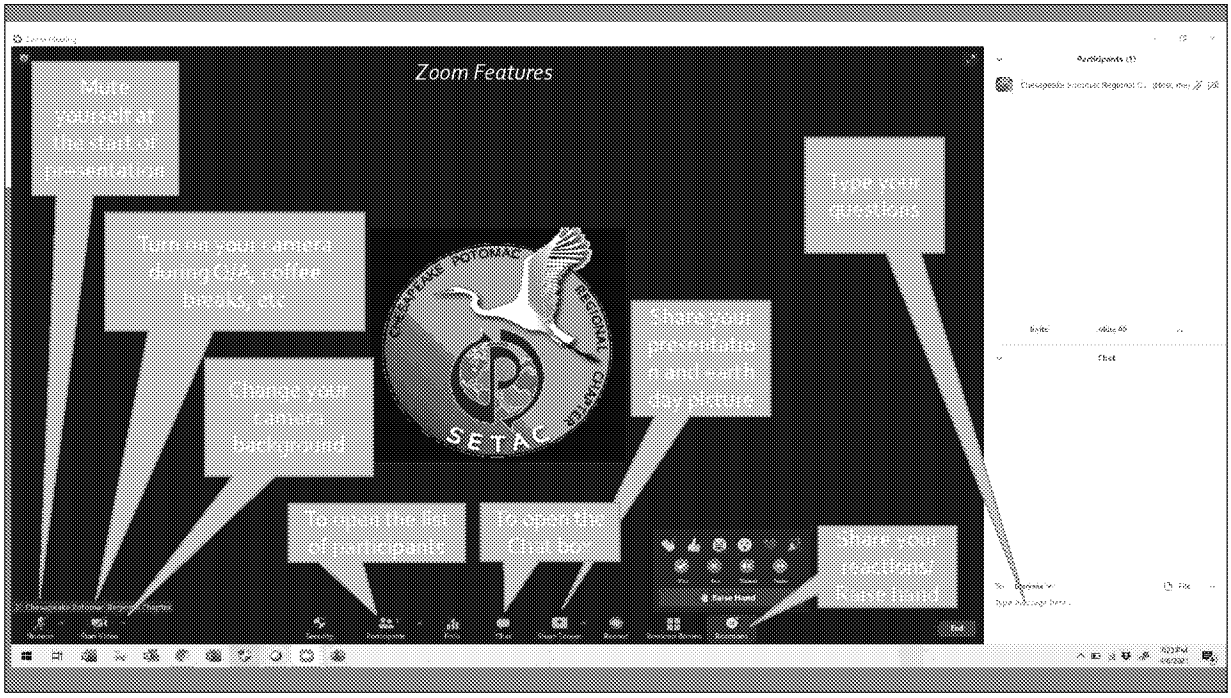
The Chesapeake and Potomac Regional Chapter (CPRC) of the Society of Environmental Toxicology and Chemistry (SETAC)

CPRC-SETAC

THE CHESAPEAKE POTOMAC REGIONAL CHAPTER
OF THE SOCIETY OF ENVIRONMENTAL
TOXICOLOGY AND CHEMISTRY

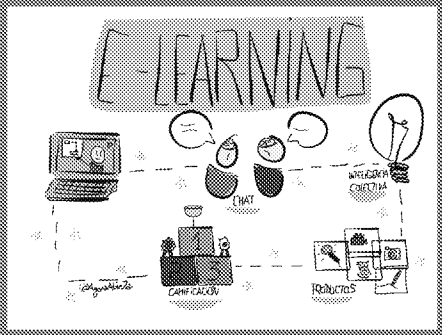
2021 VIRTUAL COURSE

Oct. 28th, 2021 10am-12pm


Zoom Features
Mute yourself at the start of presentation
Turn on your camera during Q/A, coffee breaks, etc
Change your camera background
To open the list of participants
To open the Chat box
Share your presentation and earth day picture
Share your reactions/ Raise hand
Type your questions
SETAC

AGENDA

- 10:00am: Welcome and opening
- 10:10am: Presentation from keynote speaker: Nathan Sell, title: *"TSCA 101 and Expected Changes in a New Administration"*
- 11:00am: Q&A
- 11:20am: Photos of all attendees
- 11:30am: Closing



REMINDER: FUTURE EVENTS!

