

PRIORITIZATION OF CHEMICAL SUBSTANCES UNDER TSCA

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Sarah Au

U.S. Environmental Protection Agency

Data Gathering, Management and
Policy Division | OPPT | OCSP



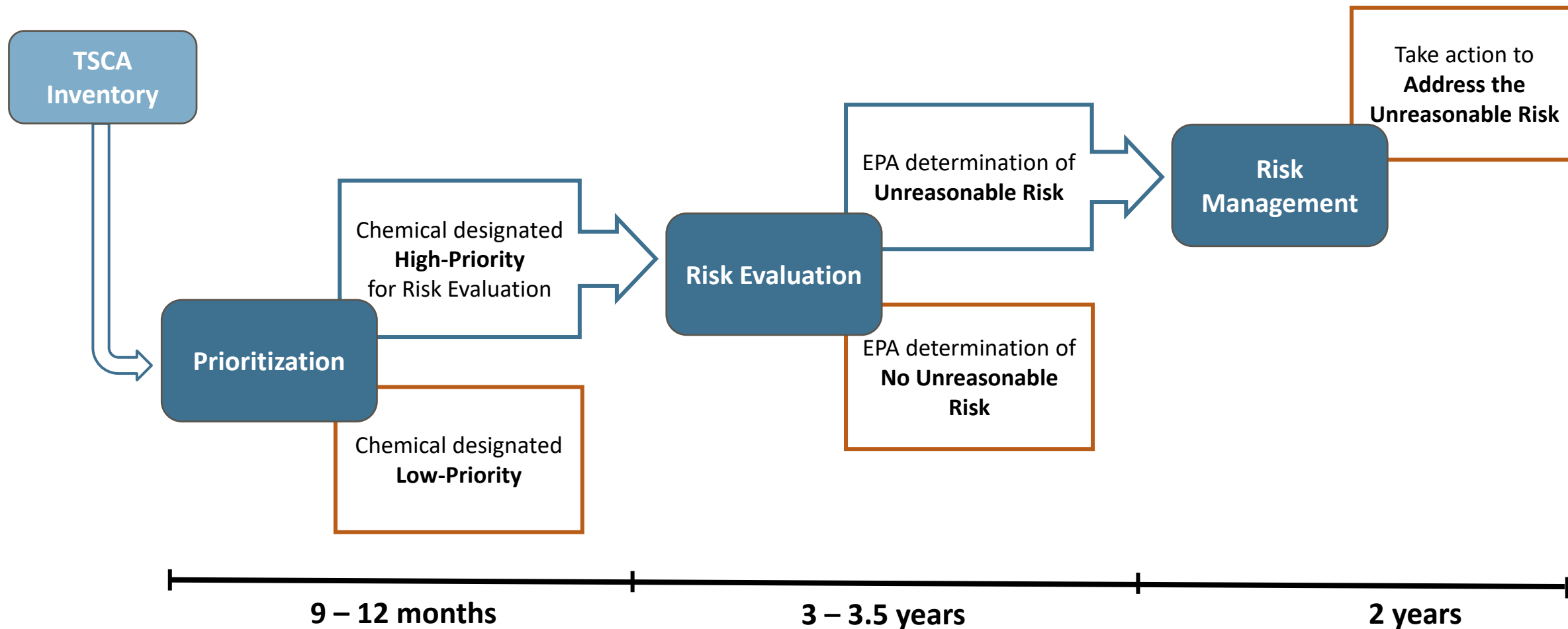
OUTLINE

- TSCA Overview: Existing Chemicals
- Requirements and Timeline for Prioritization
- Approach for Candidate Selection
- Information Sources
- Data Gathering Activities
- Exposure to Communities
- Summary
- Available Dockets

