

### **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**

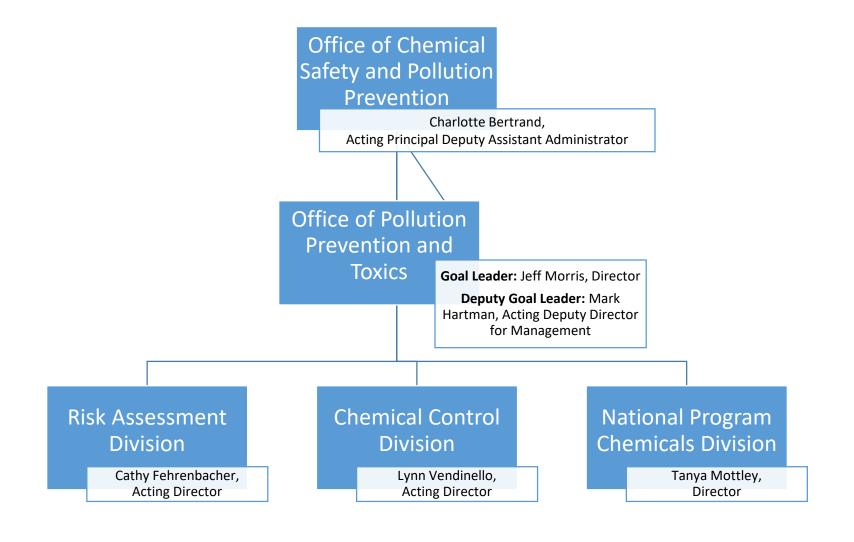
- Risk Evaluations: The TSCA amendments enacted in 2016 established tight deadlines for technically complex chemical reviews that must adhere to high scientific standards, resulting in increased demands on staff and contractor support.
- o <u>Risk Management Actions</u>: Similarly, TSCA amendments established 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**

- o 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).

<sup>\*</sup>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 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.

<sup>\*</sup>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 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); 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 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 reduce the time needed for risk assessment process:
    - ✓ Employ team-based processing;
    - ✓ Improve CBI Local Area Network (LAN) system performance;
    - ✓ Improve electronic communication with submitters; and
    - ✓ 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; 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 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

### 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 released for public comment June 1, 2018
- •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 release for public comment in Q1 and Q2 FY19
- Draft Risk Evaluations for 10 chemicals undergo peer review by Science Advisory Committee on Chemicals (SACC) in Q1 and Q2 FY19
- Final Risk Evaluations for 10 chemicals in Q1 FY20

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

For each step in the process, completion is defined as publication of the document in the Federal Register.8

# Status of Risk Management Actions

# **Status Process step** 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. • All five rules for Persistent, Bioaccumulative, and Toxic (PBT) chemicals initiated on schedule • All five rules for PBT chemicals have completed the tiering stage and been classified as Tier 2 Initiation/Tiering • No other risk management actions have been initiated that would count toward the strategic target • EPA currently expects all five PBT draft proposed rules 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 final rule •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	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		N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%	100%
management actions for existing chemicals	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		N/A	14%	31%	48%	65%	68%	72%	76%	80%	80%
		11.7%	14%	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD

Q1 Successes/Accomplishments	Q1 Challenges/Barriers	Next Steps					
<ul> <li>Existing Chemicals Risk Evaluations:</li> <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>	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	<ul> <li>Existing Chemicals Risk Evaluations:</li> <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</li> </ul>					
Existing Chemicals Risk Management Actions:	Existing Chemicals Risk Management Actions:	Formulation Documents					
• All 5 PBT Rules are at Step 2 from Slide 7 (OMB Review of Proposed Rule)	None encountered to date	5					
<ul> <li>New Chemicals:</li> <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>	New Chemicals: • FY 2018/19 APG Targets are ambitious	<ul> <li>Existing Chemicals Risk Management Actions:</li> <li>Submit Draft Proposed Rules for all 5 PBT Rules to OMB</li> <li>New Chemicals:</li> <li>Continue progress towards ambitious APG targets</li> <li>Continue to implement recommendations from the Lean exercise</li> </ul>					
*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.							