Check Our Website and stay tuned for upcoming events…

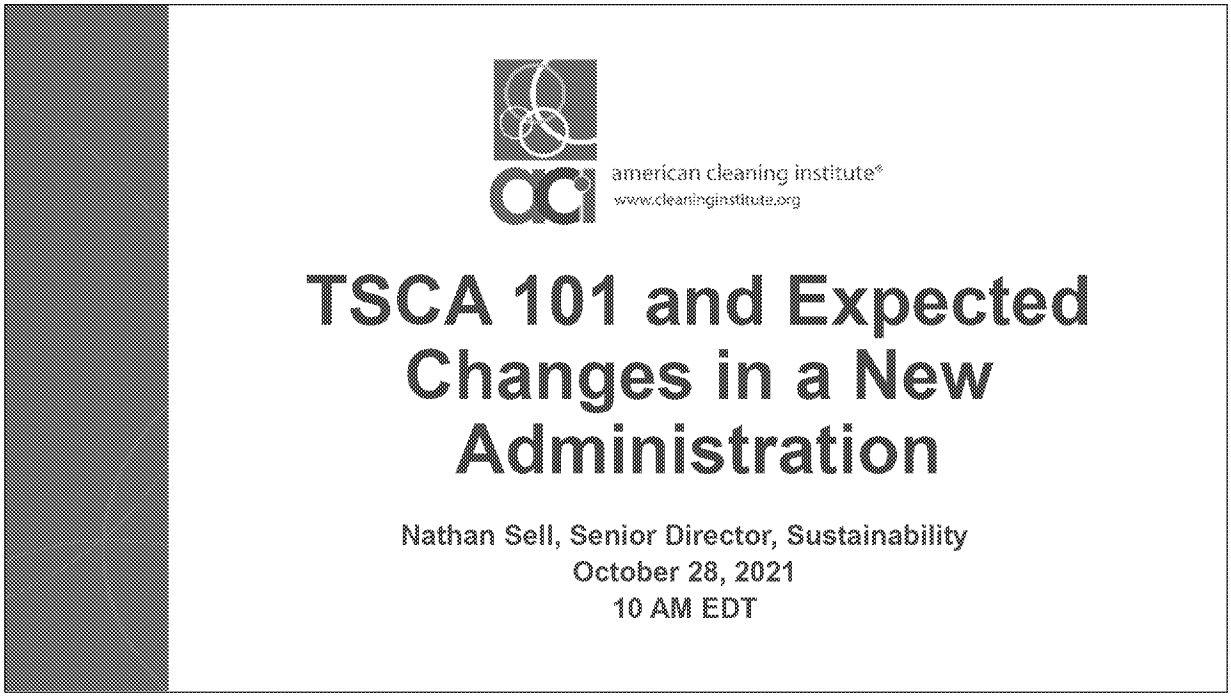
- Happy Hour: Nov, 2021
- Virtual Course: Feb/Mar, 2022
- And more…

NATHAN SELL

Nsell@cleaninginstitute.org

Nathan Sell is the Senior Director of Sustainability at the American Cleaning Institute (ACI), the trade association representing the U.S. cleaning products industry. In this role, Mr. Sell is responsible for the development and management of research strategies related to the safety of cleaning product ingredients and engagement with stakeholders.

Prior to joining ACI, Mr. Sell worked at the U.S. Environmental Protection Agency (EPA), starting in the Office of Water, later transitioning to the Office of Pesticide Programs and finally the Office of Science Coordination and Policy. Mr. Sell holds a Master's in Environmental Studies with a concentration in Environmental Sustainability from the University of Pennsylvania. Mr. Sell also holds a B.S. in Biology from Trinity College (Hartford, CT) where he conducted research on migratory and residential bird species in Connecticut. Mr. Sell was born and raised in the U.S. Virgin Islands, where he first was inspired to pursue a career in the sciences.



