2024 National Pollution Prevention Training and Conference

Pollution Prevention for Toxic Chemicals

December 10, 2024
10:45 – 11:45AM ET

Moderated by Jeff Kohn, EPA, Pollution Prevention Grants Branch

Speakers:
- **Edmond Lam, American Chemical Society (ACS)**
- **Predrag Petrovic, Yale Center for Green Science and Green Engineering**
- **Sarah Au, EPA, Data Gathering Management and Policy Division**
- **Joel Wolf, EPA, Existing Chemical Risk Management Division**

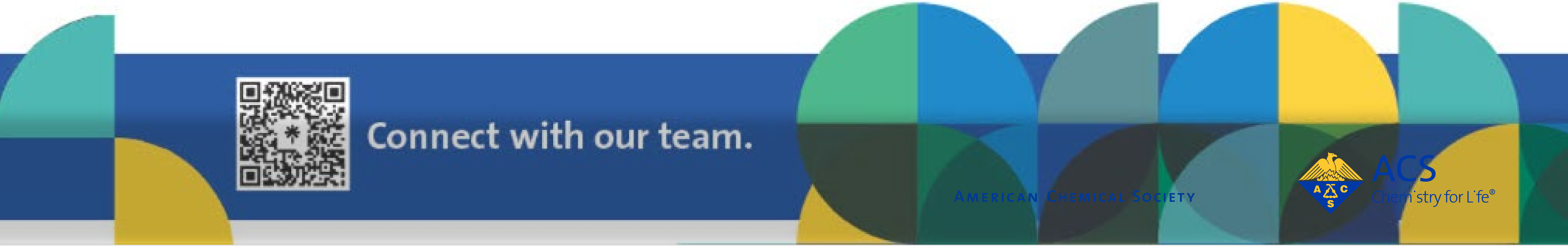
Addressing Environmental and Economic Challenges through Green Chemistry

Dr. Edmond Lam
Assistant Director, Green Chemistry Institute
Office of Sustainability

2024 National Pollution Prevention Training and Conference
Washington, DC
December 10, 2024

ACS Green Chemistry Institute
Chemistry for Life®

The ACS Green Chemistry Institute catalyzes green chemistry and engineering to promote sustainability, prosperity and equity across the global chemistry enterprise.



Green Chemistry Institute
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AMERICAN CHEMICAL SOCIETY

STRATEGIC GOALS

SCIENCE

Advance research, scholarship and innovation in green chemistry and engineering.

EDUCATION

Enable the implementation of green chemistry and engineering across the educational sector.

INDUSTRY

Accelerate industrial adoption of green chemistry and engineering.

EQUITY

Facilitate equitable adoption of green chemistry, engineering and sustainability practices worldwide.

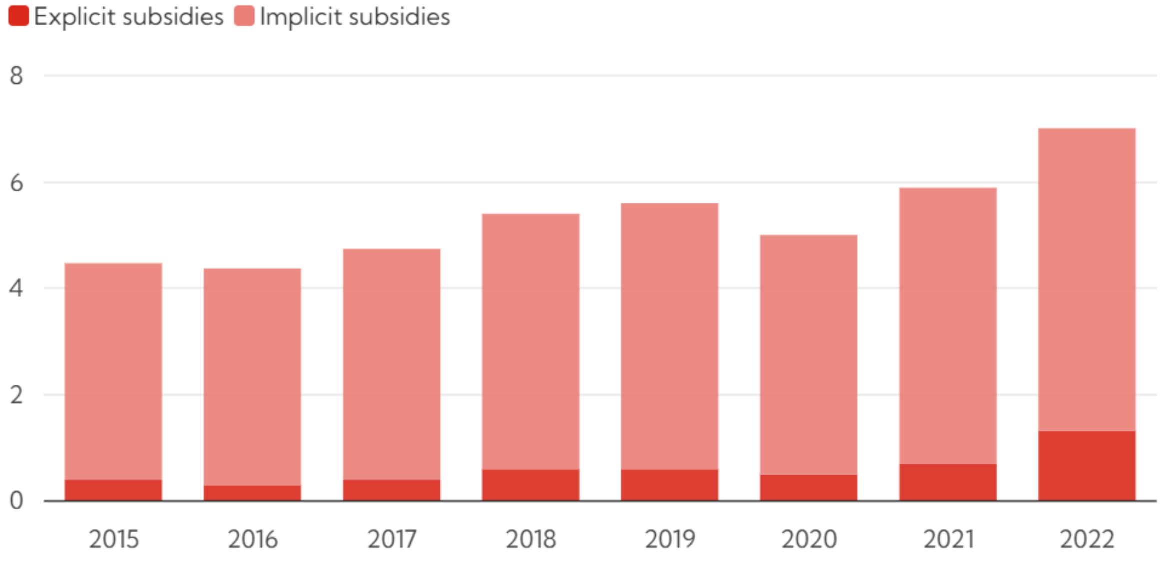
Fossil Fuel Subsidies Surged to Record $7 Trillion

Scaling back subsidies would reduce air pollution, generate revenue, and make a major contribution to slowing climate change

Simon Black, Ian Parry, Nate Vernon-Lin

August 24, 2023

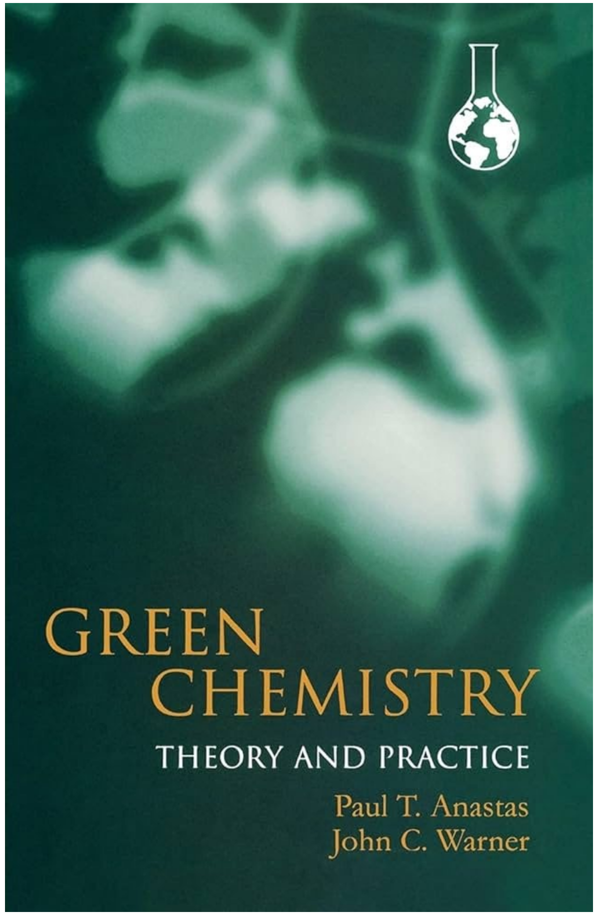
Fossil fuel subsidies topped $7 trillion last year
(total fossil fuel subsidies, trillions of USD)



Source: IMF staff calculations.
Note: Figures from 2019 onwards use projections for fuel use. Explicit subsidies: undercharging for supply costs. Implicit subsidies: undercharging for environmental costs and forgone consumption taxes, after accounting for preexisting fuel taxes and carbon pricing.

IMF

Why Green Chemistry?

