

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

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Theme: National Resources and Environment

# Overview

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## Goal Statement

- 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.

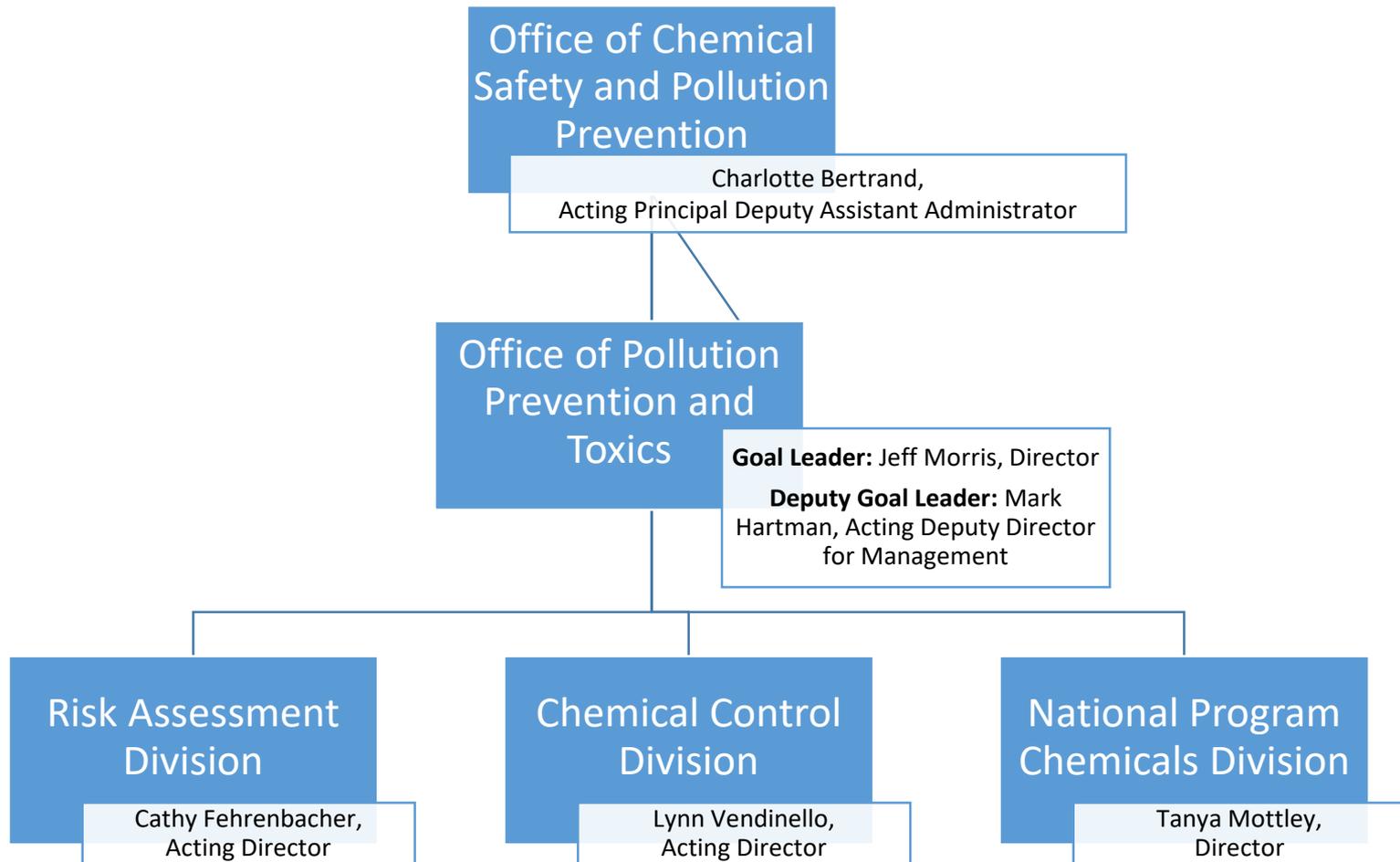
## Challenges

- 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).

# Leadership



# Goal Structure & Strategies

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## **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 ORD's 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 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.

