

TSCA Implementation Webinar Contents



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TSCA Reform: Key Legal Changes & Issues

March 27, 2017

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Comparative Perspective

- Many thought TSCA Reform would result in a more REACH-like statute.
 - REACH generally requires data to be submitted on all chemicals for each substance produced over 1 tonne a year.
- While TSCA reform may have moved the statute somewhat in the direction of REACH, still grounded in the notion that EPA can prioritize high and low risk chemical based on relatively limited information.
- US continues to be risk-based, EU hazard based.
- These issues will be discussed further in the third webinar.

Key Legal Changes

- More Rigorous New Chemical Evaluations. § 5(a)
- Review of Articles. §§ 5(a), 6(c)(2)(E)
- Review of Existing Chemicals. § 6
- Confidential Business Information. § 14
- Preemption. § 18

Key Issue 1: Mandatory EPA Regulations & Guidance

- At least 6 key mandatory regulations/guidance to issue
 - Plan for reducing vertebrate testing. § 4(h)
 - Risk-based screening process for high and low priority designations. § 6(b)
 - Procedure for conducting risk evaluations on existing chemicals. § 6(b)(4)(B)
 - Rules for persistent, bioaccumulative, and toxic chemicals. § 6(h)
 - Inventory Reset. § 8(b).
 - Guidance re: CBI. § 14(c).
- Other guidance. § 26(l).
- Will in many ways define the implementation of the statute.
- Judicial review.
- Deadline suits?

Key Issue 2: How Will EPA Regulate?

- The amendments removed the language requiring EPA to use the “least burdensome” means to regulate chemicals, which as interpreted in *Corrosion Proof Fittings* greatly limited scope of action.
- Now, EPA is to consider a multitude of factors and consider alternatives. § 6(c)(2)
- EPA likely to receive *Chevron* deference to review and application of factors.
- Unclear how EPA will weigh these factors, and how courts will interpret.

Key Issue 3: Best Available Science

- Section 26(h) requires EPA to use the “best available science,” and 26(i) requires EPA to make decisions “based on the weight of the scientific evidence”
- Unclear how EPA will interpret
- Very unclear how courts will evaluate.
- Possible precedent for other regulatory schemes? APA?
- A subject of the second webinar.

Key Issue 4: Scope of Preemption

- Section 18 dramatically changes preemption.
 - Limits state action relating to chemicals found to not present unreasonable risks or for chemicals subject to regulation.
 - Limits state action while chemicals are under risk evaluation
 - Limits state action if chemicals are subject of final regulations by EPA
- There are a number of exceptions and carve-outs, and the ability of states to seek waivers
- Unclear how EPA will implement and the courts will interpret.
- A subject of our third webinar, with Covington's Gary Guzy, a former EPA General Counsel.

Key Issue 5: Trump Executive Order

- EO 13771: “1 in 2 out” and cap on regulatory budget of each agency
- How will it apply to rules with statutory deadlines?
- How will it apply to TSCA given the relative lack of “extra” TSCA rules to repeal? Cross-program analysis?
- How will it, as a practical matter, impact rules where agency has a degree of discretion (e.g., implementing regulations on chemical substances found to present unreasonable risk)?

Key EPA Activities Under TSCA

Brian Grant

Risk Evaluation and Management of Existing Chemicals: Framework Rules and Guidance

- Risk evaluation and prioritization “framework” rules to be signed by June 22, 2017
 - Risk evaluation rulemaking:
 - How to conduct risk evaluations?
 - Proposal at 82 FR 7562 (January 19, 2017)
 - Comment period closed March 20
 - Prioritization rulemaking:
 - What chemical substances to do risk evaluation on?
 - Proposal at 82 FR 4825 (January 17, 2017)
 - Comment period closed March 20
- Guidance on draft non-EPA risk evaluations to be signed by June 22, 2017.

Risk Evaluation and Management of Existing Chemicals: On-Going Section 6(a) Rulemakings

- EPA was authorized to proceed to risk management for chemicals for which EPA completed risk assessments prior to June 22, 2016.
- Three such rules have been proposed, consistent with the scope of the risk assessments:
 - Trichloroethylene in Aerosol Degreasing and Dry Cleaning : 81 FR 91927 (December 19, 2016) – Comment period closed March 16
 - Trichloroethylene in Vapor Degreasing: 82 FR 7432 (January 19, 2017) – Comment period to close April 19
 - Methylene Chloride and N-methyl Pyrrolidone in Paint Removers: 82 FR 7464 (January 19, 2017) – Comment period to close April 19