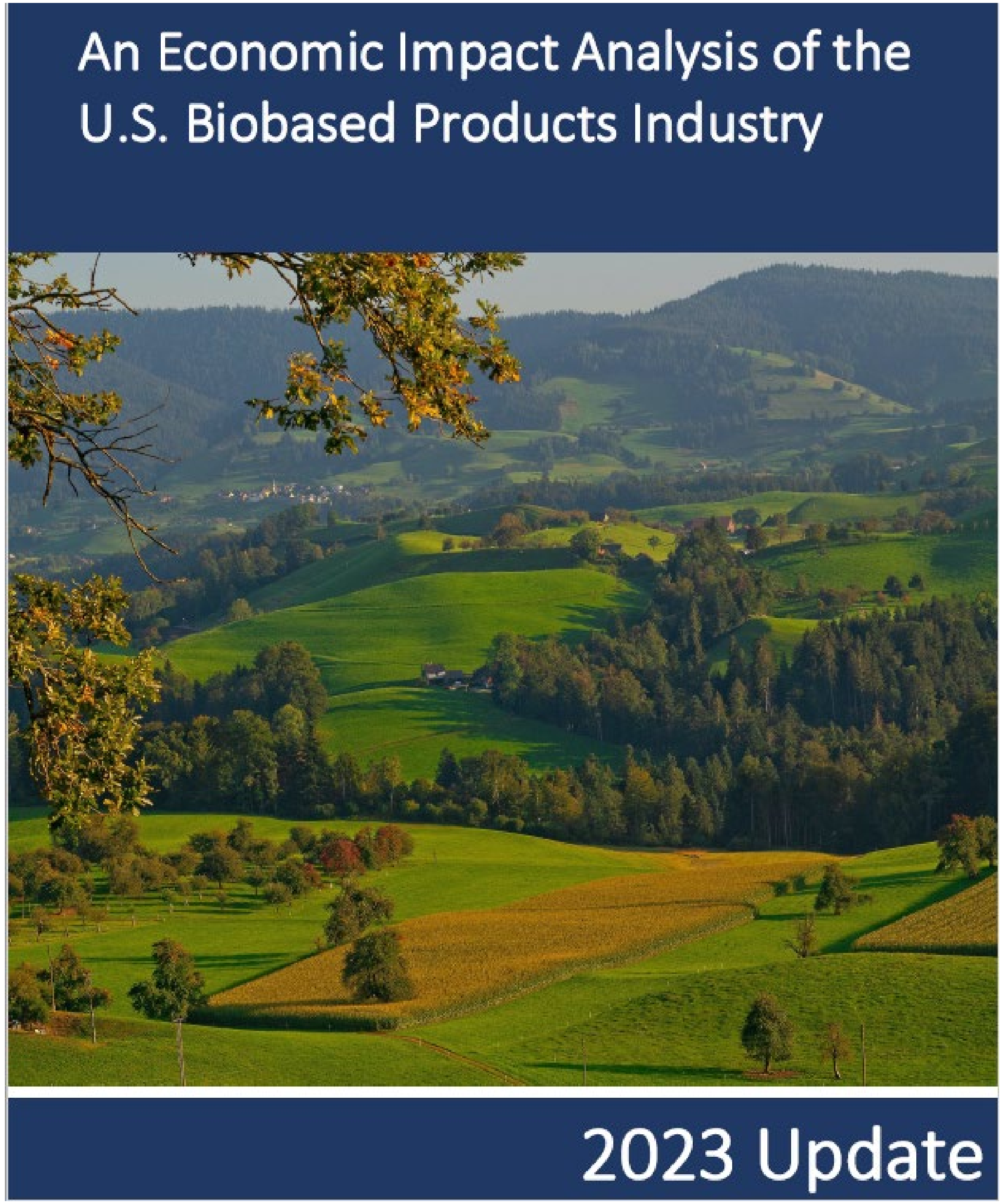


- Design chemical products or processes that reduce or eliminate the use or generation of hazardous substances

- Consider systems holistically and use life cycle thinking

- ➢ Provide the **best efficiency** for a **chemical process**
- ➢ New frontier of **exploration**
- ➢ Great opportunity for **innovation**
- ➢ Achievement of **superior synthetic efficiency** will ultimately deliver a **competitive advantage**.

https://www.acs.org/content/acs/en/greenchemistry/what-is-green-chemistry/principles.html

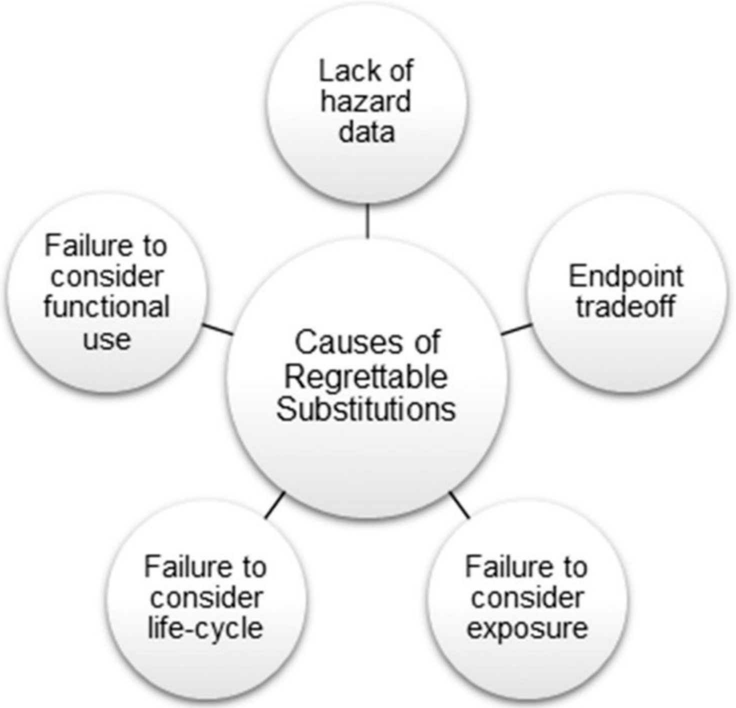


The Number of People Employed	Value added Contribution to the U.S. Economy	The Jobs Multiplier
3.94 Million	**$489 Billion**	**2.4**
in the U.S. Biobased Products Industry in 2021	from the U.S. Biobased Products Industry in 2021	For every 1 Biobased Products Industry job, 1.4 more jobs are supported in the United States

Golden, J.S., Handfield, R.B. Daystar, J., and S. Pires (2024). An Economic Impact Analysis of the U.S. Biobased Products Industry: 2023 Update. Volume V.

Regrettable substitutions – a known toxic chemical is replaced with another that proves to be just as concerning or even more harmful to human health or the environment

Original Chemical	Concern of the Original Chemical	Regrettable Substitution	Concern of the Regrettable Substitution
Bisphenol-A (for bottles)	Endocrine disruption	Bisphenol-S, Bisphenol-F	Endocrine activity
Lead (in fuel)	Neurotoxicity	Methyl tert-butyl ether (MBTE)	Aquatic toxicity
Methylene chloride (for adhesive applications)	Acute toxicity, carcinogenicity	1-Bromopropane	Carcinogenicity, neurotoxicity
Chlorofluorocarbons (for refrigerants)	Ozone depletion	Hydrofluorocarbons	Greenhouse gases
DDT (insecticide)	Reproductive toxicity	Chloropyrifos	Neurotoxicity, thyroid inhibition
γ-Hexachloro-cyclohexane (insecticide)	Neurotoxicity	Imidacloprid	Bee colony collapse



ACS Sustainable Chem. Eng. **2021**, 7749.