# Goal Structure & Strategies

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## **Indicator 2 – Risk Management Actions:**

- To address any unreasonable risk identified through a risk evaluation, EPA will pursue risk management action (regulatory action) under 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);
  - Conduct regular Senior Leadership Team status reviews.

# Goal Structure & Strategies

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## 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 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 streamline program:
    - Employ team-based processing;
    - Improve CBI Local Area Network (LAN) system performance;
    - Improve electronic communication with submitters;
    - Improve and align organizational structures.
  
  - 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;
    - Consider Significant New Use Rules (SNURs) when there are concerns with reasonably foreseen uses that are not intended conditions of use.

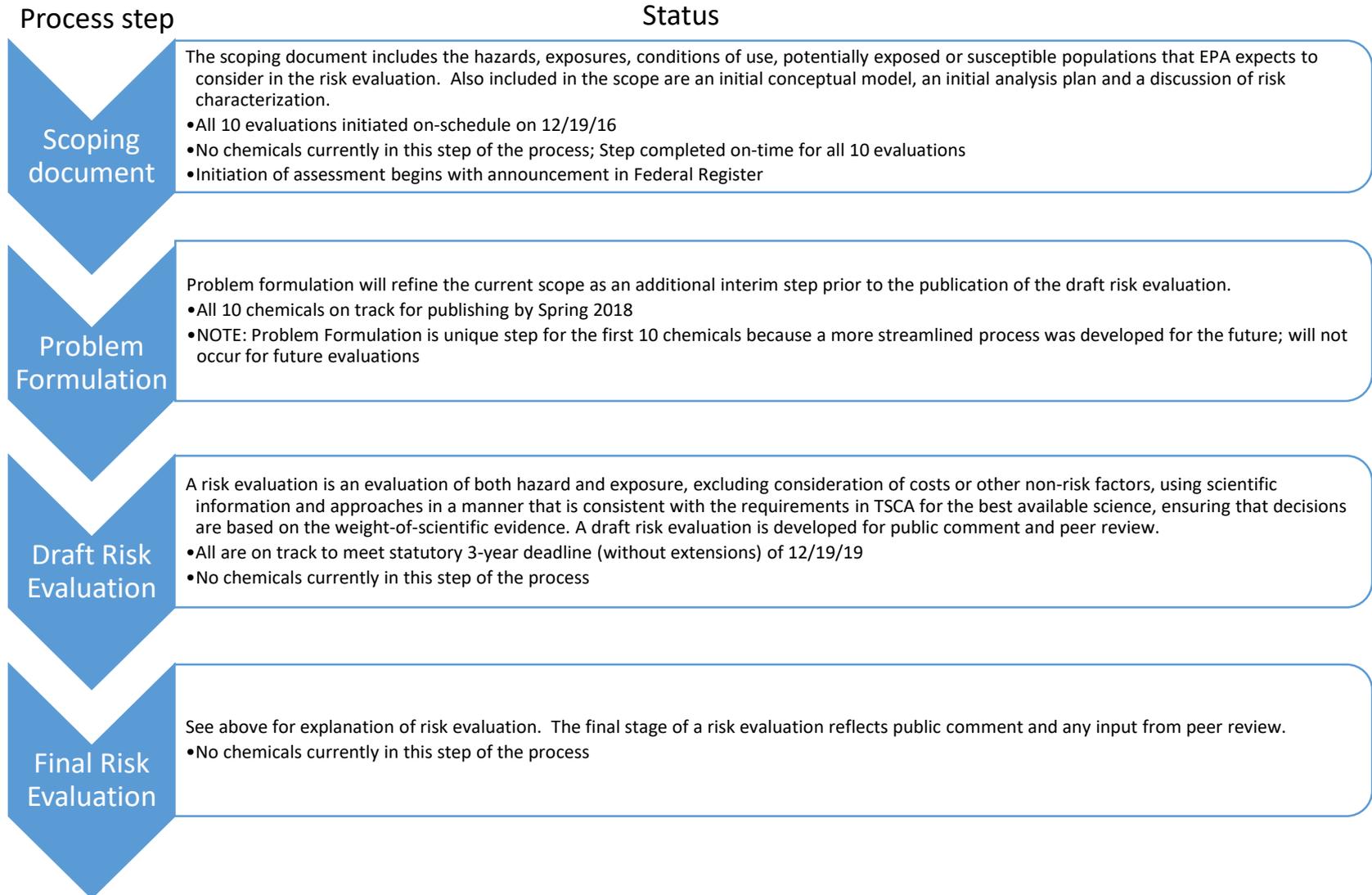
# Goal Structure & Strategies

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## **EPA Lean Management System (ELMS)**

