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OCTC Ohio Chemistry Technology Council

2021 Chemicals Workshop Webinar Series

PFAS and Prop 65: Key Practical and Regulatory Developments

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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

Kendra Sherman

Partner, Columbus

T +1 614 365 2726

E kendra.sherman@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

Allen Kacenjar

PFAS – The Basics

- **What is it?**
  - PFAS are for per- and polyfluoroalkyl substances found in a variety of consumer and industrial products.
    - Includes PFOA, PFOS, GenX, and many others (NIH estimates more than 4,700).
    - PFOA, or perfluorooctanoic acid (C8) is known for use in the production of Teflon.
  - Commonly referred to as “forever chemicals” in mainstream media.
- **Where is it used?**
  - Food items (food packaging, food processing equipment).
  - Commercial products (certain fabrics, cleaning products).
  - Industrial products (making Teflon, certain fire-fighting foams; plating bath surfactants).
  - Contaminated soil and/or drinking water.
  - Living organisms.
- **What are the risks?**
  - Potential for reproductive, developmental, immunological effects based on lab studies.
  - Epidemiological studies found effects on infant birth weights, cancer, and thyroid health.
  - CDC found PFAS present in 97% of Americans’ bloodstream.

Past Developments: US EPA PFAS Action Plan

- **2019 PFAS Action Plan**
  - Outlined EPA goals to reduce exposure, understand toxicity, identify impacted communities, and support public health research.
  - Priority planned efforts included:
    - Proposing national drinking water limits for PFAS/PFOS.
    - Listing PFOA/PFOS as CERCLA Hazardous Substances.
    - Develop groundwater cleanup recommendations and new analytical methods.
    - Develop toxicity values for GenX chemicals and PFBS.
- **Feb. 2020 Update to PFAS Action Plan**
  - Drinking Water Method 533 (identifies 29 PFAS with focus on “short chain”)
  - SW-846 Method 8327 (test for PFAS in non-potable water)
  - Interim recommendations for addressing contaminated groundwater
    - Screening level of 40 ppt; advisory remedial goal of 70 ppt
- **April 2021: EPA establishes Council to focus on PFAS Action Plan**

US EPA PFAS Strategic Roadmap 2021-2024

- **Strategic Roadmap builds on 2019 PFAS Action Plan**
  - Integrated approach with three central directives:
    - Research – invest in research to increase understanding of PFAS and effective interventions that incorporate best available science.
    - Restrict – comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that adversely impact human health and the environment ("get upstream of the problem").
    - Remediate – broaden and accelerate cleanup of PFAS contamination.
- **Provides Timeline of Expected Key Actions**
  - Examples of expected actions include:
    - Publish final toxicity assessment for GenX and five additional PFAS - PFBA, PFHxA, PFHxS, PFNA, and PFDA (Fall 2021 and ongoing).
    - Restrict PFAS discharges from industrial sources through Effluent Limitations Guidelines Program (2022 and ongoing).
    - Leverage NPDES permitting to reduce PFAS discharges (Winter 2022).
    - Designating PFOA and PFOS as hazardous substances under CERCLA (proposed rule Spring 2022; final rule Summer 2023).

Pending Legislation Update

Many PFAS measures are pending in Congress, including:

- **H.R. 2467 PFAS Action Act of 2021**
  - Key Elements: (1) enhanced detection and research; (2) new regulatory mandates; (3) cleanup assistance; (4) military exposure to PFAS; and (5) creation of tort action
    - Require designation of PFOA/PFOS as hazardous substance under CERCLA and hazardous air pollutant under CAA.
    - Require comprehensive toxicity testing under TSCA for PFAS.
    - Require national drinking water regulation within two years under CWA.
    - Require publication of human health water criteria for PFAS within three years.
  - Current Status: Passed House; Stalled in Senate.
- **H.R. 1352/S.916 Water Affordability, Transparency, Equity, and Reliability Act (WATER)**
  - Increases funding for water related infrastructure through a trust fund.
  - Percentage of funds reserved for publicly owned community water systems.
  - Current Status: In committee.
- **H.R. 2751/S. 1334 PFAS Accountability Act**
  - Amend TSCA to provide federal cause of action and remedy for exposure to PFAS.
  - Provides possibility of award of medical monitoring to individuals or classes with significant exposure.
  - Current Status: In committee.

