TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues

Background

This document describes EPA's analysis to identify the most common reasons for "rework" when conducting Toxic Substances Control Act (TSCA) Section 5 engineering assessments. EPA's review of the safety of a new chemical under Section 5 of the TSCA begins with the submission of information to EPA by chemical companies. This information is then used by EPA along with other data and materials to assess the risks posed by new chemicals. Section 5 submitters sometimes provide additional information after EPA has already begun a risk assessment of the new chemical substance (NCS). The additional information is often related to the environmental release and/or occupational exposure assessment (*i.e.,* engineering assessment) of the NCS.

EPA's Office of Pollution Prevention and Toxics (OPPT) receives hundreds of new chemical submissions each year. When additional information is submitted, EPA reviews it to determine whether it is relevant, adequately documented, and well-supported and whether the Agency needs to revise its risk assessment to incorporate it. Intake, review, and revision(s) to risk assessments (known as 'rework') take additional time and delay the new chemical review process. Accordingly, OPPT is looking for ways to increase efficiency of the review process without compromising on the quality of its risk assessments. An area of efficiency improvements EPA is focusing on is reducing "rework" during the new chemicals risk assessment workflow.

For this analysis, EPA determined which types of data were submitted as additional information, and whether these submissions resulted in a revised engineering assessment.

Methodology

EPA maintains records of Section 5 submissions (including amendments) in the Chemical Information System (CIS). In 2020, EPA began to also use an internal Microsoft Excel spreadsheet to track Section 5 engineering assessments and cases that received additional engineering information after the initial risk assessment has commenced. For this analysis, EPA identified recent cases that received additional information submissions as tracked in this internal Excel spreadsheet. EPA reviewed the additional information submissions in CIS, compiled and catalogued the engineering information submitted among these cases. EPA then compared that information to different versions of the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) model files[1] to determine whether the additional information resulted in revisions to EPA's engineering assessment, and how many times each case was revised. The analysis covered 94 unique cases, originally submitted from 2019 to 2022[2], that required a review due to submission of additional information.

[1] EPA uses the ChemSTEER software to generate Section 5 engineering assessments. Each time a case is reworked, a new version of the model file and engineering assessment would be generated.
[2] Case numbers contain 19, 20, 21 or 22 in the submission year.

Table 1: Cases Included in EPA's Analysis (Submission Year 2019 – 2022)[3]

Case Type	Number of Cases
LVE	45
LVE Modification	3
PMN	40
SNUN	1
LOREX	5
Total	**94**

For each case analyzed, EPA reviewed the company submissions to determine the type of information included in the additional submissions and catalogued it into one of the following "bins". Submitted information could fall into one or more bins:

- **Material Balance Parameters:** This bin includes information that affects material balance estimation, such as changes in production volume, production batches, and number of sites.
- **Site Information:** This bin includes information on specific sites that manufacture (including import), process, or use the NCS.
- **Lifecycle / Intended Condition of Use:** This bin includes information on the lifecycle of the NCS, such as changes in the chemical's intended condition of use and/or exposure scenario(s).
- **Environmental Release Media:** This bin includes information on the media of environmental release (*e.g.*, air, water, incineration, land) and waste disposal method.
- **Environmental Release Parameters[4]:** This bin includes information that affects environmental release estimates at manufacturing, processing, and use sites (*e.g.*, estimated loss fraction from process and cleaning activities).
- **Worker Exposure Parameters:** This bin includes 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:** This bin includes information on the engineering control (*e.g.*, ventilation, process enclosure), including the type of control technology and control efficiency.
- **Miscellaneous:** This bin covers other types of information that do not fit under any of the above bins.

Each bin above was further refined into sub-bins to provide additional detail on the types of information that triggered rework. The sub-bins are described in the "Analysis Findings" section below.

Because the compilation was a manual process, and that cataloguing the information required some expert judgment, there is potential for human error or variability affecting the results.

[3] Low Volume Exemption (LVE), Premanufacture Notice (PMN), Significant New Use Notice (SNUN), Low Release and Low Exposure Exemption (LOREX)

[4] This bin does not include qualitative information on release media and waste disposal method, which is covered under "Environmental Release Media".

