

2022 Chemicals Workshop Webinar Series: PFAS, REACH and Other Chemical Regulatory Issues

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Welcome



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Welcome and Introductions



Karen A. Winters



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Update on UK and EU Chemical Regulation



Anita Lloyd

- EU REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals (EU Regulation 1907/2006)
- **Registration** - EU manufacturers and importers – substances over 1 tonne p.a.
- Non-EU manufacturers can appoint an “only representative” (OR) in the EU to take on importer registration duties (OR does not need to import itself)
- Downstream users benefit from the registrations higher up the EU supply chain
- **Evaluation** – review by European Chemicals Agency (ECHA) of submitted dossiers
- **Authorisation** – substances of very high concern (SVHC) – after review – banned unless specifically authorised for limited uses
- **Restriction** – prohibitions on specific uses of certain substances



- UK REACH is a stand-alone ‘version’ of EU REACH
- UK REACH has applied since 1 January 2021
- More appropriate name would be GB REACH ... because EU REACH continues to apply in Northern Ireland
- Health and Safety Executive as regulator
- Actions needed to comply with UK REACH, and maintain compliance with EU REACH for:
 - GB companies with EU REACH registrations
 - GB previous ‘downstream users’ buying chemicals from EU/EEA suppliers
 - GB companies relying on EU REACH authorisations
 - GB companies importing chemical under EU REACH OR arrangements



- GB manufacturers, importers or ORs are subject to “grandfathering”, so existing registrations carry across into UK REACH (regardless of whether they have also been transferred to an EU entity to be retained under EU REACH)
- Companies had to provide basic information to HSE by **30 April 2021** about the registered substances
- Full registration dossiers need to be submitted by the relevant phase-in date (but no registration fee as not considered to be a new registration)
- Companies that were previously downstream users under EU REACH, without registration obligations, are now importers
- Two main options:
 - The GB company had to submit a Downstream User Import Notification (**DUIN**) to **the HSE by 27 October 2021**. It will then have to submit a full registration dossier for each substance according to the same timetable as existing EU REACH registrants.
 - The non-GB manufacturer/formulator may, instead, appoint a GB OR to take on the registration duties of importers
- Considered new registrations so fees apply (but no fee for DUIN)

- Original plan:

DEADLINE	OBLIGATION
30 April 2021	Last date for GB holders of EU REACH registrations to provide basic data to HSE
27 October 2021	Last date for DUIN submissions to HSE
28 October 2023	Registration of: <ul style="list-style-type: none">All substances manufactured/imported at 1000 tonnes or more per yearCarcinogenic, mutagenic or toxic for reproduction (CMR) substances manufactured/imported at 1 tonne or more per yearVery toxic to aquatic organisms (acute or chronic) substances manufactured/imported at 100 tonnes or more per yearAll candidate list substances (as at 31 December 2020)
28 October 2025	Registration of: <ul style="list-style-type: none">All substances manufactured/imported at 100 tonnes or more per yearAll candidate list substances (as at 27 October 2023) (i.e those added since December 2020)
28 October 2027	Registration of all substances manufactured/imported at 1 tonne or more per year

