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OCTC Ohio Chemistry Technology Council

2021 Chemicals Workshop Webinar Series

Biden Administration Implementation of TSCA

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Welcome

Karen A. Winters

Environmental, Safety & Health Practice Group Leader, Columbus

T +1 614 365 2750

E karen.winters@squirepb.com

Jennifer Klein

President, Ohio Chemistry Technology Council, Columbus

T +1 614 224-1730

E jklein@ohiochemistry.org

W. Caffey Norman

Senior Partner, Washington DC

T +1 202 457 5270

E caffey.norman@squirepb.com

Allen Kacenjar Jr.

Partner, Cleveland

T +1 216 479 8296

E allen.kacenjar@squirepb.com

Welcome and Introductions

Karen A. Winters

The Ohio Chemistry Technology Council

Jennifer Klein

W. Caffey Norman

2016 TSCA Amendments

- Lautenberg Chemical Safety for the 21st Century Act signed into law on June 22, 2016.
- Requires EPA to evaluate new and existing chemical substances to determine whether they present an unreasonable risk of injury to health or the environment under the conditions of their use.
  - Prohibits consideration of costs or other non-risk factors in evaluations.
  - Requires EPA to consider potentially exposed or susceptible subpopulations, including workers, in evaluating chemical substances.
  - Authorizes EPA to issue administrative orders to require testing of chemicals.
- Eliminates the “least burdensome alternative” requirement for chemical restrictions.
- Allows EPA to charge new/higher fees for chemical reviews.
- Preempts state chemical regulations under certain conditions.

Impact on Workplace Regulation

- Requires EPA to consider potentially exposed or susceptible subpopulations, **including workers**, in evaluating chemical substances.
  - This change deserves a slide of its own. By including the word "workers," the Lautenberg Act upended 50 years of workplace regulation of toxic substances, hitherto the province of the Occupational Safety & Health Administration (OSHA)
  - Permissible exposure limits under the Occupational Safety & Health Act (OSH Act) must reduce "significant risk" and be economically and technically "feasible," in accordance with Supreme Court's *Benzene* decision.
  - Under TSCA, on the other hand, where EPA finds "unreasonable risk" it must regulate "to the extent necessary so that the chemical substance no longer presents such risk." Economic consequences are only one of several factors to be considered in selecting among restrictions.

TSCA Direction on Coordination of Workplace Regulation

- TSCA § 9 requires EPA first to submit a report to OSHA describing the risks, identifying the activities that present unreasonable risks, and requesting OSHA (i) to determine if it can "prevent[] or reduce[] to a sufficient extent" said risks by action under the OSH Act, (ii) if so, to issue an order declaring whether or not such risks are presented, and (iii) to respond to EPA accordingly.
- If OSHA initiates action to address the risks or concludes there is no such risk the Administrator may not take any action under TSCA § § 6 or 7 with respect to such risk.
- If OSHA does not respond or does not initiate action to address the risks identified, EPA must initiate action under TSCA § § 6 or 7.

EPA Derivation of Cancer Risk

- As an example, the completed Risk Evaluation for carbon tetrachloride (CTC) concludes that it poses unreasonable risk in almost all conditions of use, including feedstock use in closed systems. Based on this Evaluation, and assuming an acceptable cancer risk for workers of 1 in 10,000, EPA would likely derive an Existing Chemical Exposure Limit (AEL) value of **23 ppb**.
- Unlike the EPA Evaluation, a recent REACH evaluation concluded that CTC acts as a carcinogen by a threshold mode of action. Based on this conclusion, the REACH evaluation derives an AEL of **5 ppm** for potential cancer risk after chronic exposure to CTC via inhalation. This is consistent with the OSHA/ACGIH workplace limit range, and some thousand times higher than the level deemed acceptable in the EPA Risk Evaluation.
- While EPA must still develop rules to mitigate unreasonable risk, it is unclear how further risk management in these closed systems can be achieved. Elimination of use of CTC as a feedstock would eliminate US production of hydrofluoroolefins (HFOs), low Global Warming Potential (GWP) alternatives seen as critical to efforts to combat climate change.

