The New TSCA and Its Implications

American Industrial Hygiene Association

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April 19, 2017

BEVERIDGE & DIAMOND PC

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BEVERIDGE & DIAMOND PC

BIOVIA

BIOVIA Mission
Driving Innovation …

HT

T&M

A&D

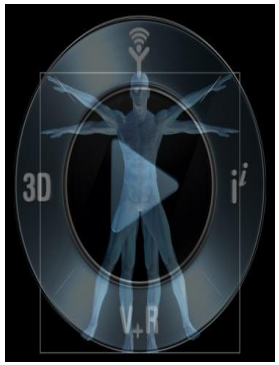
EPU

CPG

Life Sciences

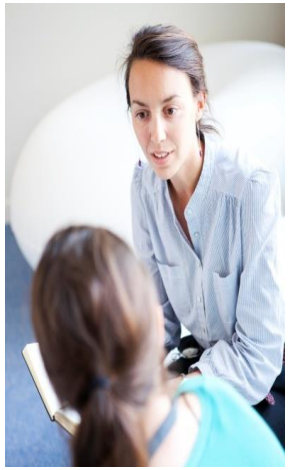
… with Science

BIOVIA / Dassault Systemes: Our Company



a **Scientific** company

Combining **Science, Technology** and **Art** for a sustainable society



14,000 passionate people

- 108 nationalities
- One global R&D / 43 labs
- Game changing **3D**EXPERIENCE solutions

190,000 enterprise customers

- 12 industries in 140 countries
- >10 million on premise users
- >100 million online users

