March 22, 2019

Data Quality Record for Long-Term Performance Goal

Long-Term Performance Goal Text: By September 30, 2022, complete all TSCA pre-manufacture notice final determinations in accordance with statutory timelines
Performance Measure Text: (PM TSCA3) Percentage of final TSCA new chemical determinations for Pre-Manufacture Notices, Significant New Use Notices and Microbial Commercial Activity Notices completed within the initial 90-day statutory timeframe.
Goal Number/Objective: Goal 1: Core Mission/Objective 1.4: Ensure Safety of Chemicals in the Marketplace
NPM Lead: Office of Chemical Safety and Pollution Prevention (OCSPP)/Office of Pollution Prevention and Toxics (OPPT)

1a. Purpose of Long-Term Performance Goal:
This long-term performance goal enables the agency to monitor and evaluate its progress in making final determinations on TSCA pre-manufacture notices submitted to EPA for review. Under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (enacted June 2016), anyone who plans to manufacture (statutorily defined to include import) a new chemical substance for a non-exempt commercial purpose[1] is required to provide EPA with notice before initiating the activity. A similar notification requirement applies to any person who intends to manufacture or process any chemical substance for a use which EPA has determined is a significant new use. On receiving notification, EPA commences a review of the new chemical substance or significant new use to determine whether or not the substance or use presents an unreasonable risk of injury to human health or the environment. In the course of review, EPA has the authority to agree to voluntary suspensions at the request of a submitter. These provide additional time to complete the required review if, for example, the submitter requires more time to develop additional information. The review culminates in a final determination by EPA, as defined below. Under the 2016 TSCA amendments, an affirmative determination is required. The final determination must be made within 90 days of EPA's receipt of the submission, subject to a possible extension by EPA of an additional 90 days. A history of timely final determinations will indicate that the agency is carrying out its responsibilities for new chemical review in conformity to the timelines set by the Congress.

Following completion of new chemical review, EPA is authorized to impose restrictions on the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance, up to and including a ban, if necessary to protect human health or the environment. This is generally accomplished through the issuance of a TSCA Section 5(e) or 5(f) order and/or a Significant New Use Rule (SNUR).

1b. Performance Measure Term Definitions:
Pre-manufacture notice: For purposes of this long-term performance goal, a pre-manufacture notice includes Pre-Manufacture Notices (PMNs), Significant New Use Notices (SNUNs) and Microbial Commercial Activity Notices (MCANs).

Final determination: A determination by EPA that:

- The relevant chemical substance or significant new use presents, may present, or is not likely to present an unreasonable risk of injury to human health or the environment;
- Information available to the agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use ("insufficient information determination"); or

[1] For further information, please see https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-new#who notifies

- The substance is or will be produced in substantial quantities and will either enter or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the chemical substance ("exposure-based" determination).

For purposes of this long-term performance goal, "final determination" also includes final actions in which EPA determines that a pre-manufacture notice submission is incomplete or invalid and instances in which pre-manufacture notices are withdrawn by submitters.

The measure tracks final determinations made for pre-manufacture notice submissions received by EPA on or after October 1 of the fiscal year.

Complete: A TSCA pre-manufacture notice final determination is considered complete when:

- In the case of a "not likely to present" determination, the submitter of the notice is notified of the determination,
- In the case of a "presents", "may present", "insufficient information" or "exposure-based" determination, an order is issued (typically a bilateral consent agreement), or
- In the case of a "presents" determination, a proposed rule is published in the Federal Register.

Reviews of pre-manufacture notices determined by EPA to be incomplete or invalid are considered complete when the submitter is notified of that determination. Pre-manufacture notices withdrawn by submitters are considered complete on the date the withdrawal notice is accepted by EPA.

New chemical: For purposes of regulation under TSCA, any chemical that is not on the TSCA Inventory is considered a "new chemical substance."

In accordance with statutory timelines: Although the statute provides for voluntary suspensions, for the purpose of this performance metric, a pre-manufacture notice completion is considered timely if it takes place within the 90 days from the date EPA determines the submission is complete and initiates review (i.e., the base period established by law, without including EPA extensions or EPA-approved submitter requests for suspension of review pending receipt of additional information;

1c. Unit of Measure: Final determinations completed within statutory timeline

2a. Data Source:

- Relevant information system: New Chemical Review Application, including Release 1 and any subsequent enhancements
- Entity that reports data to the system: Data is reported directly by EPA
- Frequency of reporting primary data: Status of EPA reviews of individual notices (including final determinations) as shown in applicable data systems is updated daily by EPA/OPPT Program Managers
- Reference to Quality Assurance Project Plan: EPA/OPPT/CCD Quality Management Plan

2b. Data needed for interpretation of (calculated) Performance Result:

- Baseline is 58.4% of determinations made within 90 days in FY 2018. (Footnote updated from FY 2018-2022 EPA Strategic Plan.) The universe is all new chemical final determinations for Pre-Manufacture Notice (PMN), Significant New Use Notice (SNUN) and Microbial Commercial Activity Notice (MCAN) submissions received in the relevant reporting year.

3. Methodology:

The performance result for the long-term performance goal is the percentage of TSCA pre-manufacture notice final determinations completed within the statutory timeline, as determined for the last fiscal year of the

strategic planning cycle. This requires a simple aggregation of data on final determinations for PMNs, SNUNs and MCANs.

4. Data Limitations/Qualifications:
No significant data limitations are anticipated and there is minimal if any possibility of error in reporting performance results.

5. Technical Contact:
Lance Wormell, Acting Director, Chemical Control Division / 202-566-0514

6. Certification Statement/Signature

I certify the information in this DQR is complete and accurate.

DAA Signature Charlotte Bertrand