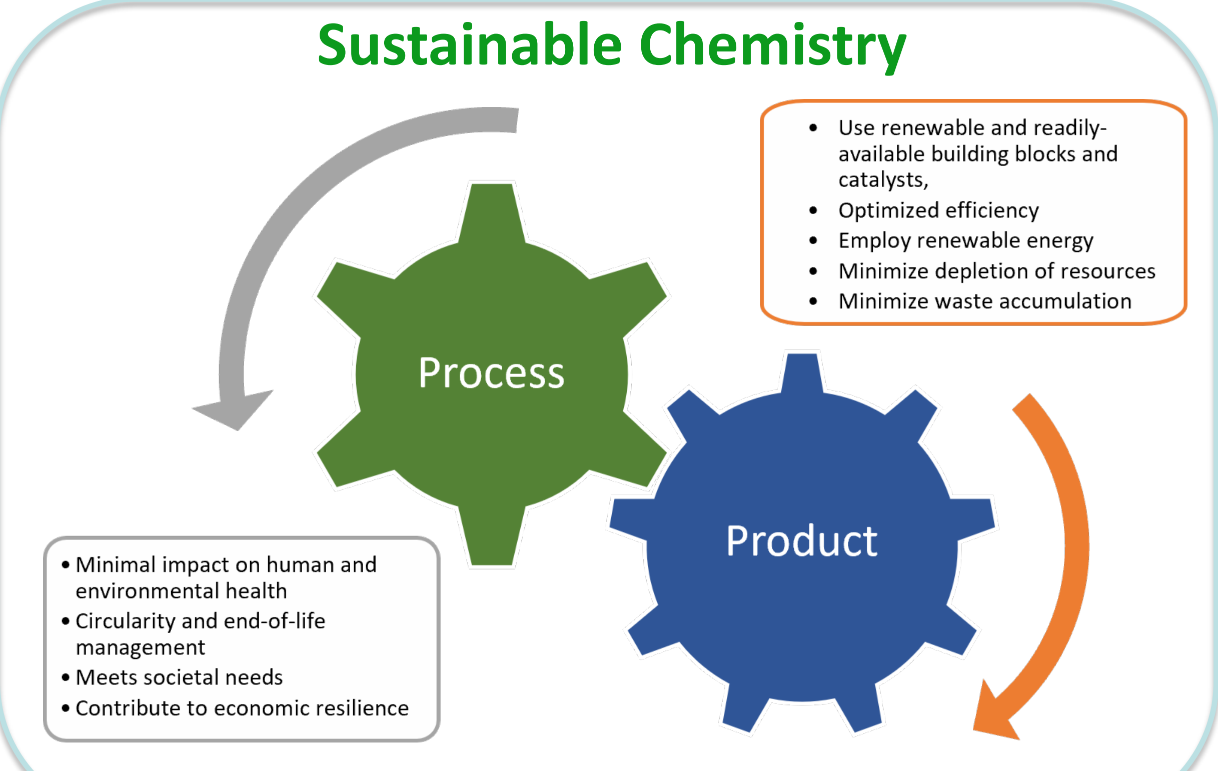
What challenges can Green Chemistry help to address through new, safer alternatives and technologies?

Negative Challenges (often emphasized; different priorities for different sectors):

- Greenhouse gas emissions
- Resource depletion
- Toxicity
- End-of-life
- Ocean pollution

Positive Challenges (less emphasized):

- Improvement to human health and the environment
- Enabling the value chain to reach sustainability goals



ACS Sustainable Chem. Eng. **2023**, 17781.

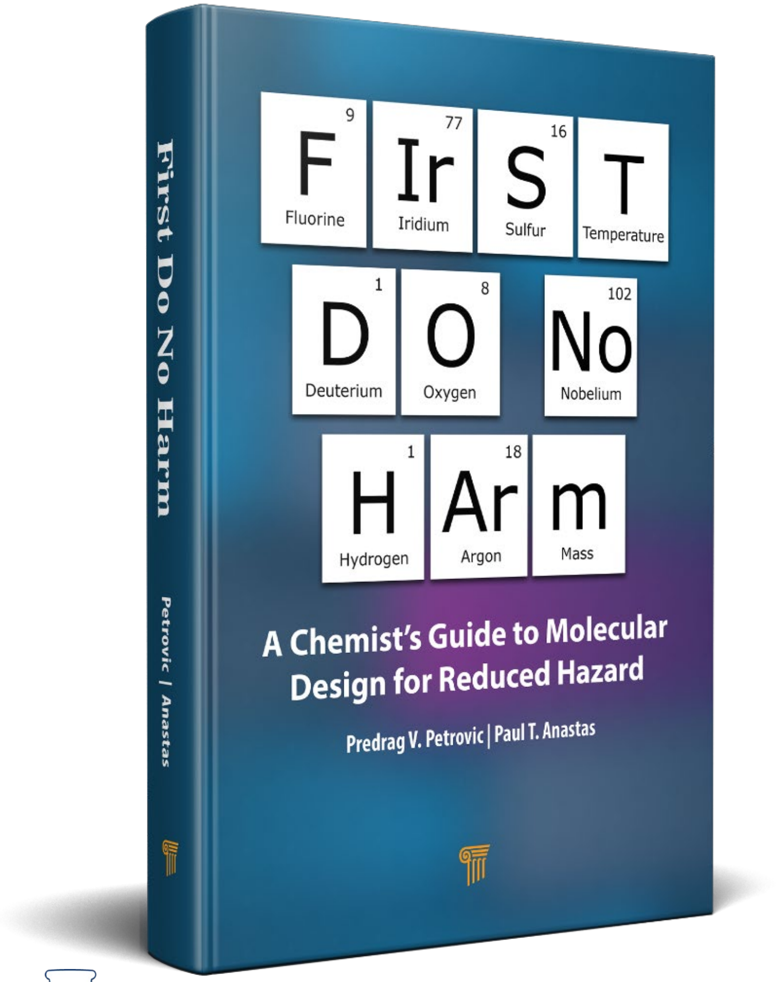
CENTER FOR GREEN CHEMISTRY & GREEN ENGINEERING AT YALE

Enabling innovation through safer chemical design

Predrag V. Petrovic, Associate Research Scientist
Yale School of the Environment

EPA P2 Conference, December 10th, 2024

Green Chemistry Principle #4
Safer chemical design



Chemical products should be designed to preserve the efficacy of function while reducing toxicity and other environmental hazards.

Anastas, P. and Warner, J., Green Chemistry: Theory and Practice, Oxford University Press, 1998.

Table of Contents

1. Hazard
2. ADME
3. Degradability
4. Dose/Response/Risk
5. Pharmacodynamics
6. Classes of Chemicals
7. Design Rules for Safer Chemicals
8. Case studies
9. The Path Forward

Petrović, P.V.; Anastas, P.T. First Do No Harm: A Chemist's Guide to Molecular Design for Reduced Hazard; Jenny Stanford Publishing Pte. Ltd.: Singapore, 2023

Brief Background: Risk: Exposure Control

$\boxed{\text{Risk} = f(\text{Hazard, Exposure})}$

<u>Historically</u>: Focus on exposure mitigation (<u>circumstantial</u> vs. inherent)

What if exposure control fails? Risk ↑↑

Brief Background: Risk: Green Chemistry Approach

$$\boxed{\text{Risk} = f(\text{Hazard, Exposure})}$$

Green chemistry is *"the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances"*.

- If the **intrinsic** hazard ↓ : risk ↓
- Ideal case: is exposure control needed?

Anastas, P.T., & Warner, J. C.: *Green chemistry: Theory and practice*, Oxford University Press, 1998

Types of Hazards

Table / 6.1

Hazard Categories and Examples of Potential Hazard Manifestations

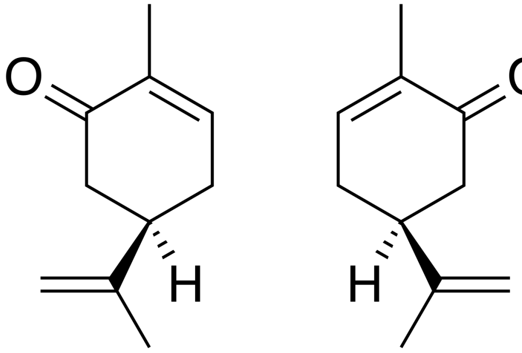
Human Toxicity Hazards		Environmental Toxicity Hazards	Physical Hazards	Global Hazards
Carcinogenicity	Immunotoxicity	Aquatic toxicity	Explosivity	Acid rain
Neurotoxicity	Reproductive toxicity	Avian toxicity	Corrosivity	Global warming
Hepatoxicity	Teratogenicity	Amphibian toxicity	Oxidizers	Ozone depletion
Nephrotoxicity	Mutagenicity (DNA toxicity)	Phytotoxicity	Reducers	Security threat
Cardiotoxicity	Dermal toxicity	Mammalian toxicity (nonhuman)	pH (acidic or basic)	Water scarcity/ flooding
Hematological toxicity	Ocular toxicity		Violent reaction with water	Persistence/ bioaccumulation
Endocrine toxicity	Enzyme interactions			Loss of biodiversity

Milhelcic, J.R. and J.B. Zimmerman, Environmental Engineering: Fundamentals, Sustainability, Design. 1 ed. 2009, New York: Wiley, John & Sons, Incorporated. 720

Why properties to complement structure?

