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

Kick-Off Meeting

July 27, 2022

Agenda

- Background
- Section 5 Rework Analysis
  - Methodology
  - Types of information causing rework
  - Results
- Example Rework Case
- Next Steps
- Additional Resources

Background

- The 2016 Lautenberg amendments to the Toxic Substances Control Act (TSCA) require EPA to make affirmative findings for every new chemical substance.
- During the new chemical review process, companies sometimes provide additional information to supplement their submission well after EPA has begun a risk assessment.
  - The additional information often relates to environmental release of and/or occupational exposure to the new chemical substance (NCS), or “engineering” information.
  - Additional information results in rework in EPA’s engineering assessment, and other downstream assessments in the risk assessment workflow.
- EPA is looking for ways to improve efficiency in the new chemical review process. Reducing “rework” is one area for potential efficiency improvement.

Section 5 Rework Analysis

- When a company amends its submission after EPA's review process has begun, EPA reviews the additionally submitted information to determine whether the Agency needs to revise its risk assessment.
- The additional information submission* may be a result of:
  - Clarification or supplement to its original submission
  - Additional information to refute EPA's initial risk determination
- Goal of EPA's "rework" analysis is to understand common additionally submitted information that cause most of the rework to EPA's engineering assessment.

*For low volume exemptions (LVEs), companies sometimes submit a second or third submission for the same NCS that was previously denied by EPA.

Rework Analysis: Methodology

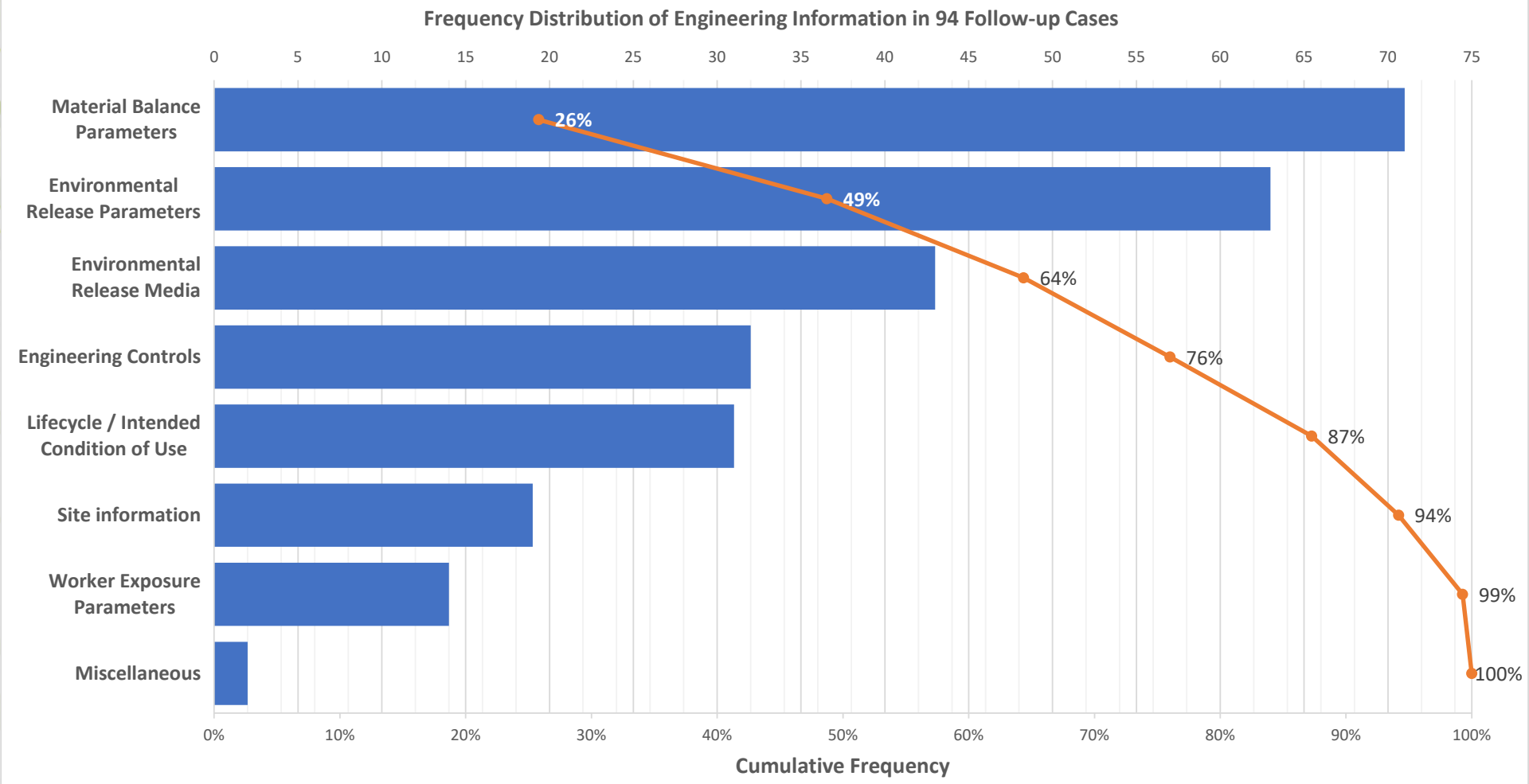
- **Sample Size:** 94 cases (originally submitted from 2019 – 2022) with additional information submissions.
- **Data Compilation:** For each case, EPA reviewed the company submissions to identify the type of information submitted. EPA then compared that information to different versions of the engineering assessment to determine whether the additional information resulted in revisions to EPA's assessment and recorded how many times each case was revised.
- **Data Analysis:** Collected information was QC reviewed, compiled, and catalogued into major "bins" relevant to environmental release and occupational exposure. Each major bin was further broken into sub-bins to develop insight into more specific causes of rework.

