



## 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, 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

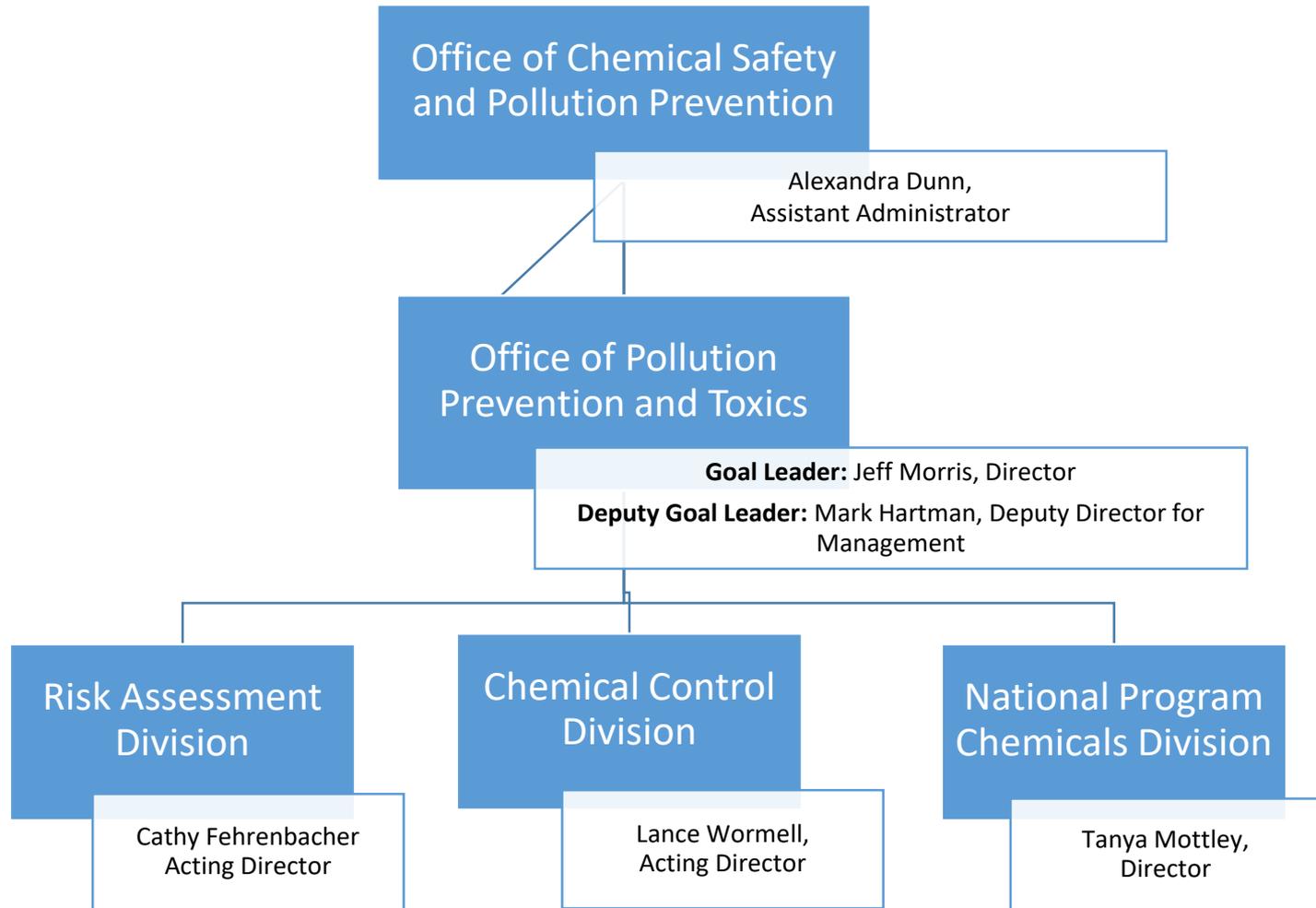
- Risk Evaluations: The TSCA amendments enacted in 2016 established tight deadlines for technically complex chemical reviews that must adhere to high scientific standards, resulting in increased demands on staff and contractor support.
- Risk Management Actions: Similarly, TSCA amendments established tight deadlines for completion of regulatory actions to address unreasonable risk identified through risk evaluations. The statute also established a requirement for expedited action for certain persistent, bioaccumulative and toxic (PBT) chemicals.
- 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/significant new 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 areas.
- 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, with an optional six-month extension making the actual deadline June 19, 2020. EPA will complete the risk evaluations within the first three quarters of FY 2020, consistent with statutory requirements. The statutory deadline for finalizing the PBT rule (i.e., the first scheduled completion of a risk management action under amended TSCA) is December 2020. Through September 30, 2019, EPA will track progress toward meeting its milestones for completing the risk evaluations and risk management actions by the statutory deadline.