Introduce yourself:

Office of water – Climate Change Adaptation and Resilience
Office of Pesticide Programs – Chemical Review Manager (FIFRA)
Office of Science Coordination and Policy (now program support after reorg)
Technical writer on the Science Advisory Committee on Chemicals (SACC)

ACI – May 2020
Director of Regulatory Science
Last month new

Toxic Substances Control Act (TSCA)

- Enacted October 11, 1976
- Enforced by EPA
- Not significantly amended until 2016

Before we being: Happy to answer questions throughout.
High Level
Hoping to make the general processes under TSCA make sense rather than go into fine detail

Provides EPA with the authority to
require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures.

Certain substances are generally excluded. GENERALLY: Food, Drugs and Cosmetics (under FDA's authority). Pesticides (under EPA's OPP)

40 years unaltered – clearly needed updating and to give regulatory teeth to EPA

What is covered under TSCA

- Chemical substances and/or mixtures (“Toxic” is misleading)
- Excludes:
  - Food, Drugs, Cosmetics – Regulated under FDCA by FDA
  - Pesticides – Regulated under FIFRA by EPA

This is a HUGE all encompassing act
“Catch All”

Certain substances are generally excluded.
GENERALLY: Food, Drugs and Cosmetics (under FDA’s authority).
Pesticides (under EPA’s OPP)

Explain what is a pesticide

EPA Structure (Headquarters)

- Office of the Administrator
- Office of Chemical Safety and Pollution Prevention (TSCA and FIFRA)
- Office of Land and Emergency Management (Superfund)
- Office of Air and Radiation (Clean Air Act)
- Office of Water (Clean Water Act)
- Office of Enforcement and Compliance Assurance
- Office of Research and Development
- Office of International and Tribal Affairs
- Office of Mission Support
- Office of Inspector General
- Office of General Counsel

Administrator Michael Regan

Most major AA ships (Assistant Administratorships) are covered by a statute

OCSPP Structure

- Office of Pesticide Programs (OPP) (FIFRA)
  - Antimicrobials Division
  - Biological and Economic Analysis Division
  - Biopesticide and Pollution Prevention
  - Health Effects Division
  - Pesticide Re-Evaluation Division
  - Registration Division
- Office of Program Support
- Office of Pollution Prevention and Toxics (OPPT) (TSCA)

When developing a risk analysis structure for OPPT, the agency looked at OPP

Program support serves as a catch all for other functions
-EJ for chemicals
-IT
-Peer Review
-Liaison between the offices

OCSPP Structure (Continued)

- Office of Pollution Prevention and Toxics (OPPT) (TSCA)
- Reorganized in 2020
  - Data Gathering and Analysis Division
  - Existing Chemicals Risk Assessment Division
  - Existing Chemicals Risk Management Division
  - New Chemicals Division
  - Project Management and Operations Division

Describe each function and how it is within TSCA

Important because it shows the two main routes (existing vs new) and where the bulk of the work is

Why is TSCA important?

- Potential for civil monetary (and criminal) penalties
- Requires advance planning
- Non-compliance can require immediate stoppage of production and quarantine of stocks
- Compliance promotes good business relations and enhances industry reputation

Why TSCA?

- Regulate chemicals that pose an “unreasonable risk” or harm to human health and the environment
- Fill gaps left by other federal regulatory schemes

Who does TSCA Impact?

- Manufacturers
- Importers
- Processors
- Distributors
- Users
- Exporters

Principal Sections of TSCA

- Section 3 – Definitions
- Section 4 – Test Rules and Orders
- Section 5 – Premanufacture Notification (PMN)
- Section 6 – Unreasonable Risk Regulation
- Section 8 – Recordkeeping and Reporting
- Section 12 – Exports
- Section 13 – Imports
- Section 14 – Confidentiality
- Section 15 and 16 – Penalties
- Section 18 – Preemption of State Laws

Record keeping and recording – "inventory"
Recorded approximate amounts through the processes that companies must comply with

Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Passed on June 22, 2016
- Passed with Bipartisan support
- Amendments:
  - Require EPA to evaluate existing chemicals with clear and enforceable deadlines
  - Risk-based chemical assessments
  - Increased public transparency for chemical information
  - Source of funding for EPA to carry out the responsibilities under the new law

Testing (Section 4)

- EPA can require manufacturers, importers and processors to test
  - Has yet to be utilized much
- Threshold:
  - EPA determines it is “necessary” for typical TSCA purposes
  - Requested by another federal agency to meet regulatory needs
- EPA must generally “tier” testing, and reduce vertebrate testing to the extent practicable

Who pays?

