

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

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Theme: National Resources and Environment

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.

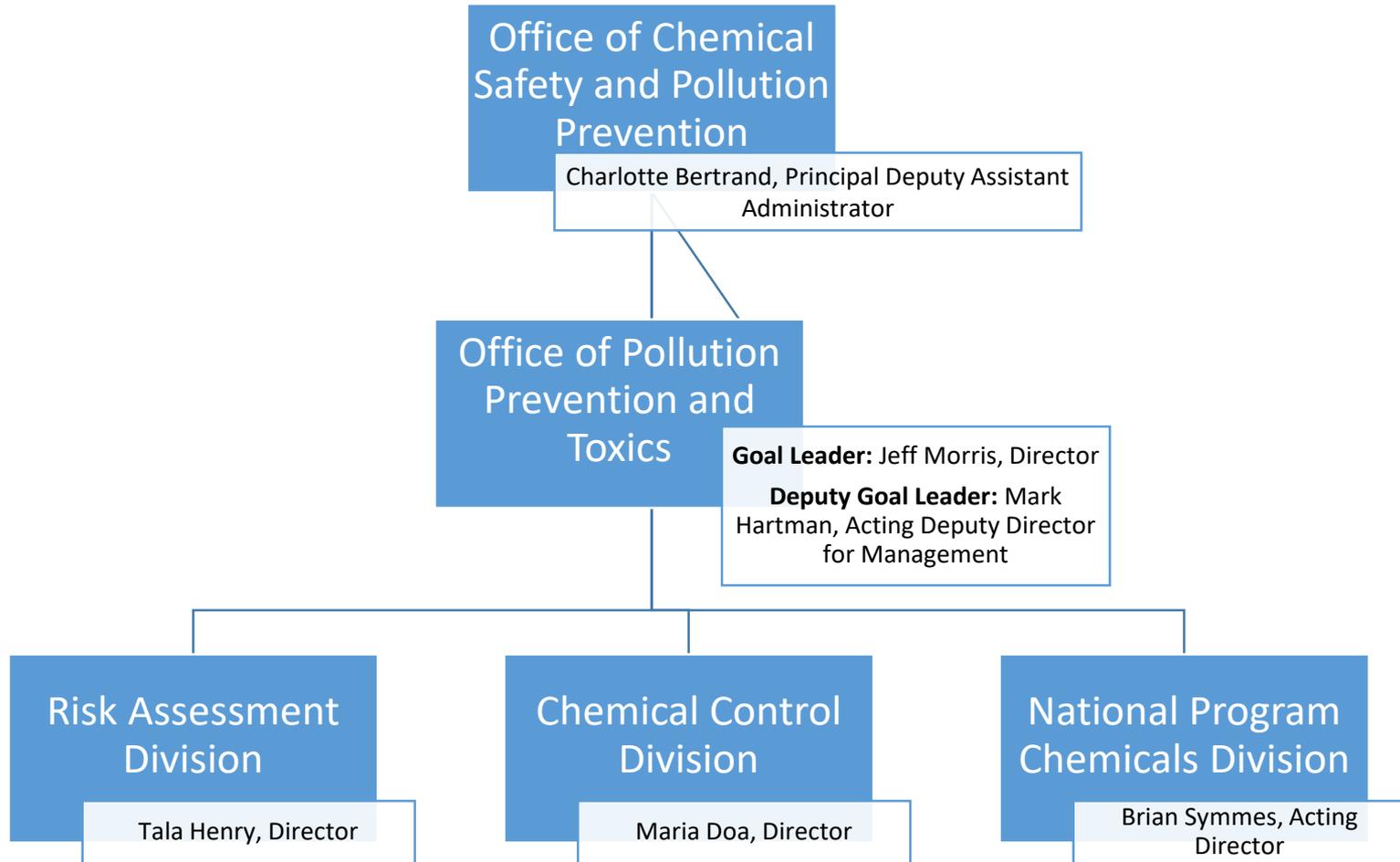
Challenge

- The TSCA amendments involve tight deadlines for technically complex chemical reviews that must adhere to high scientific standards, resulting in increased demands on staff and contractor support.

Opportunity

- The TSCA amendments of 2016 provide EPA with stronger authority 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.