# Leadership



# Goal Structure & Strategies

## Indicator 1 – Risk Evaluation\*:

- EPA will employ systematic, science-based risk evaluations to determine whether exposure to a high-priority 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 best available science and systematic review approaches in chemical prioritization and evaluation processes, as appropriate, 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
  - 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, with an optional six-month extension making the actual deadline June 19, 2020. EPA will complete the risk evaluations within the first three quarters of FY 2020, consistent with statutory requirements. The statutory deadline for finalizing the PBT rule (i.e., the first scheduled completion of a risk management action under amended TSCA) is December 2020. Through September 30, 2019, EPA will track progress toward meeting its milestones for completing the risk evaluations and risk management actions by the statutory deadline.

# Goal Structure & Strategies

## 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 address certain persistent, bioaccumulative, and toxic (PBT) chemicals as required by statute, EPA will pursue regulatory action under TSCA to address risk and reduce exposure to the extent practicable.
- To meet the goal of timely completion of all required risk management actions, EPA will:
  - Develop comprehensive, high quality supporting analyses as part of the risk evaluation process and in preparation for potential 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 potential 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.

\*The statutory deadline for completing the first 10 existing chemical risk evaluations is December 19, 2019, with an optional six-month extension making the actual deadline June 19, 2020. EPA will complete the risk evaluations within the first three quarters of FY 2020, consistent with statutory requirements. The statutory deadline for finalizing the PBT rule (i.e., the first scheduled completion of a risk management action under amended TSCA) is December 2020. Through September 30, 2019, EPA will track progress toward meeting its milestones for completing the risk evaluations and risk management actions by the statutory deadline.

# Goal Structure & Strategies

## Indicator 3 – New Chemicals:

- EPA will enhance and streamline its new chemical review process to meet the more stringent requirements of the 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 transaction time associated with the 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 to enhance tracking and transparency.
  - Utilize visual management for all backlog PMNs and SNUNs.
  - 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.

# Goal Structure & Strategies

---

## 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 December 19, 2016.
- 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, as well as interagency review.

- All evaluations are on track to meet statutory requirements for timely completion of final evaluations.
- Draft risk evaluations released for pigment violet 29 (November 2018), 1,4 dioxane (June 2019), and HBCD (June 2019).
- EPA intends to release draft risk evaluations for seven remaining chemicals to begin interagency or peer review in 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 and/or interagency review.

- No chemicals currently in this step of the process.
- Final Risk Evaluations for 10 chemicals to be issued in 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

Initiation/Tiering

- 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.
- No other risk management actions have been initiated that would count toward the strategic target.

OMB Review of Proposed Rule

- OMB review of draft proposed rule for five PBT chemicals concluded in June 2019.

Publication in Federal Register of proposal

- No rules currently in this stage, PBT rule published July 29, 2019.

OMB review of final rule

- No rules currently in this stage.

Publication in Federal Register of Final Rule

- No rules currently in this stage.

