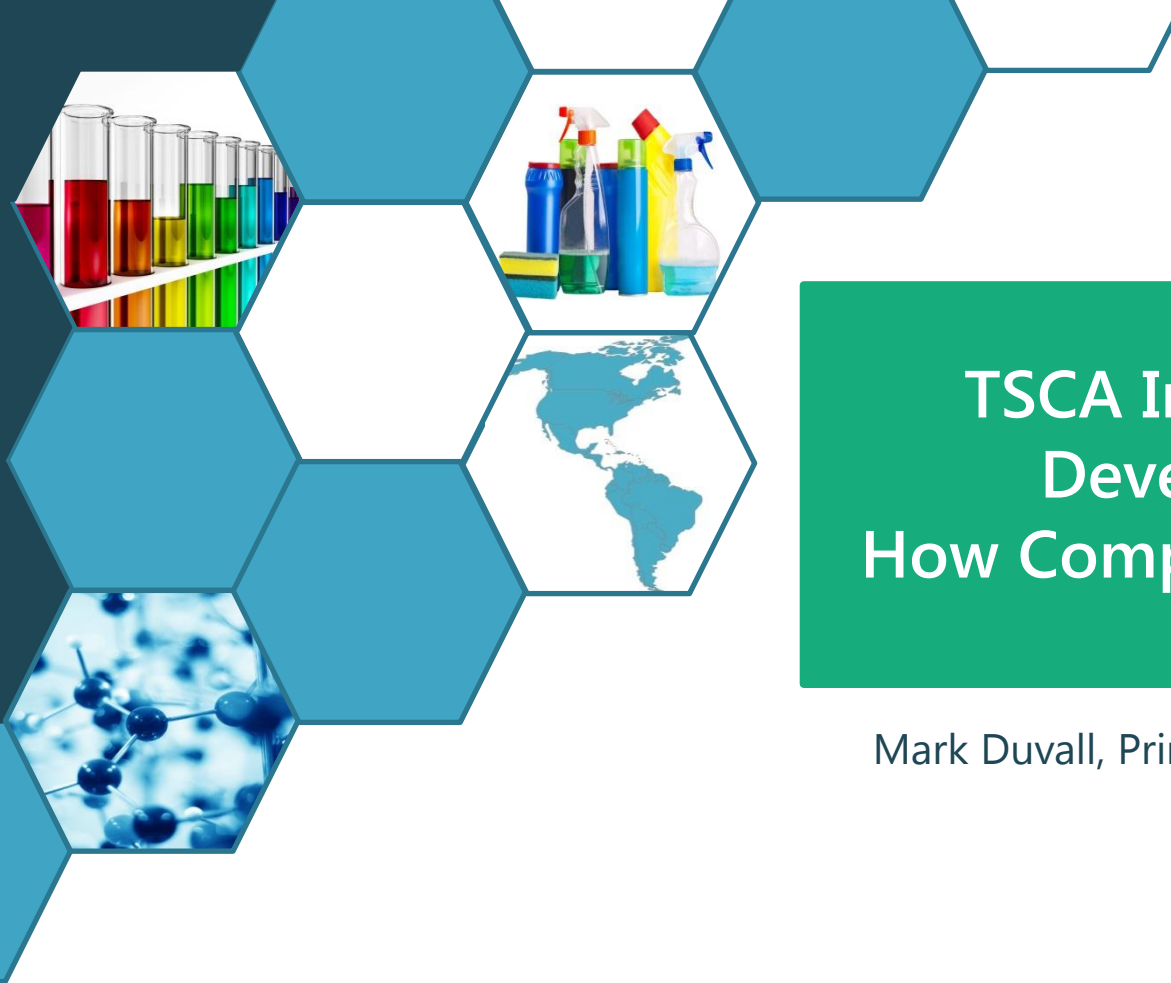




# Chemicals in the Americas

November 30, 2017  
The Houston Club, Houston TX

[www.bdlaw.com/2017ChemicalsConference](http://www.bdlaw.com/2017ChemicalsConference)



# TSCA Implementation Developments & How Companies Can Engage

Mark Duvall, Principal, Beveridge & Diamond

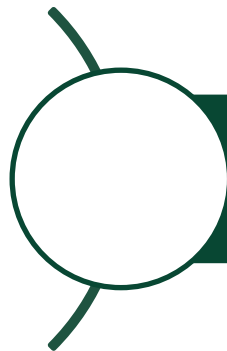
# Overview

Why should you care?