Regulation of PFAS: Safe Drinking Water Act

- EPA must publish a Contaminant Candidate List (CCL) every five years.
  - The list imposes no requirements on public water systems.
- EPA must identify at least five contaminants to regulate
  - This is a formal agency decision to develop a national drinking water regulation.
  - EPA reissued final regulatory determination in February 2021 for PFOA and PFOS under Safe Drinking Water Act as part of fourth Contaminant Candidate List.
  - Triggered a two-year timeline for EPA to formally propose MCLs. Then 18 months to finalize standards.
  - **Net Result:** Regulation of PFOA and PFOS in drinking water through formal limit in 2023.
- Draft CCL 5 (July 2021)
  - The list includes 66 individual chemicals, 12 microbes, and three chemical groups.
  - PFAS is broadly proposed as a group (excluding PFOA and PFOS – already covered).
  - The 60 day comment period recently ended (Sept. 17, 2021).
  - Could make thousands of PFAS subject to SWDA regulation.

Regulation of PFAS: SDWA

- **Safe Drinking Water Act (Continued)**
  - EPA also publishes an Unregulated Contaminant Monitoring Rule (UCMR)
    - UCMR provides EPA with data to assist with the agency's regulatory and risk decisions.
    - US EPA re-proposed UCMR 5 on Feb. 22, 2021 and included monitoring for 29 PFAS (final rule expected Fall 2021)
    - Public water systems have monitoring and quality control requirements per 40 CFR 141.40.
  - Drinking Water Treatability Database
    - Tool designed for use by utilities and for regulatory purposes to assist with treatment identification and best available technology.
    - EPA added 11 more PFAS to its Drinking Water Treatability Database (total of 37).

Regulation of PFAS: CWA and RCRA

- **Clean Water Act (CWA)**
  - EPA plans to use authority in NPDES to propose monitoring requirements.
  - EPA will develop state permitting guidance specific to PFAS and NPDES permits.
  - Testing Methods: EPA recently published analytical method 1633 (covering 40 PFAS) and plans to develop further methods by Fall of 2024 to expand testing capabilities.
- **RCRA**
  - In June 2021, New Mexico's governor petitioned EPA to declare PFAS as RCRA hazardous waste.
  - EPA is responding with two rulemakings to address PFAS under RCRA:
    - **First**: EPA is expected to propose PFOA, PFOS, PFBS, and GenX as hazardous constituents under RCRA subject to corrective action requirements. This is a precursor to a hazardous waste determination.
    - **Second**: EPA is expected to issue a rule clarifying that the RCRA Corrective Action Program can require investigation and cleanup of PFAS that fits the definition of hazardous waste – essentially a workaround to permit cleanup of emerging contaminants as part of a RCRA program.
    - EPA is not yet taking the step of declaring PFAS a hazardous waste under RCRA.

Regulation of PFAS: CERCLA

- **Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)**
  - EPA may respond and regulate releases of **hazardous substances** into the environment *or* releases or substantial releases of **pollutants or contaminants** that **present an imminent and substantial danger** to public health or welfare. 42 USC 9604(a).
  - PFAS are not yet CERCLA hazardous substances, but they are "pollutants or contaminants".
  - Thus, a finding of imminent and substantial danger is currently required.
  - EPA plans to propose the designation of PFOS and PFOA as hazardous substances in Spring 2022 per the Roadmap.
  - ASTM plans to revise the Phase I ESA standard to include PFAS as a non-scope consideration (expected end of 2021).