# Summary of Progress – FY 2018-2019

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 <sup>1</sup>	Targets	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Results	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
By September 30, 2019, complete in accordance with statutory timelines (excluding statutorily-allowable extensions) 100% of required TSCA risk management actions for existing chemicals <sup>1</sup>	Targets	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Results	N/A	N/A	N/A	N/A	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 <sup>2</sup>	Targets	N/A	30%	35%	40%	65%	80%	80%	80%	80%
	Results	28%	100%	60%	50%	70%	100%	91%	82.5%	

<sup>1</sup> The statutory deadline for completing the first 10 existing chemical risk evaluations is December 19, 2019, with an optional six-month extension making the actual deadline June 19, 2020. EPA will complete the risk evaluations within the first three quarters of FY 2020, consistent with statutory requirements. The statutory deadline for finalizing the PBT rule (i.e., the first scheduled completion of a risk management action under amended TSCA) is December 2020. Through September 30, 2019, EPA will track progress toward meeting its milestones for completing the risk evaluations and risk management actions by the statutory deadline.

<sup>2</sup> Targets and actuals for new chemicals pre-manufacture notice determinations are cumulative from start of FY 2018. Only those pre-manufacture notices received during the same fiscal year are counted in the performance result. Approximately 500 premanufacture notices are received per year.

# Summary of Progress – FY 2018 Q1

Q1 Successes/Accomplishments	Q1 Challenges/Barriers	Next Steps
<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>• Neared completion of problem formulation documents for all 10 EPA-Initiated Evaluations underway.</li> <li>• On track to complete risk evaluations for these 10 chemicals by three-year statutory deadline, without extensions (i.e., by December 2019).</li> <li>• Public meeting conducted on chemical prioritization to identify next set of EPA-initiated risk evaluations.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>• Persistent, bioaccumulative, and toxic (PBT) chemicals Rules at Step 2 (OMB Review of Proposed Rule).</li> <li>• On track to issue proposed rule covering all five PBT chemicals within three-year statutory timeline (i.e., by June 2019).</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• EPA met the FY 2017 Q1 target.</li> <li>• 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.</li> <li>• Public meetings conducted on potential program improvements.</li> <li>• Initiated Lean exercise to streamline work processes.</li> <li>• 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.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>• Problem formulation documents – unique to the first 10 Evaluations – took longer to develop than anticipated due to large numbers of uses and data challenges.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>• None encountered to date.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• FY 2018-2019 APG targets are ambitious.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>• Publish problem formulation documents for first 10 Evaluations.</li> <li>• Commence development of draft risk evaluations based on previously issued scoping documents and soon-to-be issued problem formulation documents.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>• Submit Draft Proposed Rules for all five PBT Rules to OMB.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• Continue progress towards ambitious APG targets.</li> <li>• Continue to implement recommendations from the Lean exercise.</li> </ul>

# Summary of Progress – FY 2018 Q2

Q2 Successes/Accomplishments	Q2 Challenges/Barriers	Next Steps
<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Continuing progress on problem formulation documents for all 10 EPA-initiated evaluations.</li> <li>On track to complete risk evaluations for these 10 chemicals by three-year statutory deadline, without extensions (i.e., by December 2019).</li> <li>Public meeting conducted on chemical prioritization on approaches to identify potential candidates for next set of EPA-initiated risk evaluations.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Persistent, bioaccumulative, and toxic (PBT) chemicals rule has completed the tiering stage and classified as Tier 2.</li> <li>On track to issue proposed rule covering all five PBT chemicals within three-year statutory timeline (i.e., by June 2019).</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>EPA fell short of the FY 2018 Q2 target.</li> <li>Efforts continue to meet FY 2019 target to complete 80% of pre-manufacture notice final determinations within 90-day base period, without extensions or submitter requested suspensions.</li> <li>Public meetings conducted on potential program improvements</li> <li>Initiated Lean exercise to streamline work processes.</li> <li>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.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>None encountered to date.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>FY 2018-2019 APG targets are ambitious.</li> <li>TSCA amendments added more complexity to new chemical review process.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Publish problem formulation documents for first 10 Evaluations.</li> <li>Commence development of draft risk evaluations based on previously issued scoping documents and forthcoming problem formulation documents.</li> <li>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.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Submit draft proposed rules for all five PBT rules to OMB.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Continue progress towards ambitious APG targets.</li> <li>To help streamline new chemical review, continue to implement recommendations from the Lean exercise and other efficiency improvements.</li> </ul>