EVALUATING RISKS OF EXISTING CHEMICALS

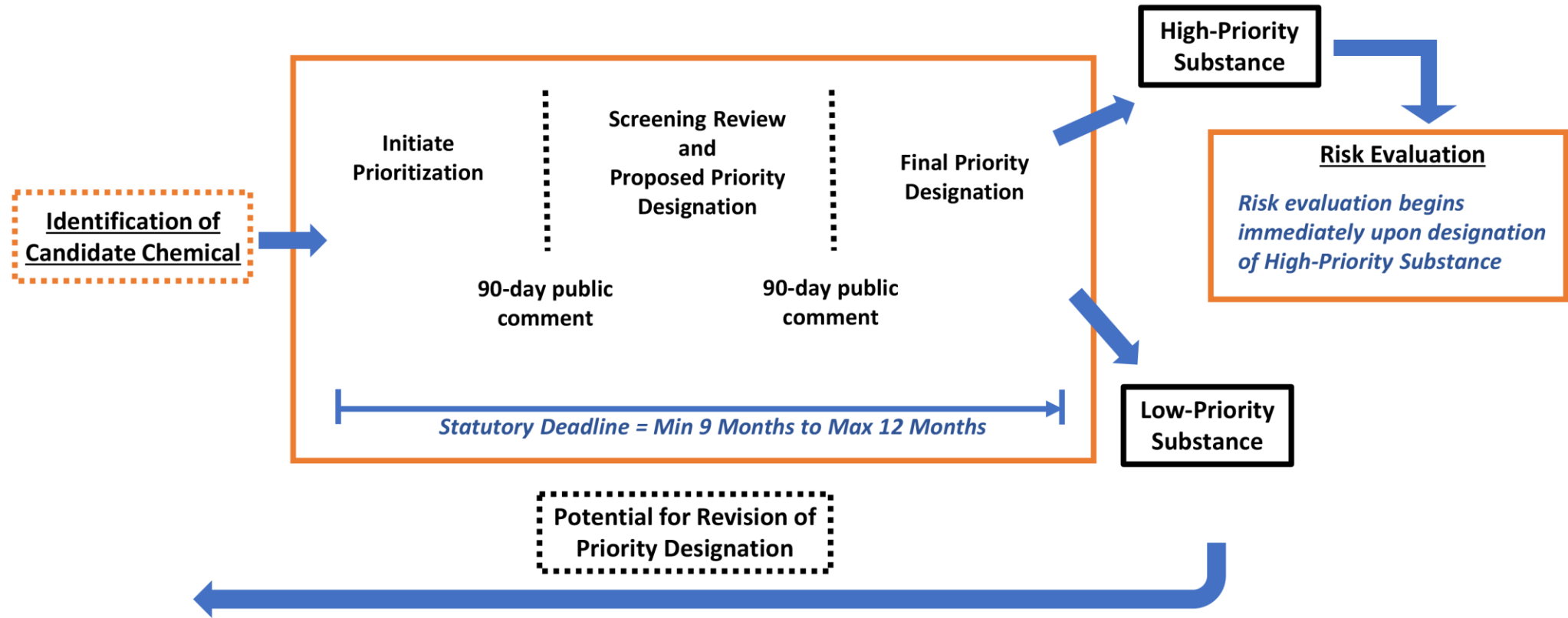
- Toxic Substances Control Act (TSCA) provides EPA with the authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures.
- As amended in 2016, TSCA also requires that EPA conducts:
 - a prioritization process to determine if chemical substances are a high- or low-priority for risk evaluation, and
 - risk evaluation for every designated High-Priority Substance, to determine whether there is an unreasonable risk to health or the environment, without consideration of costs or non-risk factors, based on the weight-of-scientific-evidence, using the best available science.
- The entire lifecycle of a chemical is considered, and the scope of the evaluation is broader than media-specific programs.