Therefore, after the initial compilation, another person performed an independent review of the submissions and model files. This quality control (QC) check was performed for 50 percent of the 94 cases. The QC process did not identify major errors that would change the overall trend or conclusion of the analysis.

Analysis Findings

Figure 1 below shows the frequency distribution of the types of additionally submitted information by bin across the 94 cases analyzed. As shown below, additional information on material balance parameter is most frequently observed. Information on environmental release and environmental release media are the second and third most common bins.

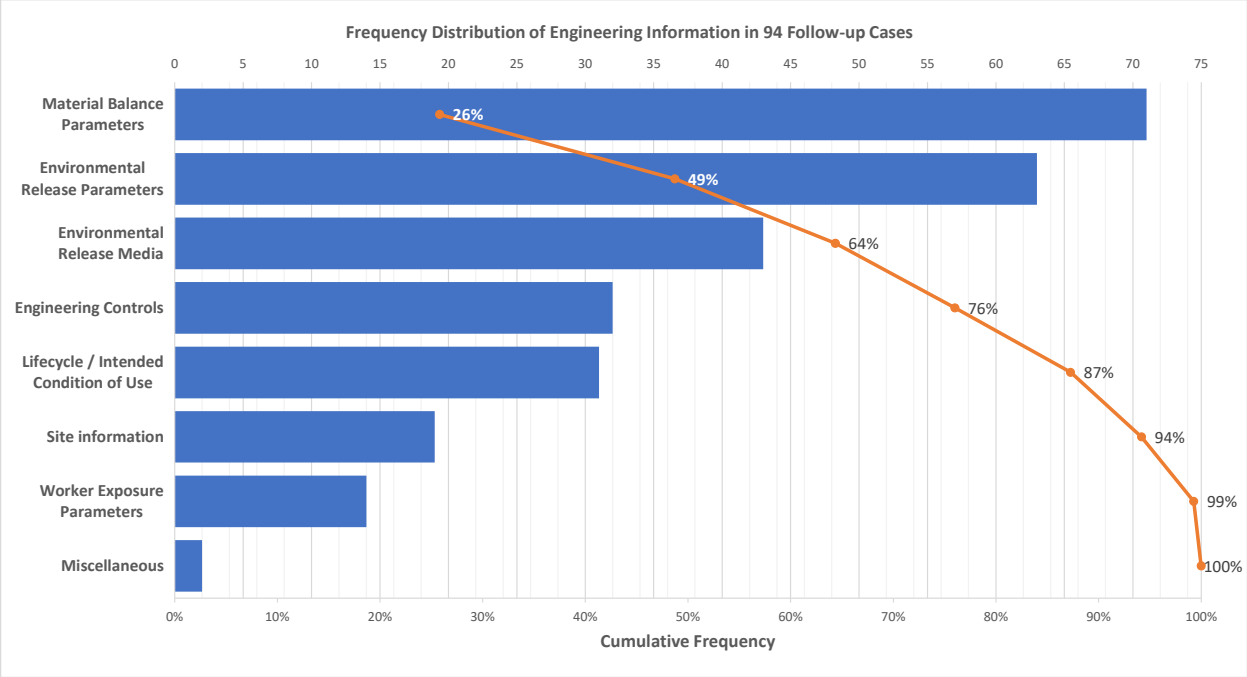

Figure 1. Frequency Distribution of Engineering Information by Bin in 94 Analyzed Cases

Note: In Figure 1, the bar chart shows the number of times information in each bin was included in the additional information submissions across the analyzed cases. Because each submission may include one or more types of information and that each case sometimes received multiple submissions, the total count of information compiled across all bins is greater than 94. The line graph represents the cumulative frequency of these bin.

Detailed Breakdown by Bin

The sections below describe each bin in additional detail.

Material Balance Parameters:
Information on material balance parameters can impact environmental release and occupational exposure estimation. For example, a change in the NCS production volume can change both the daily release rate and the frequency or duration of associated worker exposure. Figure 2 shows

that the most common sub-bins are batch parameters[5], production volume, and concentration of NCS.