Data Gathering and Scrutiny of PFAS

- **Toxic Release Inventory (TRI)**
  - Used to track and manage toxic chemicals that pose a threat to health and environment.
    - Collects data from 21,000+ facilities and more than 767 individually-listed chemicals.
  - EPA intends to propose rulemaking in Spring 2022 to include PFAS on TRI list as “Chemicals of Special Concern” and remove the de minimis eligibility requirements under 40 CFR § 372.38(a).
- **National Defense Authorization Act for FY 2020 (NDAA)**
  - Section 7321 added 172 PFAS to the TRI list of chemicals – 100 lb. reporting threshold.
  - Created framework for annual additions of PFAS to TRI.
  - NDAA adds three more PFAS to the TRI list automatically for 2021 reporting year: Perfluorooctyl iodide (507-63-1); Potassium perfluorooctanoate (2395-00-8); Silver(I) perfluorooctanoate (335-93-3).These three will also be added to EPCRA Section 313.
  - Per NDAA call for data, EPA proposed rule in June 2021 requiring any business manufacturing/importing PFAS to report imports over past decade. No small business exemptions.
- **NDAA for FY 2022 (Pending)**
  - Amended version that passed House in Sept. 2021 includes PFAS-measures.
    - Passage of drinking water standards within two years; submission of analytical reference stds.
    - Increased reporting mandates under TSCA; removal of exception for <1% for TRI.

Conflicts with State PFAS Limits and Regulations

- Lack of federal regulation has led to inconsistent state PFAS standards and guidance.
- At least 15 states have set drinking water standards (examples below).
- Ohio has issued action levels for six PFAS as guidance thresholds.
- Vermont recently passed law restricting sale of consumer products with PFAS.
- Maine passed law banned consumer products with “intentionally added” PFAS by 2030.
- California intends to regulate and study PFAS under Prop 65, and issued NOI to list PFOA as carcinogen in March 2021. The state is also looking at PFOS, PFNA, and PFDA.

States	Type	Chemicals	Standards
Vermont	Drinking Water Regulation	PFOA; PFOS; PFHxS; PFHpA; PFNA	20 ppt (summed across all five)
Michigan	Drinking Water Regulation	PFNA; PFOA; PFHxA; PFOS; PFHxS PFBS; HFPO-DA	PFOA MCL 8ppt; PFOS MCL 16 ppt
Minnesota	Health-based Guidance Values for Drinking Water	PFBS; PFHxS; PFOS; PFBA; PFPeA: PFHxA; PFOA	PFOA: 0.035 ppb PFOS: 0.015 ppb
Ohio	Guidance Action Levels for Drinking Water	PFOA; PFOS; GenX; PFBS; PFHxS; PFNA	PFOA/PFOS: 70 ppt GenX: 700 ppt PFBS: >140k ppt PFHxS: > 140 ppt PFNA: > 21 ppt

Toxic Substances Control Act (TSCA)

- **TSCA is central to data collection and future regulation of PFAS**
  - TSCA Chemical Substance Inventory
    - According to EPA: 602 Commercially Active PFAS; 621 Commercially Inactive PFAS.
  - 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.
- **Significant New Use Rules (SNURs)**
  - One example of authority is the issuance of significant new use rules (SNURs) that require agency notice before manufacture, importation, or processing of chemicals.
  - EPA makes a determination that a use of an existing chemical constitutes a “significant new use” after review of factors and issues a SNUR.
    - Factors considered include manufacturing production, exposure risk, magnitude and duration of exposure, and anticipated use in commerce.
  - After issuance of a SNUR, notification to EPA is required at least 90 days prior to manufacture, import, or processing according to that specific use.

PFAS, TSCA, and the Strategic Roadmap

- **Looking forward, EPA plans to:**
  - Review SNURs and regulatory decisions for PFAS handled under previous administrations – including the July 2020 final rule on long-chain PFAS.
  - Establish another PFAS Voluntary Stewardship Program (expected Spring 2022) challenging industry to reduce overall releases of PFAS into the environment.
  - Use TSCA Section 4 authority to require manufacturers to conduct and fund studies and toxicity testing for approximately 24 PFAS (expected fall 2021).
  - Review previous decisions on PFAS and issue TSCA Section 5(e) orders for existing PFAS for which significant new use notices have been filed (ongoing).
  - Improve tracking and enforcement of requirements in SNURs – particularly PFAS.
  - “Close the door” on new uses of abandoned PFAS (expected Summer 2022).
  - Finalize new PFAS reporting under TSCA Section 8 (expected Winter 2022) to collect more data.

