

Agency Priority Goal Action Plan

Meet New Statutory Requirements to Improve the Safety of Chemicals in Commerce

Goal Leader:

Jeff Morris, Director, Office of Pollution Prevention and Toxics

Deputy Goal Leader:

Mark Hartman, Acting Deputy Director for Management, Office of Pollution Prevention and Toxics



Overview

Goal Statement

Meet new statutory requirements to improve the safety of chemicals in commerce. By September 30, 2019, EPA will complete in accordance with statutory timelines (excluding statutorily-allowable extensions): 100% of required EPA-initiated Toxic Substances Control Act (TSCA) risk evaluations for existing chemicals; 100% of required TSCA risk management actions for existing chemicals; and 80% of TSCA pre-manufacture notice final determinations.

Challenges

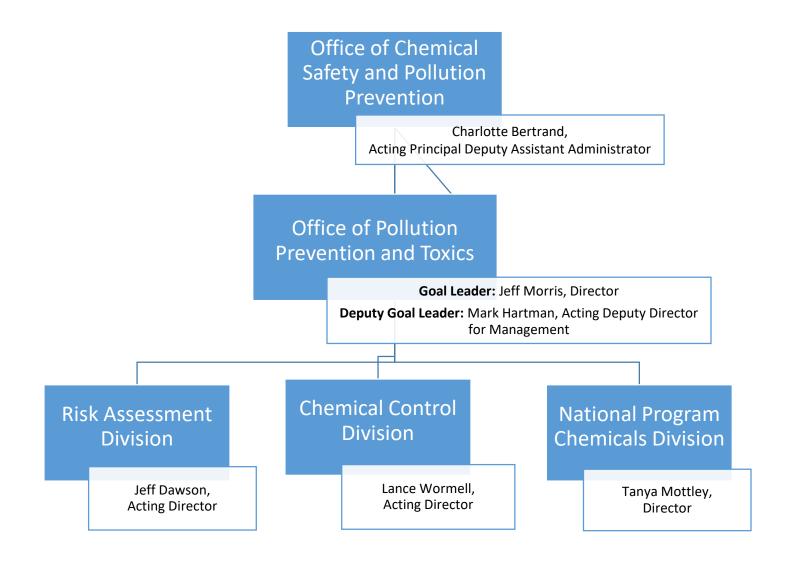
- Risk Evaluations: The TSCA amendments enacted in 2016 established tight deadlines for technically complex chemical reviews that must adhere to high scientific standards, resulting in increased demands on staff and contractor support.
- Risk Management Actions: Similarly, TSCA amendments established tight deadlines for completion of regulatory actions to address any unreasonable risk identified through risk evaluations.
- New Chemicals: TSCA amendments established more stringent standards for review, including a new requirement for EPA to make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before chemical/use is allowed into marketplace.

Opportunities

- All Goal Indicators:
 - EPA has stronger authority under TSCA, as amended, to carry out its statutory responsibilities to ensure the safety of existing chemicals in commerce and new chemicals before commercialization, leading to significant further reductions in health and environmental risks.
 - Lean projects will provide opportunities to improve program efficiency in a number of programs.
- New Chemicals: In particular, New Chemicals Lean recommendations will help streamline new chemical review and expedite completion of final determinations for pre-manufacture notices (see slide 6).

^{*}The statutory deadline for completing the first 10 existing chemical risk evaluations is December 19, 2019. Through September 30, 2019, EPA will track progress toward meeting its milestones for completing the risk evaluations by the statutory deadline.

Leadership



Indicator 1 - Risk Evaluation*:

- EPA will employ systematic, science-based risk evaluations to determine whether exposure to a highpriority chemical poses unreasonable risk to human health or the environment.
- To meet the goal of timely completion of all required risk evaluations, EPA will --
 - Maximize use of existing EPA tools, such as the Office of Research and Development's (ORD) Health and Environmental Research Online Database and commercially available tools such as Distiller, to assess and make use of available data;
 - Employ systematic review approach in chemical prioritization and evaluation processes to ensure accurate identification of high-priority chemicals;
 - Monitor progress of risk evaluations through the Office of Pollution Prevention and Toxics (OPPT)
 Project Management Tool (PMT);
 - Conduct regular Senior Leadership Team status reviews; and
 - o Explore use of software to automate the review, processing, and categorization of information.