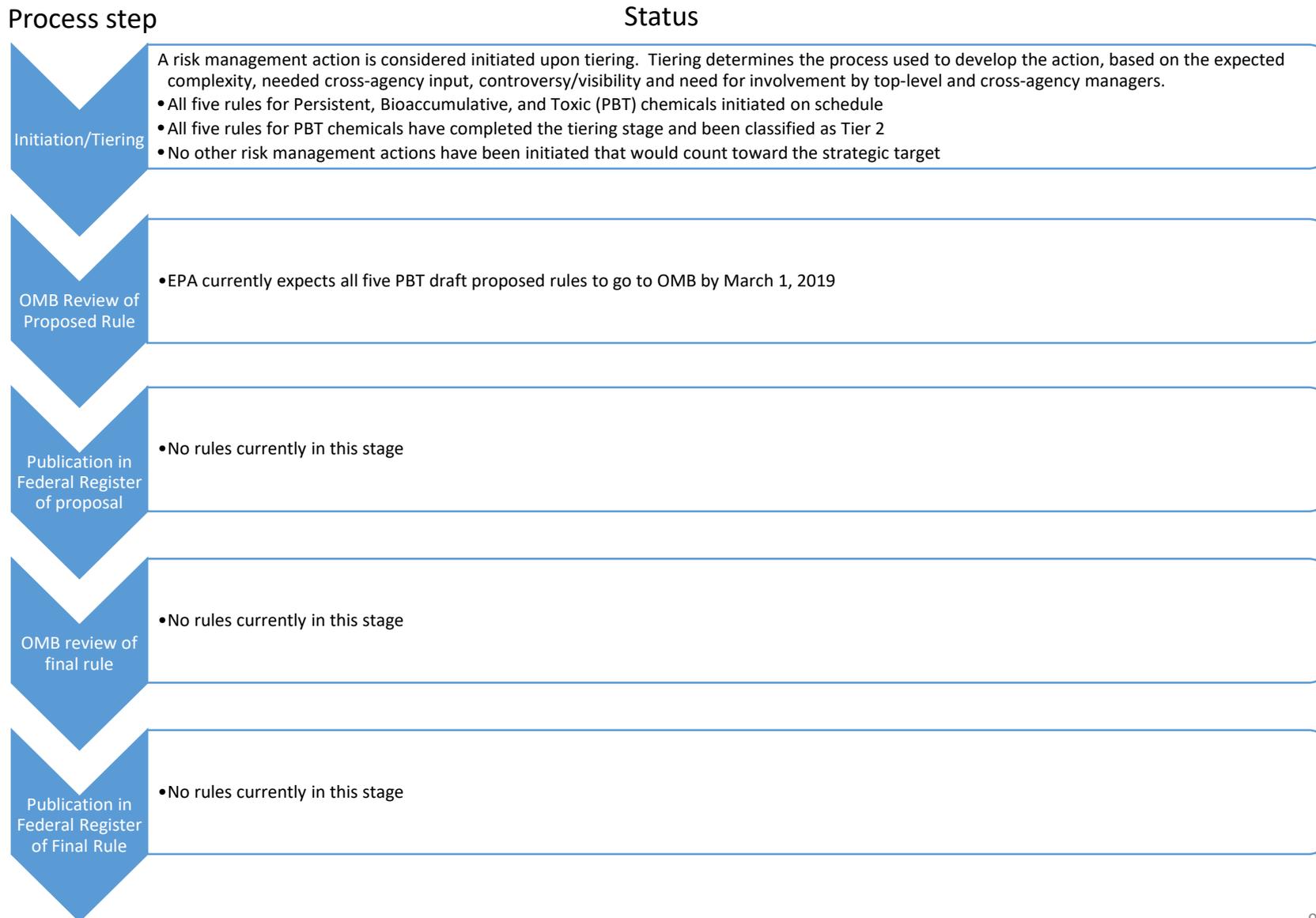
- EPA will use the deployment of the new EPA Lean Management System (ELMS) to achieve the results set forth in the Strategic Plan. As part of ELMS, EPA will conduct multi-day process improvement events to make significant progress in priority areas identified in the Strategic Plan, including this one.
- 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 in the Strategic Plan, while additional poster boards will track the flow of the work needed to achieve the targets. Managers and staff members will participate in 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.<sup>8</sup>