Risk Evaluation and Management of Existing Chemicals: First 10 Risk Evaluations

- “Designation of Ten Chemical Substances for Initial Risk Evaluation Under the Toxic Substances Control Act” -- 81 FR 91927 (December 19, 2016)
 - 1, 4 Dioxane
 - 1-Bromopropane
 - Asbestos
 - Carbon Tetrachloride
 - Cyclic Aliphatic Bromide Cluster (flame retardants)
 - Methylene Chloride
 - N-Methylpyrrolidone
 - Pigment Violet 29
 - Trichloroethylene
 - Perchloroethylene
- Public meeting held February 14; dockets closed on March 15; scoping to be announced by June 19.

Risk Evaluation and Management of Existing Chemicals: PBT Chemicals

- TSCA establishes a separate track for expedited regulatory action to address risks from certain persistent, bioaccumulative and toxic (PBT) chemicals.
- Rules to reduce exposures from these PBT chemicals *to the extent practicable*. Not based on a prior risk evaluation.
- Substances identified:
 - Decabromodiphenyl ethers (DecaBDE) (flame retardant);
 - Hexachlorobutadiene (HCBD) (solvent);
 - Pentachlorothiophenol (PCTP) (cross-linking agent);
 - Tris(4-isopropylphenyl) phosphate, (flame retardant); and
 - 2,4,6-Tris(tert-butyl) phenol, (antioxidant).

New Chemicals

- Public meeting held December 14, 2016, to review new chemicals process under amended TSCA and to discuss approaches to making the process more efficient
- Work is underway on process improvements

TSCA Inventory and Reporting Under TSCA

- Rule proposed on January 14 to require reporting to enable EPA to distinguish active from inactive inventory chemicals. 82 FR 4255 (Jan 13, 2017).
 - Comment period closed March 14
 - Rule to be signed by June 22
- EPA to undertake negotiated rulemaking to limit reporting regarding inorganic byproducts
 - Comment period on solicitation of interested parties and issues for reg neg closed on January 17. 81 FR 90843 (Dec 15, 2016)
 - Proposed rule, if any, by June 2019; final rule by December 2019

Fees

- Public meeting to obtain input on structure and content of TSCA fees rule. August 11-12, 2016.
- Proposal under development

Citizen Petitions

- Three petitions received since June 2016 under TSCA section 21
 - Petition from Fluoride Action Network et al to ban addition of fluoridation chemicals to drinking water.
 - Filed November 23, 2016
 - Denied. See 82 FR 11878 (Feb 27, 2017)
 - Petition from Earthjustice et al to require testing of Tetrabromobisphenol A
 - Filed December 13, 2016
 - Denied March 2017.
 - Petition from Earthjustice et al to require testing of Chlorinated Phosphate Esters
 - Filed January 6, 2017
 - Response due April 6

Confidential Business Information

- EPA interpretation of TSCA as requiring up-front substantiation of all non-exempt CBI claims. 82 FR 6522 (Jan 19, 2017)

TSCA Reform: Key Technical Issues

Jessie Kneeland, Ph.D.

March 27, 2017

Agenda

- Key Changes
 - New chemicals
 - Existing chemicals
 - Inventory Reset
 - Prioritization and Risk Evaluation
- Impacts and Actions
 - New chemicals – need more data
 - New data sources
 - Inventory reset
 - CBI protection
 - Vulnerable products and market pressures

Key Changes: New Chemicals

- No minimum set of information requirements, but....
- Requirement for **definitive determination** that chemical/use:
 - Presents unreasonable risk OR
 - May present unreasonable risk (more info needed) OR
 - Not likely to present unreasonable risk
- Overall, PMNs are backlogged and data requirements unclear!



Key Changes: Inventory Reset

Rule will require reporting chemicals manufactured/imported from June 2006 – June 2016

- No minimum volume to report
- All reported chemicals go on "active" TSCA inventory
- CBI claims must be made and substantiated
- Generic names must follow prescriptive guidance (100% review)



Key Changes: Existing Chemicals

- "Prioritization" of chemicals
 - EPA must complete prioritization and designate 10 high and 20 low priorities by Dec. 2019.
- Risk evaluation for (a few) high priority chemicals
 - 10 started in 2016 (from 2014 TSCA Work Plan); 10 more to begin no later than Dec. 2019.
 - Unreasonable risks must be managed with use restrictions or other risk management measures!