Major changes to TSCA

TSCA implementation

How companies can engage



Why should you care?

# Two big reasons

COMPLIANCE: If your company manufactures or processes chemicals, you may have TSCA regulatory obligations

- React chemicals? – Manufacturer
- Import chemicals? – Manufacturer
- Formulate mixtures? – Processor
- End user who recycles wastes – Manufacturer?

ABILITY TO DO BUSINESS: EPA is working to restrict or ban chemicals or certain uses of chemicals

- If your company depends on chemicals, that reliance may be in jeopardy
- Possible impact on tort suits

# Manufacturing

The term  
“manufacture”  
means to import  
into the customs  
territory of the  
United States,  
produce, or  
manufacture



If you import a  
chemical, you  
“manufacture”  
that chemical for  
TSCA purposes

If you react A +  
B to make C,  
you “process” A  
and B and you  
“manufacture” C

# Processing

If you mix D + E,  
then sell the  
mixture, you  
process D and E

If you incorporate F  
into an article, then  
sell the article, you  
process F

# Manufacturers and processors have TSCA obligations

Any chemical being manufactured (including imported) must be on the TSCA Inventory or be exempt

- PMN needed to add new chemical to the Inventory\*

Significant new use rules\*

Testing\*

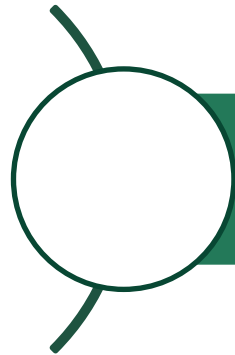
Risk management\*

Reporting, including for imports, some exports, CDR, Inventory reset\*

Protection of CBI\*

\* Affected by TSCA reform





# Major changes to TSCA

# TSCA history – in a nutshell

- October 11, 1976 – TSCA, Public Law 94-469  
- *Corrosion Proof Fittings v. EPA* (5<sup>th</sup> Cir. 1991)

25 YEARS AFTER THAT COURT DECISION

- June 22, 2016 – The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, Public Law 114-182, signed into law  
- Effective immediately, started clock on implementation

# Major changes to TSCA by LCSA

## Unreasonable risk

- Assessed on the basis of conditions of use, but without regard to cost or other non-risk factors