# Summary of Progress – FY 2018 Q3

Q3 Successes/Accomplishments	Q3 Challenges/Barriers	Next Steps
<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>• Problem formulation documents for all 10 EPA-Initiated Evaluations released for public comment June 1, 2018.</li> <li>• On track to meet statutory requirements for timely completion of final risk evaluations.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• EPA fell short of the FY 2018 Q3 target.</li> <li>• Proceeding to implement recommendations from Lean Exercise to streamline work processes.</li> <li>• Efforts underway to derive lessons learned from cases completed within 90 days.</li> <li>• 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.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>• Problem formulation documents – unique to the first 10 Evaluations – these took longer to develop than anticipated due to large numbers of uses and data challenges.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>• None encountered to date.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• FY 2018 -2019 APG targets are ambitious.</li> <li>• TSCA amendments added more complexity to new chemical review process.</li> <li>• Ability to meet FY 2019 target to complete 80% of pre-manufacture notice final determinations within 90 days will depend on successful implementation of next steps described at right.</li> <li>• A challenge has been the need for additional consultation with OGC in light of pending litigation in this area.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>• Review public comments on problem formulation documents.</li> <li>• Commence development of draft risk evaluations based on previously issued scoping documents and problem formulation documents.</li> <li>• 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.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>• Submit draft proposed rules for all five PBT Rules to OMB.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• Continue progress towards ambitious APG targets.</li> <li>• Continue to implement recommendations from the Lean exercise, hire and train new staff, make changes to the review process and finalize key policy decisions.</li> </ul>

# Summary of Progress – FY 2018 Q4

Q4 Successes/Accomplishments	Q4 Challenges/Barriers	Next Steps
<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Published white paper explaining how EPA will identify the next group of chemicals that may be designated as high priority for risk evaluation.</li> <li>Significant hiring and training of new staff underway, with 10 new hires over the quarter.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>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.</li> <li>On track to propose rules by June 2019.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Although EPA fell short of the FY 2018 Q4 target, performance improved considerably.</li> <li>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%.</li> <li>Proceeding with pilots to implement recommendations from Lean Exercise to streamline work processes.</li> <li>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.</li> </ul> <p>Cross-Program:</p> <ul style="list-style-type: none"> <li>Promulgated fees rule to ensure that sustainable resources are available</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Need for recruitment and training of new staff for critical work.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>None encountered to date.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>FY 2018-2019 APG targets are ambitious.</li> <li>Toxic Substances Control Act (TSCA) amendments added more complexity to new chemical review process.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Continue recruitment and training of new staff.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Submit draft proposed rules for all five PBT chemicals to OMB.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Continue progress towards ambitious APG targets.</li> <li>Continue to implement pilots from the Lean exercise.</li> <li>Make further improvements to new chemical review process and IT systems to enhance efficiency.</li> </ul>

# Summary of Progress – FY 2019 Q1-Q2

Q1-Q2 Successes/Accomplishments	Q1-Q2 Challenges/Barriers	Next Steps
<p><b>Progress in all areas affected by government shutdown in Q2</b></p> <p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Published draft risk evaluation for pigment violet-29.</li> <li>Released first major update to TSCA Inventory in 40 years</li> <li>Published list of 40 chemicals to undergo prioritization to determine need for risk evaluation.</li> <li>Significant hiring and training of new staff underway, with 16 new hires over the two quarters.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Submitted draft proposed rule covering five persistent, bioaccumulative and toxic (PBT) chemicals to OMB for review.</li> <li>Finalized rule under TSCA Sec. 6(a) prohibiting methylene chloride in consumer paint and coating removal (in accordance with TSCA Sec. 26(l)); issued ANPRM for methylene chloride in commercial paint and coating removal.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Substantially exceeded FY 2019 Q1 and Q2 targets, with timely completion rate of 100% and 91% vs. target of 80%.</li> <li>Proceeding with pilots to implement recommendations from Lean exercise to streamline work processes.</li> <li>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.</li> </ul> <p>Cross-Program:</p> <ul style="list-style-type: none"> <li>Implementing fees rule to ensure that sustainable resources are available.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Need for recruitment and training of new staff for critical work.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>None encountered to date.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Toxic Substances Control Act (TSCA) amendments added more complexity to new chemical review process.</li> <li>Need for recruitment and training of new staff for critical work.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Continue recruitment and training of new staff.</li> <li>Complete draft risk evaluations for public comment and peer review.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Publish proposed rule all five PBT chemicals by June 22, 2019.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Continue to implement pilots from the Lean exercise.</li> <li>Make further improvements to new chemical review process and IT systems to enhance efficiency.</li> <li>Increase transparency of new chemicals decision making.</li> </ul>