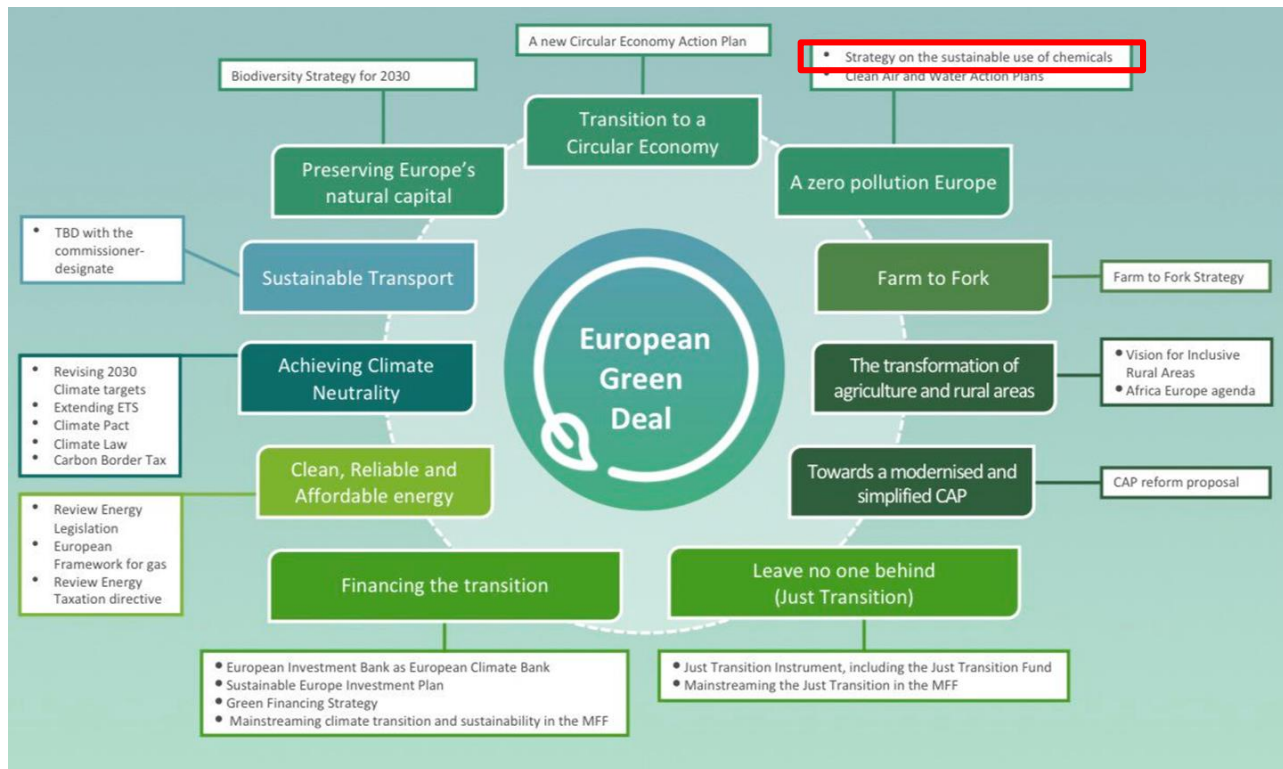
- Now proposing extensions up to 3 years (consultation July 2022)
- Plus likely acceptance of late DUINs by HSE
- New registrations of existing substances – will also follow transitional timetable

- Dec 2021 - government announced it would propose a new registration model to reduce the data costs (estimated £2bn) – no further updates since
- Long awaited UK chemicals strategy – DEFRA workshops with stakeholders recently completed but publication date TBC
- HSE capacity concerns
- Sept 2022 - Brexit Freedoms Bill - All retained EU laws and EU derived secondary legislation – REACH is one – ‘sunset’ on 31 December 2023 unless specifically continued (although some fundamental REACH principles, such as ‘no data, no market’ rule are in the Environment Act 2021)
- The UK government has not taken a position on the EU Regulatory Strategy for Sustainability and proposed REACH/CLP revisions