Likely TSCA Workplace Limits Compared to OSHA PELs

Chemical	Units for AELs and PELs	OSHA PEL/ACGIH TLV®	AEL Based on IRIS Cancer Potency Factors	PEL/Cancer AEL
Benzene	ppm	1/0.5	0.03	33
Ethylene Dichloride	ppm	50/10	0.008	6,250
Perchloroethylene	ppm	100/25	0.4	250
Butadiene, 1,3 -	ppm	1/2	0.012	83
Formaldehyde	ppm	0.75/0.1	0.048	16
Methylene Chloride	ppm	25/50	20	1.25
Trichloroethylene	ppm	100/10	0.04	2500
Vinyl Chloride	ppm	1/1	0.068	15
Chloroprene	ppm	25/1	0.0008	31,250
Carbon Tetrachloride	ppm	10/5	0.023	435

First 10 TSCA Risk Evaluations

- In late 2016 EPA initiated risk evaluations on 10 substances, including carbon tetrachloride, as just discussed, and methylene chloride.
- TSCA imposes a 3-year deadline on EPA to complete a risk evaluation, but gives EPA the ability to extend the deadline for up to 6 months.
- EPA missed the December 2019 deadline for all the risk evaluations.
- EPA completed only the methylene chloride risk evaluation by the extended June 2020 deadline.
- By the end of 2020 EPA completed the other nine risk evaluations.

Litigation on First Risk Evaluation

- As noted, EPA issued its first TSCA risk evaluation, for methylene chloride, in June 2020, finding that 47 commercial, industrial and consumer uses posed “unreasonable risk” and 6 uses did not.
- NGOs, unions, and State Attorneys General filed petitions in the US Court of Appeal challenging the “no unreasonable risk” determinations for methylene chloride.
- They also contended that EPA wrongly declined to consider certain uses and pathways that create exposures/risks, that EPA wrongly assumed use of Personal Protective Equipment (PPE), and that EPA should have made a unitary “unreasonable risk” finding for methylene chloride.

Remand to EPA

- EPA Motion to Remand the methylene chloride risk evaluation:
  - EPA asked the Court to remand its “no unreasonable risk” determinations to allow the Agency to reconsider them.
  - On July 14, the Court granted EPA’s request for remand for the limited purpose of permitting the Agency to reconsider the challenged “no unreasonable risk” determinations.
- In late June, EPA announced its intent to revisit legal and policy-based assumptions and approaches in seven of the first 10 evaluations:
  - EPA’s approach in making risk determinations on a condition-of-use by condition-of-use basis rather than a determination for the chemical as a whole,
  - Assumptions regarding workers’ use of PPE in various commercial conditions of use, and
  - Declining to analyze certain populations as a “potentially exposed or susceptible subpopulation,” or certain environmental exposure pathways regulated under other statutes.
- In August the Court issued similar remands in cases involving completed risk evaluations for the cyclic aliphatic bromide cluster (HBCD) and for 1,4-dioxane.

Current Status of EPA Reconsideration of First Ten Risk Evaluations

- Most significantly, EPA has indicated that it will, where appropriate, supplement these risk evaluations to include consideration of exposures to fenceline communities, a key component of the Biden Administration's emphasis on Environmental Justice, and may seek public comment and peer review.
- Additional analyses for previously excluded exposure pathways, such as drinking water, and for additional conditions of use, such as commercial uses of products containing the chemical as a byproduct, combined with the EJ analyses, will push reconsideration of these evaluations well into 2022.
- EPA must also take into account a highly critical National Academy of Sciences review of the systematic review methodology used for all ten of the evaluations.

Next Steps After a Risk Evaluation is Complete

- Determination of "No Unreasonable Risk" is a final agency action that is judicially reviewable, as seen in the cases just discussed.
- Determination of Unreasonable Risk
  - If EPA determines that any use of a substance presents an unreasonable risk of injury to health or the environment, the agency must "immediately" begin to develop a risk management rule under TSCA § 6 to address the risk(s).
  - Determination is not a "final agency action"; only the TSCA § 6 rule is reviewable.
  - EPA could impose a range of requirements and restrictions, including an outright ban on some (or all) uses.
  - Even after EPA makes risk determinations for chemicals as a whole, risk management will still have to be on a condition-of-use basis.
- EPA must propose a TSCA § 6 rule within one year after the final risk evaluation is issued.
  - A final § 6 rule must be adopted within 2 years after completion of the risk evaluation.
  - EPA may extend the deadline by 2 years, but extensions for risk evaluations count against this.