Leadership



Goal Structure & Strategies

- **Strategy 1: Risk Evaluation:**
 - Maximize use of existing EPA tools, such as ORD's Health and Environmental Research Online Database, to assess all available data.
 - Deploy OPPT Project Management Tool (PMT) effectively to enable senior management to monitor progress and make course corrections as needed.
- **Strategy 2: Risk Management Actions:**
 - Develop high quality risk assessments as part of risk evaluation process to support future regulatory development.
 - Deploy PMT effectively to enable senior management to monitor progress and make course corrections as needed.
- **Strategy 3: New Chemicals:**
 - 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.
 - EPA will institute a robust pre-submission program to aid companies to improve PMN submissions, EPA will allow timely amendments by submitters to refine intended conditions of use.
 - EPA will consider Significant New Use Rules (SNURs) when there are concerns with reasonably foreseen uses that are not intended conditions of use.
 - Implement recommendations from Lean event to streamline program

Goal Structure & Strategies, Continued

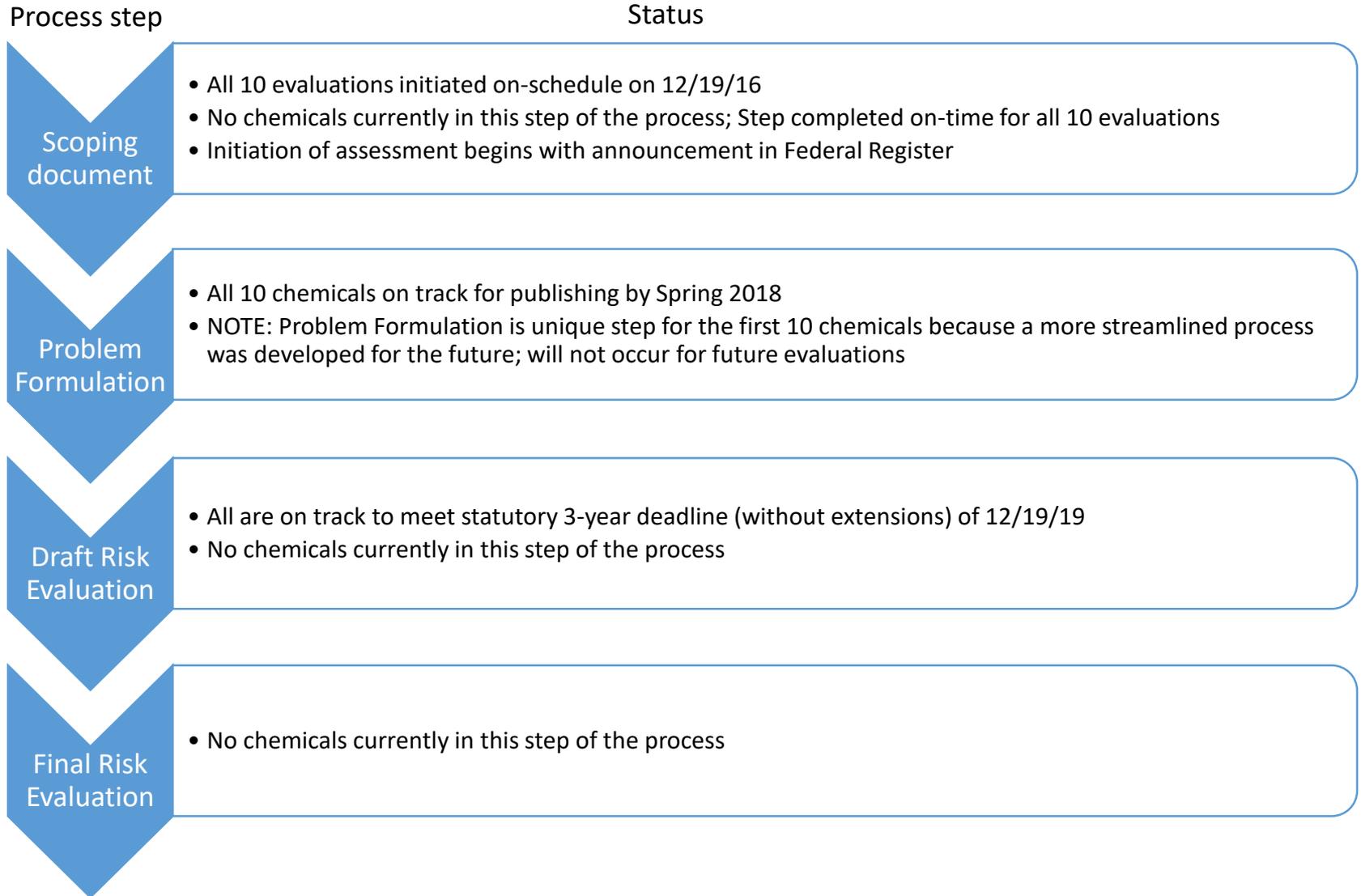
- EPA Lean Management System

EPA will be using the deployment of a new EPA Lean Management System (ELMS) to achieve the results set forth in the Strategic Plan. As part of ELMS, EPA will be conducting multi-day process improvement events to make significant progress in those priority areas identified in the Strategic Plan, including this one. Visual management will then be used to ensure that improvements from the events are achieved and sustained over time. Poster boards with regularly updated performance data will serve as visual management for monitoring progress towards meeting the targets set forth in the Strategic Plan, while additional poster boards will be used to track the flow of the work that needs to be performed to achieve the targets.