^{*}The statutory deadline for completing the first 10 existing chemical risk evaluations is December 19, 2019. Through September 30, 2019, EPA will track progress toward meeting its milestones for completing the risk evaluations by the statutory deadline.

Indicator 2 – Risk Management Actions:

- To address unreasonable risk identified through a risk evaluation, EPA will pursue risk management action (regulatory action) under Toxic Substances Control Act (TSCA) as needed so that the chemical substance or mixture will no longer present such risk.
- To meet the goal of timely completion of all required risk management actions, EPA will --
 - Develop comprehensive, high quality risk assessments as part of risk evaluation process to meet the needs of future risk management actions, minimizing need for additional evaluation as part of rule development;
 - Conduct early consultations prior to formal completion of risk evaluations to begin identifying risk management actions;
 - Monitor progress through Action Development Process (ADP) Tracker and OPPT Project Management Tool (PMT); and
 - Conduct regular Senior Leadership Team status reviews.

Indicator 3 - New Chemicals:

- EPA will enhance and streamline its new chemical review process to meet the more stringent requirements of the Toxic Substances Control Act (TSCA) amendments, expedite completion of pre-manufacture notice (PMN) reviews, and thus ensure the safety of new chemicals that enter commerce.
- To meet the goal of timely completion of final determinations for pre-manufacture notices, EPA will
 - Implement recommendations from 2018 Lean event to implement process, and IT systems improvements and reduce the time needed for risk assessment process:
 - ✓ Employ team-based review approach;
 - ✓ Improve CBI Local Area Network (LAN) system performance; and
 - ✓ Improve electronic communication with submitters.
 - Develop, enhance, and apply new electronic workflow system for expediting management of incoming submissions and continue to introduce technical improvements.
 - Continue to implement policy changes:
 - ✓ Institute a robust pre-submission program to aid companies to improve PMN submissions;
 - ✓ Allow timely amendments by submitters to refine intended conditions of use; and
 - ✓ Consider Significant New Use Rules (SNURs) when there are concerns with reasonably foreseen uses that are not intended conditions of use.

EPA Lean Management System (ELMS)

- EPA continues to deploy its new EPA Lean Management System (ELMS) to achieve the results set forth in the FY 2018-2022 EPA Strategic Plan. As part of ELMS, EPA has conducted multi-day process improvement events to make significant progress in specific priority areas, including permitting, identified in the Strategic Plan.
- Visual management is a major aspect of ELMS that is being used to ensure that improvements from the
 events are achieved and will be sustained over time. Poster boards with regularly updated performance
 data serve as visual management for monitoring progress towards meeting the targets set forth in the
 Strategic Plan, while additional poster boards are being used to track the work flow necessary to achieving
 the targets. Managers and staff have weekly stand-up huddle meetings in front of their visual management
 boards to discuss the performance and flow of the process.
- In addition, National Programs and Regional Offices hold Monthly Business Review meetings to go over both the strategic measures tracked on scorecards, and the implementation plans that track progress on Strategic Plan and priority area projects identified for EPA under President Trump's Executive Order on a Comprehensive Plan for Reorganizing the Executive Branch. The Administrator and Chief of Operations hold quarterly performance reviews to monitor overall progress on the agency's Strategic Plan and priority area projects.
- ELMS is designed to ensure that EPA regularly monitors progress toward meeting targets and takes immediate action if expected performance is off track.

Status of Existing Chemical Risk Evaluations

Process step

Status

Scoping Document The scoping document includes the hazards, exposures, conditions of use, potentially exposed or susceptible populations that EPA expects to consider in the risk evaluation. Also included in the scope are an initial conceptual model, an initial analysis plan, and a discussion of risk characterization.

- •All 10 evaluations initiated on-schedule on 12/19/16
- No chemicals currently in this step of the process; Step completed on-time for all 10 evaluations
- •Initiation of assessment begins with announcement in Federal Register

Problem Formulation

Problem formulation will refine the current scope as an additional interim step prior to the publication of the draft risk evaluation.

- Problem formulations for all 10 chemicals in initial set released for public comment June 1, 2018
- •No chemicals currently in this step of the process
- NOTE: Problem Formulation is unique step for the first 10 chemicals because a more streamlined process was developed for the future; will not occur for future evaluations

Draft Risk Evaluation A risk evaluation is an evaluation of both hazard and exposure, excluding consideration of costs or other non-risk factors, using scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, ensuring that decisions are based on the weight-of-scientific evidence. A draft risk evaluation is developed for public comment and peer review.