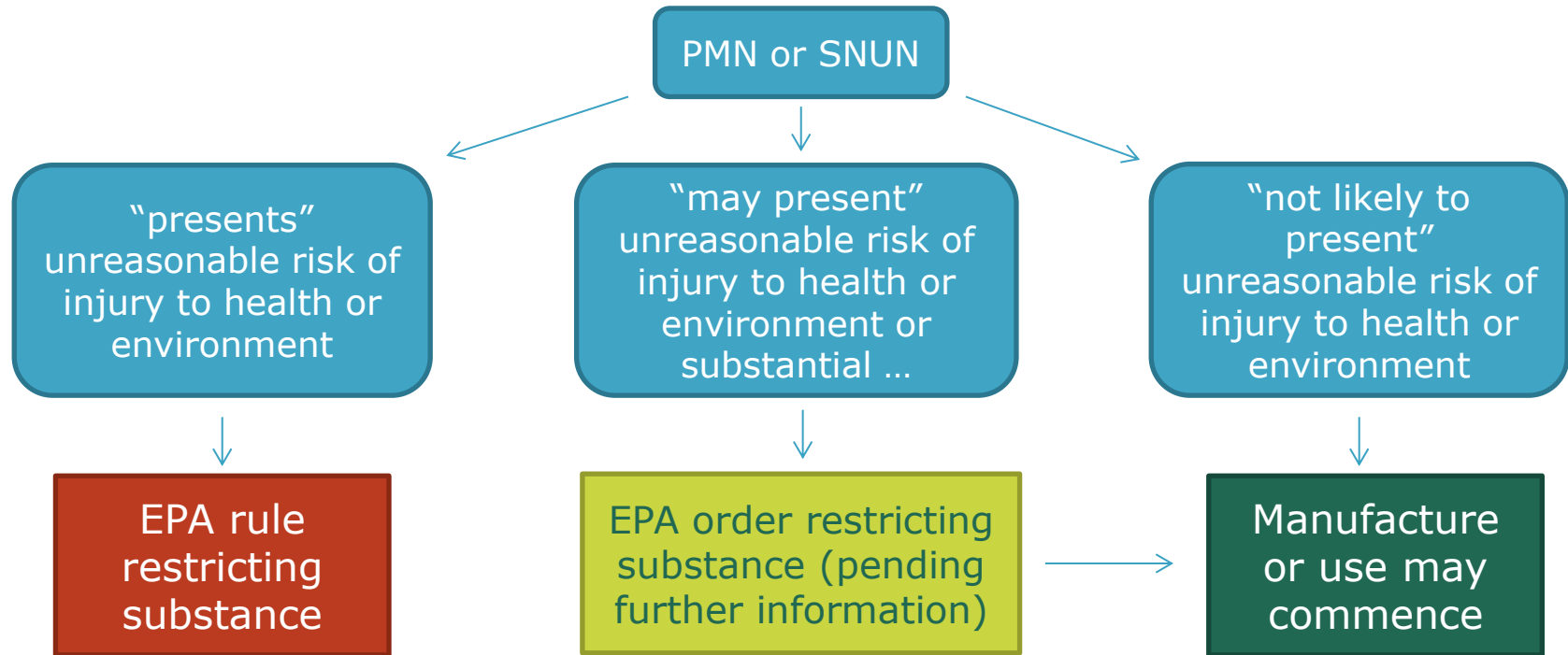
## Section 4 - testing

- EPA can require testing by order (or by rule)