Risk Evaluations for Next 20 "High-Priority" Substances

- In December 2019 EPA issued a list of 20 high-priority substances for which risk evaluations must be conducted:
  - Formaldehyde, Ethylene Dichloride, 1,3-Butadiene; o-Dichlorobenzene (Benzene, 1,2-dichloro-); p-Dichlorobenzene (Benzene, 1,4-dichloro-); 1,1-Dichloroethane; trans-1,2-Dichloroethylene; 1,2-Dichloropropane; Ethylene dibromide; 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB); 4,4′-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA); Phosphoric acid, triphenyl ester (TPP); 1,1,2-Trichloroethane; Tris(2-chloroethyl) phosphate (TCEP); Butyl benzyl phthalate (BBP); Dibutyl phthalate (DBP); Dicyclohexyl phthalate; Di-ethylhexyl phthalate (DEHP); Di-isobutyl phthalate (DIBP); Phthalic anhydride.
- Final scope documents were issued late in 2020, so the risk evaluations have been initiated.

Other TSCA Litigation

- Separately from the Ninth Circuit case on methylene chloride, the Second Circuit recently issued a decision in the first challenge to TSCA § 6 rulemaking since 1991. In *Labor Council for Latin American Advancement, et al. v. EPA*, the Court upheld EPA's regulation banning sales of methylene chloride-based paint strippers to consumers. Industry challenged the overbreadth of the regulation, which effectively eliminated retail sales for commercial as well as consumer use. The Court rejected both that challenge and that of several NGOs who argued that EPA should have banned *all* sales for commercial use as well.
- The *LCLAA* decision is unlikely to have much precedential value, as the rule was based on a risk assessment completed in 2014, before TSCA reform. It was adopted under TSCA § 26(l)(4), which allows EPA to adopt § 6(a) rules for chemicals for which EPA had "published a completed risk assessment prior to June 22, 2016," *i.e.*, only methylene chloride and two other chemicals.

TSCA Risk Evaluation Fees

- Manufacturers and importers of first 10 were not subject to a fee. In January 2020 EPA published preliminary lists of manufacturers and importers that are potentially subject to the $1.35 million fee for each of the upcoming 20 risk evaluations.
- In March 2020, EPA announced that it will be revising the TSCA fee rule to exempt companies from the risk evaluation fee if they:
  - Import the substance in an article;
  - Produce the substance as a byproduct; or
  - Produce or import the substance as an impurity.
- Because the revisions will not be done until fall 2021, EPA is exercising its enforcement discretion and will not take action against companies that fall into these three categories and did not self-identify by the deadline. “No Action” assurance expires Sept. 30, 2021 or the effective date of the final rule, whichever is earlier.

TSCA Risk Evaluation Fees, cont.

- In January 2021, EPA proposed updates and adjustments to the 2018 fees rule.
- EPA proposed modifications to the TSCA fees and fee categories for fiscal years 2022 through 2024, and explained the methodology by which the proposed TSCA fees were determined.
- EPA proposed to add three new fee categories: A Bona Fide Intent to Manufacture or Import Notice, a Notice of Commencement of Manufacture or Import, and an additional fee associated with test orders.
- EPA proposed exemptions for entities subject to certain fee-triggering activities including: An exemption for research and development activities, for entities manufacturing less than 2,500 lbs. of a chemical; for manufacturers of chemicals produced as a non-isolated intermediate; and the exemptions noted in the preceding slide.

Preemption

- Under TSCA § 16, preemption will begin on the date that the risk evaluation scope is defined and end "on the date on which the deadline … for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation …, whichever is earlier."
- This "pause preemption" does not apply to the first 10 risk evaluations. For them, preemption applies only when EPA issues a final TSCA § 6 risk management rule.
- But the delay of a final risk evaluation means a delay in the final § 6 rule, which gives states more time to act (and also cuts into EPA's time to issue the § 6 rule).

Other

- Risk Evaluation Framework Rule adopted July 2017 codifies individual conditions of use approach.
- June 2021 Regulatory Agenda shows reconsideration of Framework Rule as “long-term” Item.
- Query whether plan to reopen seven completed Risk Evaluations would first require rulemaking to revise Framework Rule.
- Also possibility that revocation of a “no unreasonable risk” determination would constitute final agency action (revocation of a final order under APA) allowing for judicial review without awaiting adoption of risk management rule for that use.

