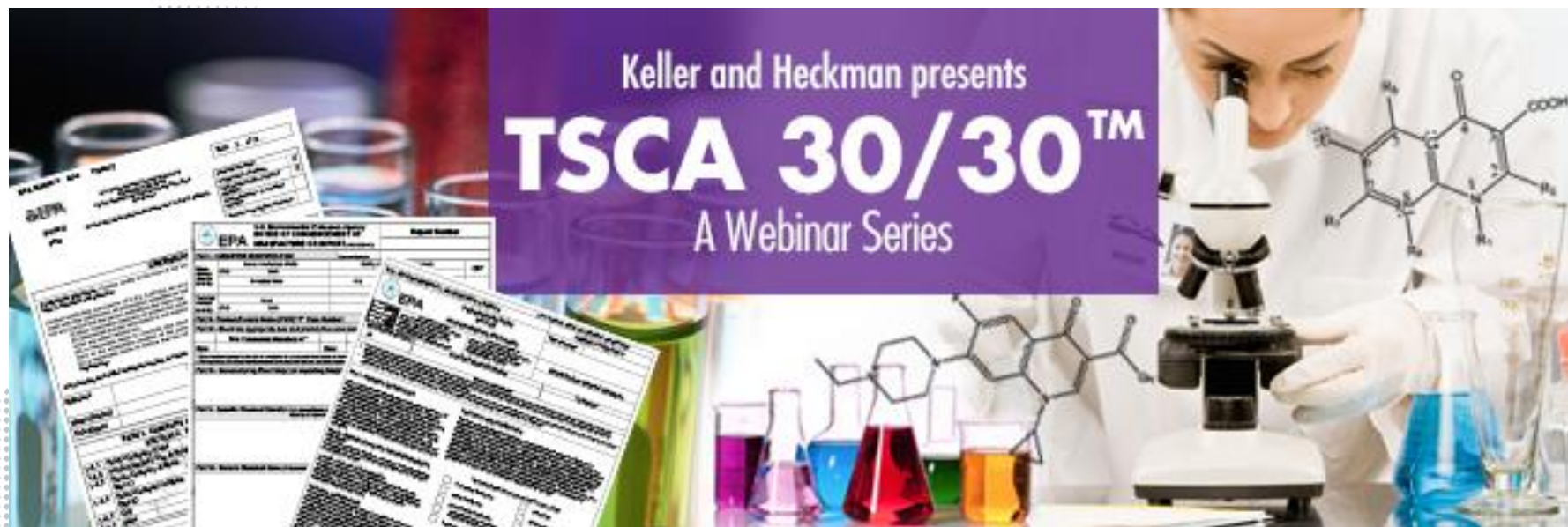


# Forever Chemicals

March 17, 2021



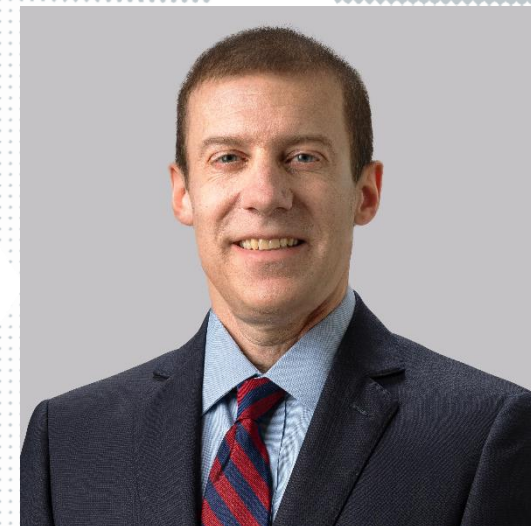
# Herb Estreicher

- ♦ 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 U.S. 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 U.S.-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.