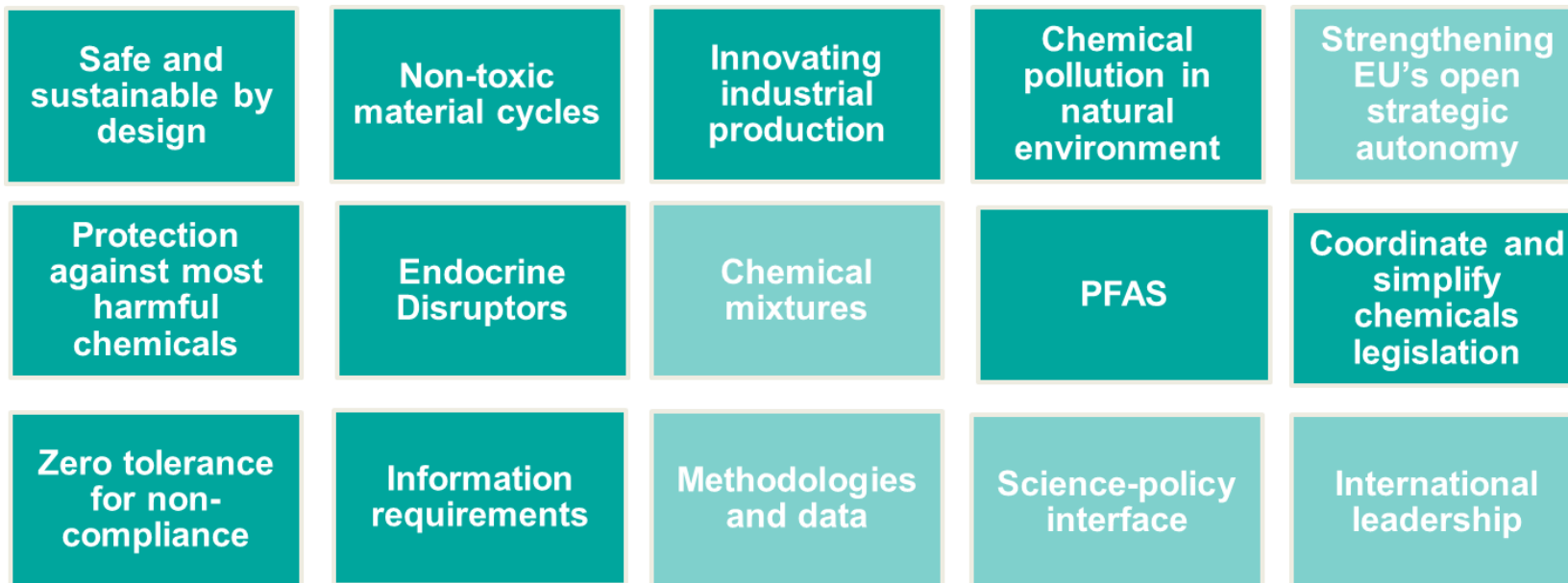


- UK REACH authorisation process is moving forward – a number of authorisations have been granted
- New restrictions have been proposed (lead in ammunition, and substances in tattoo inks and permanent make-up)
- Risk management appraisals launched for: PFAS; formaldehyde and formaldehyde releasers in articles; and bisphenols in thermal paper
- Work programme for 2022/23 - with 5 prioritised substances – the 3 above plus Intentionally added microplastics, and hazardous flame retardants
- Recent report on risk assessment of unintentional chemical mixtures under UK REACH
- But not tracking EU REACH – e.g. Candidate lists and authorisation lists are now out of sync

EU Chemical Strategy for Sustainability (CSS)



CSS – areas of focus



- January to April 2022 – open consultation – topics included:
 - information requirements – incl endocrine disruption, polymers, environmental footprint
 - changes to registration requirements
 - changes to the authorisation and restriction processes – including potential removal of the authorisation process, ‘essential use’ concept
 - the introduction of a mixture assessment factor (MAF) – issues of ‘unintentional’ mixtures
 - simplification of communication throughout the supply chain
- More substances likely to be restricted – largely by grouping chemicals / generic approach to risk management (GRA)
- “End of 2022” - Commission to present proposal for the REACH revision