- •All evaluations are on track to meet statutory requirements for timely completion of final evaluations
- •10 chemicals currently in this step of the process (those for which problem formulations were released June 1)
- •Draft Risk Evaluations for 10 chemicals to be released for public comment in Q1 and Q2 FY 2019
- •Draft Risk Evaluations for 10 chemicals to undergo peer review by Science Advisory Committee on Chemicals (SACC) in Q1 and Q2 FY 2019

Final Risk Evaluation See above for explanation of risk evaluation. The final stage of a risk evaluation reflects public comment and any input from peer review.

- •No chemicals currently in this step of the process
- •Final Risk Evaluations for 10 chemicals to be issued in Q1 FY 2020

For each step in the process, completion is defined as publication of the document in the Federal Register.

Status of Existing Chemical Risk Management Actions

Process step Status • A risk management action is considered initiated upon tiering. Tiering determines the process used to develop the action, based on the expected complexity, needed cross-agency input, controversy/visibility, and need for involvement by top-level and cross-agency managers. • Rulemaking for the five Persistent, Bioaccumulative, and Toxic (PBT) chemicals initiated on schedule; the rule has gone through tiering and been classified as Tier 2, for which extensive cross-agency involvement will occur and primary decision authority rests with the Assistant Administrator. Initiation/Tiering • No other risk management actions have been initiated that would count toward the strategic target •EPA expects the draft proposed rules for five PBT chemicals to go to OMB by March 1, 2019 •Proposed rules expected to be issued by June 22, 2019 OMB Review of Proposed Rule •No rules currently in this stage Publication in Federal Register of proposal •No rules currently in this stage OMB review of •No rules currently in this stage Publication in Federal Register of Final Rule

Meet New Statutory Requirements to Improve the Safety of Chemicals in Commerce		FY 17 EOY Baseline	FY 18 Q1	FY 18 Q2	FY 18 Q3	FY 18 Q4 and EOY	FY 19 Q1	FY 19 Q2	FY 19 Q3	FY 19 Q4 and EOY
By September 30, 2019, complete in accordance with statutory timelines (excluding statutorily-allowable extensions) 100% of required EPA-initiated TSCA risk evaluations for existing chemicals* By September 30, 2019, complete in accordance with statutory timelines (excluding statutorily-allowable extensions) 100% of required TSCA risk management actions for existing chemicals	Targets	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%
	Results	0	N/A	N/A	N/A	N/A				
	Targets	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%
	Results	0	N/A	N/A	N/A	N/A				
By September 30, 2019, complete in accordance with statutory timelines (excluding statutorily-allowable extensions) 80% of TSCA pre-manufacture notice final determinations*	Targets	N/A	30%	35%	40%	65%	68%	72%	76%	80%
	Results	11.7%	14%	7%	4%	11%				

^{*}Targets and actuals for new chemicals pre-manufacture notice determinations are cumulative from start of FY 2018. Approximately 500 premanufacture notices are received per year.

Q1 Successes/Accomplishments	Q1 Challenges/Barriers	Next Steps
 Existing Chemicals Risk Evaluations: Neared completion of Problem Formulation documents for all 10 EPA-Initiated Evaluations underway On track to complete risk evaluations for these 10 chemicals by 3-year statutory deadline, without extensions (i.e., by December 2019) Public Meeting conducted on Chemical Prioritization to identify next set of EPA-Initiated Risk Evaluations Existing Chemicals Risk Management Actions: All five Persistent, Bioaccumulative, and Toxic (PBT) chemicals Rules are at Step 2 (OMB Review of Proposed Rule) On track to issue proposed rule covering all 5 PBT chemicals within 3-year statutory timeline (i.e., by June 2019) New Chemicals: EPA met the FY 2017 Q1 target Progress continues toward FY 2019 target to complete 80% of pre-manufacture notice final determinations within 90 day base period, without extensions or submitter requested suspensions Public Meetings conducted on potential program improvements Initiated Lean Exercise to streamline work processes Note: failure to complete a determination within 90 days does not constitute a lack of compliance with the statute if the request to suspend the review has been received by the Agency from the submitter. Requests have been made for all pending submissions over 90 days indicating full statutory compliance. 	 Existing Chemicals Risk Evaluations: Problem Formulation documents – unique to the first 10 Evaluations – took longer to develop than anticipated due to large numbers of uses and data challenges Existing Chemicals Risk Management Actions: None encountered to date New Chemicals: FY 2018-2019 APG targets are ambitious 	 Existing Chemicals Risk Evaluations: Publish Problem Formulation documents for first 10 Evaluations Commence development of Draft Risk Evaluations based on previously issued Scoping Documents and soon-to-be issued Problem Formulation Documents Existing Chemicals Risk Management Actions: Submit Draft Proposed Rules for all five PBT Rules to OMB New Chemicals: Continue progress towards ambitious APG targets Continue to implement recommendations from the Lean exercise