# Eric Gotting

- ♦ Eric Gotting represents Keller and Heckman's clients in litigation and related matters, specializing in complex civil and appellate matters, internal investigations, and regulatory compliance. With an extensive background in environmental law, he has expanded his practice over the years to cover many of Keller and Heckman's industry sectors and regulatory areas. Eric is a former Am Law 50 litigation partner and U.S. Department of Justice, Civil Division, Trial Attorney.
- ♦ Eric's practice spans a broad range of legal issues, including administrative and constitutional law, agency enforcement actions, toxic torts, product liability, general business litigation, and regulatory advice. He works with a diverse set of industries, including chemicals, plastics, pesticides, fuels and pipelines, food and packaging, consumer goods, telecommunications, and e-cigarettes.
- ♦ As a litigator, Eric has tried cases to verdict and argued appeals before federal and state courts across the country. His experience includes class actions, mass tort litigation, AAA arbitrations, and agency proceedings. Eric has also litigated challenges to federal and state statutes, regulations, and orders. He has particular expertise involving the Administrative Procedure Act (APA), the Dormant Commerce Clause, the First Amendment, the Due Process Clause, and federal preemption. He has also filed amicus briefs in litigation involving regulatory issues facing a variety of industry sectors.





# James Votaw

- ♦ James Votaw has an extensive practice focusing on environmental and health and safety regulation. Within that arena, he concentrates on the regulation of conventional and nanoscale chemicals, pesticides, consumer and industrial products, and industrial processes and wastes.
- ♦ For his clients, James obtains pre-market product approvals and exemptions, including the first U.S. approval of a nanoscale pesticide. He negotiates testing orders, defends enforcement actions, advises on restrictions and disclosures associated with the chemical content of products, counsels on release and other environmental reporting, and supports environmental regulatory and liability aspects of commercial transactions (including, but not limited to regulatory due diligence and private label distribution arrangements). Further, he participates in technical rulemaking proceedings, provides strategic and regulatory compliance counseling within existing and emerging industries, initiates compliance training, conducts internal investigations, performs compliance auditing, offers facility permitting services and develops product compliance plans and systems.
- ♦ James represents clients before State and Federal regulatory agencies and federal courts. He has extensive experience in compliance counseling on matters related to the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Clean Air (CAA) and Clean Water Acts (CWA); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); the Consumer Product Safety Commission (CPSC); California's Proposition 65; Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH); Restriction of Hazardous Substances (RoHS); and Waste Electrical and Electronics Equipment (WEEE).



# AGENDA



- ◆ PFAS Regulation
- ◆ PFAS Litigation
- ◆ TSCA PBT Rulemaking

# US EPA PFAS Regulation



- ◆ Section 7321 of the National Defense Authorization Act for Fiscal Year 2020 (NDAA) added certain PFASs to the list of chemicals covered by the **Toxics Release Inventory (TRI)** and provided a framework for additional PFAS to be added to TRI on an annual basis
- ◆ EPA issued a Significant New Use Rule (**SNUR**) to ensure that uses which are phased out in products like furniture, automobile parts, electronics, and household appliances that could contain PFAS chemicals as a surface coating cannot be imported to the U.S. unless EPA reviews the new uses and puts in place necessary restrictions to address unreasonable risks
- ◆ **PFAS and PMN program:** Of the more than 600 PFAS chemicals on the active TSCA inventory, EPA has reviewed almost 60 percent of them under the new chemicals program. Since 2006, EPA has reviewed around 300 PFAS new chemical notices and has regulated about 200 with consent orders and/or new chemical SNURs
- ◆ **Toxicity Assessment for PFBS:** EPA career scientists have reviewed the Toxicity Assessment for PFBS, posted on January 19, 2021, and have made an initial determination that the conclusions in the assessment were compromised by political interference as well as infringement of authorship and the scientific independence of the authors' conclusions