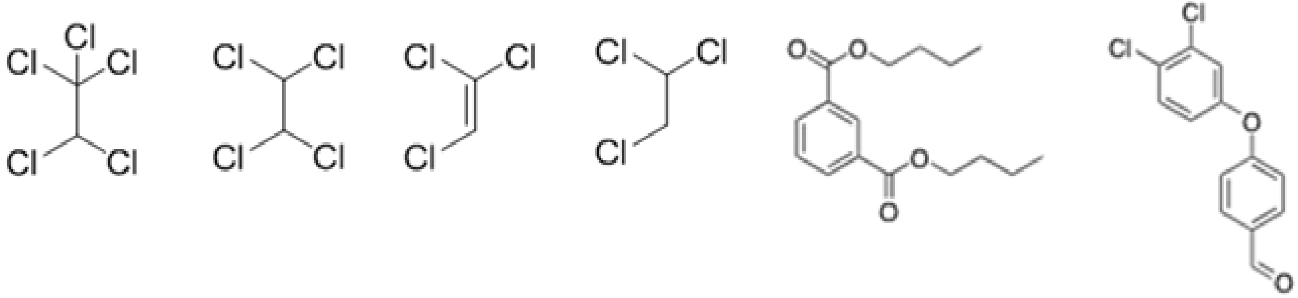
Molecular formula (C_3H_6O)			
Name	Acetone	Methyl vinyl ether	Allyl alcohol
Toxicity LD-50	9.0 g/kg (oral-rat)	4.9 g/kg (oral-rat)	0.06 g/kg (oral-rat)

Carvone



(R) *(S)*

smell/taste: spearmint caraway seeds



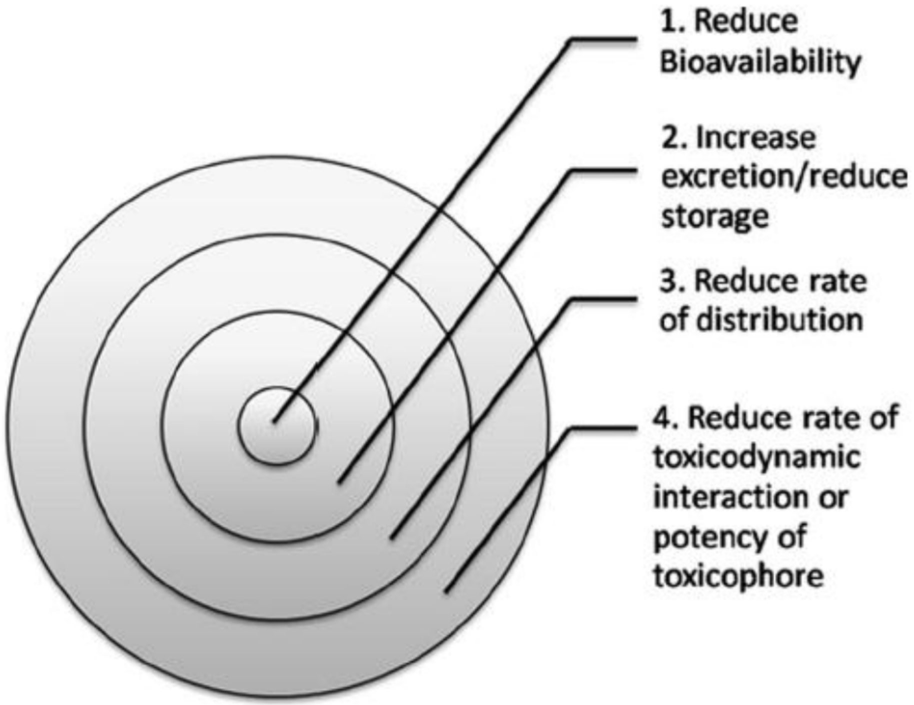
$\log P_{(o/w)}$	3.36	2.39	2.42	2.05	5.53	5.49
LUMO (eV)	-0.68	-0.23	-0.60	0.32	-0.757	-0.728
LC_{50}(mg/L)	7.53	20.3	44.1	81.6	0.900	0.300

Physicochemical properties links to toxicity

- Molecular weight
- Molecular volume
- Dipole moment
- Hydrophilic surface area
- Hydrophobic surface area
- Rotatable bonds
- Hydrogen bonding
- Ionization potential
- Electron affinity
- Partition coefficients
- Acid/base properties
- Polarizability

- ABSORBTION
- DISTRIBUTION
- METABOLISM
- EXCRETION

Acute toxicity

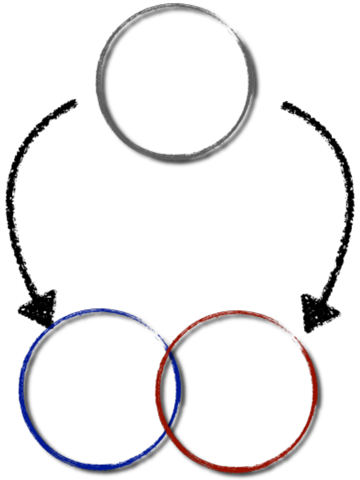


Terrestrial organism toxicity

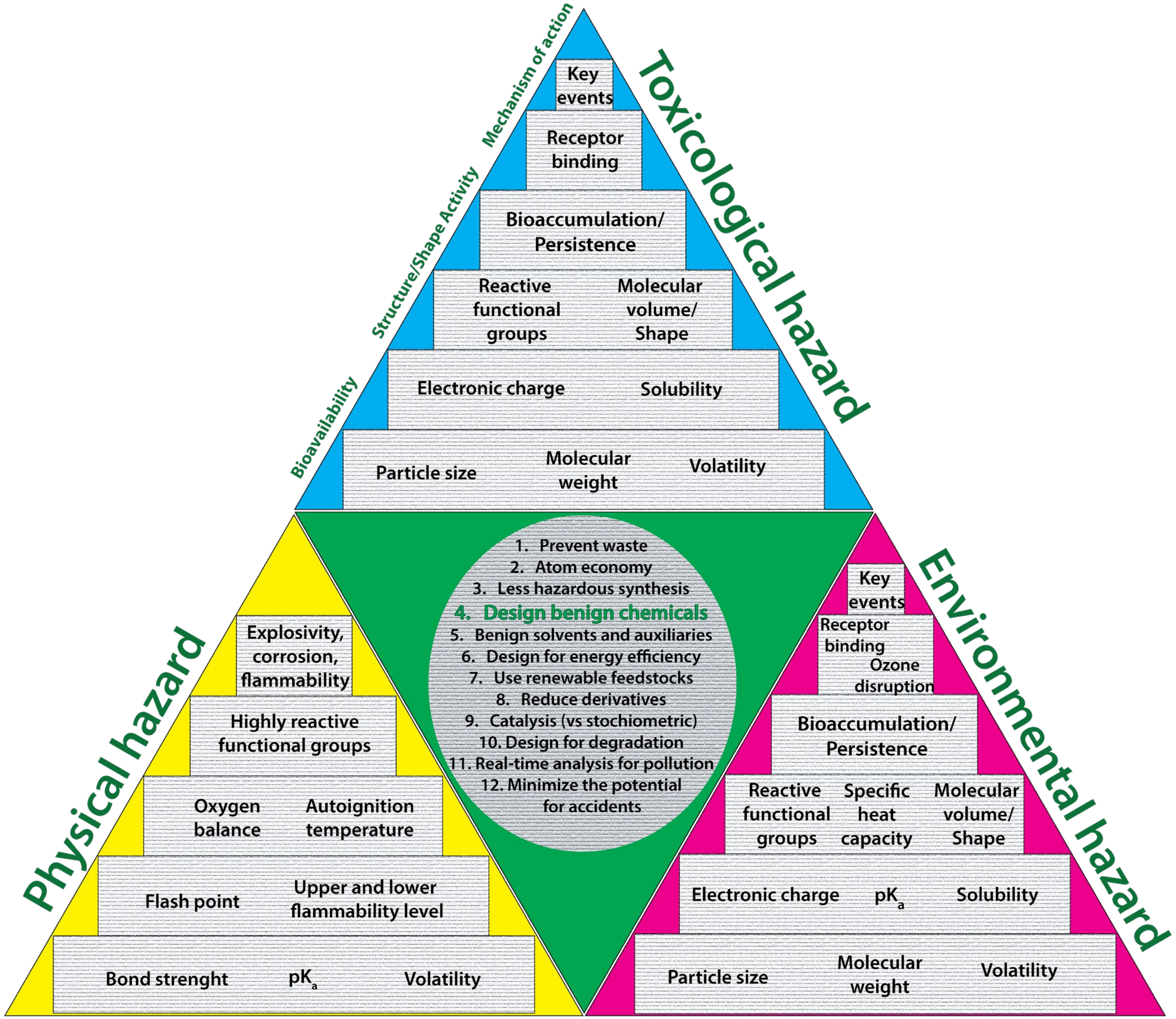
Petrović, P. V.; Anastas, P. T. First Do No Harm: A Chemist's Guide to Molecular Design for Reduced Hazard; Jenny Stanford Publishing Pte. Ltd.: Singapore, 2023
Voutchkova et al. Chem Rev 2010, 110, 5845