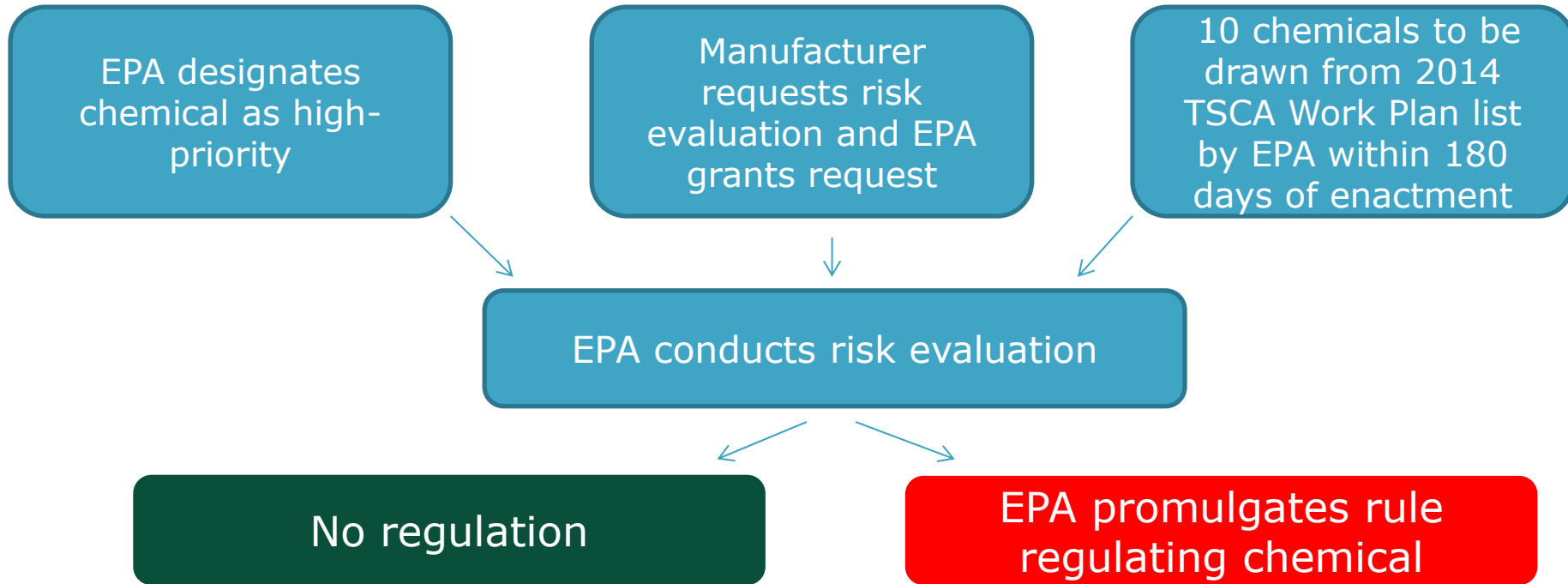
## Section 5 – new chemicals + SNURs

- Affirmative EPA findings for PMNs and SNUNs

# Section 5 – new chemicals



# Section 6 - process



# Other major changes

## Section 8

- Inventory reset

## Section 14

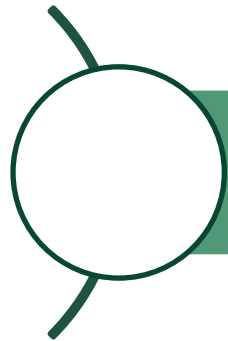
- CBI substantiation, 10-year limit

## Section 18

- Preemption

## Section 26

- Fees
- Science standards



# TSCA Implementation

# Trump Administration

## TSCA will continue to be implemented

- Scott Pruitt supports TSCA implementation
- TSCA reform recently passed, had overwhelming bipartisan support
- Statutory deadlines
  - If missed, NGO lawsuits

## EPA budget to be slashed 25%?

- Fees can make up 25% of TSCA budget
- TSCA gets a budget increase of \$13.8 million

Meanwhile, staff keeps on chugging



# Section 5 – new chemicals

## PMNs – much closer scrutiny

- Massive backlog now “under control”
- Much longer review periods
- Much more likely to be restricted

## Significant new use rules

- Many more SNURs expected
- Most companies either avoid significant new uses or avoid SNUR chemicals altogether

# Section 6 – existing chemicals

## Proposed rules for 3 chemicals

- Final risk management rules: 2018

## Designated 10 chemicals/categories for risk evaluations

- Risk evaluations underway
- Final risk management rules: 2021

## Designated 7 chemicals/categories as PBTs

- Use and exposure assessments begun
- Final risk management rules: 2020

## Accepted 2 chemicals for risk evaluations

- Projected completion: 2021

# Chemicals already designated

## First 10

- 1,4-Dioxane
- 1-Bromopropane
- Asbestos\*
- Carbon tetrachloride
- Cyclic aliphatic bromide FR cluster\*
- Methylene chloride\*\*
- N-methylpyrrolidone\*\*
- Pigment Violet 29
- Trichloroethylene\*\*
- Tetrachloroethylene

\* = category

\*\* = proposed rules

## PBTs

- Decabromodiphenyl ethers (decaBDE)
- Hexachlorobutadiene
- Pentachlorothiophenol
- Phenol, isopropylated, phosphate (3:1)\*
- 2,4,6-Tris(tert-butyl) phenol

\* = category

## Manufacturer requests

- Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,5,5-tetramethyl-2-naphthalenyl)-, CAS No. 54464-59-4
- Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-, CAS No. 55464-57-2

# More to come

By March 2019,  
EPA must tentatively  
identify 40  
chemicals or  
categories

20 candidates  
for high-priority  
designation

20 candidates  
for low-priority  
designation

By December  
2019, EPA must  
confirm 40  
chemicals or  
categories

Begin risk  
evaluations for  
20 high-priority  
substances

Designate 20  
low-priority  
substances

EPA could act  
earlier

Pre-  
prioritization  
is already  
underway

# Section 8(b) – Inventory reset

## Aim

- Identify active chemicals on Inventory

## Who and when?

- Manufacturers **MUST** report by February 7, 2018
- Processors **MAY** report by October 5, 2018