Rework Analysis

EPA catalogued each type of additionally submitted information into one of the following “bins”. Submitted information could fall into one or more bins:

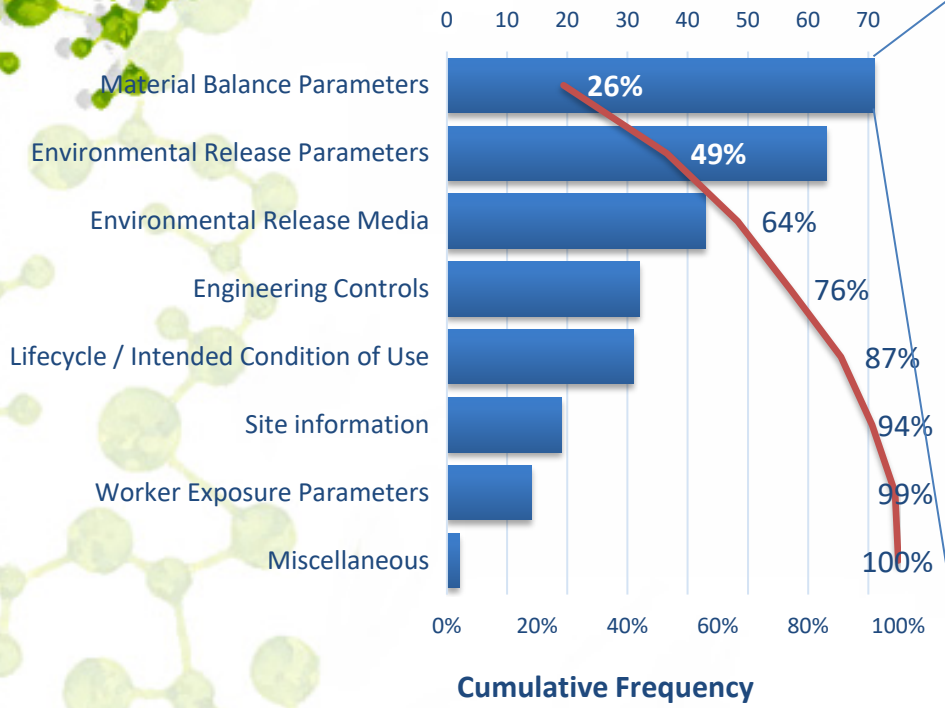
- **Material Balance Parameters:** Information that affects material balance estimation, such as changes in production volume, production batches, and number of sites.
- **Site Information:** Information on specific sites that manufacture (including import), process, or use the NCS.
- **Lifecycle / Intended Condition of Use:** Information on the lifecycle of the NCS, such as changes in the chemical’s intended condition of use or exposure scenario.
- **Environmental Release Media:** Information on the media of environmental release (*e.g.*, air, water, incineration, land) and waste disposal method.
- **Environmental Release Parameters:** Information that affects environmental release estimates at manufacturing, processing, and use sites.
- **Worker Exposure Parameters:** Information that affects worker exposure estimates, such as exposure monitoring data, particle size distribution, and estimates on the number of potentially exposed workers.
- **Engineering Controls:** Information on the engineering control (*e.g.*, ventilation, process enclosure), including type of control technology and the control efficiency.
- **Miscellaneous:** Other information that does not fit under any of the above bins.

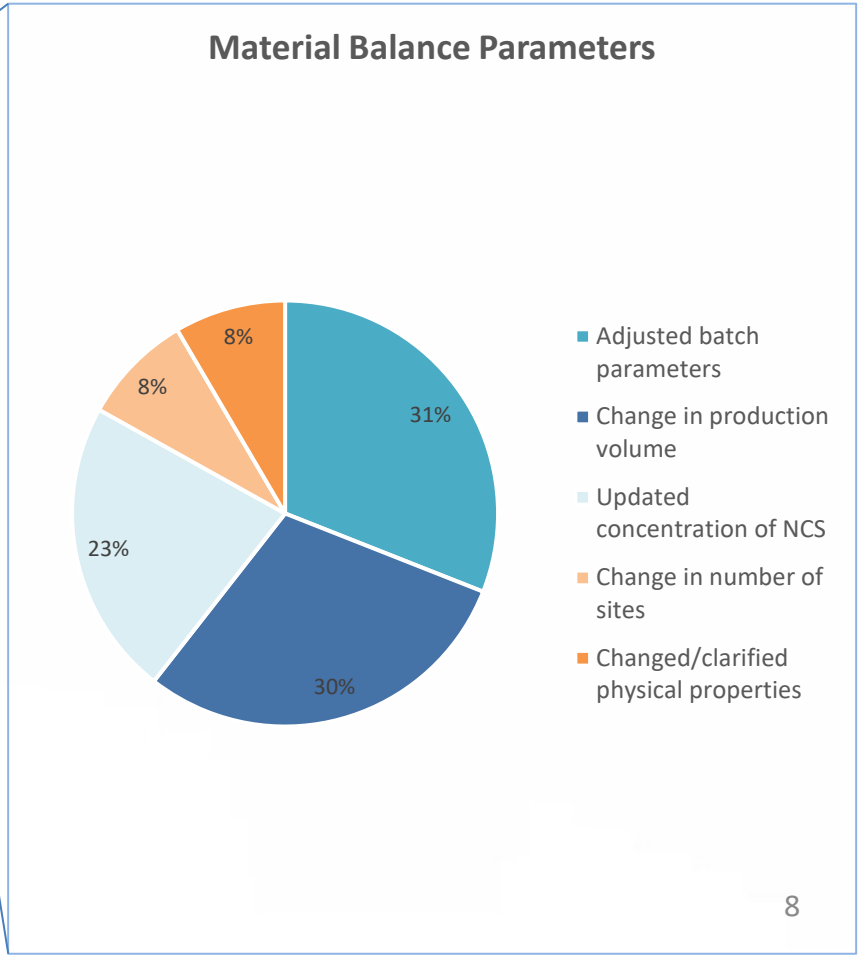
Rework Analysis: Results



Rework Analysis: Results (continued)