# Petition to US EPA



- ◆ US EPA has denied a petition from six advocacy groups seeking an order requiring the study of health and environmental effects of 54 PFASs substances that the petitioners say are linked to a Chemours facility in Fayetteville, North Carolina, near the Cape Fear River
- ◆ The petition called on EPA to use its authority under TSCA section 4 to order Chemours to fund testing of the specified PFASs under the direction of a panel of independent scientists
- ◆ But in its 7 January denial, EPA said the petitioners failed to show that there is insufficient information on the effects of the 54 substances
- ◆ EPA said the petition does not demonstrate that additional testing is needed to develop such data, citing its own efforts to address PFASs, which included its 2019 PFAS Action Plan and a SNUR issued in July to prohibit renewed use or imports of several long-chain PFASs

# California PFAS Regulation

- ◆ California's Department of Toxic Substances Control (DTSC) plans to regulate PFAS as a class under its Safer Consumer Products (SCP) program
- ◆ This is "because individual PFASs never occur in isolation" "they cannot be effectively regulated in isolation." "Taking a class approach to regulating PFASs in consumer products could also encourage innovation in developing safer alternatives and reducing the risk of regrettable substitutions."
- ◆ California is nearing completion of a priority product designation for carpets and rugs containing the substances
- ◆ Priority product proposals are also in the works for PFAS-containing textile treatments and food packaging



# Regulation in Other States and Canada



- ◆ At least 18 US states, other than California, are due to consider actions this year to restrict the use of PFASs in various products
- ◆ Focus is restriction on PFAS in food packaging and fire-fighting foam
- ◆ In November 2020 Canada's government announced it is looking at ways to "broaden its class approach" to per- and polyfluoroalkyl substances (PFASs), but unlike the European Union it has no plans to adopt a restriction on the entire class of substances, director-general at Health Canada has said

# Industry Reaction

- ◆ McDonald's has committed to globally phasing out the use of PFAS from its customer packaging by 2025
- ◆ PFASs are used to greaseproof, waterproof and give non-stick properties to food packaging, containers, cookware and consumer products
- ◆ The food chain joins a growing list of retailers moving away from using the chemicals in food packaging; Panera Bread, Taco Bell, Whole Foods, Trader Joe's, Ahold Delhaize, Albertsons, and Sweetgreen have all announced steps to reduce or eliminate PFASs in food packaging

# PFAS in Containers

- ◆ On September 1, 2020, NGOs contacted various Massachusetts state agencies about the presence of PFAS in pesticide containers of Anvil 10+10 an adulticide registered for use in public health mosquito control programs
- ◆ EPA Region 1 was notified that same day; EPA has worked with the State to request samples of the pesticide product for analysis and issued an information request seeking information on the affected pesticide's production, sales and distribution
- ◆ Source of contamination is associated with the fluorinated HDPE containers
- ◆ EPA is asking other pesticide companies and entities that fluorinate containers to engage in good product stewardship to examine their distribution chains to uncover potential areas for contamination

# Potential PFAS Litigation Liability



- ◆ Variety of sources
  - ◇ Process wastewater
  - ◇ Air emissions
  - ◇ Landfilling
  - ◇ Workplace exposures
  - ◇ Commercial products
- ◆ Additional considerations
  - ◇ Current and legacy uses
  - ◇ Even small amounts used in manufacturing processes at a given point in time can result in increased litigation risk

# Types of Litigation Liability

- ◆ Wide range of lawsuits
  - ◇ Single plaintiff
  - ◇ Mass tort
  - ◇ Class action
  - ◇ Governmental enforcement actions
- ◆ Alleged damages and injuries
  - ◇ Personal injury and wrongful death
  - ◇ Property damage
  - ◇ Drinking water and POTW contamination
  - ◇ Product liability
- ◆ Role of State regulations in setting duty or standard of care