3,500 partners

- Research & Education
- Software & Technology
- Sales & Services

Long-term driven

- Majority shareholder control

** Non-IFRS*

BIOVIA Portfolio for Scientific Product Lifecycle

LIFE SCIENCES

CONSUMER PACKAGED GOODS

ENERGY, PROCESS & UTILITIES

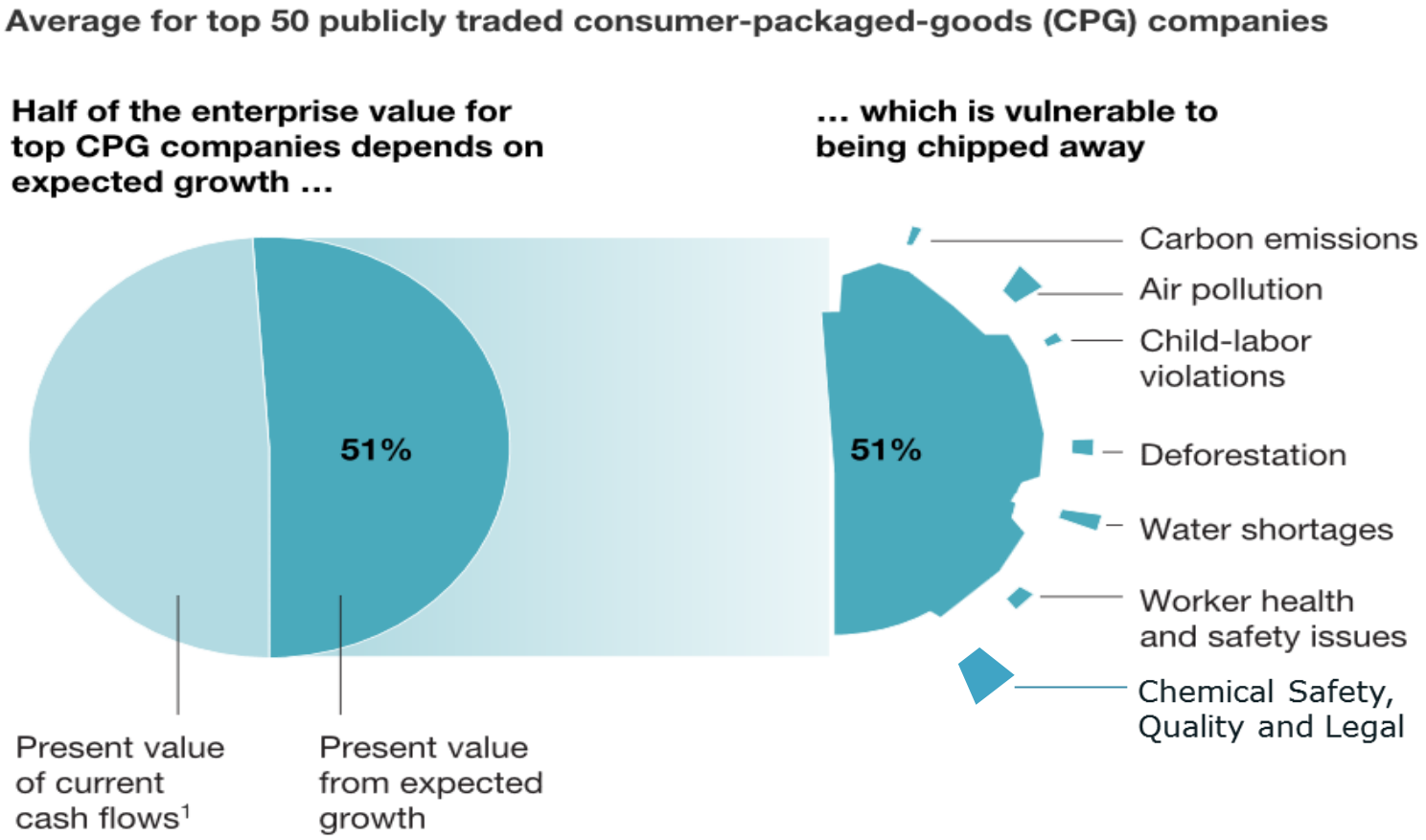
INDUSTRIAL

FOUNDATIONAL CAPABILITIES

- COLLABORATIVE SCIENCE
- UNIFIED LAB MANAGEMENT
- PROCESS PRODUCTION OPERATIONS
- QUALITY & REGULATORY MANAGEMENT

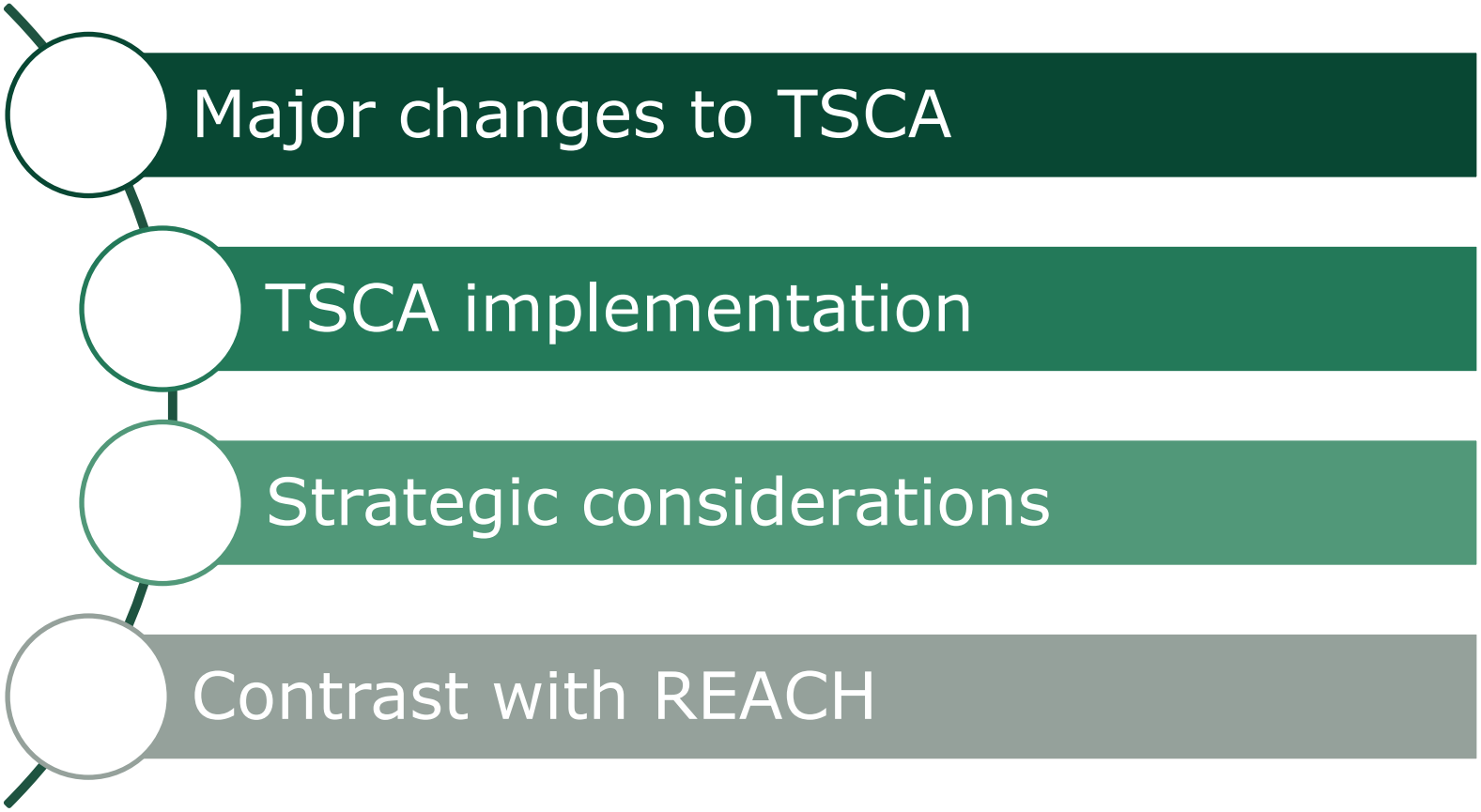
Old	New-product introduction	New
	Relying on expensive trials to introduce new products and having no knowledge of potential impact	Modeling impact and associated costs of new products across the supply chain, reducing the need for trials 
Data scientists		
	Using data to understand how failures or losses occurred	Putting data at the core of the decision-making process and using it proactively to improve performance, prevent future losses, and optimize systems 
Operators		
	Working with technology behind guards and requesting expert support when issues arise	Interacting directly with technology and handling problems independently 
	Conducting routine inspections and fixing breakdowns	Receiving information generated by equipment about potential problems and taking action to prevent breakdowns 