# Status of Risk Management Actions



# Summary of Progress – FY 2018 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
<b>Q1 Successes/Accomplishments</b>		<b>Q1 Challenges/Barriers</b>				<b>Next Steps</b>					
<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>• 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>• All 5 PBT Rules are at Step 2 from Slide 7 (OMB Review of Proposed Rule)</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>• EPA met the FY 2017 1st Quarter target.</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 2018/19 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 5 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

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	30%	35%	40%	45%	68%	72%	76%	80%	80%
	Results	11.7%	14%	7%	TBD	TBD	TBD	TBD	TBD	TBD	TBD

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>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>All five rules for PBT chemicals have completed the tiering stage and been classified as Tier 2</li> </ul> <p>New Chemicals:</p> <ul style="list-style-type: none"> <li>EPA fell substantially short of the FY 2018 2<sup>nd</sup> Quarter target, with performance declining from Q1.</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 2018/19 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 5 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 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, Bioaccumulative 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.

# Summary of Progress – FY 2018 Q2

- **Indicator 1: Risk Evaluations:**

- On track to meet 100% APG target to meet 3-year statutory deadline (12/19/19, without extensions) for the 10 initial risk evaluations.
- Statutorily-required scoping documents published on-time for all 10 chemicals.
- Problem formulation documents to further refine scope targeted for May 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.

- **Indicator 2: Risk Management Actions:**

- On track to meet 100% APG target to issue proposed rules for all five Persistent, Bioaccumulative 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.

- **Indicator 3: New Chemicals:**

- Efforts continue to meet FY 2019 target to complete 80% of TSCA pre-manufacture notice final determinations within statutory timelines (90 days, without extensions), including final determinations for Pre-Manufacture Notice (PMN), Significant New Use Notice (SNUN) and Microbial Commercial Activity Notice (MCAN) reviews.
- To help streamline new chemical review, EPA will implement recommendations from 2018 Lean project and other efficiency improvements through 2019.
- As of FY 2018 Q2, 7% of FY 2018 final determinations were made within 90-day base review period (including 3% of final determinations made within Q2).