Biden Administration Implementation of TSCA

Allen Kacenjar

New Chemicals – EPA's New Tone

- "The 2016 TSCA amendments required EPA to make affirmative determinations on new chemicals before they're allowed to enter the market. For example, if EPA determines that there is 'insufficient information' to assess the potential risks of the new chemical, or that the chemical 'may present' an unreasonable risk to human health or the environment, TSCA says that EPA quote unquote 'SHALL' issue an order to protect against those risks," "And, where appropriate, EPA also may require the development of data to support the assessment. ***But those required actions weren't always taken in the past***." Michal Freedhoff (Mar. 2021)
- "Rather than issuing enforceable orders to ensure that workers handling the chemical substances were protected against identified risks, EPA sometimes assumed -- without any guarantee whatsoever -- that the needed protections would be provided through other means. ***EPA also didn't always issue orders that covered all of the reasonably foreseeable conditions of use for new chemical substances -- instead, it deferred the assessment of risk associated with many of those uses into the future.***" Michal Freedhoff (Mar. 2021)

New Chemicals – The Whistleblower Claims

- June 28, 2021: Allegations by four scientists at EPA's chemical safety office through Public Employees for Environmental Responsibility (PEER):
  - "[D]isturbing evidence of fraud and corruption…involving deliberate tampering with chemical risk assessments conducted under" TSCA.
  - "[N]umerous instances where their risk assessments were changed by their managers or by colleagues in response to direction by management" including
    - "Deleting language identifying potential adverse effects…."
    - "Major revisions that alter the report conclusions to indicate there are no toxicity concerns despite data to the contrary."
    - "Risk assessments being reassigned to inexperienced employees in order to secure their agreement to remove issues whose inclusion would be protective of human health."
- Alleges the issues "occurred prior to Trump taking office, through the Trump years, and continue under the current administration."
- July 14, 2021: EPA's Office of Inspector General opened an inquiry.
- August 17, 2021: House Energy and Commerce Committee demand briefing by EPA on the claims.
- Sept. 22, 2021: Further allegations of "constant pressure" to find ways to approve chemicals and to avoid identifying risk from exposures.

New Chemicals – EPA Reforms

- On October 14, 2021, Office of Chemical Safety and Pollution Prevention announced actions to strengthen new chemical safety reviews.
  - Aimed at restoring “public trust” in light of the scientific integrity allegations.
- Formed “OCSPP Science Policy Counsel”
  - Chaired by Science Policy Advisor - senior staff, reports to Assistant Administrator
  - To provide guidance on emerging science policy and issues of “broad interest”
  - “Advisory perspective on matters related to scientific integrity”
  - Members selected based on expertise, impartiality
  - May include EPA experts beyond OCSPP
- Formed “New Chemicals Advisory Committee” (NCAC):
  - To “review both scientific and science policy issues related to new chemical submissions”
  - Subject matter experts will discuss difficult issues and “cross cutting science policies”
  - To resolve disputes among scientists over risk assessments
- Procedural Changes at the New Chemicals Division:
  - Focus on “proper documentation of decisions and any differing scientific opinions.”
  - Reviewed 100+ SOPs – prioritizing for updates
- Practical Ramifications….

New Chemicals – EPA Compliance Initiative

- Sharp increase in significant new use rules (SNURs) and TSCA Section 5 orders during the several years since the Lautenberg amendments.
- EPA's draft strategic plan reflects concern that "none" of these risk mitigation requirements have been checked to confirm compliance.
- During October 2021, EPA confirmed an initiative aimed at addressing this:

  "***By September 30, 2026, EPA plans to review 90% or more of all chemicals with a TSCA Section 5 order or SNUR.***"

- Key Open Questions:
  - What form will this initiative take?
  - Who will be driving?
- Action Items: Get your house in order!
  - Know your Section 5 Orders and SNURs
  - Confirm all records on file
  - Consider auditing if uncertain