EPA charges for Risk evaluations both industry initiated and EPA initiated

Inhalation
Contact
Irritation
Cancer

Environment
plants, invertebrates, vertebrates

PMN and SNUR Process

- *PMN – Pre-manufacture Notice*
- *SNUR – Significant New Use Rule*

- Procedures for EPA to review prior to bringing new chemicals to the market
  - EPA must make an affirmative determination for chemical
  - Must consider PESS (potentially exposed and susceptible subpopulations)

PMN – submit 90 days before commencing substance or activity
EPA must review notice and make affirmative decision for chemical
Conditions of use – consider PESS

If EPA has concerns will issue 5 EF

TSCA Inventory

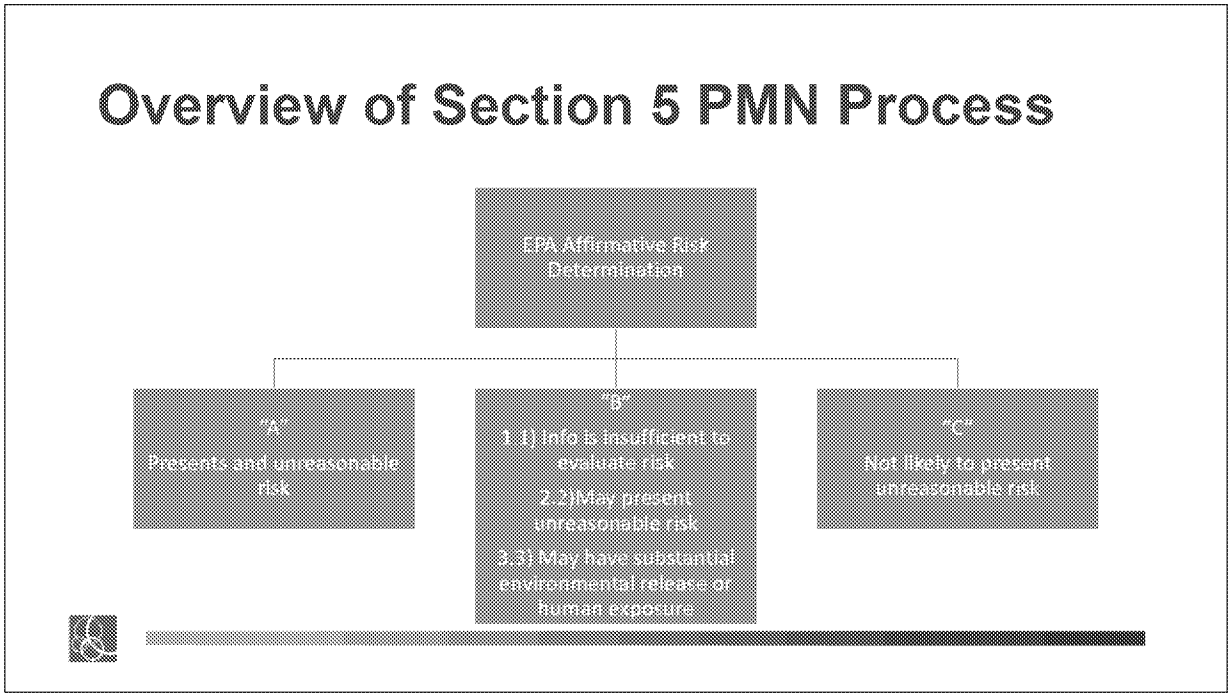
- Once on the TSCA inventory a chemical can be produced and sold
  - A new use (not currently a condition of use) requires a SNUR
  - Production of a new chemical requires a PMN
  - Over 86,000 chemicals currently on the inventory

Ideally if it is on the inventory it's risk and uses are understood
HOWEVER new TSCA is requiring prioritization and risk evaluations to better understand use and risk