# Update on TSCA PBT Rulemaking



- ◆ EPA promulgated TSCA risk management rules for 5 PBTs in January 2021
  - ◇ TSCA §6(h) – “Reduce exposure to extent practicable” without risk assessment
  - ◇ Mostly bans on manufacture, processing and distribution (including articles), with limited exclusions
  - ◇ Biden EPA allowed rules to go into effect February 5, subject to future review
- ◆ Example Criticisms of Rule(s):
  - ◇ EPA failed to regulate (a) occupational exposures, (b) disposal, (c) ongoing use
  - ◇ Exemptions/exclusions were not time limited (§6(g))
  - ◇ No regulation of any article/replacement parts permitted without risk assessment (§6(c)(2)(D&E))
- ◆ PIP (3:1) Created Special Problems: Article importers/producers not previously aware of PIP (3:1) in their supply chains
  - ◇ March 9: Ban on distribution of PIP (3:1) articles effective
  - ◇ Late notice from upstream suppliers (or not knowing one way or another)
  - ◇ Strand articles in channels of trade
  - ◇ Interrupt supply chains while substitutes identified, validated and put into use

# Summary: Five PBT rules

Substance	USE	Risk Management Controls
DecaBDE	flame retardant in plastic, textiles, in many industries	Ban all manufacture, processing and distribution, <b>except</b> <ul style="list-style-type: none"> <li>• 18 mo: curtains in the hospitality industry</li> <li>• 25 mo: wire insulation in nuclear power generation facilities</li> <li>• 36 mo: new aerospace vehicles</li> <li>• EOL: Existing cars, aerospace vehicles and replacement parts, pallets</li> <li>• Recycled plastic</li> </ul>
PIP (3:1)	plasticizer, flame retardant, anti-wear additive, industrial coatings, adhesives, sealants, plastic articles.	Ban all processing and distribution (including in articles), <b>except</b> <ul style="list-style-type: none"> <li>• 48 mo: Sealants and adhesives</li> <li>• 12 mo: Photo printing articles</li> <li>• Aviation hydraulic fluids, lubricants and greases</li> <li>• Manufacture of cyanoacrylate glue, specialized air filters</li> <li>• Recycled plastic</li> </ul>
2,4,6-TTBP	Intermediate for fuel additives; engine oils, lubricants	Ban distribution in concentrations above 0.3%: <ul style="list-style-type: none"> <li>• For use in oil / lubricants</li> <li>• In any container with a volume of less than 35 gallons (use as intermediate)</li> </ul>
HCBD	Byproduct during the manufacture of chlorinated hydrocarbons	Ban all manufacture, processing and distribution, <b>except</b> <ul style="list-style-type: none"> <li>• Production as byproduct of chlorinated solvent manufacture</li> <li>• Processing for burning as a waste fuel</li> </ul>
PCTP	Make rubber more pliable in industrial uses	Ban all manufacture, processing and distribution, <b>except:</b> <ul style="list-style-type: none"> <li>• Concentrations are at or below 1%</li> </ul>

# EPA Action on PBT Rules



- ◆ OECA Issued “No Action Assurance” March 8 for the PIP (3:1) Rule:
  - ◇ Effectively deferred the effective processing and distribution bans on PIP (3:1) for use in articles for 180 days (Sept 4, 2021) – time to make transition
  - ◇ Not applicable to PIP (3:1) in other uses
  - ◇ Water release ban and recordkeeping/notice provisions still applicable
- ◆ EPA Reopening all Five PBT Rules
  - ◇ Accepting public comment for 60 days
  - ◇ Accepting comments on appropriate compliance dates/transition periods
  - ◇ Also accepting comments on any and all other aspects of the rules
- ◆ May Extend Deadlines, Expand Scope, Narrow Current Exclusions
  - ◇ Trump EPA interpretation of the statute (e.g., regarding disposal, occupational exposure, use)
  - ◇ Propriety of current exclusions (are more exposure reductions practicable?)
  - ◇ Consistency with new Biden EOs (science integrity, transparency)
  - ◇ Environmental Justice & consideration of exposed subpopulations
- ◆ **Critical to participate in new comment period to assure substantial evidence for decision-making**

# Update on TSCA PBT Rules

## ◆ EPA promulgated TSCA risk management rules for 5 “persistent, bioaccumulative and toxic” (PBT) substances in January 2021