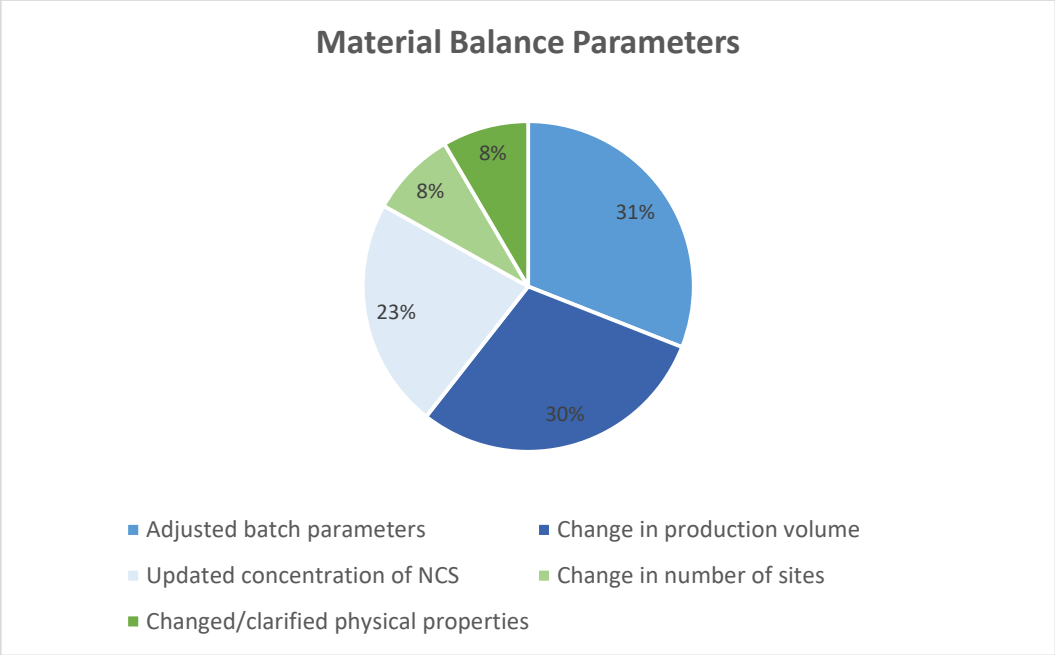

Figure 2. Breakdown of Material Balance Parameters

Environmental Release Parameters:
EPA's engineering assessment considers the potential environmental release of the NCS from cleaning of transport containers (*e.g.*, drums, totes, bottles, tank trucks) and process equipment (*e.g.*, reactor, mixing vessel, application equipment) from industrial and commercial activities. Unless site-specific information is provided with sufficient details to demonstrate its representativeness and characterization as high-end scenario, EPA typically quantifies environmental releases from these activities using default loss fractions from ChemSTEER models, EPA Generic Scenarios (GS), and OECD Emission Scenario Documents (ESD).

As seen in the blue portion of Figure 3 (below), additional information on container cleaning submitted typically includes updating or changing the type of transport container. Because EPA uses a different default loss fraction for each container type, updating the type of container changes the environmental release estimate. This type of update also typically changes the material balance (throughput) calculation due to differences in the container capacity and the quantity of chemical handled per container.

Orange portion of Figure 3 shows additional information submitted on equipment cleaning typically includes changes to the quantity of NCS released from the cleaning process. Submitters typically either provide additional information or basis on the mass of chemical released

[5] The "batch parameter" sub-bin includes changes to the number of operating days per year and mass of chemical produced per production batch.

(changes to loss fraction) or state that the equipment is never cleaned because process residue is recycled into the next batch.

Green portion of Figure 3 shows other non-equipment/container cleaning release parameters. EPA's environmental release assessment may also consider releases from other process activities specific to the NCS (*e.g.*, releases from spray coating application). The additional information submitted for these process activities most commonly involves submitters providing release estimates that are lower than EPA model defaults. Submitters also commonly provide additional information that one or more specific release sources assessed by EPA are not relevant to their chemical and request that EPA remove the specific release assessment (*e.g.*, request EPA to remove its spray coating release assessment because the NCS is not spray-applied).