EVALUATING RISKS OF EXISTING CHEMICALS



PRIORITIZATION TIMELINE

Chemical Prioritization Process



CHEMICAL SUBSTANCE DESIGNATION

- Under TSCA, EPA must establish a risk-based screening process, including criteria, for designating a chemical substance as either:
 - ***High-priority substance for risk evaluations***
 - may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a “potentially exposed or susceptible subpopulation”, without consideration of costs or other non-risk factors
 - ***Low-priority substance for which risk evaluations are not warranted at the time***
 - based on information sufficient to establish that the chemical does not meet the standard for high-priority, without the consideration of costs or other non-risk factors
- **EPA plans to conduct prioritization annually to replace completed risk evaluations.**

PRIORITIZATION FRAMEWORK REQUIREMENTS

- For the identification of chemical substances that will undergo prioritization, 50% of the chemical substances must come from the 2014 TSCA Work Plan.
- For chemical substances being considered from the 2014 TSCA Work Plan, EPA seeks chemical substances with these characteristics:
 - Persistence and bioaccumulation scores of three; and
 - Known human carcinogens, and high acute or chronic toxicity.

PRIORITIZATION STATUTORY REQUIREMENTS

To determine whether a chemical substance is high or low priority for conducting a risk evaluation, EPA considers:

- hazard and exposure potential of the chemical substance,
- persistence and bioaccumulation,
- potentially exposed or susceptible subpopulations,
- storage near significant sources of drinking water,
- the conditions of use or significant changes in the conditions of use of the chemical substance,
- the volume or significant changes in the volume of the chemical substance manufactured or processed, and
- other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

APPROACH TO CHEMICAL SELECTION

- Remaining 2014 Work Plan Chemical Substances and Non-Work Plan Chemical Substances were considered.
- Selection of chemicals focused on data availability regarding exposure and hazard information to:
 - understand what information is known about each chemical and if that information is robust enough to support a risk evaluation that can be completed within statutory deadlines, and
 - reduce the likelihood EPA would need to order testing to fully understand the chemical before evaluating risks.
- Coordination with EPA offices and other interested parties throughout the pre-prioritization and prioritization process.

INFORMATION SOURCES

Information Type	Sources of Information
Publicly Available Information	<ul style="list-style-type: none"> - Peer-Reviewed Literature (ECOTOX Knowledgebase) - Gray Literature Databases, Assessments and Documents (e.g., IRIS assessments, ECHA, NICNAS)
Uses	<ul style="list-style-type: none"> - Chemical Data Reporting - Toxics Release Inventory - Work Plan summary document
Production Volume	<ul style="list-style-type: none"> - Chemical Data Reporting
Environmental Releases and Exposure Data	<ul style="list-style-type: none"> - Toxics Release Inventory - Water Quality Portal - Discharge Monitoring Reports - National Emissions Inventory - Work Plan summary document
Occupational Exposure	<ul style="list-style-type: none"> - National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations - NIOSH Toxic Industrial Chemicals (TIC) - Occupational Safety and Health Administration (OSHA)