Key Changes: First 10 Risk Evaluations

- 1,4-Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster (HBCD)
- Methylene Chloride
- N-Methylpyrrolidone (NMP)
- Pigment Violet 29
(Antra[2,1,9-def:6,5,10-d'e'f']
diisoquinoline-1,3,8,10(2H,9H)-tetrone)
- Trichloroethylene (TCE)
- Tetrachloroethylene
(known as perchloroethylene)



Impacts and Actions: New Chemicals

Impacts

- PMNs/SNUNs are now taking longer and require more data
- Greater emphasis on workers and full chemical lifecycle (all "foreseen" uses/exposures)
- EPA wants better information with PMN filing

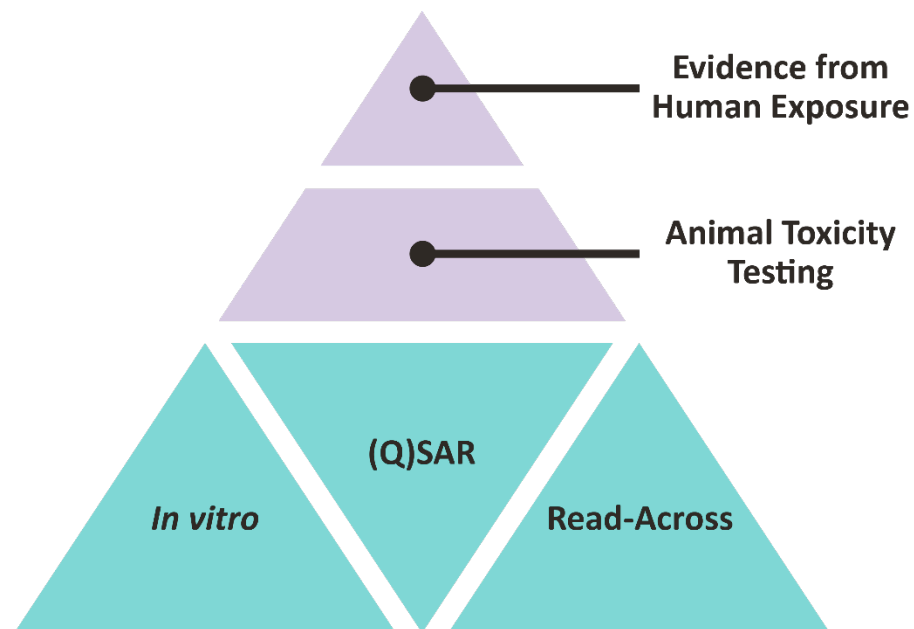
Actions

- Plan to provide stronger data package with PMNs



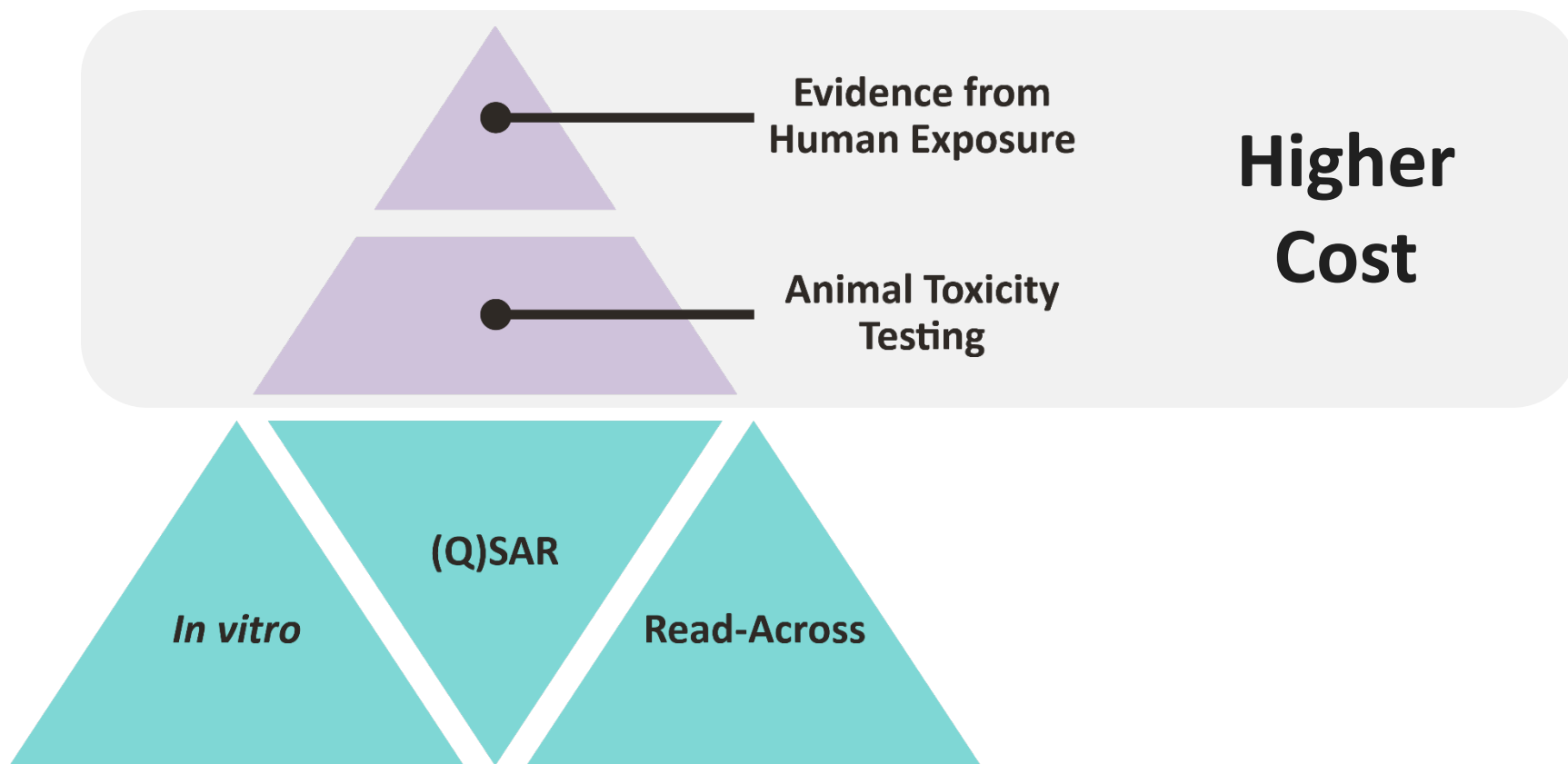
Impacts and Actions: New Data

- Potentially exposed and susceptible subpopulations (PESS)
- Prioritize non-vertebrate testing
- Strategic plan by June 2018
- Data sharing complications (*e.g.*, REACH)



Impacts and Actions: New Data

Section 26(h) specifies science decisions must be "consistent with the best available science".



Impacts and Actions: New Chemicals, New Data

Impacts

- Definitive safety determination for new chemicals: more data needed
- Best available science: fill data gaps with testing, QSAR, and read-across

Uncertainty

- The extent that EPA will prefer and accept these data in lieu of animal testing is unclear



Impacts and Actions: Inventory Reset

Impacts

- Final rule expected in June
- Need 10 years of manufacture/import (or processing) records (2006-2016)

Questions

- Do you have these data accessible?
 - What did you already report under CDR?
 - Have you already documented exemptions (*e.g.*, naturally occurring chemicals, polymers)?