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*		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%*	100%*
		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		N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%	100%
		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		N/A	30%	35%	40%	45%	68%	72%	76%	80%	80%
determinations	Results	11.7%	14%	7%	TBD	TBD	TBD	TBD	TBD	TBD	TBD

Q2 Successes/Accomplishments	Q2 Challenges/Barriers	Next Steps
Existing Chemicals Risk Evaluations:	Existing Chemicals Risk Evaluations:	Existing Chemicals Risk Evaluations:
Continuing progress on Problem Formulation documents for all 10	• Problem Formulation documents –	• Publish Problem Formulation documents for first 10
EPA-Initiated Evaluations	unique to the first 10 Evaluations –	Evaluations
Public Meeting conducted on Chemical Prioritization on approaches to	these are taking longer to develop than	·
identify potential candidates for next set of EPA-Initiated Risk	anticipated due to large numbers of	based on previously issued Scoping Documents and
Evaluations	uses and data challenges	forthcoming Problem Formulation Documents
Existing Chemicals Risk Management Actions:	Existing Chemicals Risk Management	<ul> <li>Develop a draft strategy and Implement a risk- based screening process including criteria for</li> </ul>
All five rules for PBT chemicals have completed the tiering stage and	Actions:	designating substances as high priority for risk
been classified as Tier 2	None encountered to date	evaluation or low priority for which risk evaluations
		are not warranted at this time
New Chemicals:	New Chemicals:	
EPA fell substantially short of the FY 2018 2 <sup>nd</sup> Quarter target, with	• FY 2018/19 APG Targets are ambitious	Existing Chemicals Risk Management Actions:
performance declining from Q1.	<ul> <li>TSCA amendments added more</li> </ul>	<ul> <li>Submit Draft Proposed Rules for all 5 PBT Rules to</li> </ul>
Public Meetings conducted on potential program improvements	complexity to new chemical review	OMB
Initiated Lean Exercise to streamline work processes	process	
Note: failure to complete a determination within 90 days does not		New Chemicals:
constitute a lack of compliance with the statute if the request to suspend the review has been received by the Agency from the		<ul> <li>Continue progress towards ambitious APG targets</li> <li>Continue to implement recommendations from the</li> </ul>
submitter. Requests have been made for all pending submissions		Lean exercise
over 90 days indicating full statutory compliance.		Ecan exercise
order of days management of the formation		

<sup>\*</sup>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.

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	Targets	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100%*	100%*
evaluations for existing chemicals*	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  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	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
	Targets	N/A	30%	35%	40%	45%	68%	72%	76%	80%	80%
	Results	11.7%	14%	7%	4%	TBD	TBD	TBD	TBD	TBD	TBD

-xisting	Chemical	s Risk Evaluations:	

 Problem Formulation documents for all 10 EPA-Initiated Evaluations released for public comment June 1, 2018

Q3 Successes/Accomplishments

#### **Existing Chemicals Risk Management Actions:**

 For the 5 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:**

- EPA fell substantially short of the FY 2018 -3<sup>rd</sup> Quarter target, with performance declining from Q1 and Q2.
- Proceeding 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:**

 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

Q3 Challenges/Barriers

#### Existing Chemicals Risk Management Actions:

None encountered to date

#### **New Chemicals:**

- FY 2018/19 APG Targets are ambitious
- TSCA amendments added more complexity to new chemical review process
- A challenge has been the need for additional consultation with OGC in light of pending litigation in this area

#### **Existing Chemicals Risk Evaluations:**

 Review public comments on problem formulation documents

**Next Steps** 

- Commence development of Draft Risk Evaluations based on previously issued Scoping Documents and 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 5 PBT Rules to OMB

#### New Chemicals:

- Continue progress towards ambitious APG targets
- Continue to implement recommendations from the Lean exercise

<sup>\*</sup>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 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 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

### • 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:

- 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

#### 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
- In FY 2018 Q2, 3% of all FY 2018 final determinations were made within 90-day base review period