CANDIDATE CHEMICAL SUBSTANCES FOR PRIORITIZATION

Chemical Name	CASRN	Existing Assessments	CDR	TRI	HAP	CCL5*/MCL	Hazardous Substance	Hazardous Waste	Carcinogen	Persistent and Bioaccumulative
1-Hexadecanol	36653-82-4		✓							✓
2-Ethylhexyl 2,3,4,5-tetrabromobenzoate (TBB)	183658-27-7		✓							✓
4-tert-Octylphenol (4-(1,1,3,3-Tetramethylbutyl)-phenol)	140-66-9	ECHA, NICNAS	✓	2024			✓			✓
Benzene	71-43-2	IRIS, ATSDR	✓	✓	✓	✓	✓	✓	✓	
bis(2-Ethylhexyl) - 3,4,5,6-Tetrabromophthalate (TBPH)	26040-51-7	ECHA	✓							✓
Bisphenol A	80-05-7	IRIS	✓	✓		✓*			✓	
Creosote	8001-58-9	PPRTV	✓	✓			✓	✓	✓	✓
Di-n-octyl phthalate (DnOP)	117-84-0	NICNAS, ATSDR	✓				✓	✓		
Ethylbenzene	100-41-4	IRIS, IARC, NICNAS	✓	✓	✓	✓	✓	✓	✓	
Naphthalene	91-20-3	IRIS, ATSDR	✓	✓	✓		✓	✓	✓	
N-Nitroso-diphenylamine	86-30-6	IRIS, IARC, ATSDR	✓	✓			✓		✓	✓
p,p'-Oxybis(benzenesulfonyl hydrazide)	80-51-3		✓							✓
Styrene	100-42-5	IRIS, IARC	✓	✓	✓	✓	✓		✓	
Tribromomethane	75-25-2	IRIS, PPRTV		✓	✓	✓	✓	✓	✓	✓
Triglycidyl isocyanurate	2451-62-9	NICNAS	✓	2024			✓			
m-Xylene	108-38-3	NICNAS, ATSDR	✓	✓	✓		✓			
o-Xylene	95-47-6	NICNAS, ATSDR	✓	✓	✓		✓			
p-Xylene	106-42-3	NICNAS, ATSDR	✓	✓	✓		✓			

CANDIDATE CHEMICAL SUBSTANCES FOR PRIORITIZATION

Chemical Name	CASRN	Existing Assessments	CDR	TRI	HAP	CCL5* / MCL	Hazardous Substance	Hazardous Waste	Carcinogen	Persistent and Bioaccumulative
Antimony & Antimony Compounds	Category	IRIS	✓	✓	✓		✓	✓	✓	✓
Arsenic & Arsenic Compounds	Category	IRIS	✓	✓	✓		✓	✓	✓	✓
Cobalt & Cobalt Compounds	Category	IRIS, ATSDR	✓	✓	✓	✓*	✓	✓	✓	✓
Lead & Lead Compounds	Category	IRIS, IARC, ISA	✓	✓	✓		✓	✓	✓	✓
Long-chain chlorinated paraffins (C18-20)	Category	ECHA, OPPT	✓	✓						✓
Medium-chain chlorinated paraffins (C14-17)	Category	OPPT	✓	✓						✓
Bisphenol S	80-09-1	NICNAS	✓							
Hydrogen fluoride	7664-39-3	ATSDR	✓	✓	✓		✓	✓		
<i>N</i> -(1,3-Dimethylbutyl)- <i>N'</i> -phenyl- <i>p</i> -phenylenediamine (6PPD)	793-24-8	DTSC	✓							

☐ Remaining 2014 Work Plan Chemical

☐ Non-Work Plan Chemical

DATA GATHERING AUTHORITIES UNDER TSCA

- To inform TSCA section 6 prioritization, risk evaluation and management, EPA may use its data gathering authorities.
- TSCA Section 4 gives EPA authority to require chemical manufacturers and processors to test existing chemicals and report the results to EPA.
- TSCA Section 8 gives EPA authority to require reporting and recordkeeping of existing information from chemical manufacturers and processors (and, under some provisions, distributors).
 - 8(a): Chemical-related data (e.g., production volume)
 - 8(c): Records alleging human or environmental adverse reactions
 - 8(d): Unpublished health and safety studies
 - 8(e): Notification of substantial risk of injury to health or environment

TSCA SECTION 8(d): HEALTH AND SAFETY DATA

- “Health and safety study” defined by statute to mean any study of any effect of a chemical substance or mixture on health, the environment, or both, including underlying data and epidemiological studies, studies of occupational exposure, toxicological, clinical, and ecological (including chemical & physical properties)
- EPA has used this authority for most chemicals currently undergoing risk evaluation.
- EPA anticipates final action on a rule on 16 chemicals by the end of 2024.

