

Data Quality Record for Long-Term Performance Goals

Long-Term Performance Goal Text: By September 30, 2026, review 90% of risk management actions for past TSCA new chemical substances reported to the 2020 Chemical Data Reporting Rule (CDR) compared to the FY 2021 baseline of none.

Corresponding Annual Performance Goal: Percentage of past TSCA new chemical substances decisions with risk management actions reviewed.

Goal Number/Objective: Goal 7/Objective 7.1

NPM Lead: Office of Chemical Safety and Pollution Prevention (OCSP), Office of Pollution Prevention and Toxics (OPPT)

1a. Purpose of Long-Term Performance Goal:

Under the Toxic Substances Control Act (TSCA) anyone who plans to manufacture (defined to include importation) a new chemical substance for a non-exempt commercial purpose is required to provide EPA with a premanufacture notice (PMN) before initiating the activity. A similar notification requirement, significant new use notice (SNUN), 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 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 TSCA, an affirmative determination is required. 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).

This long-term performance goal (LTPG) tracks the percentage of risk management actions in EPA TSCA Section 5 orders or SNURs that EPA reviews for adherence/non-adherence with these requirements. EPA will establish a baseline and review compliance with restrictions in TSCA section 5 orders or SNURs by cross-walking action requirements with information reported to the CDR rule. Instances of non-compliance will be relayed to EPA's Office of Enforcement and Compliance Assurance. For more information: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-new>.

1b. Performance Measure Term Definitions:

- **Chemical Data Reporting (CDR):** CDR rule, under the Toxic Substances Control Act (TSCA), requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce.

Under the CDR rule, EPA collects basic exposure-related information including information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. The CDR database constitutes the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA, and is used by the Agency to protect the public from potential chemical risks.

The information is collected every four years from manufacturers (including importers) of certain chemicals in commerce generally when production volumes for the chemical are 25,000 lbs or

greater for a specific reporting year. Collecting the information every four years assures that EPA and (for non-confidential data) the public have access to up-to-date information on chemicals.

The CDR rule is required by section 8(a) of the Toxic Substances Control Act (TSCA) and was formerly known as the Inventory Update Rule (IUR).

- **Review:** To compare new chemical risk management actions that were reported under CDR. EPA will establish a baseline for comparison of risk management actions that were reported to the 2020 CDR. The Agency will then review the risk management actions against 2020 CDR data and report out the number of reviews completed. The 2020 CDR report covers calendar years 2016 to 2019.
- **Risk Mitigation Requirements:** The specific requirements contained in EPA TSCA Section 5 orders or SNURs that can be crosswalked with information reported to CDR (i.e., site related and production volume information). This may include additional off-site compliance monitoring, on-site inspections, issuance of compliance advisory or guidances, request for information/subpoenas, and modifications/updates to TSCA section 5 consent orders, SNURs, or other applicable regulations, as appropriate.

1c. Unit of Measure:

Risk management actions reviewed for TSCA new chemical substances.

2a. Data Source:

- **Primary (Original) Source(s) of Data and Name(s) of Relevant Information System(s):** Consent orders, SNURs, and CDR database. Initial upfront work is required to prepare three data sources for comparison, which may take up to one year to complete.
- **Entity That Reports Data to the System:** EPA/OCSP/OPPT/New Chemicals Division (NCD) will report the data.
- **Frequency and Timing at Which Primary Data are Reported to EPA:** NCD will track progress on reviewing risk management actions included in past TSCA consent orders for TSCA new chemical substances on a continual basis. Data can be reported at any time.
- **Smallest Unit for Which Data are Collected:** Individual risk mitigation requirement for TSCA new chemical substance.

2b. Data Needed for Interpretation of (Calculated) Performance Result:

- **Baseline:** EPA has not conducted this activity prior to FY 2022, so no baseline for this long-term performance goal was possible. No TSCA new chemical substances with risk management actions were reviewed using information reported to EPA under the CDR rule to confirm manufacturers are adhering to TSCA section 5 consent orders and SNUR requirements in FY 2021.
- **Tracking Progress:** Progress toward strategic target is reported monthly, monitored via the associated annual performance goal and reviewed by senior management on a quarterly basis.
- **Universe:** The universe includes all risk management actions for TSCA new chemical substances established, from the beginning of the program to the present, for which EPA has also received reports under the CDR rule.

3. Calculation Methodology:

Performance results will be calculated by comparing the percentage of the number of risk management actions for chemical substances reviewed to the total number of chemical substances with new chemical

risk management actions that were also reported to the 2020 CDR.

4. Quality Assurance/Quality Controls:

This is a new activity that does not require a Quality Assurance Project Plan (QAPP). Standard operating procedures for this activity will be developed and documented. Results will be reviewed by senior management on a quarterly basis.

5. Data Limitations/Qualifications:

EPA anticipates data errors will be minimal. This LTPG does not report on the findings of the review of new chemical risk management actions.

6. Technical Contact:

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7. Certification Statement/Signature:

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

DAA Signature Original signed by Richard Keigwin **Date** 2/14/2024