Safer chemical design framework

Property-Function Relationships

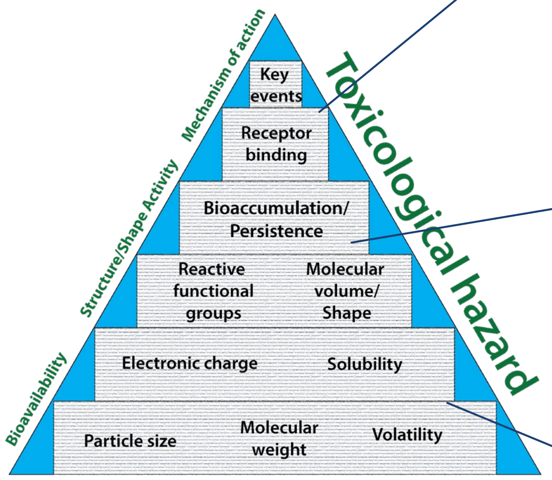


Property-Hazard Relationships



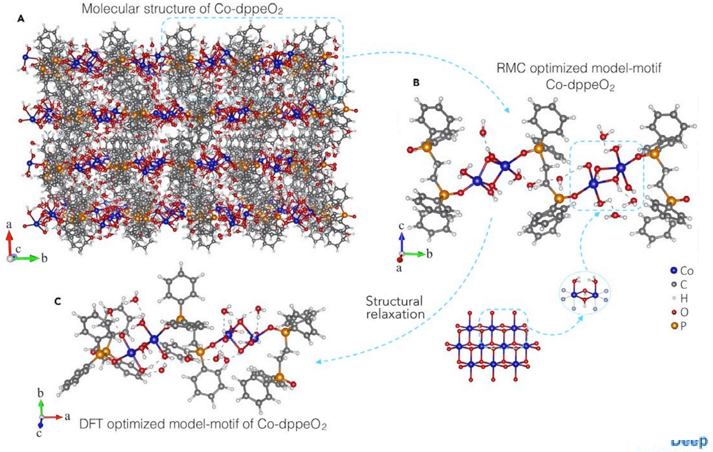
Chem. Soc. Rev., 2015, *44*(16), 5758-5777 (DOI: 10.1039/C4CS00445K); *Nature Nanotech.* 2018, 13, 708-714 (DOI: 10.1038/s41565-018-0120-4)
Petrović, P. V.; Anastas, P. T. First Do No Harm: A Chemist's Guide to Molecular Design for Reduced Hazard; Jenny Stanford Publishing Pte. Ltd.: Singapore, 2023

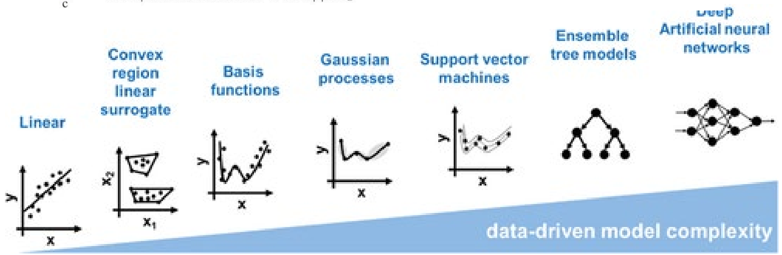
In silico methodology for Hazard Minimization through Molecular Design

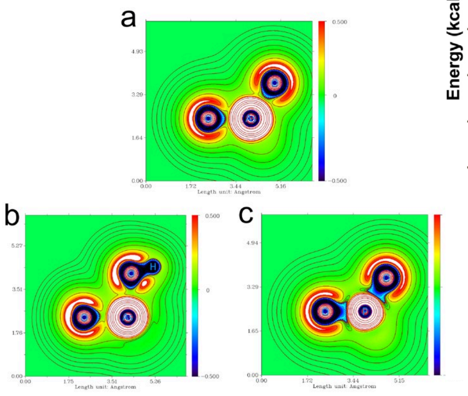


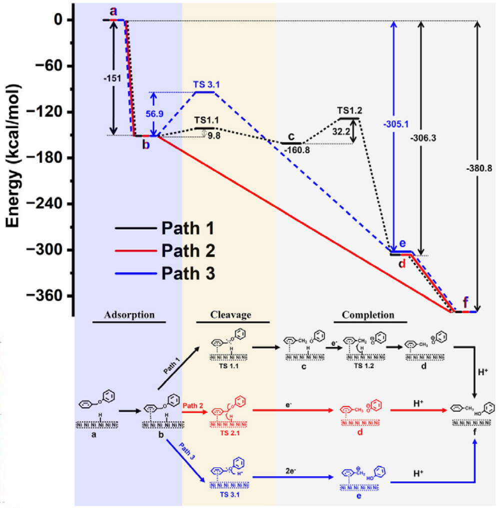
Monte Carlo, Molecular dynamics

QM methods
Machine learning/AI (big data)
statistical analysis
Structural alert systems