Recent PFAS SNUR

- EPA finalized new PFAS SNUR in July 2020 originally proposed in 2015.
  - Applicable to long-chain perfluoroalkyl carboxylate and perfluoroalkyl sulfonate chemical substances (LCPFAC).
  - EPA OIG is currently investing previous administration's handling of the final rule.
- Notice required to EPA 90 days' prior to the following:
  - Manufacturing, importing, or processing of LCPFAC not ongoing after December 31, 2015;
  - Manufacturing, importing, or processing of all other LCPFAC with no ongoing uses as of January 21, 2015;
  - Import of a subset of LCPFAC chemicals for surface coating;
  - Import of perfluoroalkyl sulfonate chemical substances as part of carpets.
- Trump EPA issued guidance in January 2021 for implementation of the SNUR.
  - The guidance generally limited the applicability of surface coatings to those in contact with humans and/or the environment.
  - In June 2021, EPA withdrew the previous administration's guidance because it "inappropriately narrowed the scope and weakened the SNUR."

Efforts to Restrict PFAS Production

- **Environmentalist Petition**
  - On April 27, 2021, environmental organizations submitted a petition to EPA regarding TSCA exemptions and PFAS.
  - Requests included the following:
    - Make PFAS ineligible for TSCA exemptions including byproducts, low volume exemption (LVE), and Low Release and Exposure exemption (LoREX).
    - Ensure PFAS polymers ineligible for polymer exemption.
    - Prevent EPA from making “Not Likely to Present Unreasonable Risk Findings” for pre-manufacture notice (PMN) review.
- **Related EPA Activity**
  - EPA issued a press release the same day that pending and new LVE submissions for PFAS will be declined.
    - The Strategic Roadmap reinforces this with a plan to apply rigorous pre-manufacture notice & review for new PFAS.
  - Rationale: PFAS chemistry, health effects, longevity, and bio-accumulation.
  - Question remain on whether EPA can legally cancel previously issued LVEs.

Environmental Justice Considerations

- EPA committed to prioritizing protection of disadvantaged communities in its Strategic Roadmap.
- PFAS Project Lab at Northeastern University identified approximately 22% more people of color and 15% more low-income households live within five miles of PFAS contamination.
- Issuance of Executive Orders 14008 (Tackling Climate Crisis) and 13990 (Public Health and Environment) directly address EJ concerns
  - 14008 directs creation of Office of EJ; directs creation of geospatial tool.
  - 13990 directs review of regulations and actions that conflict with the order.
- April 30, 2021 memo entitled "**Strengthening Enforcement in Communities with Environmental Justice Concerns**" instructs EPA to:
  - Strengthen enforcement to prevent further pollution and mitigate past impacts.
- Close to Home: Rainwater in Ohio contained 1,000 ppt PFAS in April 2021.

Key Takeaways

- Sharp near-term increase in PFAS regulation and business risk
- Know your PFAS profile:
  - Fully understand any role PFAS plays in your business/operations
  - Critically Assess TRI reporting
  - Assess PFAS exposure risks
- Proactively identify EJ concerns
- Plan for the Regulatory Future
  - Track federal and state regulatory developments
  - Assess product restrictions and impacts
  - R&D (Contingency planning & opportunities)

- Assess liability risk if PFAS becomes CERCLA hazardous substance

Kendra Sherman

Overview

- Background and Key Provisions of Prop 65
- Prop 65 Enforcement
- Chemicals on the List & Recent Additions
- 2021 NOVs in Q2 and Q3
- Prop 65 Notice for PFOA and PFOS
- Clear & Reasonable Warning Amendments
- Changes Since 2018 Amendments & Current Proposed Rulemakings (“Short Form Warnings”)
- Risk Management Tools

Statutory and Regulatory Background

- Officially known as the **Safe Drinking Water and Toxic Enforcement Act of 1986,** enacted as a ballot initiative in California in November 1986.
- Original goal to protect the State's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm
- Enforcement Statutes: CA Health & Safety Code, Sections 25249.5 through 25249.13
- Implementing Regulations: CA Code of Regulations, Title 27, Division 4, Sections 25102 through 27001 by CA EPA Office of Environmental Health Hazard Assessment ("OEHHA")