Managers and staff will 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 will hold monthly business reviews 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 will hold quarterly reviews to monitor overall progress on the agency's Strategic Plan and priority area projects.

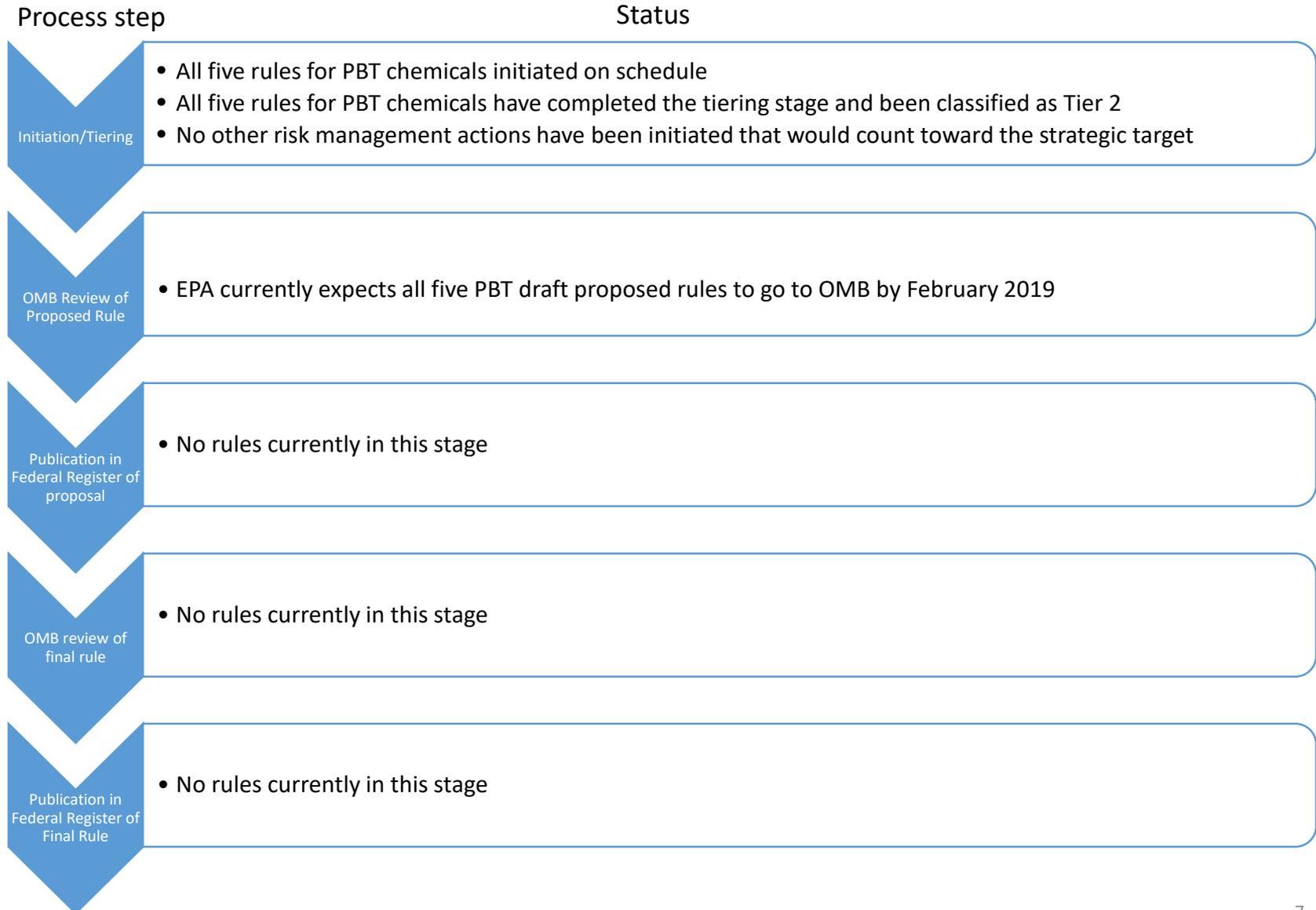
ELMS is designed to make sure that EPA is regularly monitoring progress towards meeting the targets set forth in the Strategic Plan, and taking immediate action if expected performance is off track.