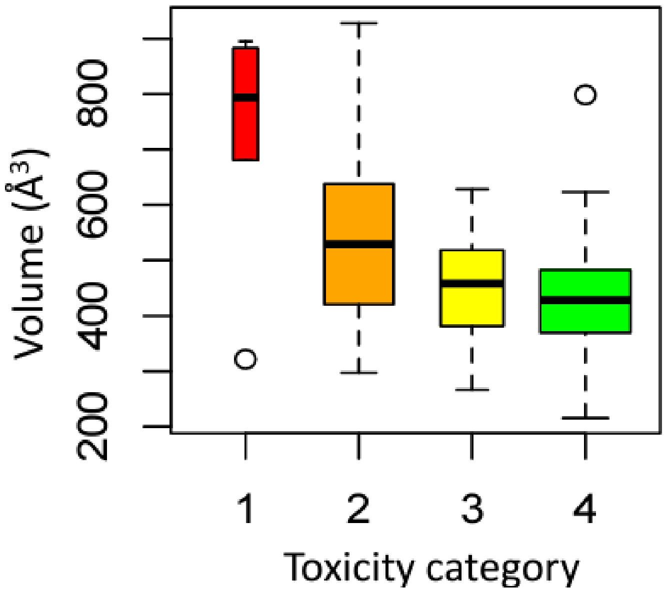


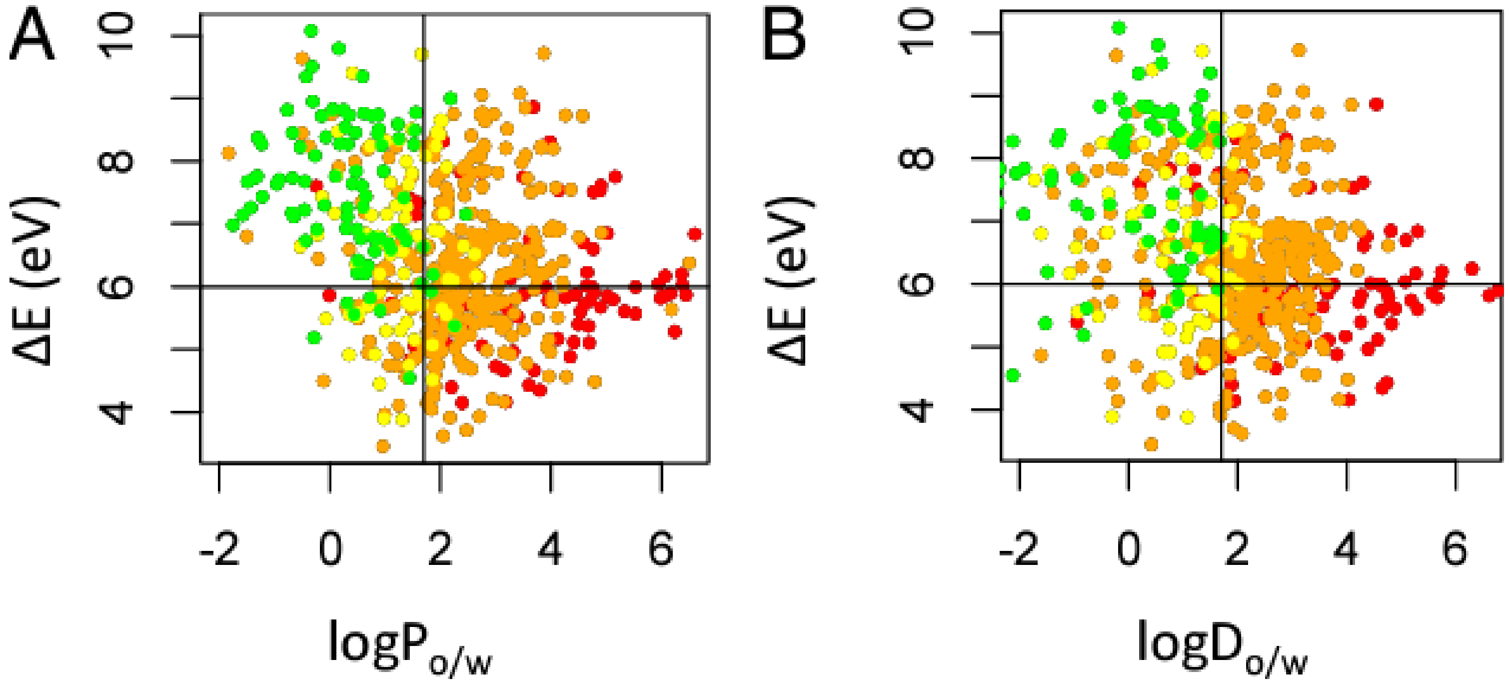


Quantum Mechanic (QM): WFT, DFT, semi empirical
Structure alerts: QSPR

Matter, 2019, 1, 1354–1369 (DOI: 10.1016/j.matt.2019.06.021)
Environ.Sci.Technol.2020,54,9769−9790, (DOI: 10.1021/acs.est.0c01666)
Green Chem., 2023, 25, 9720-9732 (DOI: 10.1039/D3GC01814H)

Minimizing ecotoxicity



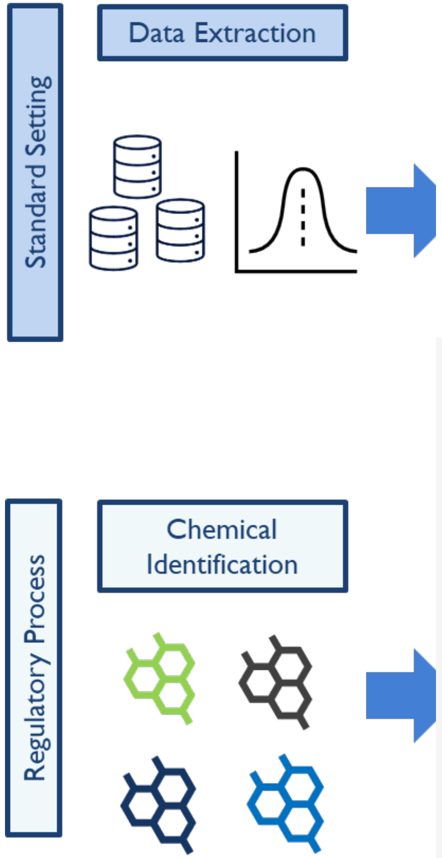


High concern
Moderate concern
Low concern
No concern

Log $P_{o/w}/D_{o/w} < 1.7$
$\Delta E > 6$ eV
Molecular Volume < 680 Å^3

PNAS, 2015, 112 (20), 6289-6294, (DOI: 10.1073/pnas.1314991111)

Tool for innovation



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Environmental Science & Technology
pubs.acs.org/est
Policy Analysis

Toward Property-Based Regulation

Tobias D. Muellers, Predrag V. Petrovic, Julie B. Zimmerman, and Paul T. Anastas*

Cite This: *Environ. Sci. Technol.* 2023, 57, 11718–11730 | Read Online

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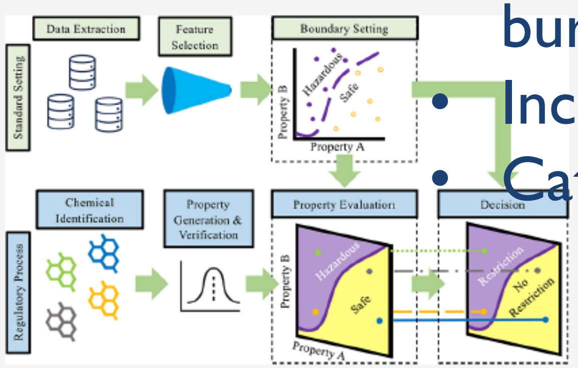
ABSTRACT: An expanding web of adverse impacts on people and the environment has been steadily linked to anthropogenic chemicals and their proliferation. Central to this web are the regulatory structures intended to protect human and environmental health through the control of new molecules. Through chronically insufficient and inefficient action, the current chemical-by-chemical regulatory approach, which considers regulation at the level of chemical identity, has enabled many adverse impacts to develop and persist. Recognizing the link between fundamental physicochemical properties and hazards, we describe a new paradigm—property-based regulation. By regulating physicochemical properties, we show how governments can delineate and enforce safe chemical spaces, increasing the scalability of chemical assessments, reducing the time and resources to regulate a substance, and providing transparency for chemical designers. We highlight sparse existing property-based approaches and demonstrate their applicability using bioaccumulation as an example. Finally, we present a path to implementation in the United States, prescribing roles and steps for government, nongovernmental organizations, and industry to accelerate this transition, to the benefit of all.



KEYWORDS: *Physicochemical properties, chemical regulation, chemical assessment, safe chemical space, molecular design for reduced hazard*

- Accelerating chemical discovery
- Reducing regulatory burden
- Increasing transparency
- Catalyzing innovation

Thank you!

Questions?

Acknowledgments:

- Prof. Paul T. Anastas, Tobias Muellers, MSc
- Prof. Julie Zimmerman, Prof. Adelina Voutchova-Kostal, Prof. Jakub Kostal
- Members of the Center for Green Chemistry and Green Engineering at Yale
- Jenny Stanford Publishing, Ltd.

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IG: **@greenchemistry.yale**