New Chemicals – EDF v. EPA

- Filed March 2020 by Environmental Defense Fund in the U.S. District Court for the District of Columbia. Plaintiffs:
  - Allege that EPA:
    - Doesn't notify "the public when a new chemical is under review…as required by law."
    - "Allows companies to conceal crucial information about chemicals under review."
    - "Doesn't audit companies' CBI claims to determine whether they are warranted."
  - Argue that Congress intended "to provide the public with knowledge about new chemicals that might enter the market and so that interested persons can provide input into EPA's decision-making."
  - Seek to require EPA to post all information about newly filed PMN in publicly-accessible dockets. In particular, seems focused on exposure and toxicity data.
- Trump EPA vs. Biden EPA
  - October 9, 2020 : no "realistic possibility of settling the case."
  - October 1, 2021: "agreement is possible on some or all of the…issues in dispute."
- Potential Results:
  - Opens the PMN Process to public scrutiny
  - Competitive and PR ramifications
  - Risks complicating the PMN process.
  - Additional pressure on CBI claims.

New Chemicals – Potential Ramifications

- Demands for significantly more data up front (rulemaking?)
- Increased use of SNURs – setting conditions on new chemical uses to address “reasonably foreseeable” uses of the chemical.
- Particular focus on worker protection and challenges to any assumptions about the use of PPE.
- Risk adverse decisions
- More challenges to CBI Claims
- Public transparency on PMN documents
- Possible Public involvement
- Increased Process
- Less Certainty
- Longer reviews
- Increased enforcement risk

Regulation of Articles

- "Generally speaking, articles are manufactured goods or finished products – and the chemicals in them ARE subject to TSCA." – Michal Freedhoff (Sept. 28, 2021)
- General public assumption that articles are exempt, but….
  - "The Administrator may require notification …for the ***import or processing*** of a chemical substance as part of an article or category of articles…if the Administrator makes an ***affirmative finding***…that the reasonable potential for exposure to the chemical substance through the article…justifies notification."
  - "In selecting among prohibitions and other restrictions, the Administrator ***shall apply such prohibitions or other restrictions to an article or category of articles*** containing the chemical substance or mixture ***only to the extent necessary*** to address the ***identified risks from exposure*** to the chemical substance or mixture from the article or category of articles ***so that the substance or mixture does not present an unreasonable risk*** of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)." § 6(c)(2)(E)

Regulation of Articles

- Key Questions
  - What threshold must EPA clear to regulate an article?
    - Breadth of “Processing”?
  - Scope of authority?
  - Process for making and supporting findings?
  - What about impurities and byproducts? De Minimis Limits?
  - Consequences of noncompliance?
- Key Issues & Ramifications:
  - Difficulty knowing exactly what’s in your products
    - Dramatic increase in information needed from upstream supply chain
    - Dramatic increase in information demands from downstream customers
  - Pressure on CBI and sensitive supply chain information
  - Renegotiation of compliance costs and risks
  - Expands TSCA to the uninitiated
  - Tension and overlap with Consumer Product Safety Commission
- Likely Targets

Regulation of PBTs – Actions to Date

- January 2021: EPA issued final rules under TSCA § 6(h) to address risk and reduce exposures for 5 PBT chemicals:
  - DecaBDE (flame retardant)
  - PIP (3:1) (plasticizer, anti-wear additive)
  - 2,4,6-TTBP (intermediate, fuel additive)
  - HCBD (chemical manufacturing byproduct)
  - PCTP (peptizer)
- Use of these chemicals was sharply restricted under the rules. Subject to very limited exceptions:
  - Prohibited the manufacture (including import)
  - Prohibited processing/distribution of the chemicals
  - Prohibited processing/distribution of articles containing the chemicals
- Most manufacture, processing and distribution was barred immediately on the effective date – February 5, 2021.

Regulation of PBTs – PIP (3:1)

- What is it?
  - Widely used plasticizer, flame retardant, anti-wear additive
  - Used in hydraulic fluid, lubricating oils, industrial coatings, adhesives, sealants, and wiring for electronics
- How regulated?
  - EPA prohibited processing and distribution in commerce of PIP (3:1), and products and articles containing this substance for all except certain very specific uses
  - Requires those manufacturing, processing or distributing the chemical or articles containing it to notify customers.
  - No de minimis threshold or exemption for impurities/byproducts
  - Imposed recordkeeping obligations documenting exceptions for uses still allowed
- EPA's rationale?
  - Concluded that TSCA § 6(c)(2)(E) requirement to complete a risk evaluation before regulating articles so it could restrict only to "the extent necessary" was inapplicable.
  - EPA "does not believe that Congress intended, through the article provisions incorporated into the TSCA amendments to absolve importers of the duty to know what they are importing."