- ◆ TSCA §6(h) – “Reduce exposure to extent practicable” *without risk assessment*
- ◆ Mostly bans on manufacture, processing and distribution (including articles), with limited exclusions
- ◆ Biden EPA allowed rules to go into effect February 5, subject to future review

## ◆ Example Criticisms of Rule(s):

- ◆ EPA failed to regulate (a) occupational exposures, (b) disposal, (c) ongoing use
- ◆ Exemptions/exclusions were not time limited [§6(g)]
- ◆ No regulation of any article/replacement parts permitted without risk assessment showing articles present risks [§6(c)(2)(D&E)]

# Summary of TSCA §6(h) PBT Rules

Substance	Uses	TSCA Risk Management Controls
DecaBDE	<ul style="list-style-type: none"> <li>➤ Flame retardant</li> <li>➤ Used in plastic, textiles, in many industries</li> </ul>	<b>Ban all manufacture, processing and distribution, <u>except</u></b> <ul style="list-style-type: none"> <li>• 18 mo: curtains in the hospitality industry</li> <li>• 25 mo: wire insulation in nuclear power generation facilities</li> <li>• 36 mo: new aerospace vehicles</li> <li>• EOL: Existing cars, aerospace vehicles and replacement parts, pallets</li> <li>• Recycled plastic</li> </ul>
PIP (3:1)	<ul style="list-style-type: none"> <li>➤ Plasticizer, flame retardant, anti-wear additive</li> <li>➤ Used in industrial coatings, lubricants, hydraulic fluid, adhesives, sealants, polymer articles</li> </ul>	<b>Ban all processing and distribution (including in articles), <u>except</u></b> <ul style="list-style-type: none"> <li>• 48 mo: Sealants and adhesives</li> <li>• 12 mo: Photo printing articles</li> <li>• Aviation hydraulic fluids, lubricants and greases</li> <li>• Manufacture of cyanoacrylate glue, specialized air filters</li> <li>• Recycled plastic</li> </ul>
2,4,6-TTBP	<ul style="list-style-type: none"> <li>➤ Intermediate for fuel additives;</li> <li>➤ Used in engine oils, lubricants</li> </ul>	<b>Ban distribution in concentrations above 0.3%:</b> <ul style="list-style-type: none"> <li>• For use in oil / lubricants</li> <li>• In any container with a volume of less than 35 gallons ( allow use as intermediate)</li> </ul>
HCBD	<ul style="list-style-type: none"> <li>➤ Byproduct from manufacture of chlorinated hydrocarbons</li> </ul>	<b>Ban all manufacture, processing and distribution, <u>except</u></b> <ul style="list-style-type: none"> <li>• Production as byproduct of chlorinated solvent manufacture</li> <li>• Processing for burning as a waste fuel</li> </ul>
PCTP	<ul style="list-style-type: none"> <li>➤ Plasticizer;</li> <li>➤ Make rubber more pliable in industrial uses</li> </ul>	<b>Ban all manufacture, processing and distribution, <u>except</u>:</b> <ul style="list-style-type: none"> <li>• Concentrations are at or below 1%</li> </ul>




# The Problem with PIP (3:1)

- ◆ **PIP (3:1) Rule Created Special Problems for Industry**
  - ◇ March 9: Effective date for ban on all distribution of articles containing PIP (3:1)
  - ◇ Downstream article importers/producers not previously aware of PIP (3:1) in their supply chains
    - Flame retardant and plasticizer
    - Presence in basic wire cable insulation, for example, may affect many industries
  - ◇ Ban threatens to interrupt supply chains while substitutes identified, validated and put into production
  - ◇ Ban threatens to strand articles in channels of trade
  - ◇ Emergency appeals to EPA to extend the implementation timeline
- ◆ **EPA took the opportunity to both provide practical relief and to move immediately to reconsider all five PBT rules**