Status of Existing Chemical Risk Evaluations



For each step in the process, completion is defined as publication of the document in the Federal Register.⁶

Status of Risk Management Actions



Summary of Progress – FY18 Q1

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	FY 19 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	Targets	N/A	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	N/A	N/A	N/A	TBD	TBD
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	100%	100%	100%
	Results	0	N/A	N/A	N/A	N/A	N/A	N/A	TBD	TBD	TBD
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	14%	31%	48%	65%	68%	72%	76%	80%	80%
	Results	11.7%	14%	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD

Q1 Successes/Accomplishments	Q1 Challenges/Barriers	Next Steps
<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> Neared completion of Problem Formulation documents for all 10 EPA-Initiated Evaluations underway Public Meeting conducted on Chemical Prioritization to identify next set of EPA-Initiated Risk Evaluations <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> All 5 PBT Rules are at Step 2 from Slide 7 (OMB Review of Proposed Rule) <p>New Chemicals:</p> <ul style="list-style-type: none"> EPA met the FY 2017 1st Quarter target. 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. 	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> Problem Formulation documents – unique to the first 10 Evaluations – took longer to develop than anticipated due to large numbers of uses and data challenges <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> None encountered to date <p>New Chemicals:</p> <ul style="list-style-type: none"> FY 2018/19 APG Targets are ambitious 	<p>Existing Chemicals Risk Evaluations:</p> <ul style="list-style-type: none"> 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 <p>Existing Chemicals Risk Management Actions:</p> <ul style="list-style-type: none"> Submit Draft Proposed Rules for all 5 PBT Rules to OMB <p>New Chemicals:</p> <ul style="list-style-type: none"> Continue progress towards ambitious APG targets Continue to implement recommendations from the Lean exercise

Summary of Progress – FY18 Q1

Strategy 1: Risk Evaluations:

- On track to meet 100% APG target to complete 1 risk evaluation in FY 2019 (ahead of statutory timeline) and to meet 3-year statutory deadline (12/19/19, without extensions) for the other 9 initial risk evaluations
- Statutorily-required scoping documents published on-time for all 10 chemicals
- Problem formulation documents to further refine scope targeted for March 2018 publication
- On-track progress continues on data gathering and analysis for fate, exposure, health and ecological hazard assessments needed to complete draft and final risk evaluations within or ahead of statutory timelines

Strategy 2: Risk Management Actions:

- On track to meet 100% APG target to issue proposed rules for all five Persistent, Bio accumulative and Toxic (PBTs) Chemical actions within the 3-year statutory timeline (without extensions): June, 2019
- Future APGs may focus on risk management actions for chemicals determined through a risk evaluation to pose unreasonable risk under TSCA

Strategy 3: New Chemicals:

- On track to meet FY 2019 target of 80% to complete TSCA pre-manufacture notice final determinations within statutory timelines (90 days, without extensions), including Pre-Manufacture Notice (PMN), Significant New Use Notice (SNUN) and Microbial Commercial Activity Notice (MCAN) reviews
- Program continues to make progress towards long-term goal to complete 100% of reviews within statutory timelines (without extensions), with a Lean project occurring in FY 18 and Lean recommendations and other improvements implemented through FY 2019
- In FY 2017, 11.7% of all final determinations made within 90-day base review period