## What?

- Chemicals manufactured (or processed) June 21, 2006 through June 21, 2016
- But not those already designated as active

# Section 8(b) – Inventory reset

## How?

- Electronically, via CDX
- If chemical identity is unknown, ask supplier to join company in a joint submission

## What if a chemical is not reported?

- After about January 2019, no one may manufacture, import, or process that chemical, even though on the Inventory
- Without first submitting notice to EPA of intent to manufacture or process

# Section 14 – CBI

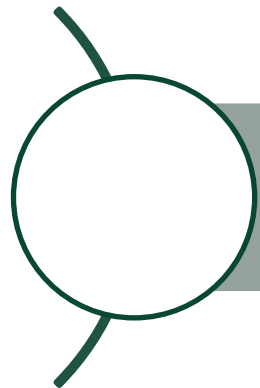
Claims limited to 10 years, renewable

Much stricter substantiation requirements

- No substantiation, no CBI protection
  - Except for certain categories of information
  - Unless FOIA request submitted

CBI for chemical identities

- Structurally descriptive generic name
- Unique identifier
- Not readily discoverable by reverse engineering
- EPA must review 100% of claims



# How companies can engage



# Section 8 – Inventory reset

Be working now to complete manufacturer submissions by February 7, 2018

Joint submissions very challenging

Respond to customer requests for assurance

Processor reporting – probably wait until after additional active substances identified

Consider requesting disclosure under confidentiality agreement instead

Consider asking suppliers for confirmation

# Participate – EPA's not done yet

## Public meetings

- December 6, 2017 – PMN process
- December 11, 2017 – Pre-prioritization process

## Rulemaking proposals

- Fees
- Pre-prioritization

## Comments on prioritization candidates

## Use and exposure information on PBTs, other chemicals

## Hazard information

# Section 5 – increased scrutiny

Anticipate the  
EPA hazard  
concerns

Consider testing  
on hazard  
concerns

Ensure exposure  
is limited

Limit recycle  
time

Fight for EPA  
staff attention

# Section 6 – prioritization

Critical decision – when will EPA address chemicals important to your company?

- > 20,000 to assess – EPA must be selective

Prepare to defend your important chemicals

- Identify them
- Review 2014 TSCA Work Plan Update list
- Consider actions by ECHA, Canada
- Assess database adequacy, especially for exposure
- Consider new studies, especially for exposure
- Monitor EPA interest in your chemicals
- Consider pushing information to EPA

# Section 6 – risk evaluation

Comment on the scope

Ensure that EPA has the data it needs to determine that your chemical does not present an unreasonable risk under the conditions of use

Distinguish your conditions of use from others that arguably present an unreasonable risk

REACH studies?

Early data submission

Submit your own risk evaluation

# Section 6 – risk management

- Get comments to EPA early
- Limit rule to scope of risk determination
- Costs, benefits, alternatives now relevant
- Different remedies for different conditions of use?
- Application to chemicals in articles?

# Section 14 – CBI substantiation

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Templates for substantiation on EPA website

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Some items exempt from routine substantiation under section 14(c)(2)

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Avoid boilerplate – be specific

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Scrutinize potential CBI claims and eliminate those not necessary

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Keep track of CBI claims for reassertion in 10 years

# Audit Policy

## When you find non-compliance

- Stop it immediately if ongoing
- Chemicals not on Inventory – quarantine
- Consider notification under Audit Policy
  - 9 criteria
  - Including notification within 21 calendar days

## Audit Policy now electronic

- Consult eDisclosure guidance
- Meet reporting deadlines



# Summary



It's a new world

EPA has a LOT more authority

EPA is exercising that authority

There are multiple opportunities for stakeholder involvement – and potential rewards for involvement

# Questions?



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