# “No Action Assurance” for PIP (3:1) Rule

- ◆ **OECA pledges not to enforce, for 180 days (September 4, 2021):**
  - ◇ Ban on distribution and processing of PIP (3:1)
  - ◇ Requirements to have a written statement that the company’s products containing PIP (3:1) comply with the PIP (3:1) rule
  - ◇ EPA to take action within 180 days to issues practicable deadlines
  - ◇ Time for orderly product component substitutions; get affected products through and out of the channels of trade
- ◆ **Only applies to PIP (3:1) in articles and intended for use in articles**
  - ◇ Does not apply to other uses of PIP (3:1)
  - ◇ Does not apply to ban on releases to water and downstream notification



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
ENFORCEMENT AND  
COMPLIANCE ASSISTANCE

March 8, 2021

**MEMORANDUM**

**SUBJECT:** No Action Assurance Regarding Prohibition of Processing and Distribution of Phenol Isopropylated Phosphate (3:1), PIP (3:1) for Use in Articles, and PIP (3:1)-containing Articles under 40 CFR 751.407(a)(1)

**FROM:** Lawrence E. Starfield  
Acting Assistant Administrator

**LAWRENCE STARFIELD**  
Digitally signed by LAWRENCE STARFIELD  
Date: 2021.03.08 15:01:58 -0500

**TO:** Michal Freedhoff  
Acting Assistant Administrator  
Office of Chemical Safety and Pollution Prevention

The U.S. Environmental Protection Agency is providing a no action assurance (No Action Assurance) to certain entities that are subject to the Toxic Substances Control Act (TSCA) Section 6(h) Rule that prohibits the processing and distribution of PIP (3:1) and PIP (3:1) containing articles under Section 751.407(a)(1) of EPA's final rule, "Phenol, Isopropylated Phosphate (3:1) (PIP (3:1)); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA Section 6(h)," 86 Fed. Reg. 894 (Jan. 6, 2021) (Final PIP (3:1) Rule). This No Action Assurance is being issued in response to your request of March 8, 2021. As explained more fully below, this No Action Assurance establishes that the EPA will exercise its enforcement discretion to not pursue enforcement actions for violations of the prohibitions on processing and distribution of PIP (3:1) for use in articles, and the articles to which PIP (3:1) has been added, outlined at 40 CFR § 751.407(a)(1) and for the requirement in 751.407(d)(2) that records required to be kept under 40 CFR § 751.407(d)(1) contain a statement that the PIP (3:1), or the PIP (3:1)-containing articles, are in compliance with 40 CFR § 751.407(a), for those entities covered by the exercise of enforcement discretion regarding 40 CFR § 751.407(a)(1).

As explained in your request, EPA, as required by statute, issued a proposed rule for regulation of five PBT chemicals, including PIP (3:1), on July 29, 2019, and the final rule was published on January 6, 2021. Since the publication of the final rule, many stakeholders, for example from the electronics and electrical manufacturing community and their customers, have raised significant concerns about the March 8, 2021, compliance date in the final rule applicable to the prohibition of processing and distribution of PIP (3:1) and PIP (3:1)-containing articles. These stakeholders requested an extension of the compliance date in order to clear the existing articles through the supply chain, find and certify an alternative chemical, and produce or import new articles or complex goods that do not contain PIP (3:1).