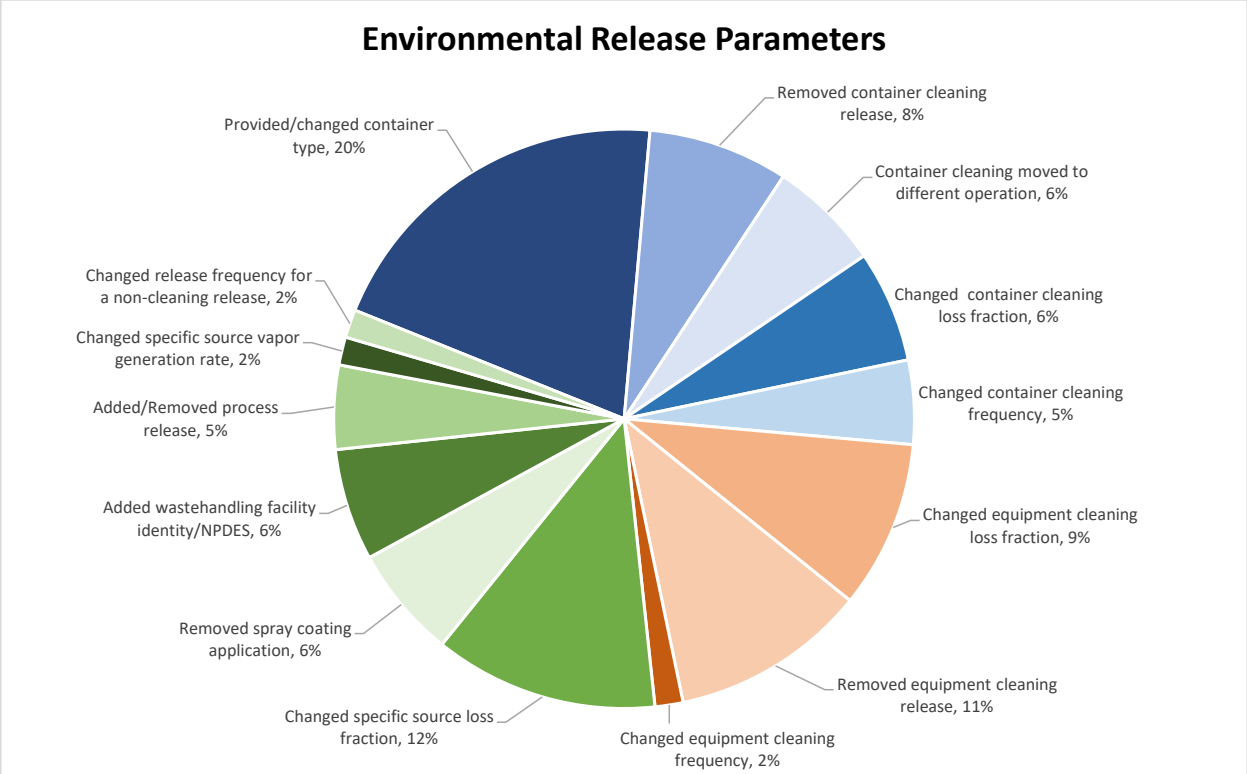

Figure 3. Breakdown of Environmental Release Parameters

Environmental Release Media:

In the absence of acceptable information on process operation and waste disposal method, EPA typically assumes process wastes and residues may be disposed to uncertain media, resulting in potential environmental release to water, incineration, and landfill, and assuming the entire quantity of NCS could be released to each of three possible media. Companies frequently submit additional information on waste disposal method and associated media of release that differs from EPA default assumptions. For example, submitters may state that all process waste and cleaning solvent are collected and incinerated, or that there are no environmental releases of the NCS to water from a manufacturing, processing or use site. These changes are common causes of Section 5 engineering (and downstream exposure) rework. For this bin, each instance of additional information submission can affect multiple release activities in the assessment.