Key Provisions

"No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . ." CA HSC § 25249.6

- Applies to businesses with 10 or more employees
- Applies to all businesses in the chain of commerce (manufacturers, distributors, packagers, importers, suppliers and retailers)
- Applies to out-of-state companies selling or distributing products in California
- "Knowingly and intentionally" (but "actual knowledge" for retailers – heightened standard)
- "Expose"
- Chemicals known to cause cancer or reproductive toxicity
- Without first giving a "clear and reasonable warning"
  - **Clear and Reasonable Warning Amendments (CA Code of Regulations § 25601-25605.2), effective August 30, 2018.**

Prop 65 Enforcement

- Potential liabilities and costs of defending/responding to an alleged Prop 65 violation can be significant
- Largely enforced privately by citizens and plaintiff law firms
- Must include a 60-day Notice of Violation
- **Civil Penalties ($2500 per day per violation)**
  - **25% to the prosecutor (citizen plaintiff or AG)**
  - **Each unwarned exposure = one violation**
  - **Plaintiffs can allege over $1M in fines**
- **Plaintiff Attorneys' fees**
- **Injunctive relief**
  - **Add warnings to products**
  - **Reformulation of products**

Recent Enforcement Statistics – Prop 65 Filings Not Impacted by COVID

- 2020 was a record year for the filing of Prop 65 Notices of Violation and 2021 will be higher
  - **46% increase in NOVs filed in 2020 as compared to 2019**
  - **$70M in fines/settlements collected in 2020, as compared to $35M in fines/settlements collected in 2019**
- In past 10 years, businesses have spent more than $182 million to settle Prop 65 cases
- 75% of settling businesses were located outside California

What Chemicals Are On The List & Trending?

- **900+ listed chemicals**
- Carcinogens and Reproductive/Developmental Toxins
- Prop 65 requires the State to maintain and update its list of chemicals at least once per year
- Chemicals that most often appear in recent Prop 65 NOVs or lawsuits:
  - **DEHP or phthalates such as DINP and DBP** (plasticizers, vinyl handles, fashion accessories)
  - **Lead and lead compounds** (food, dietary supplements, tools)
  - **Hexavalent Chromium** (leather sports gloves, belts, mitts)
  - **Bisphenol A (BPA)** (plastic containers, headphones, tool sets)
  - **Diethanolamine** (soaps, sunscreens)
  - **Cadmium** (food including seafood and seaweed snacks)
  - **Acrylamide** (roasted foods, crispy snack foods)
  - **N-Nitrosodiethylamine** (swim caps, workout bands)
  - **Pulegone** from peppermint extract (mints, essential oils)

Q2 2021 Notices of Violation

- 880 NOVs were filed in Q2 2021
  - Phthalates and Lead continue to top NOVs, along with cadmium, wood dust, arsenic and acrylamide
  - However, 67 of the 68 NOVs filed for wood dust in Q2 were withdrawn.

Q2 2021 - Notices of Violation		
Chemical	**NOVs**	**Example Products**
Phthalates (DEHP, DINP, DIDP, DBP)	339	PVC products and product components, wallets, purses, bags, and totes, belts, handle grips, sandals
Lead	244	Lead solder wire, various foods and spices
Cadmium	69	Sunflower seeds, spinach, seaweed, vegetables, dietary supplements
Wood dust	68	Saws, saw blades, sand paper, steel wool
Arsenic	37	Dietary supplements, seaweed, spices
Acrylamide	34	Biscuits, cereal, cookies, crackers, tortilla chips, phyllo dough
Mercury	20	Salmon, sardines, dietary supplements
Bisphenol A (BPA)	16	Phone cases, plastic containers
Chromium (hexavalent compounds)	16	Leather gloves
Asbestos	7	Cosmetics
Carbon monoxide	6	Fire starter
N-Nitrosodiethylamine	5	Swim caps, workout bands
Coconut oil diethanolamine condensate (cocamide diethanolamine)	3	Cosmetics, hand soap
Furan	3	Pretzels and pretzel sticks
Pulegone	3	Peppermint oil and extract