- CBI claims and substantiation needed

Actions

- Compile manufacture/import records and CBI claims



Impacts and Actions: CBI

Impacts

- CBI claims now expire after 10 years
- CBI claims must be well justified, and will be checked by EPA (100% of generic names, 25% of others)

Actions

- Prepare to substantiate CBI claims

Questions

- Have you taken measures to protect the CBI?
 - Would the disclosure cause substantial harm?
 - Could the CBI be readily discovered (*e.g.*, reverse engineered)?
- Longer-term: Track expiration of CBI claims

Impacts and Actions:

Vulnerable Products and Market Pressures

Impacts

- Understand risks of products
 - Toxicity/hazards, including vulnerable subpopulations
 - Product use, including full life cycle and exposed populations
- EPA considers risk evaluations from interested parties

Questions

- Do you want to help inform EPA's risk evaluations?
- Do you have the toxicity and exposure data needed?

Actions

- Monitor EPA's risk evaluation process
- Perform independent risk evaluation
- Consider alternatives



Summary

- Key Changes
 - New chemicals: definitive determination of risk
 - Existing chemicals
 - Inventory Reset
 - Prioritization and Risk Evaluation
- Business Impacts and Actions
 - New chemicals: need more data
 - New data sources: toxicity, exposure
 - Inventory reset: prepare to report
 - CBI protection: substantiation
 - Vulnerable products and market pressures

Questions?



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Thank You!



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**Webinar Topic:
TSCA Webinar Part Two**

“Emerging Science and Alternative Test Methods in Implementing the LCSA”

Wednesday, April 19, 2017

12:00-1:30