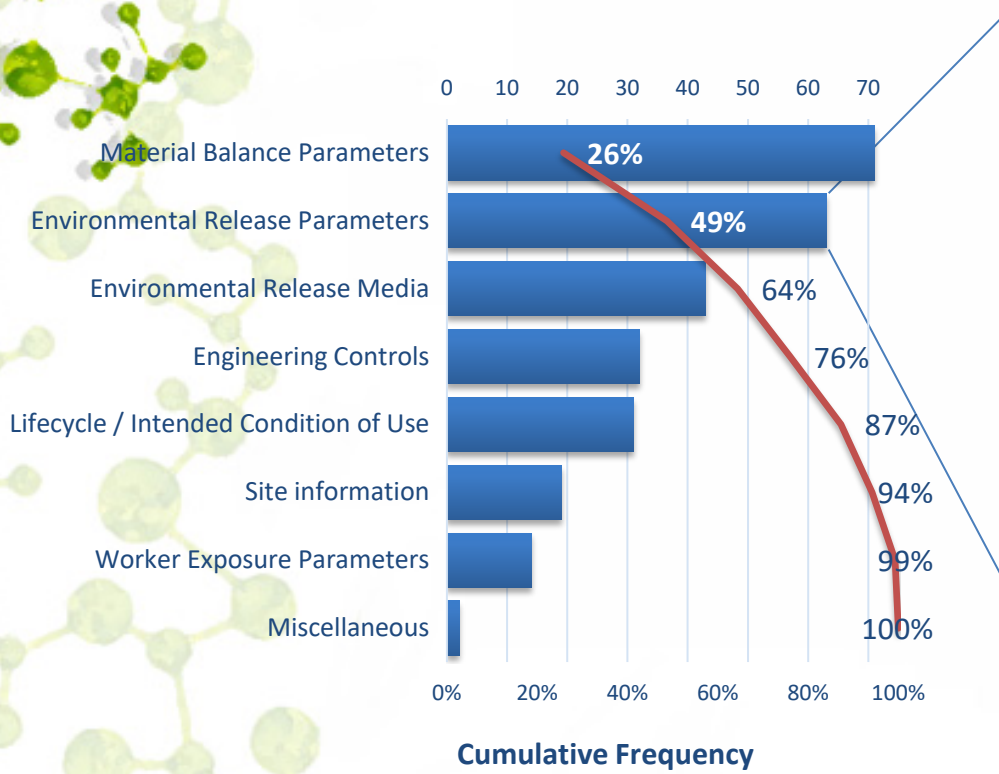
The **Material Balance Parameters** bin includes information that affects calculation of material balance of the NCS. Information in this bin can affect both environmental release and worker exposure estimation.