Q3 2021 Notices of Violation

- 893 NOVs were filed in Q3 2021
  - Similar targets to Q2, but diethanolamine and BPA are increasing
  - THC in CBD Oil NOVs now filed following new enforcement period (Jan. 3, 2021)

Q3 2021 - Notices of Violation		
Chemical	**NOVs**	**Example Products**
DEHP	360	Sandals, PVC components, purses and tote bags, seat covers, sporting goods
Lead	257	Dietary supplements, dried seafoods, spices, ceramic ware, processed foods and cereals
Acrylamide	93	Breadsticks, molasses, snack chips, pop corn, hash browns
Cadmium	54	Dried seafoods, vegetables, and fruits
Bisphenol A (BPA)	31	Safety glasses, receipt paper, face shields, phone and ear bud cases
Diethanolamine	18	Cosmetics
Acetaldehyde	17	Hand sanitizer
Arsenic	14	Dried and powdered shrimp, seaweed, kelp, spices
Mercury	11	Dietary supplements, abalone
Chromium (hexavalent compounds)	10	Leather work gloves
Benzene	9	Sunscreen and hand sanitizers
Titanium dioxide (airborne, unbound particles of respirable size)	5	Art materials, cosmetics, vegan powder
Coconut oil diethanolamine condensate (cocamide diethanolamine)	3	Hand soap, shampoo, skin cleanser
Styrene	3	Epoxy repair kit, 3D pens, 3D printers and printer filaments
Benzophenone	2	Sunscreen
delta-9-Tetrahydrocannabinol	2	CBD oil

Chemicals Recently Added to Prop 65 List

Chemical	Endpoint	Enforcement Date Begins
Molybdenum Trioxide & Tin Oxide	Cancer	March 2022
PFOA, PFOS, PFDA, PFHxS, PFNA, and PFUnDA	Reproductive Toxicity Cancer (pending)	November 2018 Pending, likely 2023
Delta-9-tetrahydrocannabinol (THC)	Reproductive Toxicity	January 2021
2-Amino-4-chlorophenol (used in hair dyes)	Cancer	September 2020
2-Chloronitrobenzene	Cancer	September 2020
1,4-Dichloro-2-nitrobenzene (intermediate in pigments)	Cancer	September 2020
2,4-Dichloro-1-nitrobenzene (intermediate in dyes, pesticides)	Cancer	September 2020
N,N-Dimethylacetamide (industrial solvent, resin)	Cancer (Reproductive Toxicity)	September 2020 (May 2011)
para-Nitroanisole (antioxidant, anti-corrosion agent)	Cancer	September 2020
para-Chlorobenzotrifluoride, PCBTF (solvent in paints/coatings)	Cancer	June 2020
Bevacizumab (cancer medication)	Reproductive Toxicity	March 2020
Gentian violet / Crystal violet (antiseptic or coloring agent)	Cancer	November 2019
N-Nitrosohexamethyleneimine	Cancer	November 2019
TRIM® VX (metal lubricant / cooling agent)	Cancer	May 2019

Prop 65 Listing for PFOA & PFOS

- In March 2021, OEHHA published a notice of intent to add PFOA and PFOS to the Prop 65 chemical database as cancer-causing
  - **Comment period ended May 2021**
  - **Final listing has not yet taken effect**
  - **The two chemicals were listed as reproductive toxins in November 2017**
    - Enforcement period began in November 2018
    - Exposures in drinking water and dermal exposure

- In March 2021, OEHHA also published a notice announcing a review of the reproductive toxicity hazards of perfluorodecanoic acid (PFDA) and its salts, perfluorohexanesulfonic acid (PFHxS) and its salts, perfluorononanoic acid (PFNA) and its salts, and perfluoroundecanoic acid (PFUnDA)
  - **Comment period ended May 2021**
  - **The final listing has not yet taken effect**

Clear and Reasonable Warning Amendments

- **Definitions and Responsibilities** (applies to all warnings)
- **Warnings – Methods and Content** ("safe harbor" provisions)
- **Consumer Products Exposure Warnings**
- **Environmental Exposure Warnings & Occupational Exposure Warnings**
- **Specified Circumstances for Specific Products, Chemicals and Area Exposure Warnings**