Exceptions Exist

- Export Only
- R&D purposes
- Naturally Occurring
- Mixtures
- Others

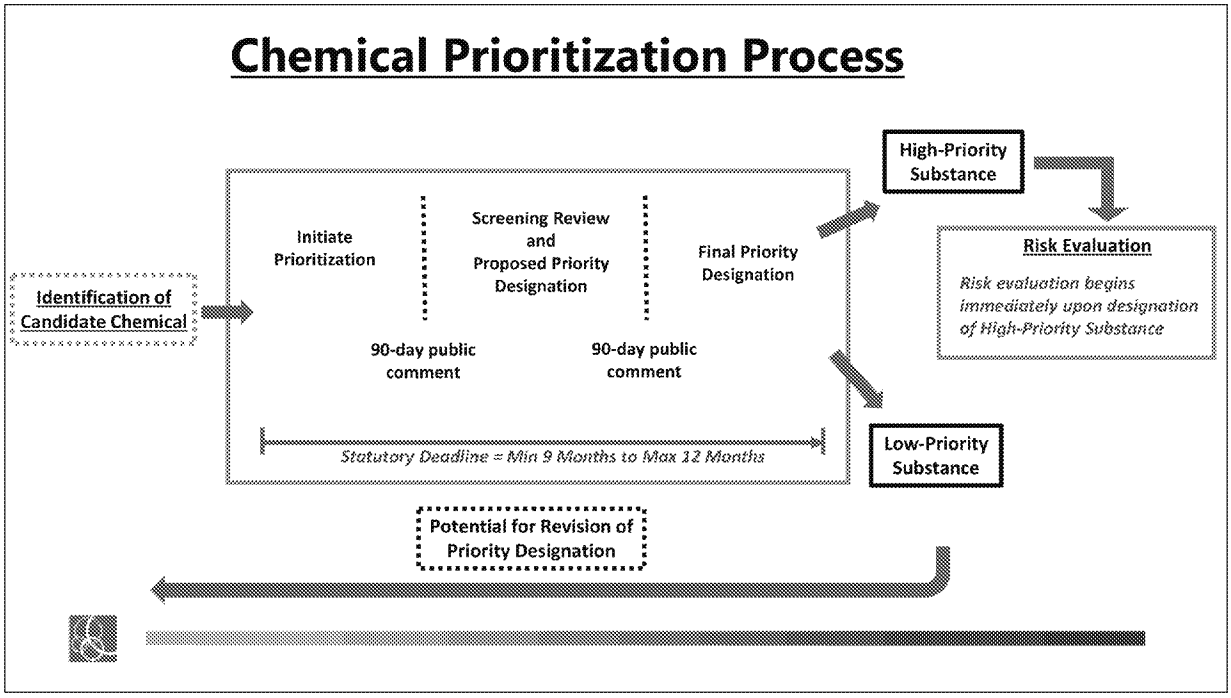
Naturally occurring – must be unprocessed (only processed manually, gravitational means, dissolving or removing water)
Mixture is exempt but individual components are not
Impurities – covers unintentionally present substances
Byproducts
Non-isolated intermediates
Incidental reactions
Test marketing
Low volume exemptions (under 10,000kg.year



A- Must Act – must control and mitigate identified risks to move forward
B – extent necessary mitigate risk
C- submitter may start manufacture – determination published and subject to judicial review

Existing Chemicals

- Regulate existing chemicals (those on the TSCA inventory)
- Amendments:
  - Most impacted by the amendments
  - Risk evaluation mandate for existing chemicals
    - Prioritization Screening
      - High Priority vs Low Priority
    - Risk Evaluation for high priority chemicals
    - Risk Management



