloading NCS from transport container to reactor with pictures.
Impact on Case	Inhalation exposures to both total and respirable particulates were removed from the assessment.

Case Study 4

Scenarios	NCS was present as 100% solid when charged from super sacks into process equipment. Particles size data indicated presence of both inhalable and respirable particulates. Inhalation exposure to particulate was expected.
Type of Information	Qualitative: Submitter identified an engineering control and the expected efficiency and will install the control to eliminate particulate exposure (see next slide).
Substantiation	A letter with expected control efficiency.
Determination	Not accepted.
Rationales for Determination	Engineering assessment cannot be performed based on engineering controls which have not yet been installed.
Impact on Case	Inhalation exposures to both total and respirable particulates were assessed using OSHA Particulates Not Otherwise Regulated (PNOR) Total and Respirable Dust, Permissible Exposure Limit (PEL) Model.

Case Study 4 (continued)

Example screen shot from the Section A- Industrial Sites Controlled by Submitter.



d. Process description	Mark (X) to indicate your willingness to have your process description binding. → ☐

(1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.).
(2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

☐

Identified dust capture system that will eliminate exposure to workers, during charging of the new chemical substance.

Case Study 5

Scenarios	NCS is a 100% solid when charged to the reactor at a non-submitter site. Submitter did not provide any information on engineering controls but provided monitoring data for a surrogate chemical. Inhalation exposure to particulates is expected based on the process description.
Type of Information	Quantitative: The monitored employees' exposures to total particulates were less than OSHA PEL.
Substantiation	IH Monitoring data for a surrogate chemical.
Determination	Not Accepted.
Rationales for Determination	1. There was no explanation provided to infer if NCS would behave similarly to the surrogate chemical included in the IH monitoring. 2. NCS was not/ would not be a constituent in the surrogate chemical. For Example: If NCS is present in small quantity in the surrogate chemical (*e.g.*, 1% in the resin particles), EPA would likely use that data since presence of small concentration of NCS in the resin particles are unlikely to affect airborne concentration of surrogate material, as measured during IH monitoring. 3. There was high **uncertainty** in data, because no comparison of physical properties (e.g., Particle Size Distribution, Shape, Moisture Content and Density) were provided to assess whether airborne concentration between the NCS and surrogate chemical would be similar under the same process conditions.
Impact on Case	Inhalation exposures to both total and respirable particulates were assessed using OSHA Particulates Not Otherwise Regulated (PNOR) Total and Respirable Dust, Permissible Exposure Limit (PEL) Model.

Case Study 6

Scenarios	NCS is manufactured at the Toller site (controlled by submitter) and releases from Equipment and Container Cleaning are likely based on the process described in submission.
Type of Information	No Information was provided (see next slide).
Substantiation	No Information was provided.
Determination	Not Applicable: No Information was provided.
Rationales for Determination	Submission did not estimate releases and did not provide any information on the media of release. Because no information was submitted, EPA assessed releases using EPA defaults and standard models. EPA assumed releases may go to uncertain media (*i.e.*, to water, incineration and landfill), assuming the entire quantity of NCS could be released to each of three possible medium.

Case Study 6 (continued)

3. Environmental Release and Disposal -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the new substance will be released from that release point.
(5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number	Amount of New Substance Released		CBI	Medium of release e.g. Stack air	Control technology and efficiency (you may wish to optionally attach efficiency data)			CBI
(1)	(2a)	(2b)	(3)	(4)	(5a)	Binding Mark (X)	(5b)	(6)
Stack 1		[redacted]		Stack Air	[redacted]		0	
Stack 2				Stack Air	[redacted]		0	
Stack 3		[redacted]		Stack Air	[redacted]		0	
Air	[redacted]			Fugitive Air	[redacted]		[redacted]	

From Process Tanks/Vessels

Submission did not identify equipment and container cleaning as release source.