Q2 Successes/Accomplishments	Q2 Challenges/Barriers	Next Steps
 Existing Chemicals Risk Evaluations: Continuing progress on Problem Formulation documents for all 10 EPA-Initiated Evaluations On track to complete risk evaluations for these 10 chemicals by 3-year statutory deadline, without extensions (i.e., by December 2019) Public Meeting conducted on Chemical Prioritization on approaches to identify potential candidates for next set of EPA-Initiated Risk Evaluations Existing Chemicals Risk Management Actions: All five rules for Persistent, Bioaccumulative, and Toxic (PBT) chemicals have completed the tiering stage and been classified as Tier 2 On track to issue proposed rule covering all 5 PBT chemicals within 3-year statutory timeline (i.e., by June 2019) New Chemicals: EPA fell substantially short of the FY 2018 Q2 target, with performance declining from Q1 Efforts continue to meet FY 2019 target to complete 80% of premanufacture notice final determinations within 90 day base period, without extensions or submitter requested suspensions Public Meetings conducted on potential program improvements Initiated Lean Exercise to streamline work processes Note: failure to complete a determination within 90 days does not constitute a lack of compliance with the statute if the request to suspend the review has been received by the Agency from the submitter. Requests have been made for all pending submissions over 90 days indicating full statutory compliance. 	 Existing Chemicals Risk Evaluations: Problem Formulation documents unique to the first 10 Evaluations – these are taking longer to develop than anticipated due to large numbers of uses and data challenges Existing Chemicals Risk Management Actions: None encountered to date New Chemicals: FY 2018-2019 APG targets are ambitious TSCA amendments added more complexity to new chemical review process 	 Existing Chemicals Risk Evaluations: Publish Problem Formulation documents for first 10 Evaluations Commence development of Draft Risk Evaluations based on previously issued Scoping Documents and forthcoming Problem Formulation Documents Develop a draft strategy and Implement a risk-based screening process including criteria for designating substances as high priority for risk evaluation or low priority for which risk evaluations are not warranted at this time Existing Chemicals Risk Management Actions: Submit Draft Proposed Rules for all five PBT Rules to OMB New Chemicals: Continue progress towards ambitious APG targets To help streamline new chemical review, continue to implement recommendations from the Lean exercise and other efficiency improvements

Existing Chemicals Risk Evaluations: Problem Formulation documents for all 10 EPA-Initiated Evaluations released for public comment June 1, 2018 On track to meet statutory requirements for timely completion of final risk evaluations Existing Chemicals Risk Management Actions: For the five Persistent, Bioaccumulative, and Toxic (PBT) chemicals classified as Tier 2, EPA is reviewing input from letter peer reviews of the Use and Exposure Assessment and the Human Health and Environmental Hazard Summary; on track to propose rules by June 2019. New Chemicals: Fer A fell substantially short of the FY 2018 Q3 target, with performance declining from Q1 and Q2 Proceeding to implement recommendations from Lean Exercise to streamline work processes Efforts underway to derive lessons learned from cases completed within 90 days Significant recruitment and hiring effort underway, with more than 12 new hires made and more in the queue. Note: failure to completa a determination within 90 days does not constitute a lack of compliance with the statute if the request to suspend the review has been received by the Agency from the submitter. Requests have been made for all pending submissions over 90 days indicating full statutory Existing Chemicals Risk Evaluations: Problem Formulation documents on problem formulation documents Listing Chemicals Risk Evaluations: Review public comments on problem formulation documents Commence develophan anticipated due to large numbers of uses and data challenges Scoping Documents Develuations Scoping Documents and Problem Formulation Documents New Chemicals: New Chemicals: Fy 2018 -2019 APG targets are ambitious TSCA amendments added more complete to complete 80% of pre-manufacture notice final determinations within 90 days does not constitute a lack of compliance with the statute if the request to suspend the review has been received by the Agency from the submitter. Requests have been made for all pending submissions over 90 days indicating full statutory
compliance.