"Safe Harbor" Provisions – non-mandatory method and content requirements that establishes what is a "clear and reasonable" warning

- Provides a "safe harbor" against enforcement actions
- Businesses can choose to use other warning methods and content but must be prepared to defend a NOV or lawsuit

Long Form and Short Form Warnings

- Long form “clear and reasonable” Prop 65 warning:

  ⚠ **WARNING**: This product can expose you to chemicals including [name one or more listed chemicals] which [is/are] known to the State of California to cause cancer and [name one or more listed chemicals] which [is/are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

- Short form, on product “clear and reasonable” Prop 65 warning:

  ⚠ **WARNING:** Cancer and Reproductive Harm – www.P65Warnings.ca.gov.

Proposed Changes to Short Form Warning – Smaller Size and More Words

- On January 8, 2021, OEHHA proposed to amend its short-form warning regulations
- Limits the size of a short-form warning (total surface area of the label must be 5 square inches or less)
- Requires **including** the name of one or more chemicals in the product, must include “risk” and “exposure” in label
- Removes option to short-form warn online or in catalogs
- Comment period closed on March 29, 2021
    - OEHHA continues to evaluate large volume of public comments

⚠ **WARNING:** Cancer Risk and Reproductive Harm from Lead Exposure – www.P65Warnings.ca.gov.

Other Recent Proposed Rulemakings

- **Proposed Text Cannabis (Marijuana) Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposure Warnings**
- **Comment period ended October 8, 2021**
  - In response to public comments, OEHHA has now included a delayed effective date for the regulations.
  - The modifications plan to provide a 1-year delayed effective date to allow businesses to transition to the new warnings and provide an unlimited sell-through period for products manufactured prior to the effective date of the regulation labeled using the general safe harbor warning.

- **Proposed Rulemaking New Subsection 25607.2(b) Warning Content for Acrylamide Exposure from Food**
- **Comment period ends November 8, 2021**
  - Specialized warning for food containing acrylamide:
    - "Consuming this product can expose you to acrylamide, a probable human carcinogen formed in some foods during cooking or processing at high temperatures. Many factors affect your cancer risk, including the frequency and amount of the chemical consumed. For more information including ways to reduce your exposure, see www.P65Warnings.ca.gov/acrylamide."

Other Recent Proposed Rulemakings

- Additional amendments have been proposed by OEHHA recently.
  - **Modification of Text Proposed Amendments to Article 5 Section 25505 Exposures to Listed Chemicals in Cooked or Heat Processed Foods**
    - **Comment period ended May 7, 2021**
      - Clarifies that a business is not required to make any further showing of feasibility or compliance with good manufacturing practices to rely on the safe harbor levels established for specific foods.
      - Removed roasted almond butter and prune juice from exemption in order to further review and include in a potential future rulemaking
  - **Proposed Rulemaking, Warnings for Exposures to Glyphosate from Consumer Products New Sections 25607.48 and 25607.49**
    - **Comment period ended October 7, 2021**
    - Specialized warning for glyphosate products:
      - "Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. Other authorities, including USEPA, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive. A wide variety of factors affect your personal cancer risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate."

Risk Management Tools

- Assess products for warnings
- Review contracts (reps, warranties, and indemnities)
- Verify suppliers/sellers' compliance audits of products
- Provide downstream letter disclosing potential presence of Prop 65-listed chemicals as appropriate
- Communicate with employees on new requirements
- Maintain proper records
- Analyze if similar products and competitors are the subject of Notices of Violations
- Prepare compliance programs
- Conduct product audits and testing