Case Study 6 (continued): Rework

Scenarios	NCS is manufactured at the Toller site (controlled by submitter) and releases from Equipment and Container Cleaning are likely based on the process described in submission.
Type of Information	Qualitative: There would be no releases to water, because all wastes from cleaning operation are sent to incineration.
Substantiation	1. Letter from Submitter. 2. Waste Stream Profile Letter from Waste Handler. 3. Audit Information Package for Waste Handling Site.
Determination	Accepted.
Rationales for Determination	• Letter from submitter identifying sites and describing waste handling method. • Third-party documentation validating waste handling method described by the submitter, with RCRA permit and detail facility information.
Impact on case	EPA modified the assessment to reflect releases from Equipment and Container Cleaning as going to incineration only, instead to all potential media, due to specific and well substantiated information.

Case Study 7

Scenarios	NCS is additive used for electroplating. Based on the function of the chemical and process description in the submission, the NCS would not be consumed during the electroplating process. Therefore, 100% release of NCS is expected from the process.
Type of Information	Quantitative: Various daily releases estimates, see the next slide.
Substantiation	None.
Determination	Not Accepted.
Rationales for Determination	• PMN submission provided release estimates for non-submitter site without any explanation or supporting information. • Provided releases estimates did not add up to a 100% release scenarios, which was expected based on the use of NCS (per submission) and Generic Scenario.
Impact on Case	100% releases assessed per the Electroplating Generic Scenario (GS).

Case Study 7 (continued)

Example screen shot from the Section B2.10&12 - Industrial Sites Controlled by Others. Actual values edited to protect CBI. Releases estimates were provided without any basis/documentation and provided release did not add up to the expected 100% release scenario.

Release Number	Amount of New Substance Released		CBI	Media of Release & Control Technology	CBI
(9)	(10a)	(10b)	(11)	(12)	(13)
1	0	0.044		On site WWT to POTW	
2	0	0.0028		On site WWT to POTW	
3	0	0.0014		On site WWT to POTW	
4	0	0.22		On site WWT to POTW	

Case Study 8

Scenarios	NCS is an additive used for fabric dyeing. Submission provided the NCS loss fraction (LF) from the spent dye bath.
Type of Information	Quantitative: Fixation rate (~consumption) of NCS in process is 98%, hence LF of NCS release to the environment from rinse water is 2%. (LF = 1-0.98).
Substantiation	None.
Determination	Not Accepted.
Rationales for Determination	Fixation rate from 2015 ESD on Use of Textile Dyes is 75% which gives LF = 25%. Submitter stated LF in the submission was less than 1/10th of LF from relevant ESD, **with no substantiation provided**. Hence, release was estimated based on ESD.
Impact on Case	Releases to water were assessed using default loss fraction (LF) from the 2015 ESD on Use of Textile Dyes.

Questions & Answers

Common questions from last webinar

Q1: Does EPA still do pre-notice consultation, and can it be used to address potential data gaps or misunderstanding before EPA begins assessment?

A1: Yes. EPA still conducts pre-notice consultation, and the pre-notice inquiry may be submitted via CDX, EPA's website, or via phone/email to coordinator/EPA staff. The consultation may provide an opportunity to discuss what information would be useful to include in the submission. We encourage submitters to review the Points to Consider document before requesting any pre-notice meeting. Note the pre-notice communication is not intended to obtain EPA's decision on content/likely outcome of the new chemical review.

Q2: Where can submitters find detailed information about modeling assumptions and default values to understand where it makes sense to apply resources for monitoring or testing?

A2: EPA OPPT's predictive tools and models are published via this webpage: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate. Specifically, default model input values for models such as ChemSTEER can be found in the User Guide, available here: https://www.epa.gov/tsca-screening-tools/chemsteer-quick-start-guide-and-user-guide-tsca-predictive-screening-tool.

Questions & Answers (continued)

Q3:.We understand that if a submitter does not specify disposal / release media, EPA will use a conservative approach. How should the method of disposal/media of release be substantiated?

A3: This webinar provides several case studies on this issue. Some examples of substantiation include customer notification on waste disposal method, or a facility-specific SOP on waste management and disposal practices.

Q4: Does EPA plan on updating the 2018 Points to Consider document or issue similar new guidance?

A4: We do not have immediate plans to update the Points to Consider document. However, we welcome any feedback on the 2018 document and will consider these feedback during the next update.

Additional questions?