# Summary of Progress – FY 2019 Q3

Q3 Successes/Accomplishments	Q3 Challenges/Barriers	Next Steps
<p><b>Progress in all areas affected by government shutdown in Q2</b></p> <p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Released draft risk evaluations for peer review and public comment under amended TSCA for HBCD and 1,4 Dioxane.</li> <li>Received manufacturer request to evaluate risks of two phthalates, DIDP and DINP.</li> <li>Significant hiring and training of new staff underway, with 11 new hires over the quarter.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Published proposed rule covering five persistent, bioaccumulative and toxic (PBT) chemicals.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Exceeded FY 2019 Q3 targets, with timely completion rate of 82.5% vs. target of 80%.</li> <li>Continuing with pilots to implement recommendations from Lean exercise to streamline work processes.</li> <li>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.</li> </ul> <p>Cross-Program:</p> <ul style="list-style-type: none"> <li>Collecting fees to ensure that sustainable resources are available – cumulative fees collected from October 2018 start-up through June 2019 exceed \$2.03 million, projected collections for full FY approximately \$3.112 million.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Need for recruitment and training of new staff for critical work.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>None encountered to date.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Toxic Substances Control Act (TSCA) amendments added more complexity to new chemical review process.</li> <li>Need for recruitment and training of new staff for critical work.</li> </ul>	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> <li>Continue to 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.</li> <li>Continue recruitment and training of new staff.</li> <li>Complete draft risk evaluations of remaining seven chemicals from original list of ten for public comment and peer review, as well as interagency review, within first three quarters of FY 2020.</li> </ul> <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> <li>Review public comments on proposed PBT rule and proceed to finalization stage.</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>Continue to implement pilots from the Lean exercise.</li> <li>Make further improvements to new chemical review process and IT systems to enhance efficiency.</li> <li>Increase transparency of new chemicals decision making.</li> </ul>

