

Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions

Background

The Toxic Substances Control Act (TSCA) new chemicals program is required by the 2016 Lautenberg amendments to TSCA to make an affirmative formal finding on the safety of every new chemical or significant new use of an existing chemical before it is allowed into the marketplace. EPA's Office of Pollution Prevention and Toxics (OPPT) receives hundreds of new chemical submissions each year. The requirement to complete a formal finding on the safety of hundreds of new chemicals each year has created additional work for OPPT without a commensurate increase in resources to meet statutory deadlines for completing these reviews. Accordingly, OPPT is looking for ways to increase the efficiency of the review process without compromising on the quality of its risk assessments. One area of EPA focus for improvements in efficiency is in reducing "rework" in the completion of new chemicals risk assessments.

EPA's typical risk assessment consists of an assessment of chemistry, environmental fate and transport, environmental release and occupational exposure (engineering), environmental, general population and consumer exposure, ecological hazard and risk, and human health hazard and risk. TSCA Section 5 submitters sometimes provide additional information to EPA to supplement their initial submission well after EPA has already begun a risk assessment of the new chemical substance (NCS). The additional information often relates to environmental release and/or occupational exposure assessment of the new chemical substance (*i.e.*, engineering information).

Intake, review, and inclusion of new information takes time. When additional information is submitted, EPA reviews the qualitative claim or quantitative data to determine whether the information warrants a revised assessment. If EPA determines the information is relevant, adequately documented, and well-supported, the Agency may rework its risk assessment. Depending on the nature and quality of the data, any or all of the engineering, general population and consumer exposure, ecological risk, and human health risk reports, may be revised. The need to rework any of these reports always leads to delays of the completion of the new chemical case review. When many companies do this at the same time—sometimes more than once for some new chemical reviews—it can result in long queues and delays for many chemical cases and as explained below, rework can add months of often-avoidable delays to the review process.

Recently, submitters have also expressed concern that EPA does not always use submitted data in its risk assessments and does not provide enough information on what EPA deems as "acceptable data." To help better understand and address the concerns raised, EPA conducted an analysis to determine which types of data were most often submitted as additional information (*i.e.*, the most frequent data elements and information gaps causing revision and delays to new chemical review cases) and whether these submissions typically resulted in the need for revisions to the risk assessment, or "rework".

Methodology

The Agency compiled and analyzed TSCA Section 5 new chemical submissions for which companies provided additional engineering information from 2019 to 2022. EPA identified a total of 94 unique cases during this time period (see Table 1).

Table 1: Section 5 New Chemical Cases Included in Analysis

Case Type ¹	Number of Cases
LVE	45
LVE Mod	3
PMN	40
SNUN	1
LoREX	5
Total	94

Types of Information / Data Elements Provided in Re-submissions

For each case, EPA reviewed the original submission and the amendments to determine what type of additional information was provided. EPA then catalogued the submitted information to understand the types of data that were included in the additional information submission. For example, a company may provide additional information on engineering controls, which can result in a change in the occupational exposure assessment, or provide new information on waste disposal methods, which can also result in a change to the environmental release assessment. The results of EPA's analysis show the following as some of the most common data types that contributed to EPA having to rework the initial risk assessment:

- Additional information on engineering controls companies plan to utilize (*e.g.*, local exhaust ventilation to capture and remove airborne emissions, process enclosures). Engineering controls protect workers by removing hazardous conditions or by placing barrier between the worker and the hazard.
- Additional information on environmental release media (*e.g.*, air, water, land) and waste disposal methods. This includes information on how process equipment and transport containers will be cleaned, and how the associated waste will be disposed of (*e.g.*, on-site wastewater treatment, POTW, incineration, landfill).
- Changes to planned batch parameters (*e.g.*, number of operating days per year, mass of chemical produced per production batch). For the purpose of this analysis, this data element includes parameters that would affect the calculated throughput of the new chemical substance.
- Changes in planned production volume, which directly impact model outputs. For example, an increase in production volume typically increases the potential for environmental release.
- Additional information on sites not under submitter control (*e.g.*, customers downstream of the manufacturer and/or importer of the new chemical substance).

From the analysis, EPA concluded that there are certain types of data elements and information gaps that, if not provided or well described in the initial submission, cause the most "rework". More detailed information will be provided at an upcoming webinar during which EPA will further explain the analysis and the results, provide an opportunity for dialogue between the regulated community and EPA on the analysis and results, and further characterize the type of information that submitters should include with their initial submission.