Average For the Top 50 Consumer Goods Companies



BIOVIA Provides 20+ Years Experience in Delivering Knowledge Management

Overview


Major changes to TSCA
TSCA implementation
Strategic considerations
Contrast with REACH

TSCA History – In a Nutshell

October 11, 1976 – TSCA, Public Law 94-469, signed into Law

- *Corrosion Proof Fittings v. EPA* (5th Cir. 1991)

25 years later…

June 22, 2016 – The Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114-182, signed into law

- Effective immediately, started clock on implementation

Major Changes to TSCA

Major Changes

Unreasonable risk

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

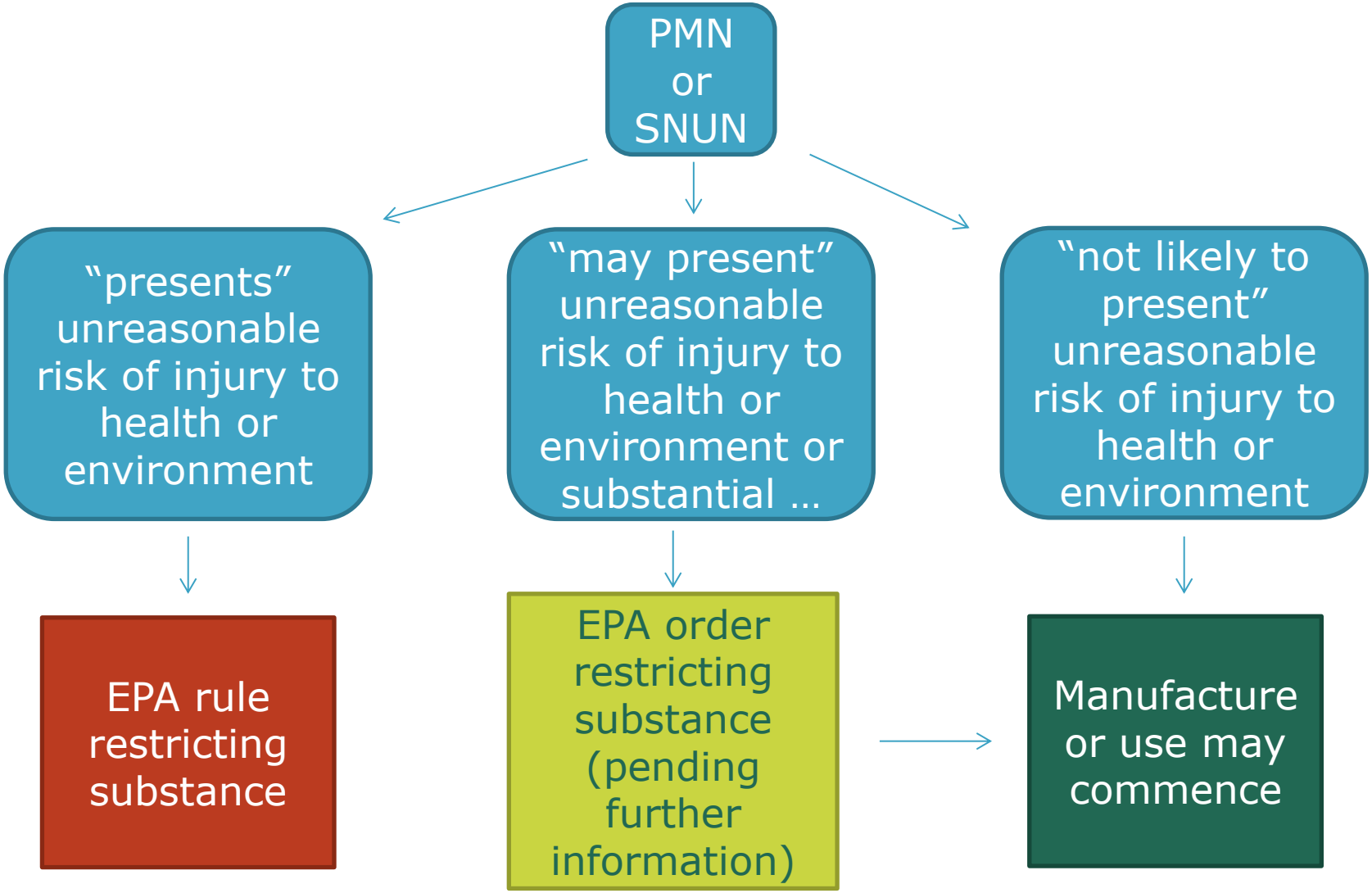
Section 4 - testing

- EPA can require testing by order or by rule

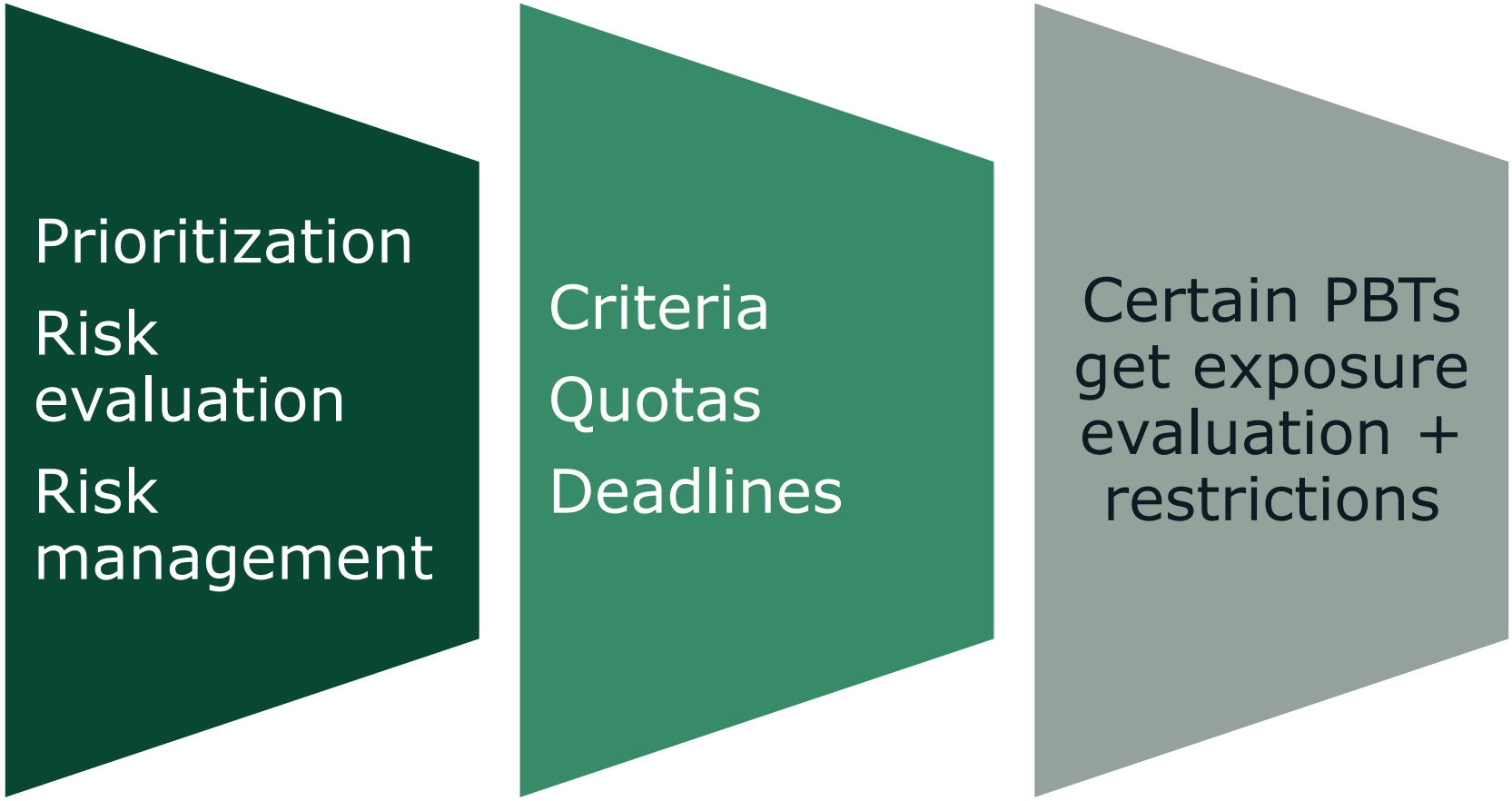
Section 5 – new chemicals + SNURs

- Affirmative EPA findings for PMNs and SNUNs

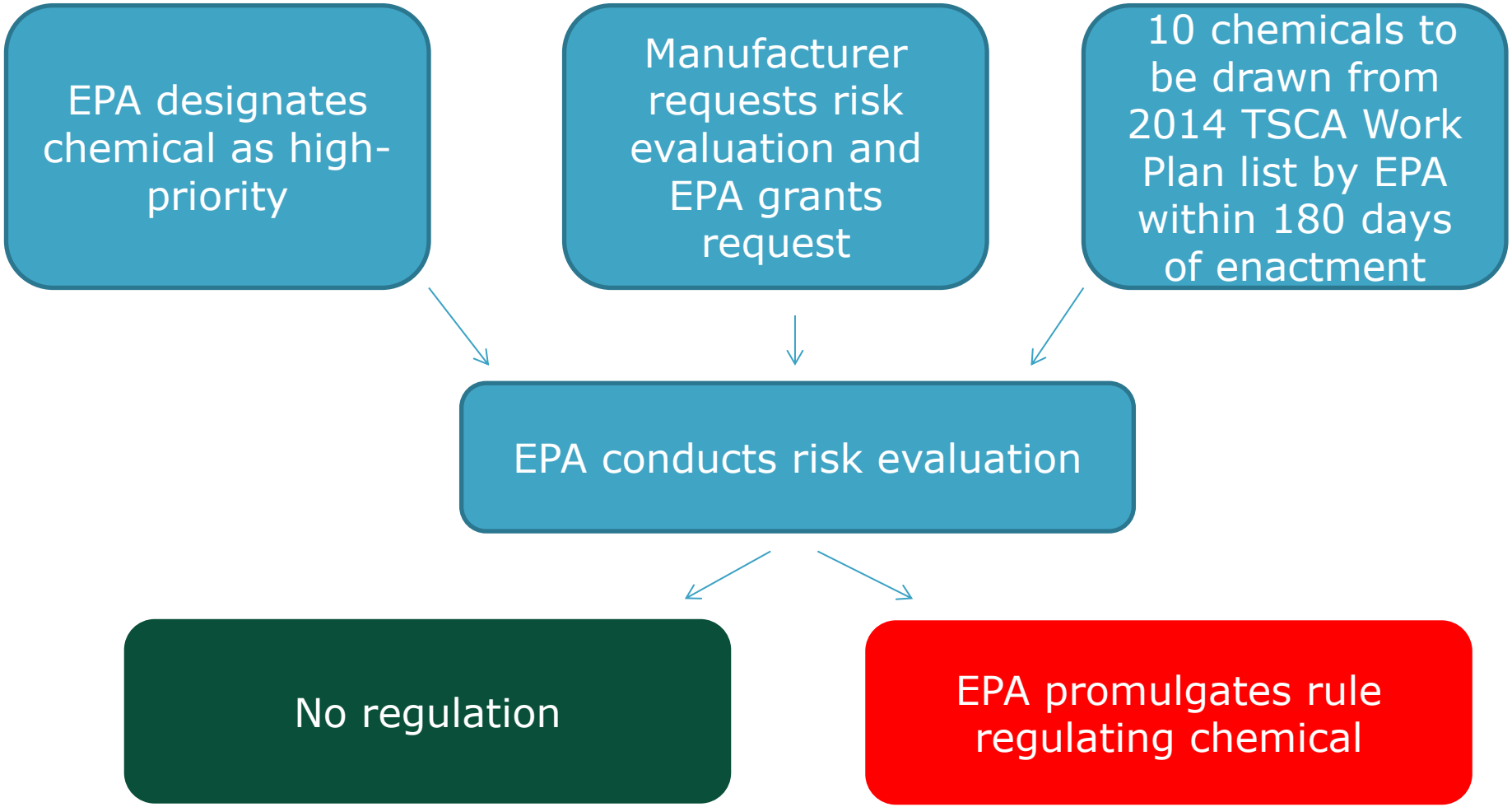
Section 5


PMN or SNUN
"presents" unreasonable risk of injury to health or environment
"may present" unreasonable risk of injury to health or environment or substantial …
"not likely to present" unreasonable risk of injury to health or environment
EPA rule restricting substance
EPA order restricting substance (pending further information)
Manufacture or use may commence

Section 6


Prioritization
Risk evaluation
Risk management
Criteria
Quotas
Deadlines
Certain PBTs get exposure evaluation + restrictions

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

1st Three Months

Immediately upon enactment – June 2016

- New "unreasonable risk" standard