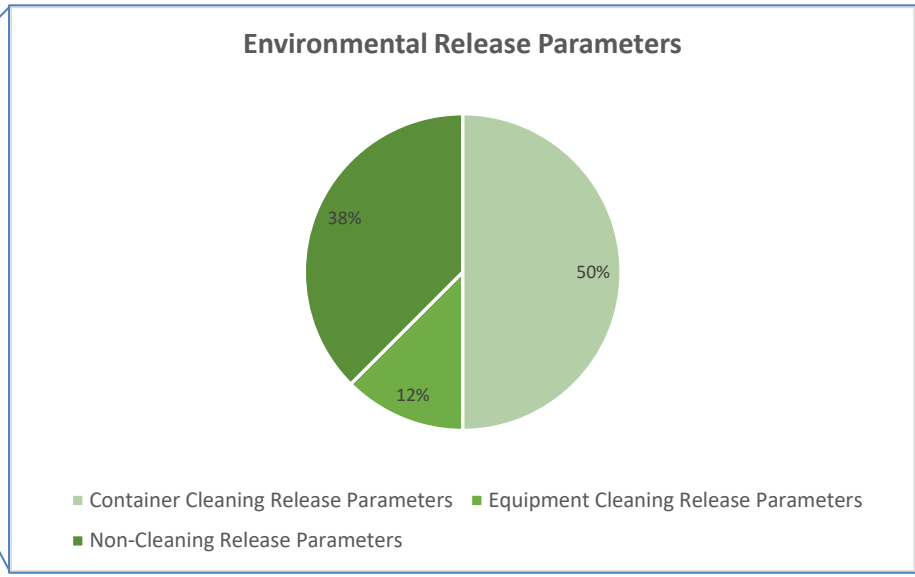




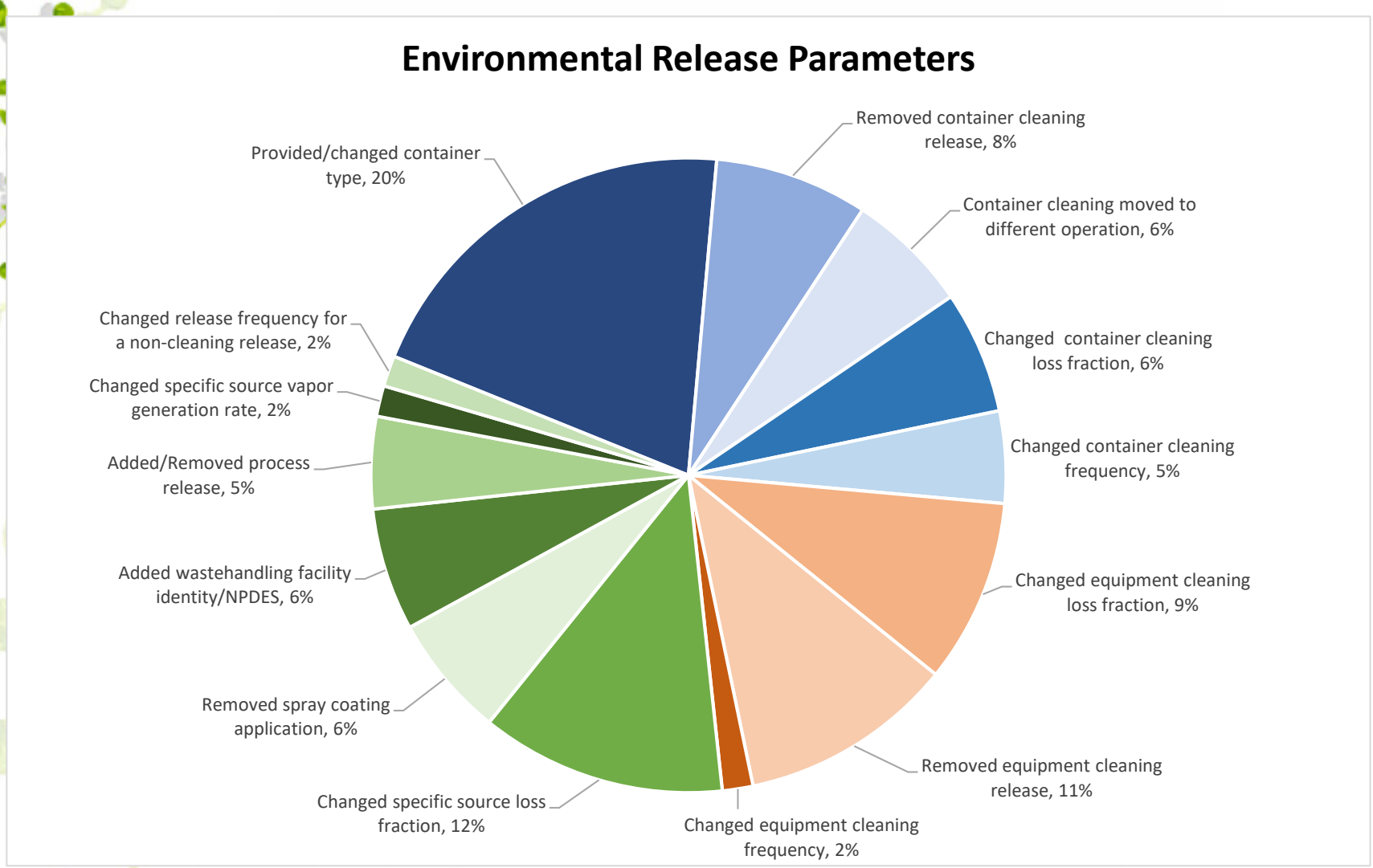
Rework Analysis: Results (continued)

The **Environmental Release Parameters** bin includes information that affects calculation of releases from various industrial and commercial activities, including cleaning of transport containers and process equipment.