Analysis and Example of Rework

EPA compared the information provided in the amendments to different versions of the engineering reports to determine whether the information resulted in a rework of its risk assessment. EPA found that

¹ LVE = low volume exemption, LVE Mod = low volume exemption modification, PMN = pre-manufacture notice, SNUN = significant new use notification, LoREX = low releases and low exposure exemption

an individual case risk assessment may be **reworked anywhere from one to five times**, with each rework being the result of an additional information submission, and the reworks could add at least several months to the case review.

An example of a case where additional information about the planned manufacture of a new chemical substance was submitted multiple times is provided in Table 2. In this example, for each re-submission, EPA evaluated the additional information and revised the risk assessment when the information provided had an acceptable basis. In the original submission, the company provided some information on how the new chemical substance would be used by its customer without identifying the specific customer site. The submission indicated the new chemical substance would be present as a solid but did not specially address the issue of whether there was a potential for dust generation when the substance was being used. Moreover, the submission did not provide any basis for the environmental release and worker exposure estimates which were provided. Accordingly, in order to ensure an accurate assessment of potential risk to human health and the environment, EPA performed its risk assessment assuming there was potential for dust release from solid transferring activities and used default release and exposure assumptions and EPA’s standard model, Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER). The assessment identified risk to human health and the environment.

In the first re-submission, the company identified the specific customer use site and provided a detailed description on how containers and equipment would be cleaned at the site. EPA then reviewed the information and concluded that there would not be an environmental release associated with these activities. The first re-submission also claimed there would be no dust generation associated with the operation but did not provide a basis for that claim. As a result, EPA revised its environmental release assessment and removed the container and equipment cleaning releases but continued to assess the potential for a dust release.

In the second re-submission, the company provided specific information on dust control and prevention measures, including the type of control technology that would be used to reduce potential dust releases. As a result, EPA revised its assessment to reflect the engineering controls used and accounted for the control efficiency in its release estimates.

Table 2. Example New Chemical Substance (NCS) Case Study:

	Initial Submission	Re-submission (Rework 1)	Re-submission (Rework 2)
Company submission	Submission identified the NCS as a solid, that it would be used at a single, unknown site not controlled by the submitter. Submission provided a process description and release/exposure estimates without basis.	Amendment identified the specific use site and added details to substantiate claims that container and equipment cleaning do not result in a release. Amendment also claimed there is no dust generation but did not provide a basis.	Amendment provided a detailed description of dust control and prevention measures, including the specific engineering control that would be used.
EPA assessment for Non-Submitter-Controlled Site	<ul style="list-style-type: none"> • Dust release to air, water, incineration or land, no control (EPA model default) • Container residue release to water, incineration or land • Equipment cleaning release to water, incineration or land 	<ul style="list-style-type: none"> • Dust release to air, water, incineration or land, no control (EPA model default) • No container cleaning release • No equipment cleaning release 	<ul style="list-style-type: none"> • Dust controlled by an electrostatic precipitator (87% efficiency) • No container cleaning release. • No equipment cleaning release

This example demonstrates that EPA often finds a lack of details to support submitter claims, especially when the process operation occurs at a site not controlled by the submitter, sometimes resulting in multiple re-submissions of information. Although the time required to conduct the rework can vary substantially across different cases, for this example the re-submissions and rework increased the new chemical case review time by 5-7 months. EPA has observed approximately 30 percent of all new chemical submissions have additional information submitted after the initial submission that results in rework. As noted previously, each individual case may be reworked anywhere from one to five times.

Next Steps

The goal of this effort was to analyze and communicate to the regulated community the causes of risk assessment rework that have contributed to delays in EPA completing its review of TSCA new chemicals in order to make the process more efficient for EPA and companies. EPA's analysis and case studies have led to the conclusion that there is a need to conduct outreach and discussion with new chemical notice submitters on:

- What information is required to be included in a Section 5 new chemical submission;
- How the Agency evaluates data for new chemicals submissions; and
- Common issues that cause EPA to have to redo or rework risk assessments for these submissions.

For next steps, EPA will conduct webinars that will include information on typical release/exposure activities that are addressed by EPA when evaluating a new chemical submission (and which require submission of any relevant data in the possession of the submitter). The outreach will also include information on how EPA evaluates quantitative data and qualitative claims relating to release and exposure. For example, when a company submits quantitative release or exposure estimates derived from a surrogate chemical, EPA may consider whether the data would be representative of the new chemical substance based on similarity in physical-chemical properties and operating conditions. EPA will provide additional information on its considerations during a series of Webinars.