# EPA Reopens All Five PBT Rules



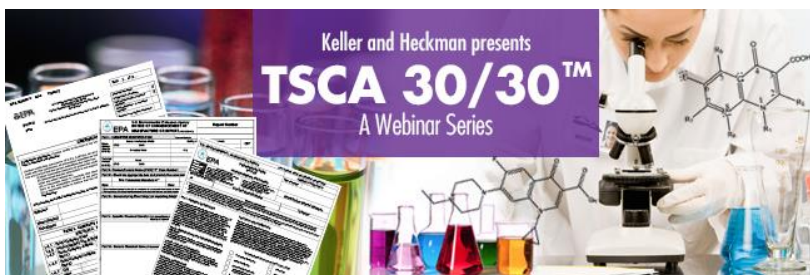
- ◆ **Full re-examination of all five PBT rules**
  - ◇ Comment on appropriate compliance dates/transition periods for different uses
  - ◇ Also accepting comments on *any and all other aspects* of the rules
  - ◇ Notice published March 16 [86 FR 14,398]
  - ◇ Accepting public comment for 60 days, until **May 17, 2021**
- ◆ **EPA May Extend Deadlines, Expand Scope, Narrow Current Exclusions**
  - ◇ Change interpretation of statute (e.g., regarding disposal, occupational exposure, use)?
  - ◇ Propriety of current exclusions (are more exposure reductions practicable?)
  - ◇ Consistency with new Biden EOs (science integrity, transparency, Environmental Justice, and exposed subpopulations)
- ◆ **Critical to participate in new comment period to assure substantial evidence for decision-making:** e.g., practicable deadlines, treatment of articles, appropriate exclusions



Please join us at 1:35 PM Eastern U.S.

March 17, 2021

[www.khlaw.com/REACH-3030](http://www.khlaw.com/REACH-3030)



Please join us at 1:00 PM Eastern U.S.

Wednesday, April 7, 2021

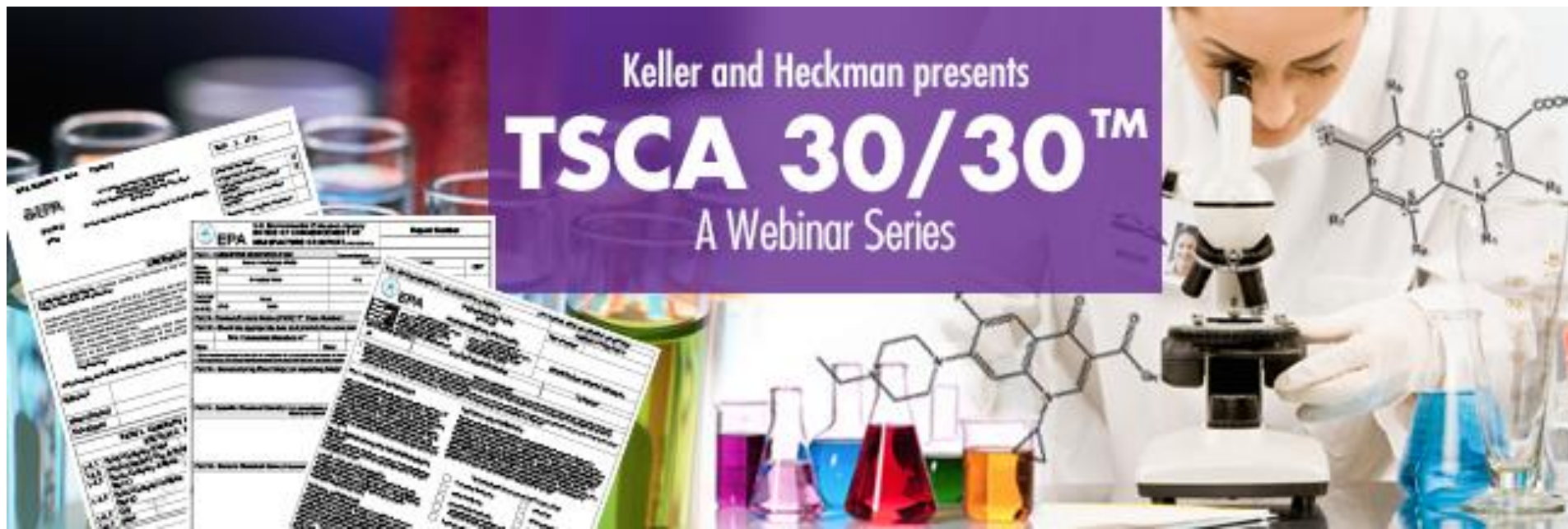
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Please join us at 1:00 PM Eastern U.S.

Wednesday, March 24, 2021

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# Thank You!

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