Regulation of PBTs – The Aftermath

- Immediate reaction – particularly on PIP (3:1), and particularly by industries rarely impacted by TSCA.
- March 8, 2021: EPA issues 180-day "No Action Assurance" providing "EPA will exercise its enforcement discretion not to pursue enforcement actions for violations of the prohibitions on processing and distribution of PIP (3:1) for use in articles"
  - Warranted by "wide range of key consumer and commercial goods" that "could be affected by the prohibitions" and the risk of "significant disruption of domestic and international supply chains."
- March 16, 2021: Published notice broadly requesting additional public comment on all five PBT Rules. Particular focus on PIP (3:1) timing.
- September 2021: Extension of deadline for eliminating most PIP (3:1) uses until March 8, 2022 (a one-year extension)
  - EPA acknowledged industry comments regarding widespread use of PIP (3:1) and time needed to replace it.
- October 21, 2021: Pre-publication rule proposing a further extension of the PIP (3:1) compliance deadline until October 31, 2024.
  - EPA invited comments providing specific information and documentation supporting a further compliance date extension

Regulation of PBT Chemicals - Outlook

- Moving Targets:
  - In the proposed extension, EPA reiterated its intent to issue new rules regarding the 5 PBT chemicals – anticipated 2023
  - Expected to further assess and restrict uses due to risk and focus on Biden Administration's Executive Orders – particularly environmental justice
  - Pending DC Circuit Appeal by multiple trade groups challenging the PIP (3:1) rule – no substance yet…
- The PIP (3:1) saga emphasizes the significant challenges faced by regulators and the regulated community alike when regulating articles.
  - Untested statutory provisions & prerequisites
  - Widespread economic ripple effects
  - Implications for companies unfamiliar with TSCA
- More to follow:
  - EPA recently proposed classifying 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB) as a PBT chemical (air care products and odor agent)

PFAS Preview!

- **PFAS and EPA**
  - TSCA Chemical Substance Inventory includes hundreds of CBI and non-CBI PFAS and potentially thousands of PFAS fall under the scope of the TSCA program.
  - PFOA Stewardship Program (2010/2015)
    - Voluntary agreement by eight major chemical companies to phase out use of PFOA and PFOA-related chemicals from facilities.
  - PFAS Low Volume Exemption (LVE) Stewardship Program (Renewed 2021)
    - EPA asks companies to voluntarily withdraw LVEs as a continuation of previous outreach.
- **PFAS Roadmap for TSCA**
  - **Increased Attention on SNURs:** EPA is preparing to review SNURs and regulatory decisions for PFAS handled under previous administrations. This includes a July 2020 final rule on long-chain PFAS, such as those used in surface coatings and carpets.
  - **Increased Testing:** EPA plans to exercise authority under TSCA to make manufacturers conduct and fund studies and toxicity testing for approximately 24 PFAS.
  - **Future Reporting Rules for PFAS in 2022-2023:**
    - Toxics Release Inventory (TRI): EPA will propose rulemaking to categorize PFAS as “Chemicals of Special Concern” and remove de minimis eligibility for such chemicals.
    - Data Gathering: EPA will use Section 8(a)(7) of TSCA to collect data on PFAS since 2011.

Questions?

Karen A. Winters

Environmental, Safety & Health Practice Group Leader, Columbus

T +1 614 365 2750

E karen.winters@squirepb.com

Jennifer Klein

President, Ohio Chemistry Technology Council, Columbus

T +1 614 224-1730

E jklein@ohiochemistry.org

W. Caffey Norman

Senior Partner, Washington DC

T +1 202 457 5270

E caffey.norman@squirepb.com

Allen Kacenjar Jr.

Partner, Cleveland

T +1 216 479 8296

E allen.kacenjar@squirepb.com

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A couple business days after today's session you will receive an email with a link to the ***uniform certificate of attendance*** and ***program evaluation*** to complete and SUBMIT to Robin Hallagan at robin.hallagan@squirepb.com.

2021 Chemicals Workshop Webinar Series

- PFAS and Prop 65: Key Practical and Regulatory Developments
- Wednesday, November 3
- 11 a.m. – noon EDT