Q4 Successes/Accomplishments	Q4 Challenges/Barriers	Next Steps
 Existing Chemicals Risk Evaluations: Published white paper explaining how EPA will identify the next group of chemicals that may be designated as high priority for risk evaluation Significant hiring and training of new staff underway, with 23 of expected 34 new hires already selected Existing Chemicals Risk Management Actions: For the five Persistent, Bioaccumulative, and Toxic (PBT) chemicals, EPA is reviewing input from letter peer reviews of the Use and Exposure Assessment and the Human Health and Environmental Hazard Summary On track to propose rules by June 2019 New Chemicals: Although EPA fell short of the FY 2018 Q4 target, performance improved considerably For Q4, 33% of final determinations were made within 90 days, in September 71.4% were made within 90 days, and on cumulative basis from start of FY, as tracked for APG, the figure was 11%. Proceeding with pilots to implement recommendations from Lean Exercise to streamline work processes Note: failure to complete a determination within 90 days does not constitute a lack of compliance with the statute if the request to suspend the review has been received by the Agency from the submitter. Requests have been made for all pending submissions over 90 days indicating full statutory compliance 	 Existing Chemicals Risk Evaluations: Need for recruitment and training of new staff for critical work Existing Chemicals Risk Management Actions: None encountered to date New Chemicals: FY 2018-2019 APG targets are ambitious Toxic Substances Control Act (TSCA) amendments added more complexity to new chemical review process 	 Existing Chemicals Risk Evaluations: Implement a risk-based screening process including criteria for designating substances as high priority for risk evaluation or low priority for which risk evaluations are not warranted at this time Continue recruitment and training of new staff Existing Chemicals Risk Management Actions: Submit Draft Proposed Rules for all five PBT rules to OMB New Chemicals: Continue progress towards ambitious APG targets Continue to implement pilots from the Lean exercise Make further improvements to new chemical review process and IT systems to enhance efficiency
 Cross-Program: Promulgated fees rule to ensure that sustainable resources are available 		

Key Milestones

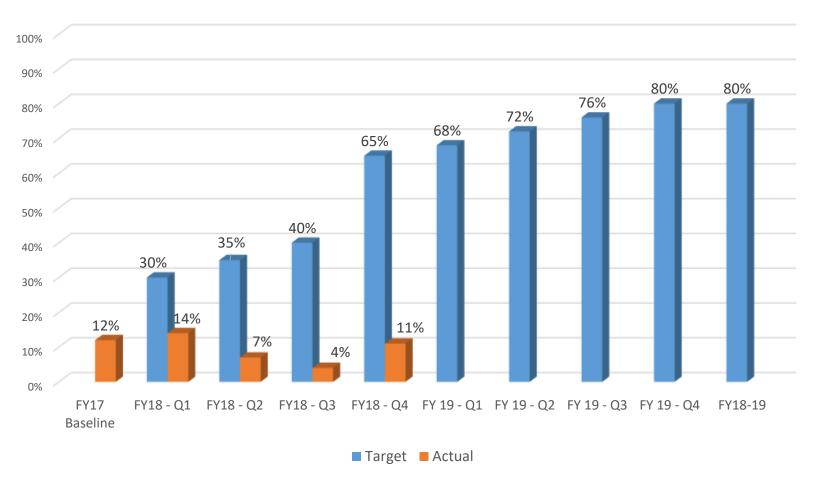
- EPA's Office of Pollution Prevention and Toxics' (OPPT) strategy for meeting performance measure deadlines is to make system enhancements, i
 particular for tracking New Chemical reviews and Risk Evaluations. The New Chemical Review Application will allow for electronic transmission of
 TSCA Section 5 data from the EPA Central Data Exchange. The Project Management Tool (PMT) tracks progress of risk evaluations towards
 completion within statutory timelines.
- The New Chemical Review application (NCR), deployed to production in early December 2018, replaced the PMN Gold system in April 2018 after phase-in period. OPPT has developed several reports in the PMT for tracking project deadlines.