- New PMN provisions
- PMN review periods reset at Day 0
- New science provisions
- CBI provisions

3 months after enactment – September 2016

- Initial guidance, FAQs
- Public meetings
- Initial PMN reviews – backlog, new standards

1st Six Months

6 months after enactment – December 2016 (into January 2017)

- Published list of first 10 chemicals to receive risk evaluations
- Proposed rules
  - Prioritization process
  - Risk evaluation process
  - Inventory reset
  - Methylene chloride and NMP; trichloroethylene

Year 1

1 year after enactment – June 2017

- Scope for first 10 risk evaluations
- Final rules
  - Prioritization process
  - Risk evaluation process
  - Inventory reset

Year 2

1½ years after enactment – December 2017

- Manufacturer reports due for Inventory reset; interim active substances list
- Proposed CBI substantiation rules
- Final rules for methylene chloride and NMP, trichloroethylene

2 years after enactment – June 2018

- Processor reports due for Inventory reset; active substances list
- Final CBI substantiation rules
- Develop any policies, procedures, or guidance
- Proposed rule for review of confidential chemicals on active substances list
- Generic names guidance

Year 3

2½ years after enactment – December 2018

- Final rule for review of confidential chemicals on active substances list

3 years after enactment – June 2019

- Propose rules on certain PBTs
- Propose inorganic byproducts negotiated rule

3½ years after enactment – December 2019

- Ensure that 20 high-priority substances have risk evaluations underway