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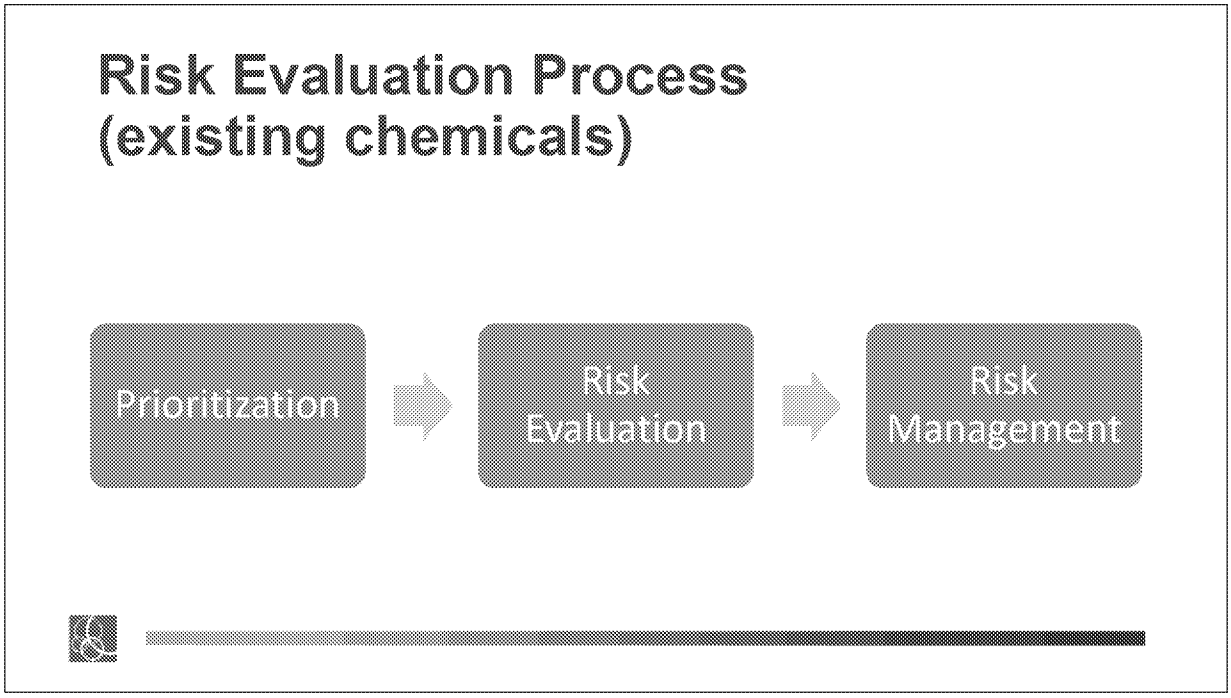

Modelled off of OPP's risk assessment program

Tools available: EFAST, utilize Human health hazard and environmental hazards

What does risk management look like?
PPE
Discontinue certain COUs
Limit production
Limit use sites

Types of Data and why it may be hard to call in?/ From whom?

10 High (pilot) Priority Chemicals

- Asbestos
- 1-Bromopropane
- Carbon Tetrachloride
- Pigment Violet 29 (PV29)
- Cyclic Aliphatic Bromide Cluster (HBCD)
- 1,4 Dioxane
- Methylene Chrloide
- N-Methylpyrrolidone
- Perchloroethylene
- Trichlorethylene (TCE)

Science Advisory Committee on Chemicals (SACC)

- EPA's Peer Review Committee for TSCA
- Made up of academics, industry and other gov officials
  - Review EPA's risk evaluations

20 High and Low Priority Substances

- For the next round of Risk Evaluations EPA identified 20 that required risk evaluation and 20 for which a risk evaluation is not warranted at this time
- Added 30 Organohalogen flame retardants
- Likely going forward there will only be High Priority chemicals named
- As the first 10 RE are honed, they will inform the process for these 20

TSCA under the Trump Administration

- Staffing
  - Assistant Administrator of OCSPP
- Implementation
  - First attempt under Amended TSCA
  - Only considered COUs
  - Strict on statutory deadlines

Alexandra Dunn

Dunn – previously region 1 administrator and served in several professorial positions including at Pace University and Catholic University

Chronically understaffed

Reorganized to prioritize various aspects of the TSCA evaluations

TSCA Under the Biden Administration

- Staffing
  - Assistant Administrator of OCSPP
- Revising many of the existing REs
- Revisiting the intent of TSCA
  - New focus on EJ and PESS
- Exploring a “whole chemical” approach

Dr. Michal Freedhoff

Freedhoff – previously minority director of oversight for Senate Environment and Public Works committee (began her congressional service in 1996 after receiving a PhD in physical chemistry

Will likely exercise the ability to call in data

Explore Climate

Safer Choice

Design for Environment

Expanding employees

1,4 Dioxane

Questions?

PHOTOS OF ALL ATTENDEES