TIERED DATA REPORTING

- Goal is to establish a standardized reporting framework to collect data for TSCA Section 6-related activities
 - Establish a data collection framework via TSCA sections 8(a), (c), and (d) focused on chemicals of interest for TSCA section 6-related activities (Tiered Data Reporting (TDR))
 - Data collected via TDR would be continually collected and reviewed at earlier timeframes to support prioritization efforts and risk evaluations
- Final rule is anticipated in 2026

INFORMATION TO CHARACTERIZE EXPOSURE

Types of information that could help characterize exposure to communities and potentially associated health effects resulting from exposure:

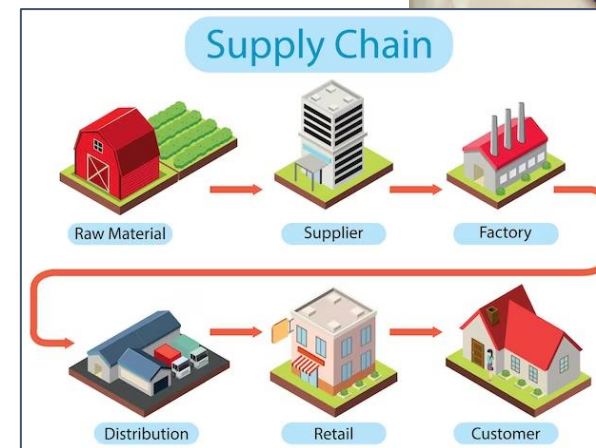
- Facility emissions/release data
- Environmental monitoring (e.g., air, water, soil chemical concentrations in specific locations) resulting from activities near communities
- Product data (e.g., consumer products or uses; chemical concentrations found in or used to manufacture or process certain products; emissions from consumer products)
- Use information (e.g., how products may be used by different individuals/groups)
- Activity or use patterns (e.g., activities or scenarios that may lead to greater exposure)



INFORMATION TO CHARACTERIZE EXPOSURE

Types of information that could help characterize occupational exposure and potentially associated health effects resulting from exposure:

- Occupational monitoring (e.g., air concentrations)
- Process and operational descriptions of relevant industrial and commercial activities and worker monitoring information
- Industry and supply chain information (e.g., industries involved at different steps of a product lifecycle)



SUMMARY

- EPA envisions that the data gathering process to inform annual prioritization efforts will encompass earlier and continued:
 - solicitation of input from various stakeholders and individuals,
 - identification of data needs for chemical substances that may be identified for prioritization efforts in the future, and
 - incorporation of process improvements to more efficiently review readily available information that may be used to identify potential exposure and hazard of industrial chemicals being considered.
- The identified *potential* chemical candidates for each round of prioritization may change annually.

PRE-PRIORITIZATION: DOCKET AVAILABLE FOR COMMENTS AND INFORMATION SUBMISSION

EPA is accepting public comments and information on chemical substances being considered for future prioritization efforts from October 1 to 31, 2024, at www.Regulations.gov using Docket ID No. [EPA-HQ-OPPT-2023-0606](https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0606).

PRIORITIZATION: DOCKETS AVAILABLE FOR COMMENTS AND INFORMATION SUBMISSION

EPA is accepting public comments and information until October 23, 2024, on five chemical substances currently proposed as High-Priority Substances and on the prioritization process at www.Regulations.gov:

- Chemical-specific dockets
 - Acetaldehyde: [EPA-HQ-OPPT-2018-0497](https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0497)
 - Acrylonitrile: [EPA-HQ-OPPT-2018-0449](https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0449)
 - Benzenamine: [EPA-HQ-OPPT-2018-0474](https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0474)
 - 4,4'-Methylene bis(2-chloroaniline) (MBOCA): [EPA-HQ-OPPT-2018-0464](https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0464)
 - Vinyl Chloride: [EPA-HQ-OPPT-2018-0448](https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0448)
- Prioritization process
 - [EPA-HQ-OPPT-2023-0601](https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0601)



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FOR YOUR TIME