- Public consultation late 2021 – high level on hazard classes, classification, labelling, scope and exemptions, online sales and poison centres
- Current consultation on new hazard classes open until 18 October 2022 –
 - Proposing new hazard classes for Endocrine Disruptors (ED); Persistent, Bioaccumulative and Toxic (PBT); very Persistent and very Bioaccumulative (vPvB); Persistent, Mobile and Toxic (PMT) and very Persistent and very Mobile (vPvM) substances
 - Updates to labels, Safety Data Sheets and REACH registration dossiers
 - Ripple effect - changes in classification under CLP automatically trigger restrictions and bans of chemicals under the GRA
 - Blacklisting effect – when manufacturers do not want ‘hazardous’ products in their portfolio
 - Changes likely to apply before equivalent changes adopted under GHS (UN system)
- “Second half of 2022” - Commission to present proposal for the CLP revision

EU

- CSS (Oct 2020) included staff working documents on PFAS - EU intends to ban all PFAS that are not “essential”
- Existing EU REACH restrictions, SVHC listings, and POPs Regulation, target named PFAS substances, but:
 - The Netherlands, Germany, Norway, Denmark and Sweden are preparing a restriction proposal to cover a wide range of PFAS uses – expected to submit the proposal to ECHA in January 2023
 - ECHA submitted in January 2022 a restriction proposal for PFASs used in firefighting foams (consultation held March to Sept 2022)

UK

- Dec 2021 to Jan 2022 - UK, Welsh and Scottish Governments asked the Health and Safety Executive and the Environment Agency to prepare a regulatory management options analysis (RMOA) for PFAS - to investigate the risks posed by PFAS and recommend the best approach to protect human health and the environment
- RMOA was due for publication in summer 2022 – awaited - but PFAS is one of the 5 priorities for the 2022 to 2023 UK REACH work programme

PFAS



Allen Kacenjjar

■ What is it?

- PFAS are a *class* of per- and polyfluoroalkyl substances found in a variety of consumer and industrial products.
 - Includes PFOA, PFOS, GenX, and many others (per NIH more than 9,000).

■ Where are PFAS used?

- Food items (food packaging, food processing, and cookware).
- Commercial products (certain fabrics, cleaning products, personal care/cosmetic items).
- Industrial products (making Teflon, fire-fighting foams, metal plating and finishing baths).
- Some Plastics
- Certain electronics

■ 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's goals to reduce exposure, understand toxicity, identify impacted communities, and support public health research.
- Priority plans 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 certain PFAS (GenX and PFBS).

■ October 2021: Strategic Roadmap

- Integrated approach with three central directives:
 - Research – invest in research to increase understanding of PFAS, the effects of PFAS, and effective interventions using the 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.

- **June 2022: Key PFAS Roadmap Items in EPA's Regulatory Agenda**
 - Proposing to designate PFOA and PFOS as CERCLA hazardous:
 - ANPRM published Sept. 2022.
 - Comment period is **open** and ends on Nov. 7, 2022.
 - Final rule expected Summer 2023.
 - National primary drinking water regulation for PFOA and PFOS:
 - Delayed from previous timeline of fall of 2022.
 - Proposed Rule now expected Dec. 2022.
 - Final rule expected Dec. 2023.
 - Finalizing new PFAS reporting under TSCA Section 8:
 - To better characterize sources and quantities of PFAS manufactured in the US.
 - Notice of proposed rulemaking published in June 2021.
 - Final rule expected Dec. 2022.

PFAS bills that are currently pending will likely die with the 117th Congress as the election approaches. Examples include:

- **S. 4829 PFAS Intergovernmental Coordination Act**

- Require OMB to establish a working group for better cooperation, coordination, and accountability in holistic response to PFAS contamination.
- Current Status: Introduced September 13, 2022.
- Referred to the Committee on Homeland Security and Governmental Affairs.

- **H.R. 7289 Federal PFAS Research Evaluation Act**

- Require EPA to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (NASEM).
- Require EPA and NASEM to: (1) study and report on research and knowledge gaps identified by the Federal Governmental Human Health PFAS Research Workshop, and (2) identify development needed to identify, categorize, evaluate and address PFAS.
- Current Status: Introduced March 30, 2022; Passed House; Stalled in Senate.