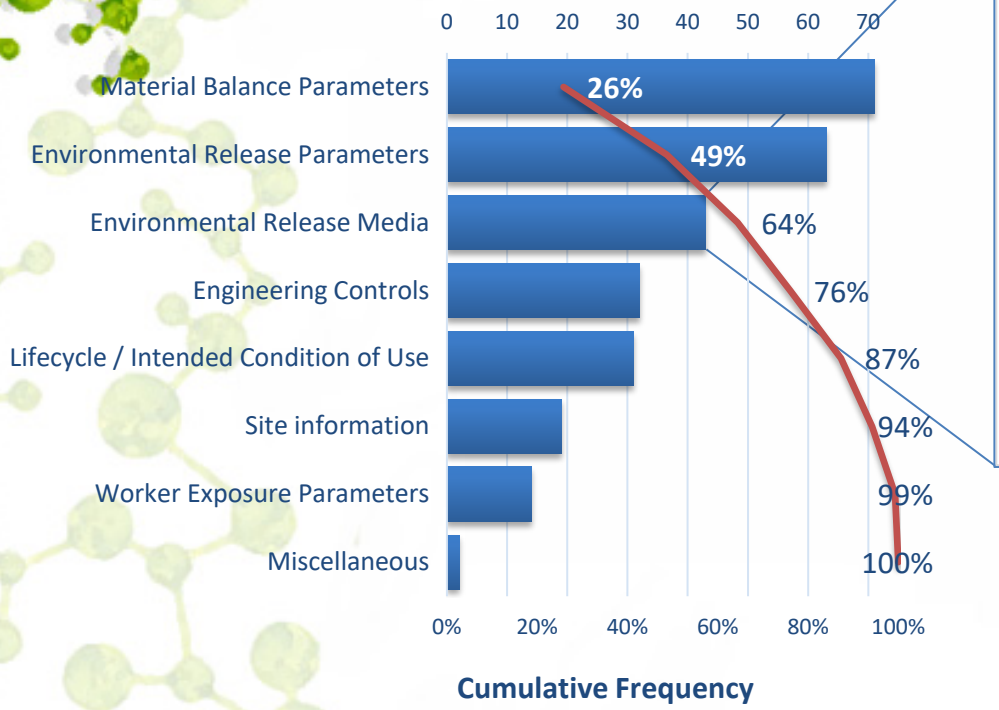


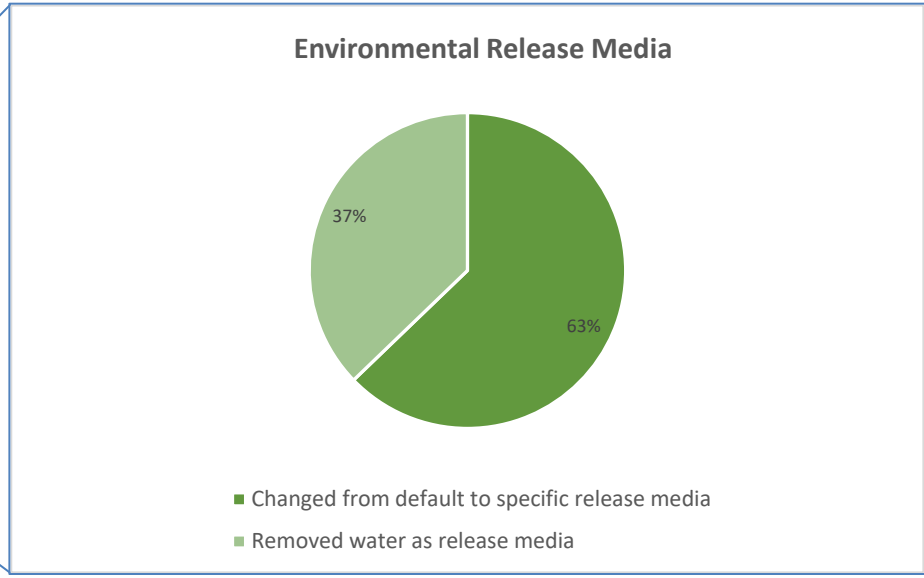
Rework Analysis: Results (continued)



Rework Analysis: Results (continued)

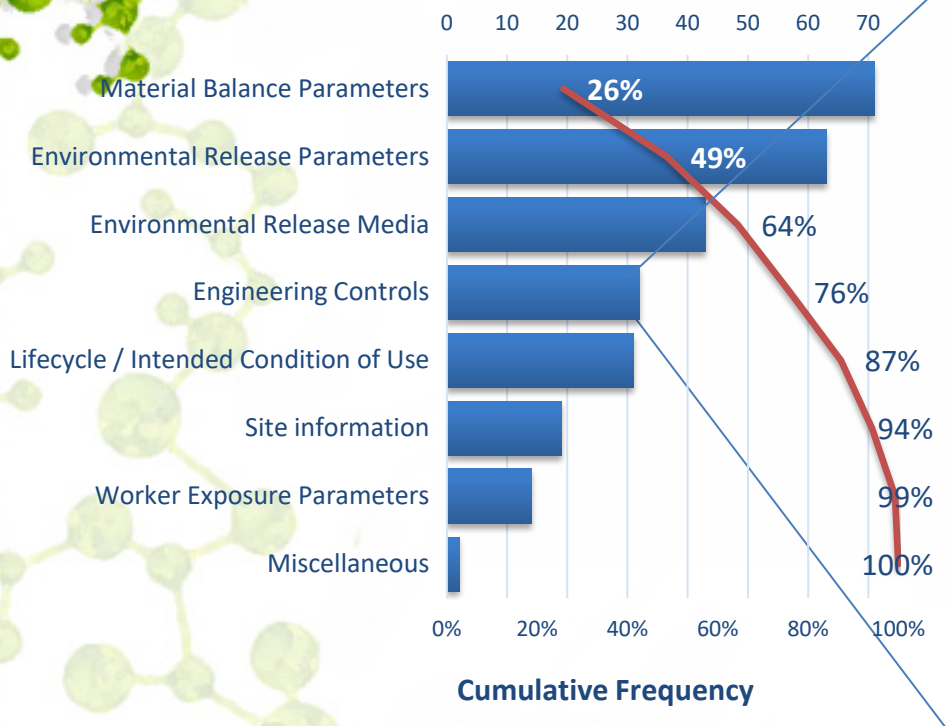
The **Environmental Release Media** bin covers additional information on disposal of process wastes and releases to various environmental media. Where there is uncertainty, EPA typically assumes process wastes may be disposed to water, incineration and landfill as default.





Rework Analysis: Results (continued)

The **Engineering Controls** bin includes additional information on control technology that protect workers by removing hazardous conditions or by placing barrier between the worker and the hazard.