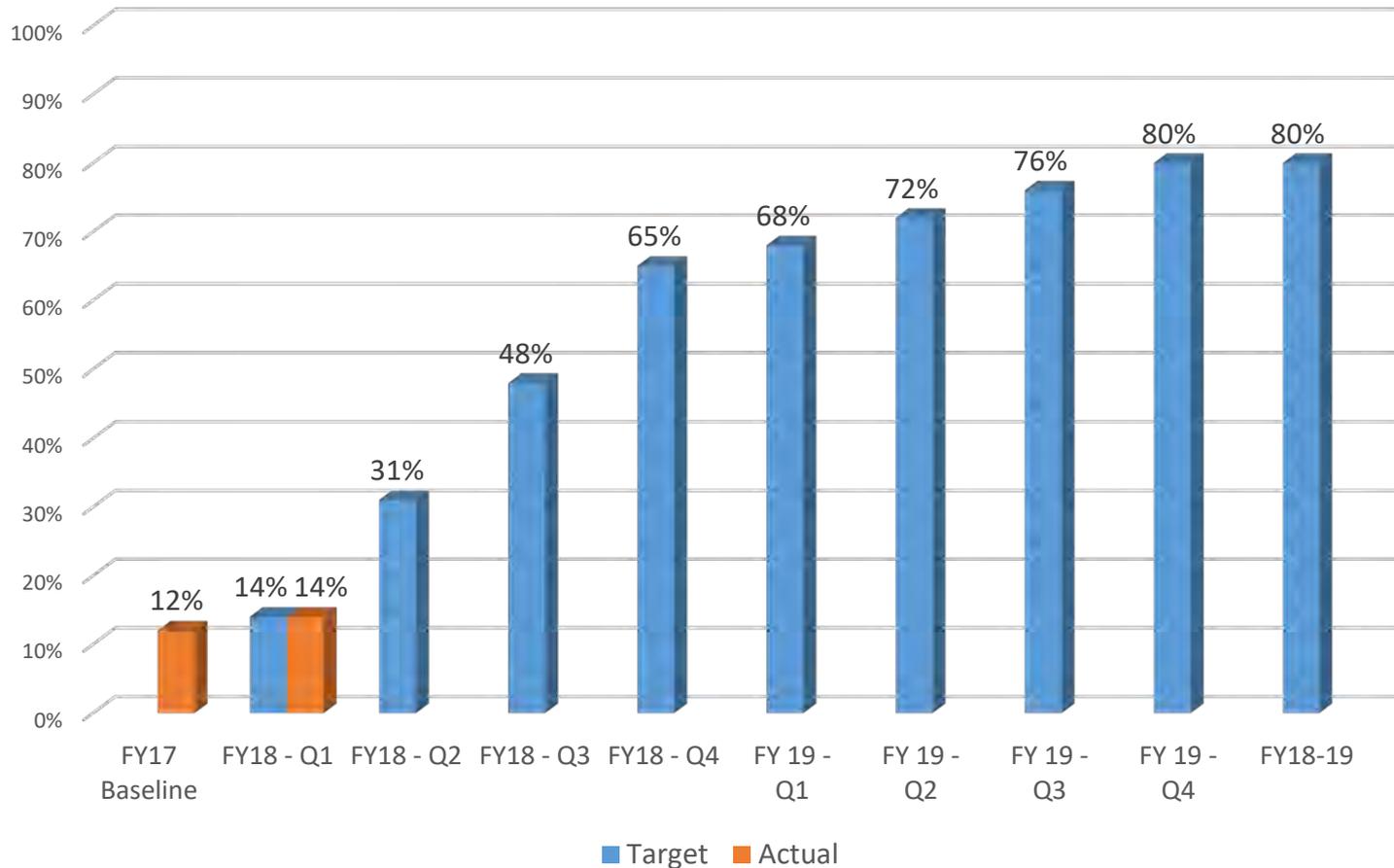
Key Milestones

- OPPT's 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 PMT tracks progress of risk evaluations towards completion within statutory timelines.
- The New Chemical Review Application (NCRA), released in early December, replaced the PMN Gold system. 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	6/22/17	Completed		RAD	Statutory deadline
Problem Formulations completed for first 10 Chemicals	Spring 18	On-Track		RAD	Will Publish all 10 for comment
<i>Risk Management Actions</i>					
Action Development Process tracker for risk management actions under further development	N/A	On-Track		EPA	Lotus Notes system to be replaced end of December 2017.
Issuance of Proposed Rules for PBTs	6/22/19	On-Track		CCD	Statutory deadline is 3 years from date of enactment
<i>New Chemicals</i>					
New Chemical Review Application, Release 1	12/8/17	Completed		IMD	Will replace existing PMN Gold system
Enhancements to New Chemical Review Application	3/31/18	On-Track		IMD	Will improve new workflow efficiency
<i>Other</i>					
Two-Way Communication Feature Deployment	6/1/18	On-Track		IMD	Will replace paper communications with electronic transmissions

Key Indicators: New Chemicals



Percent of PMN, SNUN, and MCAN Final Determinations Completed within Statutory Timeline

Data Accuracy and Reliability

EPA-initiated TSCA risk evaluations for existing chemicals:

- OPPT 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.

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.

TSCA Pre-manufacture notice final determinations for new chemicals:

- OPPT NCRA 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 PMNs, SNUNs, MCANs and simple division.
 - NCRA phased implementation underway to replace prior tool. Phase 1 completed in December, 2017.

APG-Wide:

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

Additional Information

Contributing Programs

Organizations:

- OCSPP
- ORD
- OGC

Program Activities:

- Chemical Risk Review and Reduction Program

Stakeholder / Congressional Consultations

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