X(Twitter): **@YaleGreenChem**

Facebook: Center for Green Chemistry & Green Engineering

Center for Green Chemistry & Green Engineering at Yale

Advance Science

Catalyze Implementation

Prepare the next generation

Raise Awareness

ENGINEERS
BREADTH·DEPTH·PURPOSE

CHEMICAL PRIORITIZATION UNDER TSCA

December 10, 2024

Sarah Au

U.S. Environmental Protection Agency

Data Gathering, Management and Policy Division | OPPT | OCSPP

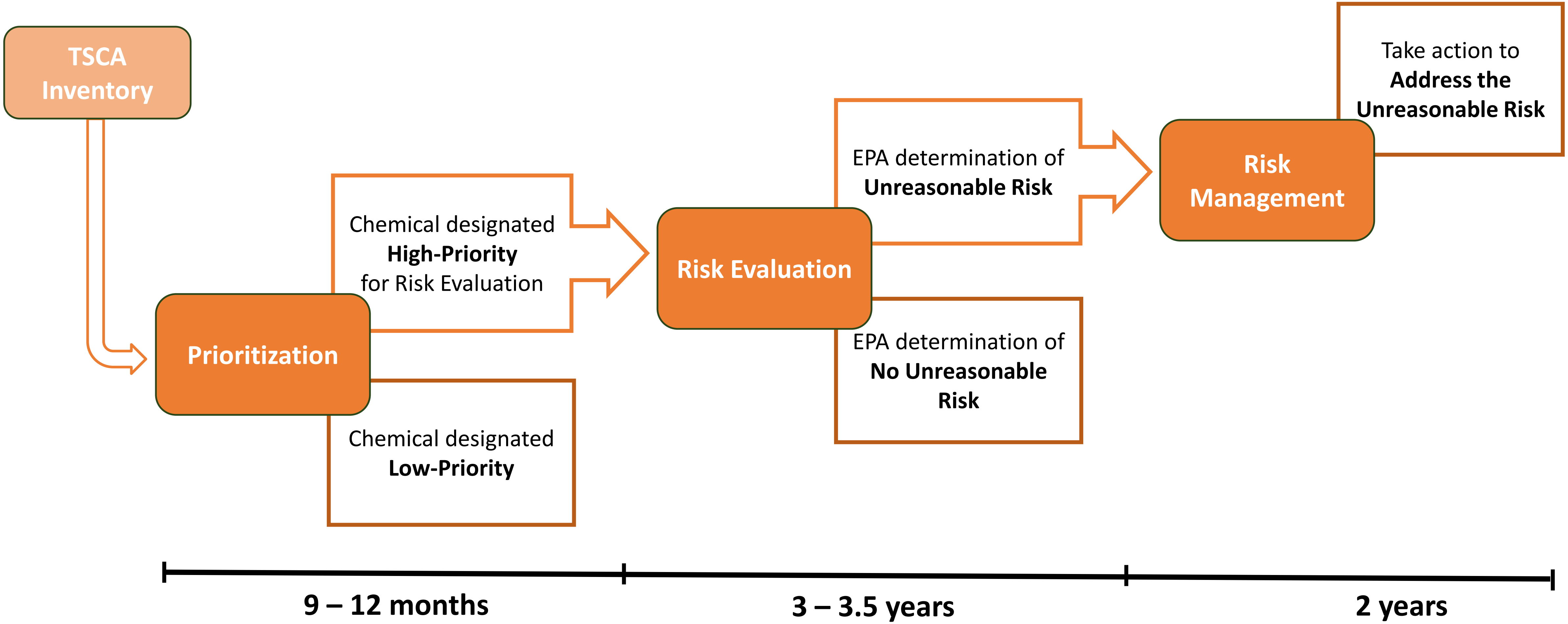
OUTLINE

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

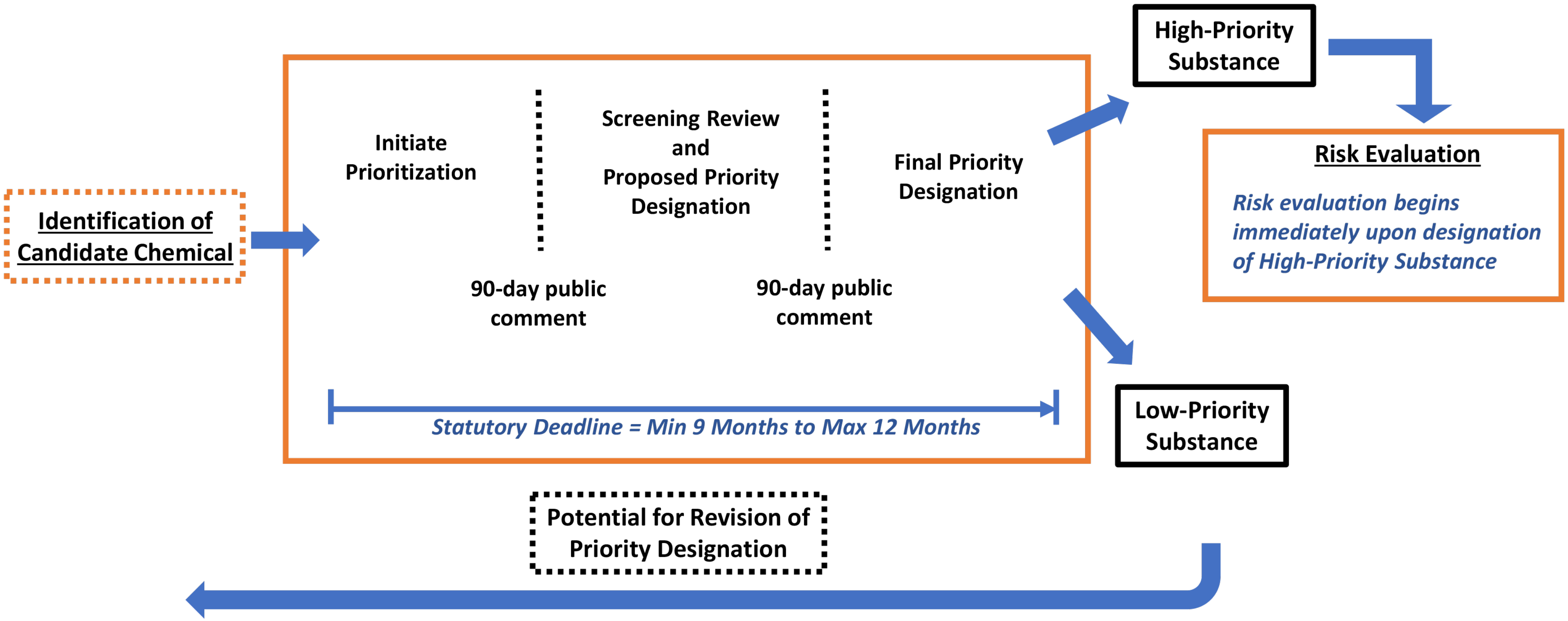
EVALUATING RISKS OF EXISTING CHEMICALS

- 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



Chemical Prioritization Process



CHEMICAL SUBSTANCE DESIGNATION

- Under TSCA, EPA must establish a regulatory 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 considered from the 2014 TSCA Work Plan, EPA prioritized 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

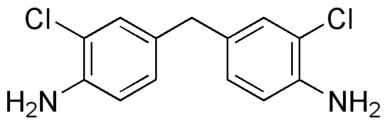
Information Type	Sources of Information
Publicly Available Information	- Peer-Reviewed Literature (ECOTOX Knowledgebase) - Gray Literature Databases, Assessments and Documents (e.g., IRIS assessments, ECHA, NICNAS)
Conditions of Use	- Chemical Data Reporting - Toxics Release Inventory - Work Plan summary document
Production Volume	- Chemical Data Reporting
Environmental Releases and Exposure Data	- Toxics Release Inventory - Water Quality Portal - Discharge Monitoring Reports - National Emissions Inventory - Work Plan summary document
Occupational Exposure	- National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations - NIOSH Toxic Industrial Chemicals (TIC) - Occupational Safety and Health Administration (OSHA)

PROPOSED FOR HIGH-PRIORITY SUBSTANCED DESIGNATION

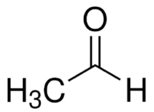
Chemical Name	Existing Assessments	CDR	TRI	HAP	MCL	Hazardous Substance	Hazardous Waste	Carcinogen	Persistent and Bioaccumulative	Environmental Hazard Data	Environmental Exposure Data
4,4'-Methylene bis(2-chloroaniline)	**PPRTV**	✓	✓	✓				✓	✓		✓
Acetaldehyde	**IRIS**	✓	✓	✓		✓	✓	✓		✓	✓
Acrylonitrile	**IRIS, ATSDR**	✓	✓	✓		✓	✓	✓		✓	✓
Benzenamine	**IRIS, PPRTV**	✓	✓	✓		✓	✓	✓		✓	✓
Vinyl chloride	**IRIS, ATSDR**	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Potential Uses

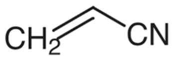
- **4,4'-Methylene bis(2-chloroaniline):** CASRN 101-14-4
  - Manufacturing and processing of chemicals (e.g., rubber, plastics, resins)



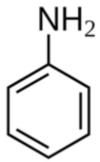
- **Acetaldehyde:** CASRN 75-07-0
  - Manufacturing and processing of chemicals (e.g., adhesives, petrochemicals)
  - Intermediates for products (e.g., packaging and construction materials)