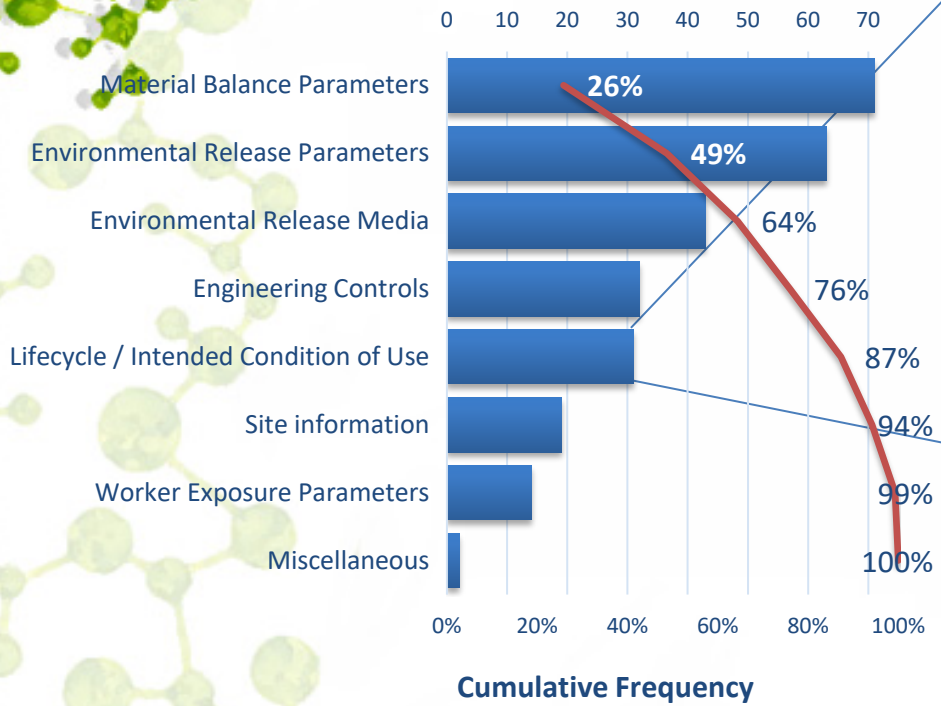


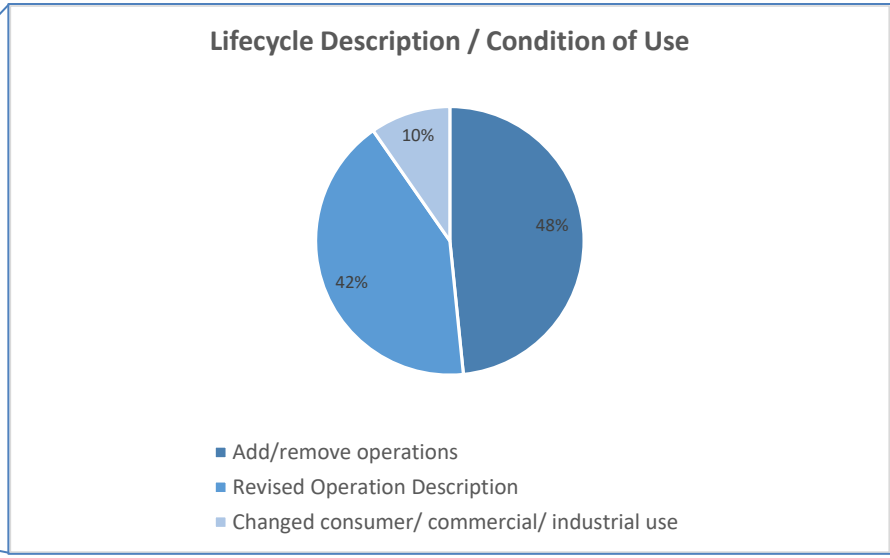
Engineering Controls:

Example engineering controls may include local exhaust ventilation or process enclosures. Engineering controls to capture and remove dust emissions are the most common type of control included in Section 5 additional information submissions. Information on control technology and efficiency typically affects both the environmental release and worker exposure assessment.

Rework Analysis: Results (continued)

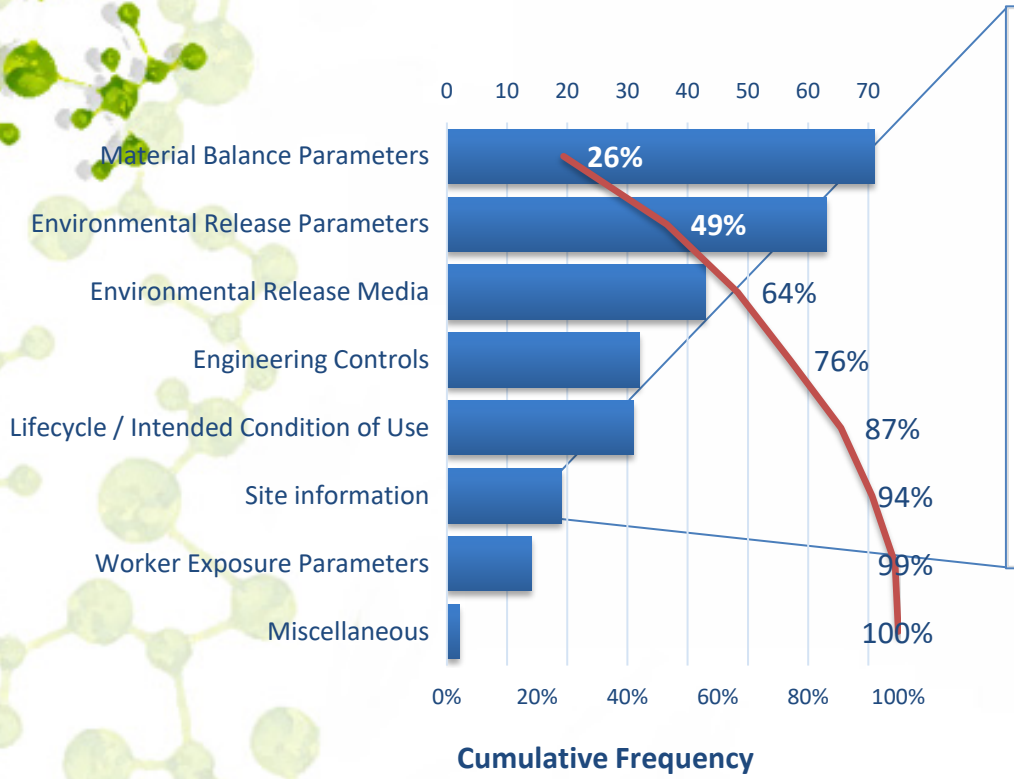
The **Lifecycle / Intended Condition of Use** bin includes information that affects the assessment on the manufacturing (including import), processing, or use of the NCS.