- Ensure that 20 low-priority substances are designated
- Final inorganic byproducts negotiated rule

Later Years

3½ years after enactment (+ extensions)

- Complete risk evaluations on the first 10 chemicals

4½ years after enactment (+ extensions)

- Complete PBT rulemakings
- Propose risk management rules for first 10 chemicals found to present an unreasonable risk

5½ years after enactment (+ extensions)

- Final risk management rules for first 10 chemicals found to present an unreasonable risk

6½ years after enactment (+ extensions)

- Complete risk evaluations on 20 high-priority chemicals
- Complete review of confidential chemicals on active list

Strategic Implications

New 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 – PMNs

Expect delays, increased scrutiny, and restrictions

- Provide more information up-front
- "90-day" review period can take 8+ months

Section 5(e) orders likely even where PMN does not present a concern

- "The term '**conditions of use**' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, **or reasonably foreseen** to be manufactured, processed, distributed in commerce, used, or disposed of."
- EPA is regulating PMN submitters based on what others might do

500+ action letters issued since June 2016

Section 5 – SNURs

SNURs remain an important tool for EPA

- 6 SNUNs expected per year for > 2,800 SNURs
- Expect SNURs for all section 5(e) orders
- SNURs operate as substantive rules, because customers:
  - Avoid engaging in significant new use, or
  - Avoid SNUR chemicals altogether