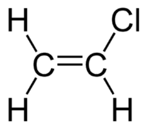
- **Acrylonitrile:** CASRN 107-13-1
  - Manufacturing and processing of chemicals (e.g., plastics, paint, petrochemicals)



- **Benzenamine:** CASRN 62-53-3
  - Manufacturing and processing of chemicals (e.g., dyes, pigments, plastics, petrochemicals)



- **Vinyl Chloride:** CASRN 75-01-4
  - Manufacturing and processing of chemicals (e.g., plastics)



CANDIDATE CHEMICAL SUBSTANCES FOR FUTURE 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	✓	✓	✓		✓	✓		
N-(1,3-Dimethylbutyl)-*N'*-phenyl-*p*-phenylenediamine (6PPD)	793-24-8	DTSC	✓							

Remaining 2014 Work Plan Chemical (grey)   Non-Work Plan Chemical (orange)

INFORMATION TO CHARACTERIZE EXPOSURE

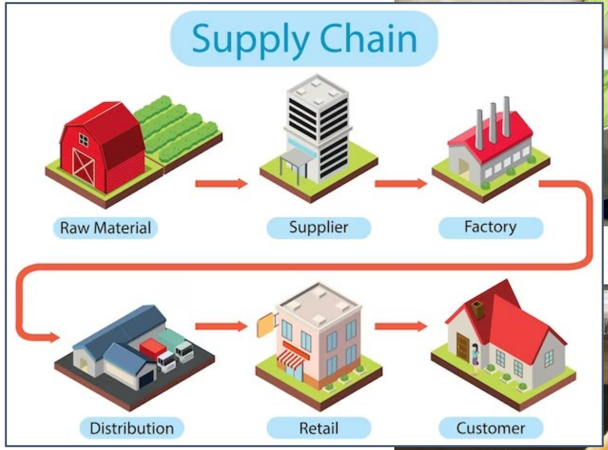
Types of information that could help characterize exposure to communities and potentially associated health effects resulting from exposure:

- 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 chemical candidates for each round of prioritization may change annually (most recently shared in September and October 2024).
- Public comment periods for recent prioritization actions have closed. EPA is reviewing and considering those comments.

FOR YOUR TIME

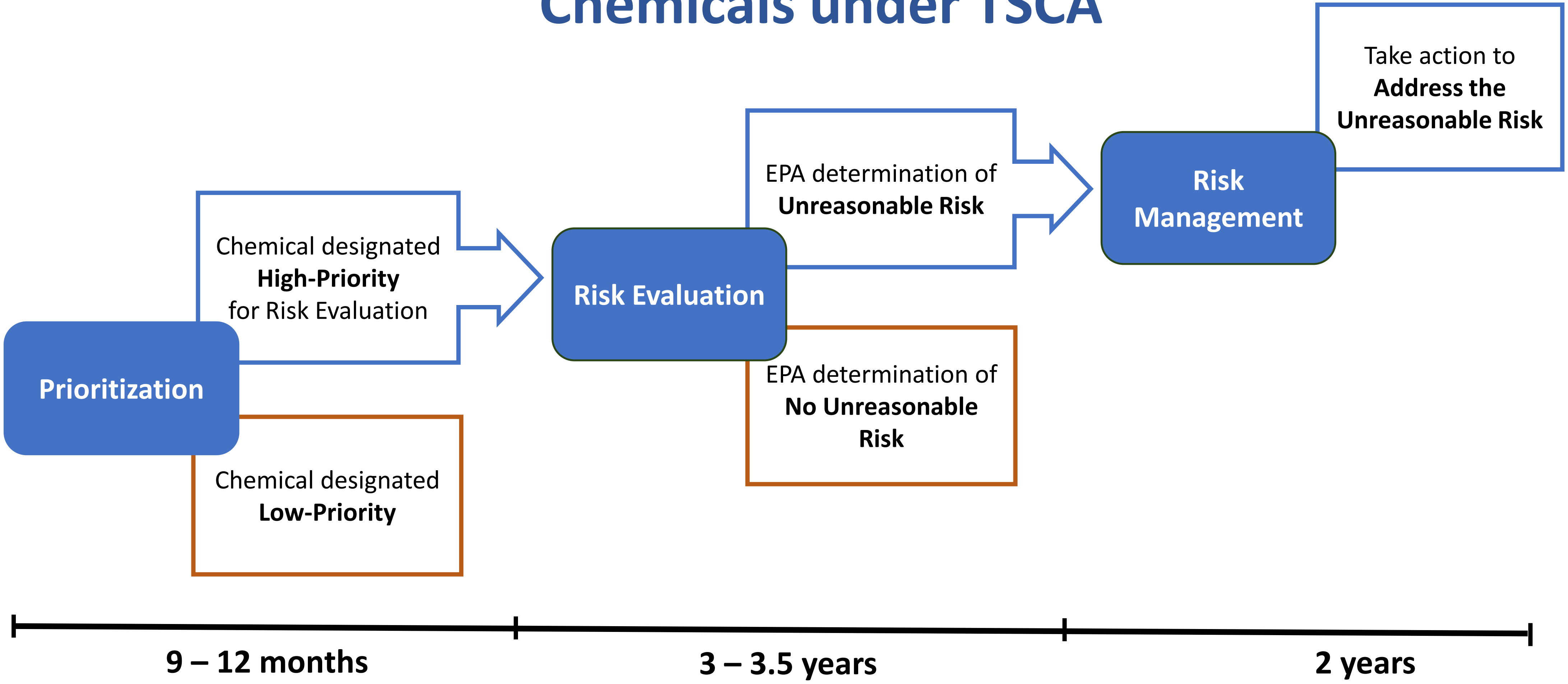
Alternatives and Risk Management of Existing Chemicals under the Toxic Substances Control Act

Joel Wolf, Branch Supervisor
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Agenda

- From Prioritization to Risk Management
- Risk management under TSCA
- Consideration of Alternatives
- Additional Resources

Process to Assessing and Managing Existing Chemicals under TSCA



Risk Management Requirements

- EPA is required to take action, to the extent necessary, to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule within 2 years following risk evaluation to address all identified unreasonable risks:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture (includes import), processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

The section 6(a) menu of regulatory options can be applied alone or in combination.

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

TSCA Section 6(c)(2)(C)

- Consideration of Alternatives
  - Based on the statement of effects, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.
- Information on alternatives will be available in the Economic Analysis and Alternatives Analysis for each chemical in the rulemaking docket

TSCA Section 6(g)

TSCA Section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use.

- To provide an exemption, EPA must find that:
  - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
  - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
  - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
  - Provide a time limit for the exemption
  - Analyze the need for the exemption and make the analysis public

Importance of P2 and Alternatives for Existing Chemicals Under TSCA

- EPA seeks to avoid regrettable substitution situations with TSCA section 6 rules, so it is important to have a robust understanding of alternatives
- As more chemicals are evaluated under TSCA, opportunities for P2 and alternatives research will grow
- Pre-prioritization and prioritization are important times to understand uses and begin to gather information on alternatives
- COUs are fairly well defined by the final scope
- Refinement of COUs, alternatives, feasibility/implementation issues (e.g., measurement, analytic methods) continue from draft risk evaluation, NPRM, and final rule
- Engagement early is key; EPA welcomes input

Stay Informed

- **EPA's TSCA website:**
  - www.epa.gov/chemicals-under-tsca
- **General TSCA:**
  - www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- **Chemicals Undergoing Risk Evaluation under TSCA:**
  - www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca
- **Current Chemical Risk Management Activities:**
  - www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities

2024 National Pollution Prevention Training and Conference

Pollution Prevention for Toxic Chemicals

December 10, 2024
10:45 – 11:45AM ET

Moderated by Jeff Kohn, EPA, Pollution Prevention Grants Branch

Speakers:

- **Edmond Lam, American Chemical Society (ACS)**
- **Predrag Petrovic, Yale Center for Green Science and Green Engineering**
- **Sarah Au, EPA, Data Gathering Management and Policy Division**
- **Joel Wolf, EPA, Existing Chemical Risk Management Division**