Mi	les	tone	Sun	nmar	У
----	-----	------	-----	------	---

Key Milestone	Milestone Due Date	Milestone Status	Change from last quarter	Owner	Comments
Risk Evaluations					
Scoping Documents completed	June 22, 2017	Completed	No Change	RAD	Statutory deadline
Problem Formulations completed for first 10 Chemicals	May 18, 2018	Completed	No Change	RAD	All 10 released for public comment June 1
Draft risk evaluations for first 10 chemicals released for public/peer review	Q1/Q2 FY 2019	On-Track	Newly added	RAD	No specific statutory deadline for this step
Final risk evaluations completed for first 10 chemicals	Dec. 19, 2019	On-Track	Newly added	RAD	Statutory deadline is 3 years from date of initiation of risk evaluation, with a possible 6-month extension
Risk Management Actions					
Action Development Process (ADP) tracker for risk management actions under further development	Q3 FY 2019	Completed Ongoing	Changed from Completed	EPA	Currently, ADP Tracker still utilizes Lotus Notes but new system expected to be finished by spring
Issuance of Proposed Rule s for PBTs	June 22, 2019	On-Track	No Change	CCD	Statutory deadline is 3 years from date of enactment
New Chemicals					
New Chemical Review Application, Release 1	Dec. 8, 2017	Completed	No Change	IMD	Replaced PMN Gold system
Enhancements to New Chemical Review (NCR) application	April 9, 2018	Completed and Ongoing	No Change	IMD	NCR now primary tool for managing new chemical reviews; enhancements will improve workflow efficiency
Two-Way Communication Feature Deployment	June 1, 2018	Completed and Ongoing	No Change	IMD	Completed for TSCA Sec. 8(e) submissions and Notices of Deficiency. Will continue to replace paper communications with electronic transmissions for specific types of TSCA submissions as new features are deployed.

T2

Key Indicators: New Chemicals



Percent of Pre-Manufacture Notice (PMN), Significant New Use Notice (SNUN), and Microbial Commercial Activity Notice (MCAN) Final Determinations Completed within 90 days

(Targets and actuals cumulative from start of FY 2018)

Data Accuracy and Reliability

EPA-initiated Toxic Substances Control Act (TSCA) risk evaluations for existing chemicals:

- EPA's Office of Pollution Prevention and Toxic's (OPPT) Project Management Tool (PMT) will be used to monitor status of risk evaluations with respect to statutory timelines. APG results based on simple counting and division.
- Completion of risk evaluation defined in terms of publication in the Federal Register.
- A Data Quality Record (DQR) has been developed for the strategic measure associated with this activity: https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-risk-evaluation.pdf.

TSCA risk management actions for existing chemicals:

- Action Development Process (ADP) tracker will be used to monitor status of risk management actions with respect to statutory timelines.
- Completion of a risk management action defined as publication of final rule in the Federal Register.
- A DQR has been developed for the strategic measure associated with this activity: https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-risk-management-actions.pdf.

TSCA Pre-manufacture notice final determinations for new chemicals:

- OPPT New Chemical Review (NCR) tool will be used to monitor status of pre-manufacture notice reviews with respect to statutory timeline. APG results determined by aggregation of data for Pre-Manufacture Notices (PMNs), Significant New Use Notices (SNUNs), Microbial Commercial Activity Notices (MCANs) and simple division.
- NCR has now replaced PMN Gold as the primary tool for managing new chemical reviews. Additional enhancements
 will improve workflow efficiency; enhancements will continue to be deployed on a rolling basis and continue into FY
 2019.
- A DQR has been developed for the strategic measure associated with this activity: https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-new-chemicals.pdf.

APG-Wide:

• No significant data limitations expected; minimal chance of error in reporting performance results.

Additional Information

Contributing Programs

Organizations:

- Office of Chemical Safety and Pollution Prevention (OCSPP)
- Office of Research and Development (ORD)
- Office of General Counsel (OGC)

Program Activities:

Chemical Risk Review and Reduction Program (CRRR)

Stakeholder / Congressional Consultations

- Public meetings and comment periods continue to be conducted
- Public comment built into several stages of Risk Evaluation process
- EPA's Action Development Process (ADP) governing the process of developing proposed and final risk management actions includes opportunity for public comment

Abbreviations

- ADP Action Development Plan
- APG Agency Priority Goal
- CRRR Chemical Risk Reduction and Review
- ELMS EPA Lean Management System
- LAN Local Area Network
- MCAN Microbial Commercial Activity Notice
- NCR New Chemical Review
- PBT Persistent, Bioaccumulative and Toxic
- PMN Pre-Manufacture Notice
- PMT Project Management Tool
- SNUN Significant New Use Notice
- SNUR Significant New Use Rule