

January 16, 2018

Data Quality Record for Strategic Measures

Strategic Measure Text: By September 30, 2022, complete all TSCA Pre-Manufacture Notice final determinations in accordance with statutory timelines

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 Strategic Measure:

This strategic measure 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 (defined to include importation) a new chemical substance for a non-exempt commercial purpose¹ 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 will present an unreasonable risk of injury to human health or the environment. This 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 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 strategic measure, 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
- 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 strategic measure, “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.

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

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: A pre-manufacture notice completion is considered timely if it takes place no later than 90 days from the date EPA determines the submission is complete and initiates review (i.e., the base period established by law, without including any potential extensions).

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

2a. Data Source:

- Relevant information system: PMN Gold System (to be replaced by CIS New Chemical Review System in FY 2018)
- 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: Over the past three years EPA received 640 submissions on average per year. In FY 2017, EPA received 512 submissions and completed roughly 11.5% of these final determinations within 90 days.
- Progress toward strategic target (timely completions of pre-manufacture notice final determinations) is tracked via the associated GPRA Budget Measure, reported annually, and the associated Quarterly Measure and Agency Priority Goal, reported quarterly.
- Universe is all Premanufacture Notices (PMNs), Significant New Use Notices (SNUNs) and Microbial Commercial Activity Notices (MCANs).

3. Methodology:

The performance result is simply 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. The total number of timely final determinations made in the fiscal year of the cycle is divided by the total number of final determinations made in that year; the result of this division is the strategic measure performance result. No further calculation or aggregation is needed.

4. Data Limitations/Qualifications:

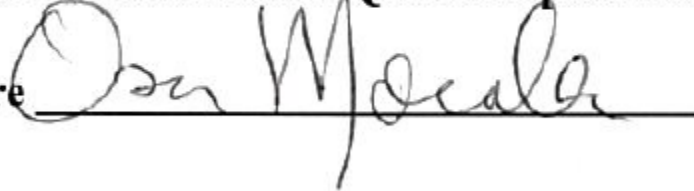
No significant data limitations are anticipated and there is minimal if any possibility of error in reporting performance results.

5. Technical Contact:
Maria Doa/202-566-0718

6. Certification Statement/Signature

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

DAA Signature

A handwritten signature in black ink, appearing to read "Don Morales", is written over a solid horizontal line. The signature is cursive and somewhat stylized.