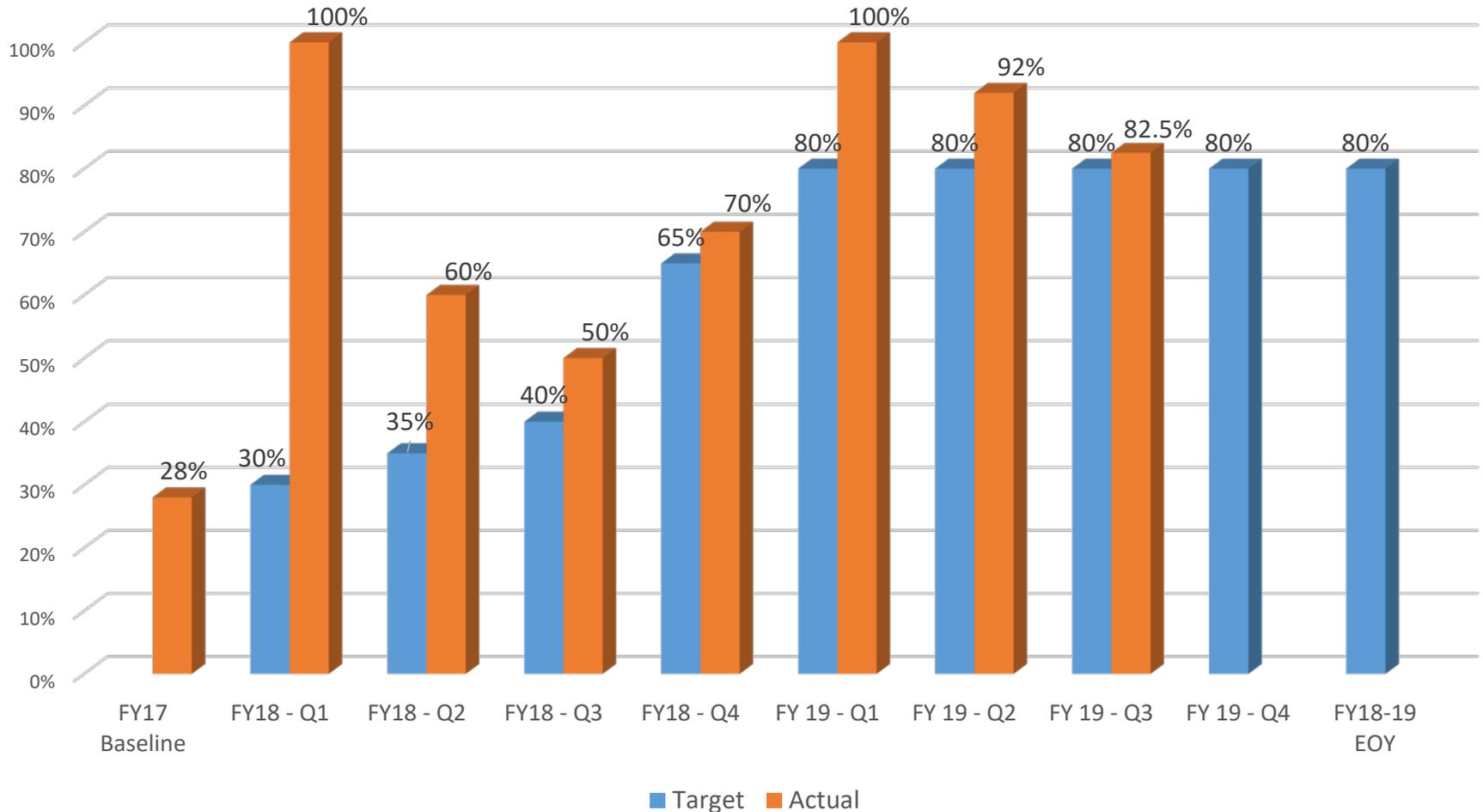
# Key Milestones

- EPA's Office of Pollution Prevention and Toxics' (OPPT) strategy for meeting performance measure deadlines is to make system enhancements, in 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.

## Milestone Summary

Key Milestone	Milestone Due Date	Milestone Status	Change from last quarter	Owner	Comments
<i>Risk Evaluations</i>					
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	Q4 FY 2019	Completed and Ongoing	Changed Status from "On Track"	RAD	Draft risk evaluations released for peer review and public comment for pigment violet 29 (November 2018), 1,4 Dioxane (June 2019), and HBCD (June 2019). Remaining draft risk evaluations expected to be completed within the first quarter of FY 2020. No specific statutory deadline for this step.
Final risk evaluations completed for first 10 chemicals	June 19, 2020	On-Track	Changed Milestone Due Date from "Dec. 19, 2020"	RAD	Statutory deadline is three years from date of initiation of risk evaluation, with a possible six-month extension.
<i>Risk Management Actions</i>					
Action Development Process (ADP) tracker for risk management actions under further development	Q1 FY 2020	Completed and Ongoing	Changed Milestone Due Date from "Q3 FY 2019"	EPA	Currently, ADP Tracker still utilizes Lotus Notes but new system under continuing development.
Issuance of Proposed Rules for PBTs	June 22, 2019	Completed	Changed Status from "On Track and No Change"	CCD	Statutory deadline for proposed rule is three years from date of enactment.
<i>New Chemicals</i>					
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- in progress for Section 5 Acknowledgment Letters and CBI Review Final Determination templates. Will continue to replace paper communications with electronic transmissions for specific

# 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

(Only those pre-manufacture notices received during the same fiscal year are counted in the performance result.)

# 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