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

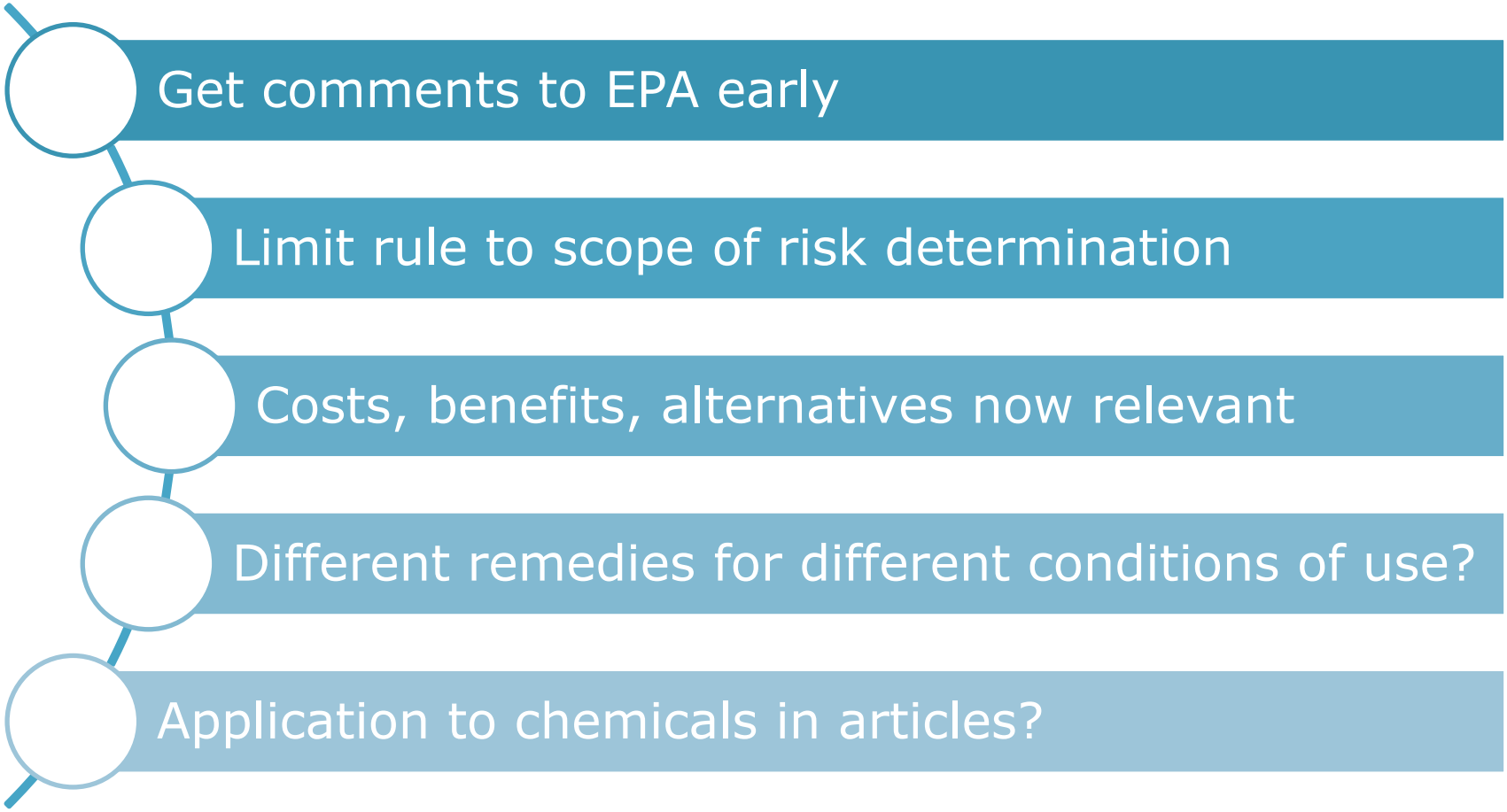
Comment on the scope

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

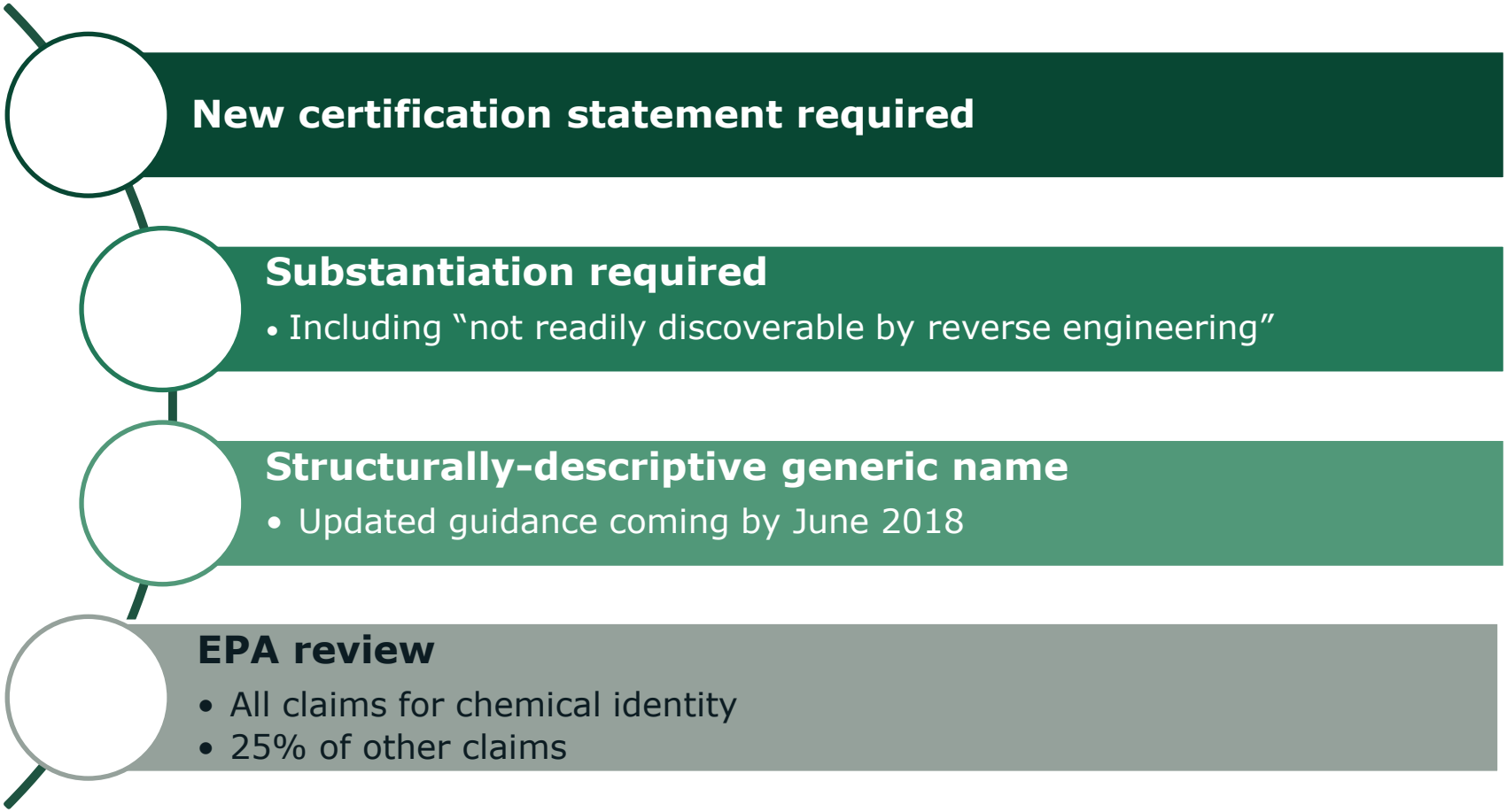
- REACH studies?
- Early data submission
- Submit your own risk evaluation

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

Section 6 – risk management



CBI – claims now harder to make



Contrast with REACH

Differences from REACH

Which chemicals	• **REACH**: all chemicals except polymers > 1 tonne/year • **TSCA**: new chemicals; active substances once prioritized
When	• **REACH**: 3 bands, ending 2018 for all chemicals • **TSCA**: Once prioritized (20 ongoing at one time)
Data requirements	• **REACH**: Full up-front dossier • **TSCA**: None, unless ordered to test

Differences from REACH

Process	• **REACH**: SIEF prepares dossier • **TSCA**: No submissions required; opportunities for advocacy
Evaluation	• **REACH**: Completeness check; CoRAP possible • **TSCA**: Within 3 to 3.5 years of prioritization
Precautionary principle	• **REACH**: Accepted • **TSCA**: Not accepted; EPA has burden of proof

Differences from REACH

Market impact before regulation	• **REACH**: Substances of very high concern • **TSCA**: "May present" to "presents"
Regulation	• **REACH**: Authorisation or restriction • **TSCA**: Wide range of available remedies
Judicial review	• **REACH**: European Court of Justice • **TSCA**: Substantial evidence on the record

Summary


It’s a new world
EPA has a LOT more authority
EPA plans to exercise that authority
There are multiple opportunities for stakeholder involvement – and potential rewards for involvement

Questions?

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