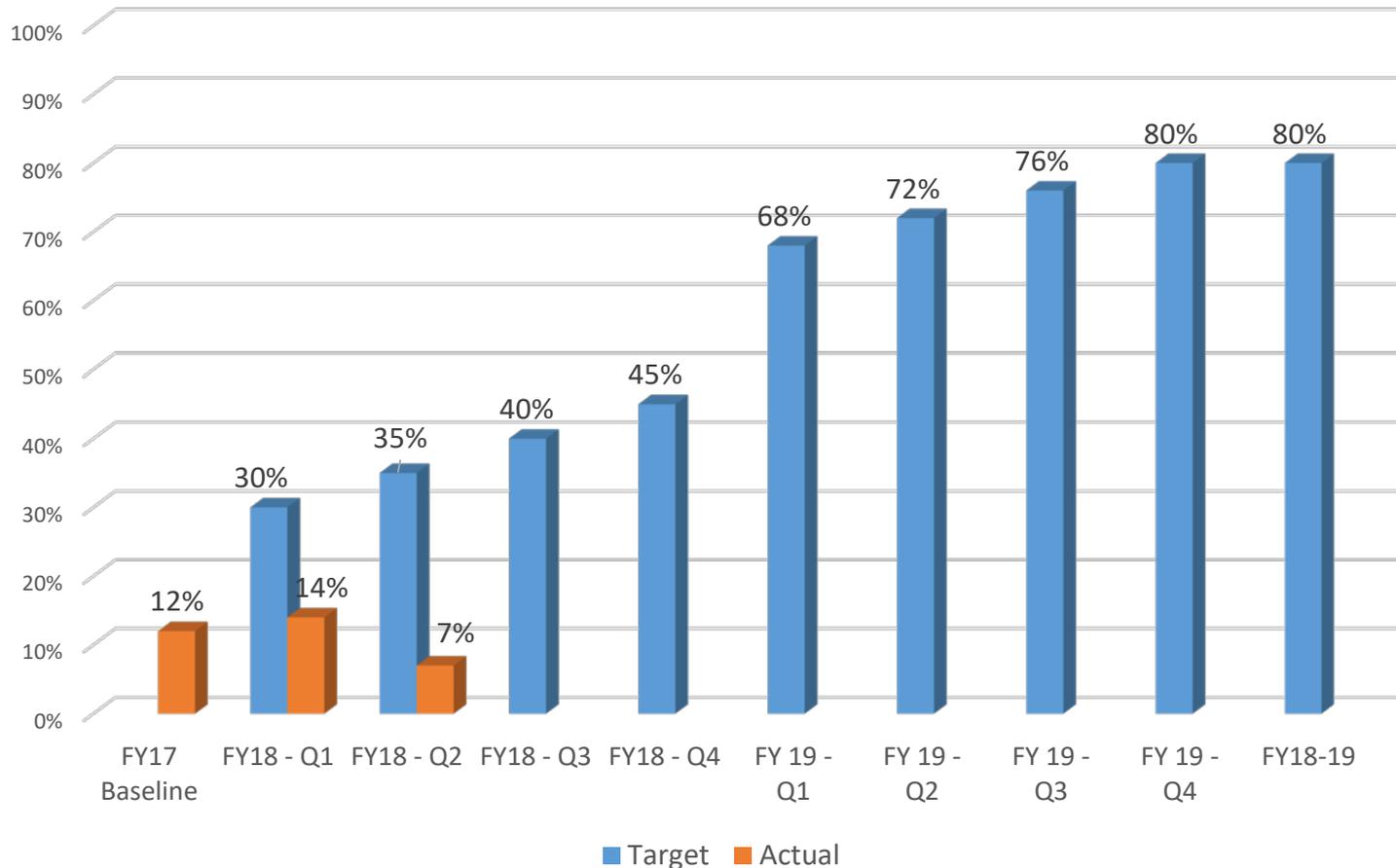
# Key Milestones

- 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 Project Management Tool (PMT) tracks progress of risk evaluations towards completion within statutory timelines.
- The New Chemical Review application (NCR), 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	No Change	RAD	Statutory deadline
Problem Formulations completed for first 10 Chemicals	May 18	On-Track	No Change	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	No Change	EPA	Lotus Notes system to be replaced end of December 2017.
Issuance of Proposed Rules for PBTs	6/22/19	On-Track	No Change	CCD	Statutory deadline is 3 years from date of enactment
<i>New Chemicals</i>					
New Chemical Review Application, Release 1	12/8/17	Completed	No Change	IMD	Replaced PMN Gold system
Enhancements to New Chemical Review application	4/9/18	Completed and Ongoing	Changed from "On-track"	IMD	NCR now primary tool for managing new chemical reviews; enhancements will improve workflow efficiency
<i>Other</i>					
Two-Way Communication Feature Deployment	6/1/18	On-Track	No Change	IMD	Will replace paper communications with electronic transmissions

# Key Indicators: New Chemicals



**Percent of PMN, SNUN, and MCAN Final Determinations Completed within 90 days**

# Data Accuracy and Reliability

## **EPA-initiated TSCA risk evaluations for existing chemicals:**

- 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 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:**

- 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 Data Quality Record 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 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 PMNs, SNUNs, MCANs and simple division.
- NCR replaced PMN Gold as the primary tool for managing new chemical reviews on 4/9/18. Additional enhancements will improve workflow efficiency; enhancements will be launched by 9/30/18 and continue into FY19.
- A Data Quality Record 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

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## Contributing Programs

### **Organizations:**

- Office of Chemical Safety and Pollution Prevention (OCSP)
- 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 on TSCA Framework Actions
- 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