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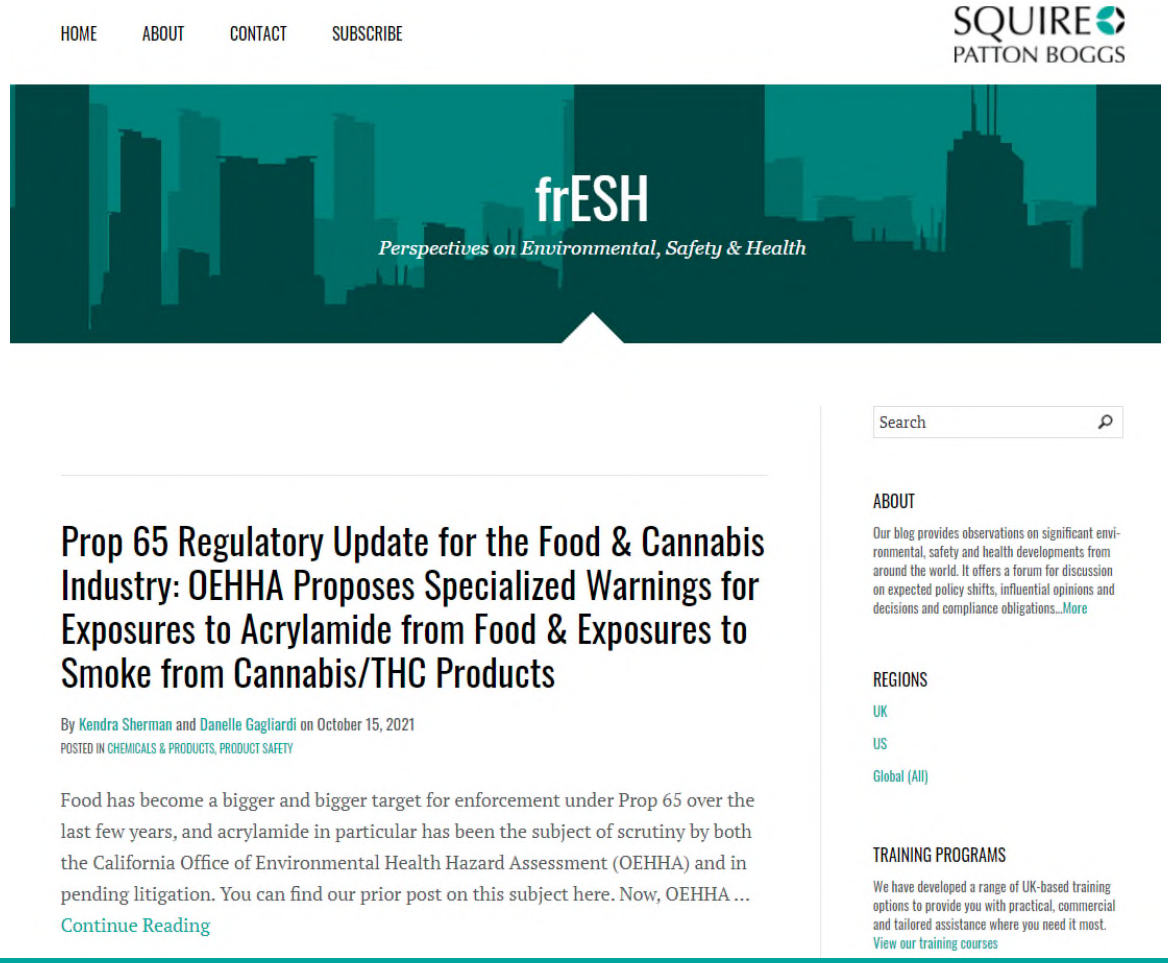
- In addition to comments in Law360, Chemical Watch & other media sources, we provide updates on Proposition 65 in our frESH Blog:



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

Kendra Sherman

Partner, Columbus

T +1 614 365 2726

E kendra.sherman@squirepb.com

Allen Kacenjar Jr.

Partner, Cleveland

T +1 216 479 8296

E allen.kacenjar@squirepb.com

CLE

For those of you who require CLE credits please note the following states have been approved for CLE in AZ, CA, CT, NJ, NY and TX. The program is pending CLE CO and OH.

Please write down the following affirmation code [PFAS113]

A couple business days after today's session you will receive an email with a copy of 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

- UK REACH - Its Implementation and Challenges, and the EU Chemicals Strategy for Sustainability
- Speakers: Dave Gordon (Birmingham), Ken Heustebeck (Brussels)
- Wednesday, November 10
- 11 a.m. – noon EST