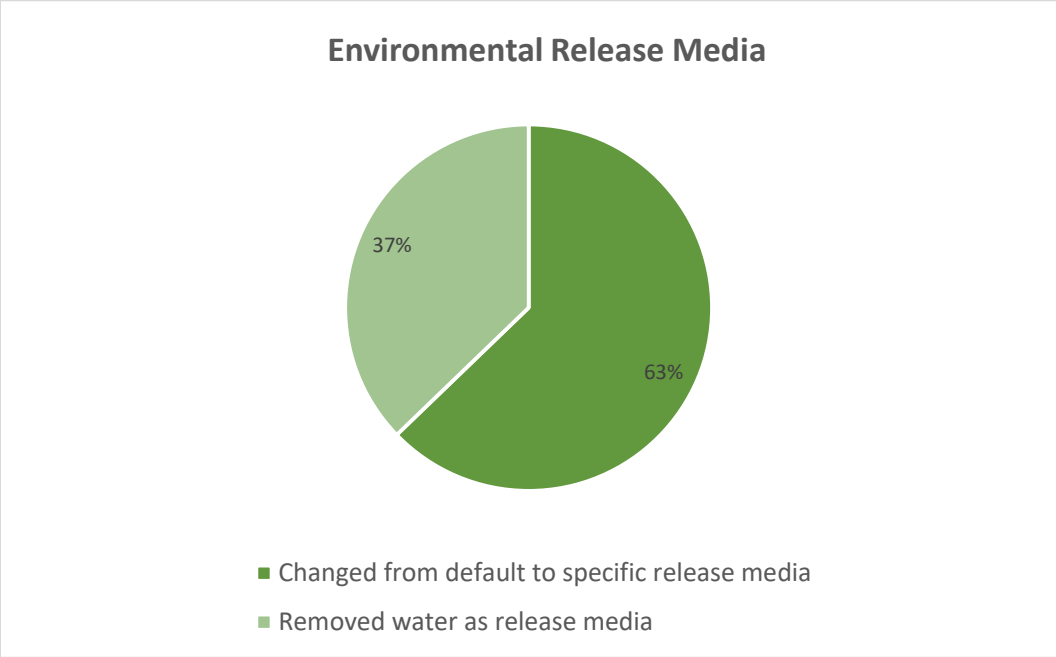

Figure 4. Breakdown of Environmental Release Media

Engineering Controls:
Engineering controls protect workers by removing hazardous conditions or by placing barrier between the worker and the hazard. Examples of 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. Submitted additional information on control technology and efficiency typically affects both the environmental release and worker exposure assessment.

Lifecycle / Intended Condition of Use:
Occasionally submitters provide additional information that describes the lifecycle, uses, or exposure scenarios of the NCS. For example, submitters may provide additional information on the lifecycle of the NCS that indicates the chemical has an additional processing/formulation step that was not previously assessed, or vice versa. Figure 5 shows that the most common type of change is to either add or remove an assessed operation (lifecycle step), which impacts both environmental release and worker exposure estimates. Changes to the operation description may or may not have a quantitative effect on the engineering assessment.

