



# TSCA SECTION 6 WAKE-UP CALLS

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# Herb Estreicher

- ◆ Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his US law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few US-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.
- ◆ Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.
- ◆ Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.



# Section 6 Proposed Risk Management (RM) Rules

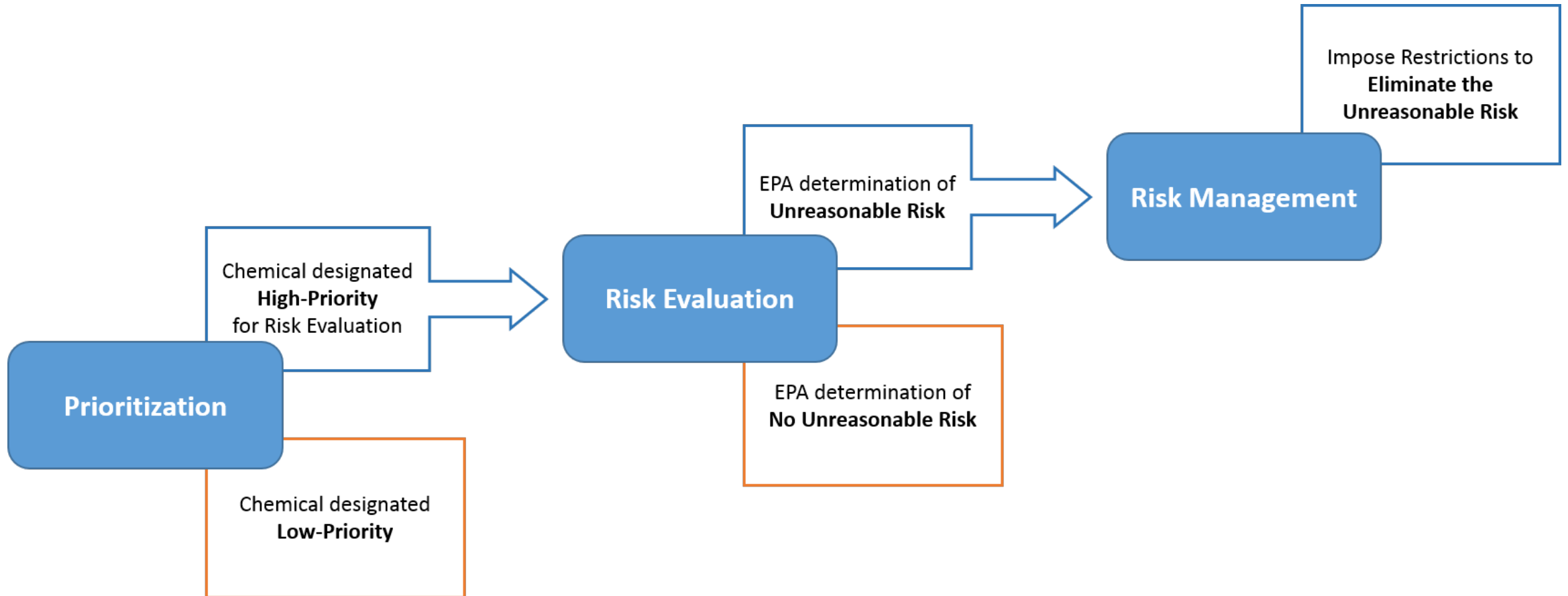
- ◆ Methylene Chloride – most uses to be phased out. 88 Fed Reg. 28,284 (May 3, 2023)
- ◆ Perchloroethylene– most uses to be phased out. 88 FR 39,652 (June 16, 2023)
- ◆ The final risk evaluation (RE) documents identified the uses that EPA considered to drive the unreasonable risk determination.
- ◆ The Trump-era REs were published in 2020, and the revised Biden-era REs were published in 2022.

# No Secret As to What is Next

- ◆ Carbon Tet – ECEL likely to be 0.03 ppm (30 ppb, 0.2 mg/m<sup>3</sup>) for inhalation exposures to carbon tetrachloride as an 8-hour TWA.  

All uses drive the unreasonable risk determination except processing as a reactant/intermediate in reactive ion etching, and distribution in commerce
- ◆ 1-Bromopropane – All uses drive the unreasonable risk determination except distribution in commerce and commercial and consumer uses of building/construction materials (insulation)
- ◆ NMP – RE is final
- ◆ TCE – RE is final
- ◆ 1,4-Dioxane – RE released for public comment and peer review.
- ◆ Others

# EPA Section 6 Process



# Opportunities for Industry Engagement – Risk Evaluation Phase



- ◆ **Draft Scope** published in the Federal Register no later than 3 months from the initiation of the RE process.
- ◆ 45-day public comment period on the draft scope.
- ◆ Final Scope published no later than 6 months after initiation of the RE.
- ◆ **Draft RE** will be published in the Federal Register.
- ◆ Each draft risk evaluation will be peer reviewed.
- ◆ 60-day public comment period on the draft risk evaluation.
- ◆ A final risk evaluation will be published no later than 3 to 3.5 years after identification of the chemical as a high priority for risk evaluation.