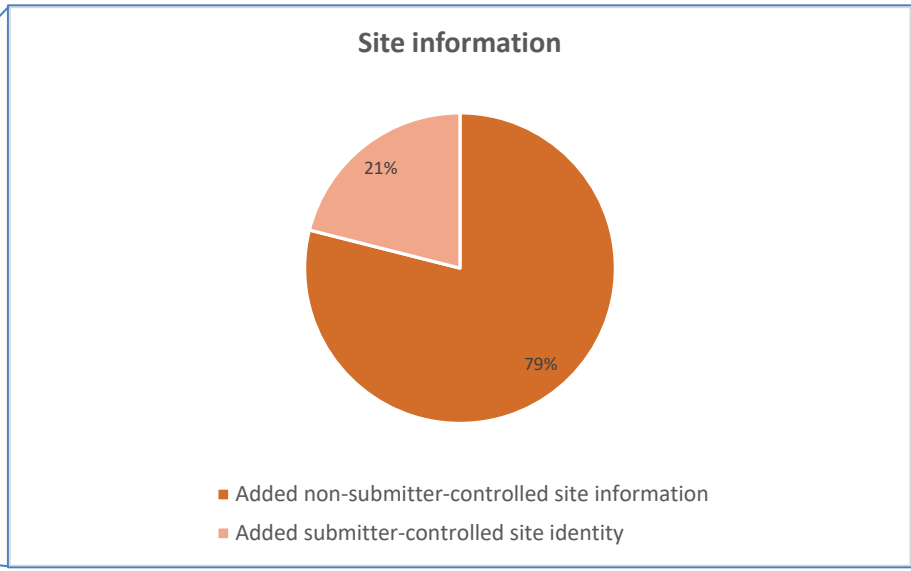




Rework Analysis: Results (continued)

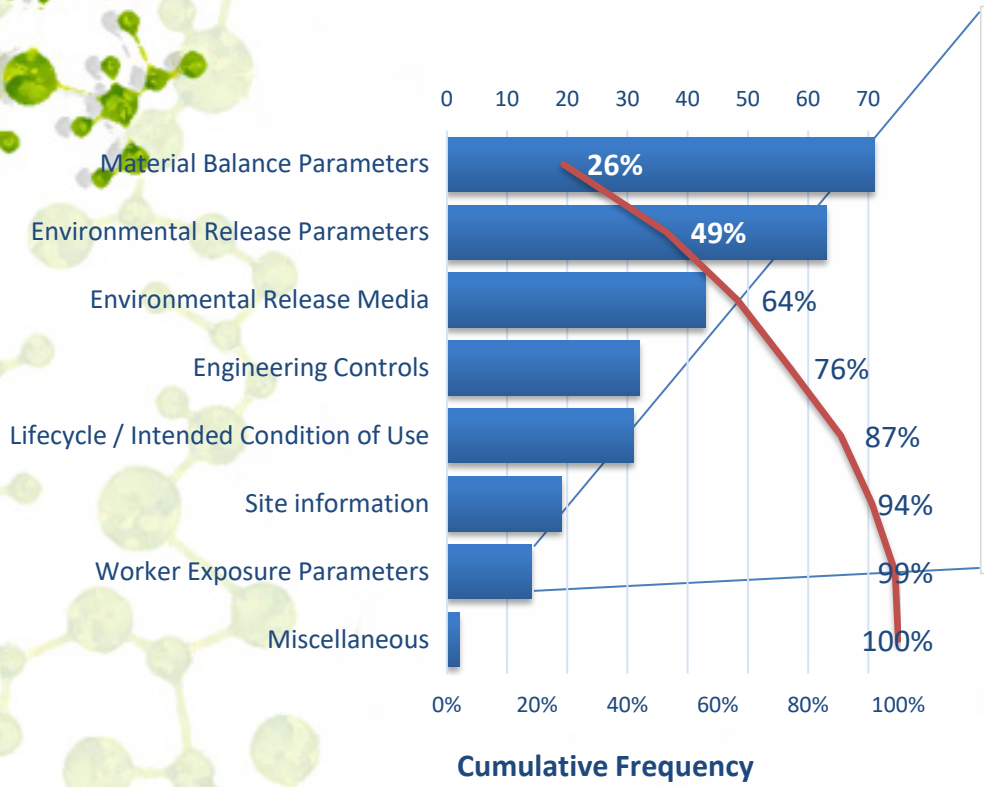
The **Site Information** bin covers additional details on the site/facility, most commonly for downstream customer sites not controlled by the submitter.