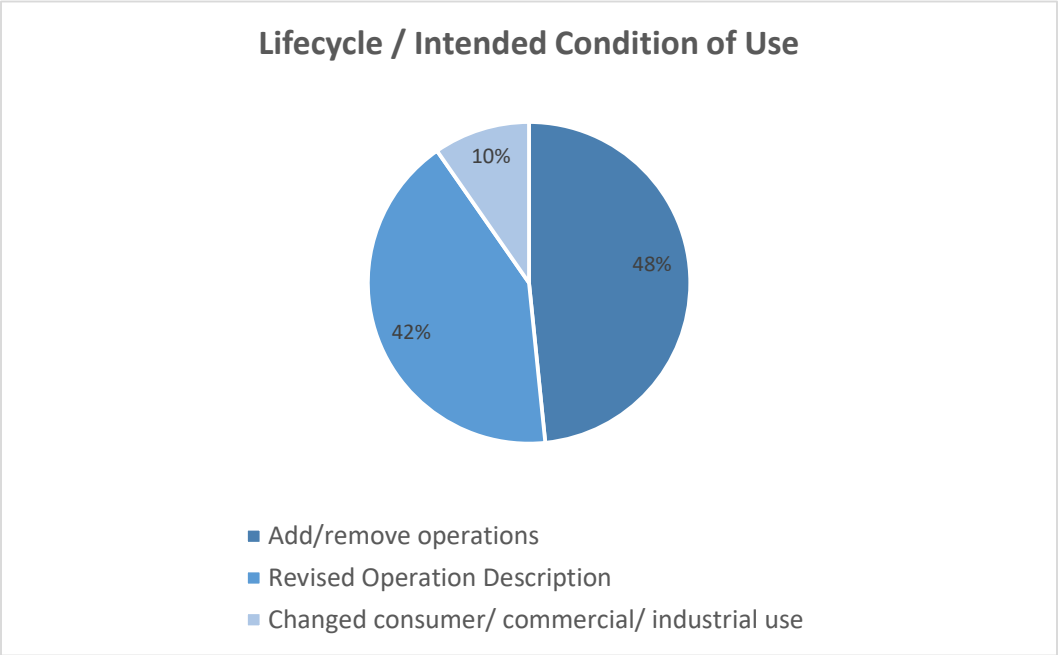

Figure 5. Breakdown of Lifecycle / Intended Condition of Use

Site Information:

This bin of additional information submission involves the submitter identifying or providing additional details on site information, most commonly for downstream customer sites not controlled by the submitter (as shown in Figure 6). For example, submitters may provide the identity and geographic location of specific sites (facilities) that process or use the NCS. This bin is typically accompanied by other information that also affects the environmental release or worker exposure assessment.

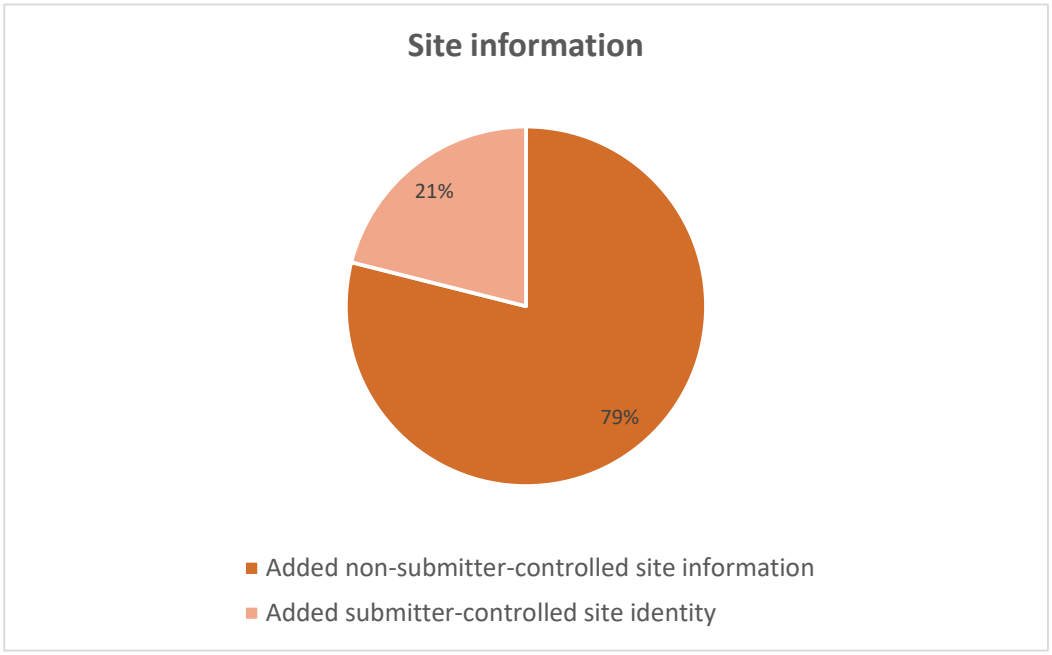

Figure 6. Breakdown of Site Information

Worker Exposure Parameters:
This bin includes information affecting the worker exposure assessment. Figure 7 shows that the most common sub-bins of additional information are worker exposure monitoring data and exposure estimate (*e.g.*, change in the estimated exposure duration or frequency).