# Opportunities for Industry Engagement— Risk Management Phase



- ◆ Required Consultations with different governmental entities. Some consultations will be open to the public.
- ◆ Public Meetings and Webinars
- ◆ One-on-One Meetings
- ◆ Public Comment period on proposed Risk Management rule

# How to Identify Uses that Will Likely be Phased Out (1)

- ◆ The RE tells you which uses drive the unreasonable risk determination.
- ◆ The RE provides information for each use:
  - ◆ Whether the concern is Human Health Effects -- Cancer, Acute Non-cancer; Chronic Non-cancer; Environmental Effects.
  - ◆ Whether workers, consumer, professional, occupational non-users (ONUs), bystanders, or general population are at risk.
- ◆ Consumer and professional (commercial) uses are likely candidates for bans and phase-outs because these uses can not effectively employ workplace chemical protection programs (WCPP).



# How to Identify Uses that Will Likely be Phased Out (2)

- ◆ Uses with unacceptable risks to ONUs, bystanders, general populations are likely to be phased out.
- ◆ Laboratory use will likely be subject to WCPP.
- ◆ Within the category of industrial uses the following uses likely will be subject to WCPP: manufacture, processing, distribution in commerce, processing as an intermediate/reactant, closed uses, and uses where EPA has data to demonstrate that the WCPP will be consistently applied.

# How to Identify Uses that Will Likely be Phased Out (3)



- ◆ Chemicals where the ECEL is 1 or more orders of magnitude lower than the OSHA PEL will face difficulties.
- ◆ Uses where respirators with an APF >50 are needed to meet the ECEL will face difficulties.
- ◆ For chemicals where there are ecotox concerns the likely risk management measure will be a ban on water releases. Some uses may be subject to a water release limit.

# How to Predict the ECEs

- ◆ Some announced by EPA already, i.e., Carbon Tet
- ◆ Look at “Existing Chemical Exposure Limit (ECEL) for Occupational Use of Carbon Tetrachloride” [downloads.regulations.gov/EPA-HQ-OPPT-2020-0592-0007/content.pdf](https://downloads.regulations.gov/EPA-HQ-OPPT-2020-0592-0007/content.pdf)
- ◆ Give equations EPA uses to set ECEs for:
  - ◆ Cancer risk
  - ◆ Acute non-cancer risk
  - ◆ Chronic non-cancer risk

# Section 6(g) Exemptions

- ◆ Uses critical to national security such as those for military and space applications likely will be granted 6(g) exemptions.
- ◆ Also likely for uses essential to critical infrastructure, the environment, or public safety.
- ◆ What about other uses that are critical to a company or industry?

# What Happens If Your Use is Not in the Scope?

- ◆ At some point after the final Scope issues EPA will issue a proposed SNUR for all uses not covered in the Scope.
- ◆ EPA did this in connection with the PBT flame retardants tris (2-chloroethyl) phosphate (TCEP), 4,4'- (1-methylethylidene)bis [2, 6-dibromophenol] (TBBPA), and triphenyl phosphate (TPP).

Flame Retardants; Significant New Uses Rules for Certain Non-ongoing Uses, June 22, 2023 (88 FR 40728)

- ◆ Important to be vigilant and raise your hand to tell EPA this is an ongoing use.

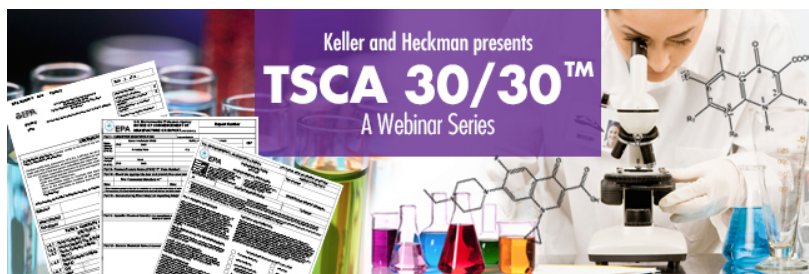
# FINAL THOUGHTS



Please join us at 10:00 AM Eastern U.S.  
Wednesday, August 23, 2023  
[www.khlaw.com/REACH-3030](http://www.khlaw.com/REACH-3030)



Please join us at 1:00 PM Eastern U.S.  
Wednesday, July 19, 2023  
[www.khlaw.com/OSHA3030](http://www.khlaw.com/OSHA3030)



Please join us at 1:00 PM Eastern U.S.  
Wednesday, August 9, 2023  
[www.khlaw.com/TSCA-3030](http://www.khlaw.com/TSCA-3030)



# Thank You

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