#### • Indicator 1: Risk Evaluations:

- On track to meet statutory requirements for timely completion of final risk evaluations
- Statutorily-required scoping documents published on-time for all 10 chemicals
- Problem formulation documents to further refine scope released for public comment 6/1/18
- 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:

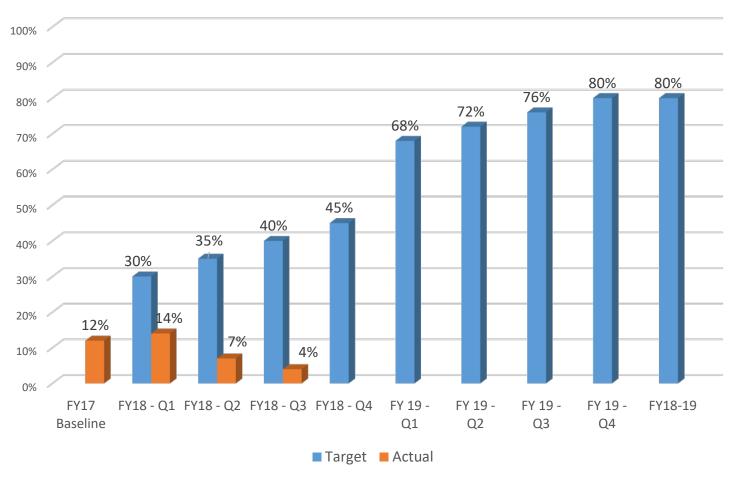
- Ability to meet FY 2019 target of 80% to complete TSCA pre-manufacture notice final determinations within statutory timelines (90 days, without extensions), including Pre-Manufacture Notice (PMN), Significant New Use Notice (SNUN) and Microbial Commercial Activity Notice (MCAN) reviews, will depend upon successful implementation of Lean effort, hiring and training new staff to perform this critical work, and finalizing policy decisions that impact key aspects of the program.
- Efforts continues to improve performance on completing pre-manufacture notice reviews within statutory timelines (without extensions), with a Lean project occurring in FY 18 and Lean recommendations and other improvements implemented through FY 2019.
- Efforts underway to derive lessons learned from cases that have been completed within 90 days and apply to current review processes.
- Significant recruitment and hiring effort is underway to fill key vacancies in the new chemicals program. More than 12 new hires have been made and more are in the queue. Training new staff is also underway.
- In FY 2017, 11.7% of all final determinations made within 90-day base review period. In FY 2018, cumulative figure for Q1-Q3 is 3.8%, and zero percent for Q3. However, EPA has made all final determinations in accordance with regulatory provisions that allow for the agency and submitter to agree to voluntary suspensions pending receipt of additional information.

# **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), deployed to production in early December, 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			
Risk Evaluations								
Scoping Documents completed	6/22/17	Completed	No Change	RAD	Statutory deadline			
Problem Formulations completed for first 10 Chemicals	May 18	Completed	Changed from "On Track"	RAD	All 10 released for public comment June 1			
Risk Management Actions								
Action Development Process tracker for risk management actions under further development	N/A	Completed	Changed from "On Track"	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			
New Chemicals								
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	No Change	IMD	NCR now primary tool for managing new chemical reviews; enhancements will improve workflow efficiency			
Two-Way Communication Feature Deployment	6/1/18	Completed and Ongoing	Changed from "On Track"	IMD	Recently 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.			

# **Key Indicators: New Chemicals**



Percent of PMN, SNUN, and MCAN Final Determinations
Completed within 90 days
(Targets and actuals cumulative from start of FY 2018)

# 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: <a href="https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-risk-evaluation.pdf">https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-risk-evaluation.pdf</a>.

### 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 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
  through 9/30/18 and continue into FY19.
- A Data Quality Record has been developed for the strategic measure associated with this activity: <a href="https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-new-chemicals.pdf">https://www.epa.gov/sites/production/files/2018-05/documents/dqr-1-4-new-chemicals.pdf</a>.

### 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