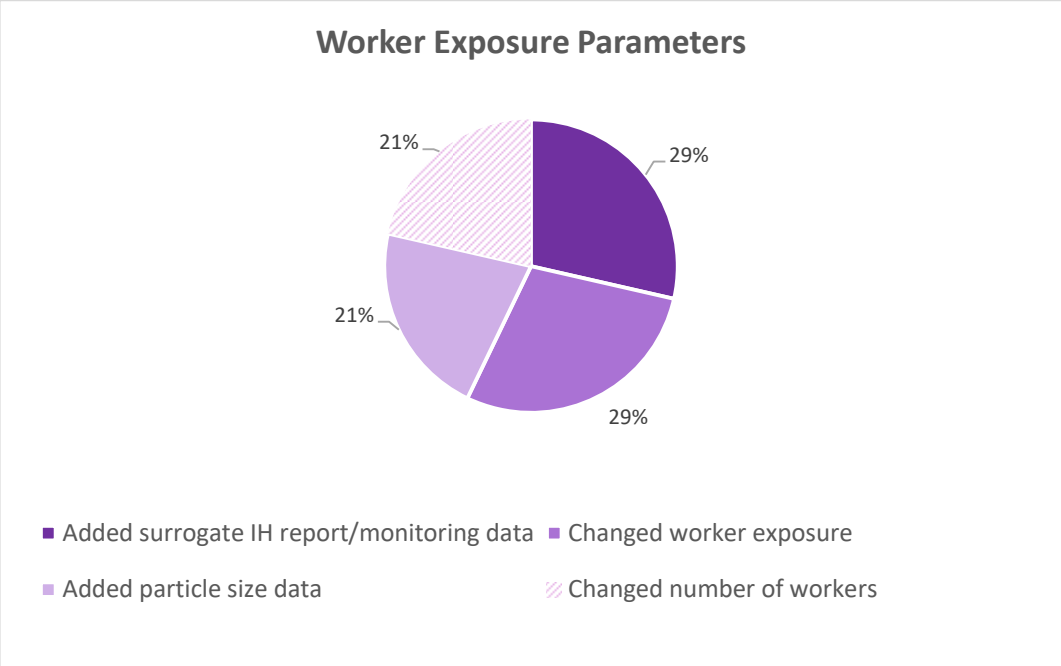

Figure 7. Breakdown of Worker Exposure Parameters

Miscellaneous:
This bin is a collection of information that does not fit in any of the other above bins. Only two types of information fall under this bin; one is a change in the submission to include a joint submitter. These changes alone did not result in a "rework" but were accompanied by information in other bins that affected the engineering assessment.

Conclusion

EPA typically models environmental release and worker exposure to NCS using model default values when chemical-specific data are not available or are not well supported. As described in detail above, companies commonly submit additional information suggesting the use of alternative parameters that may deviate from EPA's default assumptions. The objective, evidence-based analysis described here shows the various types of submitted information that become available after EPA has started its evaluation. This information, when acceptable, can be useful for improving the scientific support for EPA's risk assessment. However, the frequency and amount of information submitted after EPA has started its evaluation causes substantial rework and delays in completing the analysis.

Although not documented in this analysis, EPA has also observed that in many cases, the same types of information were submitted multiple times by a submitter because they were not

accepted by EPA due to a lack of supporting data or documentation. This situation can result in several rounds of EPA review and rework. This situation is particularly common when the information is for a site not under submitter control. EPA finds that companies often lack understanding what information is needed for a Section 5 engineering assessment, including the level of detail and/or documentation is needed to support their statements relating to environmental release and worker exposure.

Based on the findings of this analysis, EPA believes that additional outreach to Section 5 submitters will be helpful to increase the efficiency, transparency, and scientific support of its new chemicals review process. Specifically, EPA plans to conduct outreach to stakeholders through a series of webinars.

- The first webinar will provide an overview of this rework analysis, including results and key takeaways. The first webinar is scheduled for July 27, 2022.
- The second webinar will discuss how EPA generally evaluates qualitative and quantitative information, with examples on the level of detail needed to support the submitted information to be accepted by EPA. For example, the webinar may include case studies on additional information submission related to environmental release estimates and engineering control, both of which are common causes of rework based on EPA's analysis. The second webinar will be held in fall 2022.
- The third webinar will cover the types of information that are commonly missing in Section 5 submissions, how EPA evaluates environmental release information on sites not controlled by submitter, and their impacts on engineering assessment. The third webinar will be held in fall 2022.

The goal of these webinars is to reduce rework of EPA's engineering assessments that is caused by companies supplementing new chemical submissions, which has contributed to delays in EPA's Section 5 review process. Moreover, EPA believes this outreach will improve transparency and the scientific support for EPA's risk assessments of new chemicals.