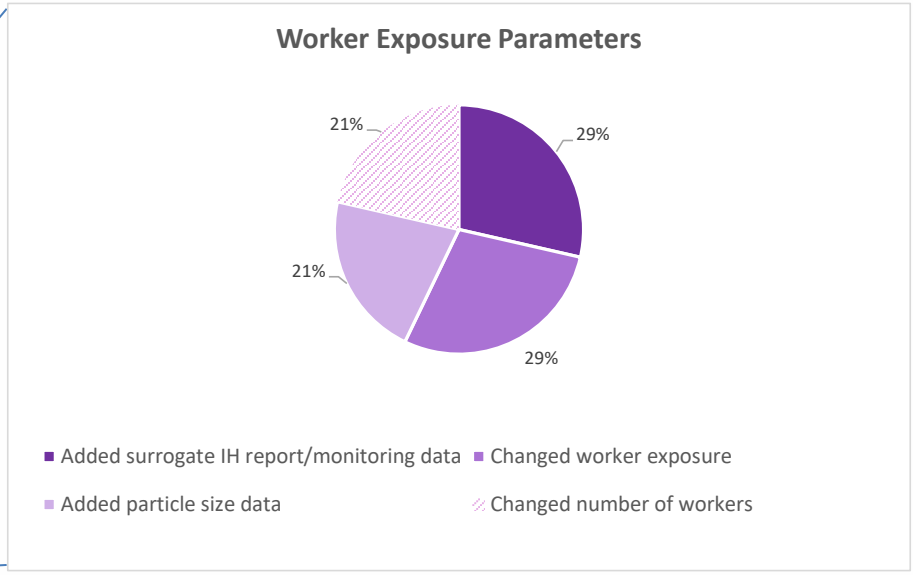




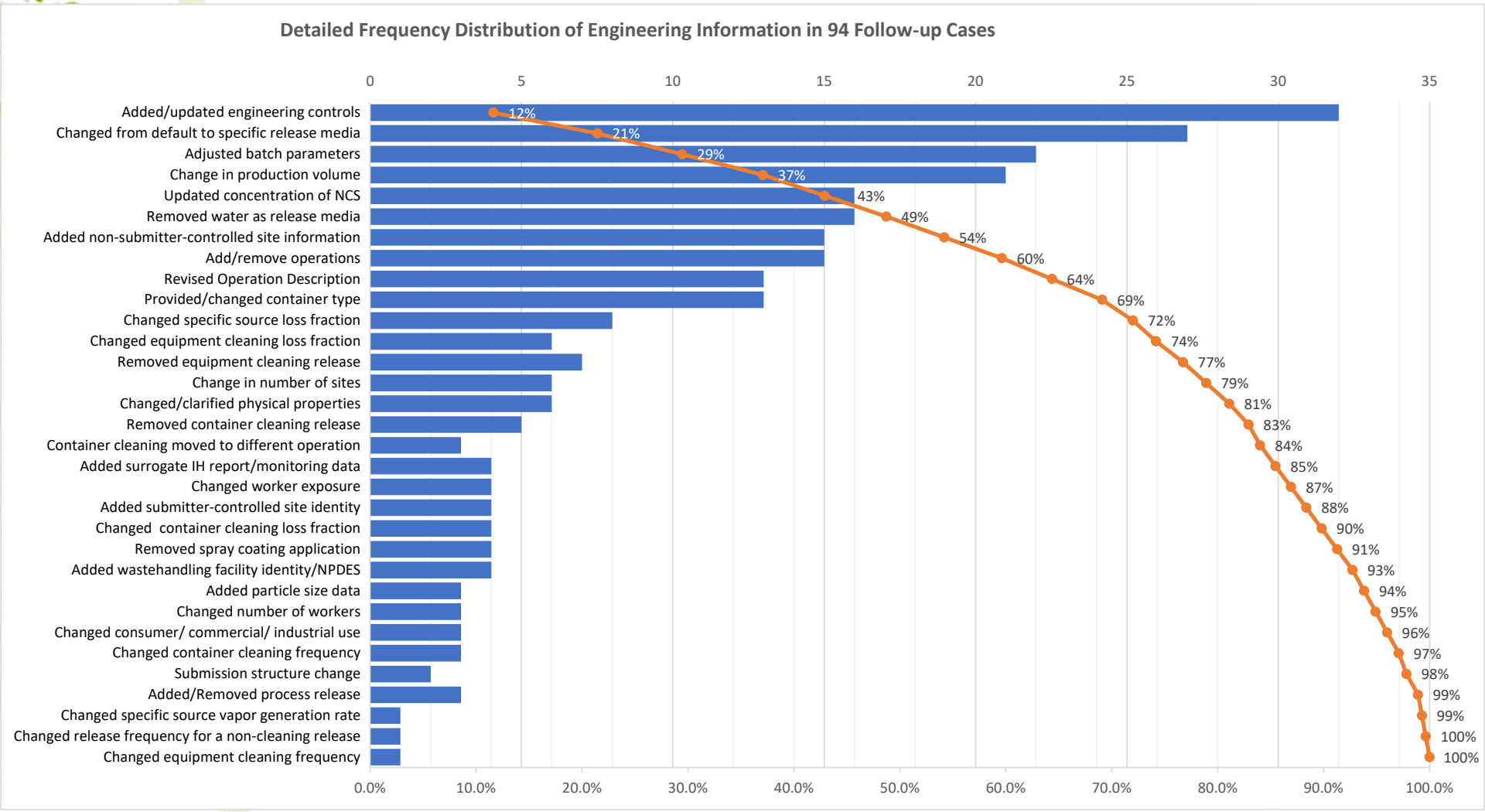
Rework Analysis: Results (continued)

The **Worker Exposure Parameters** bin includes information affecting the worker exposure assessment. The most common types of additional information in this bin are exposure monitoring data and changes to exposure estimate.





Rework Analysis: Results (continued)



Example Rework Case

	Initial Submission	Re-submission (Rework 1)	Re-submission (Rework 2)
Company submission	NCS is a liquid. Single unknown use site. No information on use except concentration of NCS.	Provides detail describing container being rinsed with solvent and rinsate recycled back to process. States NCS is consumed reaction and there is no equipment residue.	Identifies customer site and indicates customer has separate Processing and Use operations, specifies 50 day/yr operation, provided Stewardship Program certification letter which requires all release to incineration.
EPA assessment for Non-Submitter-Controlled Site	1 site, 250 day/yr (default) operation	1 site, 250 day/yr (default) operation	Separate proc/use sites, 50 day/yr operation
	Container residue release to water, incin. or land	No container cleaning release.	No container cleaning release.
	Equipment cleaning residue to water, incin. or land	Equipment cleaning residue to water, incin. or land	Equipment cleaning residue to incineration

Next Steps

- From the analysis, EPA observes 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 assumption.
  - Companies often lack understanding on what information is needed for a Section 5 engineering assessment, including the level of details needed to support their statements relating to environmental release and worker exposure.

Next Steps (continued)

- Additional webinars over the next few months will cover:
  - How EPA evaluates quantitative and qualitative information, with examples on the level of detail needed to support the submitted information to be accepted by EPA (Fall 2022).
  - The types of information commonly missing in Section 5 submissions, how EPA evaluates environmental release information on sites not controlled by submitter, and their impact on engineering assessment (Fall 2022).

Additional Resources

- EPA's TSCA New Chemical Engineering Outreach Initiative website
- Applicable Regulations for Premanufacture Notice (40 CFR 720) and Significant New Use Notice and Rules (40 CFR 721)
- EPA's "Points to Consider When Preparing TSCA New Chemical Notifications"
- Information about Filing a Premanufacture Notice