Regulation of PFAS: Safe Drinking Water Act



- EPA must publish a **Contaminant Candidate List (CCL)** every five years.
 - July 2021: EPA announced the Draft CCL 5, with PFAS proposed as a broad group.
 - Excludes PFOS and PFOA, which were included in CCL 4, triggering a two-year requirement to propose MCLs under the SDWA by the end of 2023.
 - January 2022 : EPA initiated consultation meetings with the Science Advisory Board for Draft CCL 5.
- EPA Publishes **Non-Enforceable Health Advisories**
 - June 15, 2022: EPA Updates PFAS Health Advisories
 - EPA issued final lifetime health advisories for GenX and PFBS.
 - EPA revised the 2016 interim advisories for PFOA and PFOS from a combined **70 ppt** to significantly lower amounts based on “new science”.

Chemical	Lifetime Health Advisory Level/Value (parts per trillion or ppt)	Minimum Reporting Level ¹ (ppt)
PFOA	0.004 (Interim)	4
PFOS	0.02 (Interim)	4
GenX Chemicals	10 (Final)	5
PFBS	2,000 (Final)	3

¹ Unregulated Contaminant Monitoring Rule (UCMR) 5 MRL is the minimum quantitation level that, with 95 percent confidence, can be achieved by capable analysts at 75 percent or more of the laboratories using a specified analytical method. These MRLs are based on the UCMR 5 requirement to use Method 533.

■ **Clean Water Act (CWA)**

- April 2022: EPA published a new draft method (Method 1621) that can broadly screen for chemical substances that contain carbon-fluorine bonds.
- April 28, 2022: EPA issued memo instructing proactive use the NPDES program to restrict PFAS discharges.
- May 3, 2022: EPA proposed CWA aquatic life criteria for PFOA and PFOS.

■ **Resource Conservation and Recovery Act (RCRA)**

- June 2021: New Mexico's governor petitioned EPA to declare PFAS as a RCRA hazardous waste.
- October 2021: EPA promised rulemakings to address PFAS under RCRA: (1) proposing PFOA, PFOS, PFBS, and GenX as RCRA hazardous, and (2) clarifying that the RCRA Corrective Action Program can require investigation and cleanup of PFAS that fits the definition of hazardous waste.
- EPA has not yet taken official steps toward the two RCRA rulemakings, which were not in the Spring 2022 Regulatory Agenda.

■ Toxic Release Inventory (TRI) and PFAS

- Used to track and manage toxic chemicals that pose a threat to health and environment.
- Collects data from 21,000+ facilities and 775 individually-listed chemicals across 33 categories.
- More than 170 PFAS compounds are now subject to TRI reporting.

■ July 2022 Final Rule per the National Defense Authorization Act (NDAA) of 2020:

- EPA rule adds **5 more** PFAS to the TRI listA.
 - One PFAS applied to Reporting Year 2021 (due July 1, 2022):
 - 2-Propenoic acid, 2-methyl-, [. . .] (65104-45-2)
 - Four PFAS applied to Reporting Year 2022 (due July 1, 2023):
 - Perfluorobutane sulfonic acid (375-73-5)
 - Potassium perfluorobutane sulfonate (29420-49-3)
 - Perfluorobutanesulfonate (45187-15-3)
 - 2-Propenoic acid, 2-methyl-, hexadecyl ester, polymers with 2-hydroxyethyl methacrylate, .gamma.-.omega.-perfluoro-C10-16-alkyl acrylate and stearyl methacrylate (203743-03-7)

■ Future TRI Activity

- EPA plans to propose rulemaking to include PFAS on TRI list as “Chemicals of Special Concern” (removing de minimis eligibility requirements).
- **Spring Unified Agenda 2022:** EPA will consider additional PFAS for reporting year 2023. EPA expects to issue a Proposed Rule in February 2023 and a Final Rule in Nov. 2023.

State Regulations and PFAS Limits

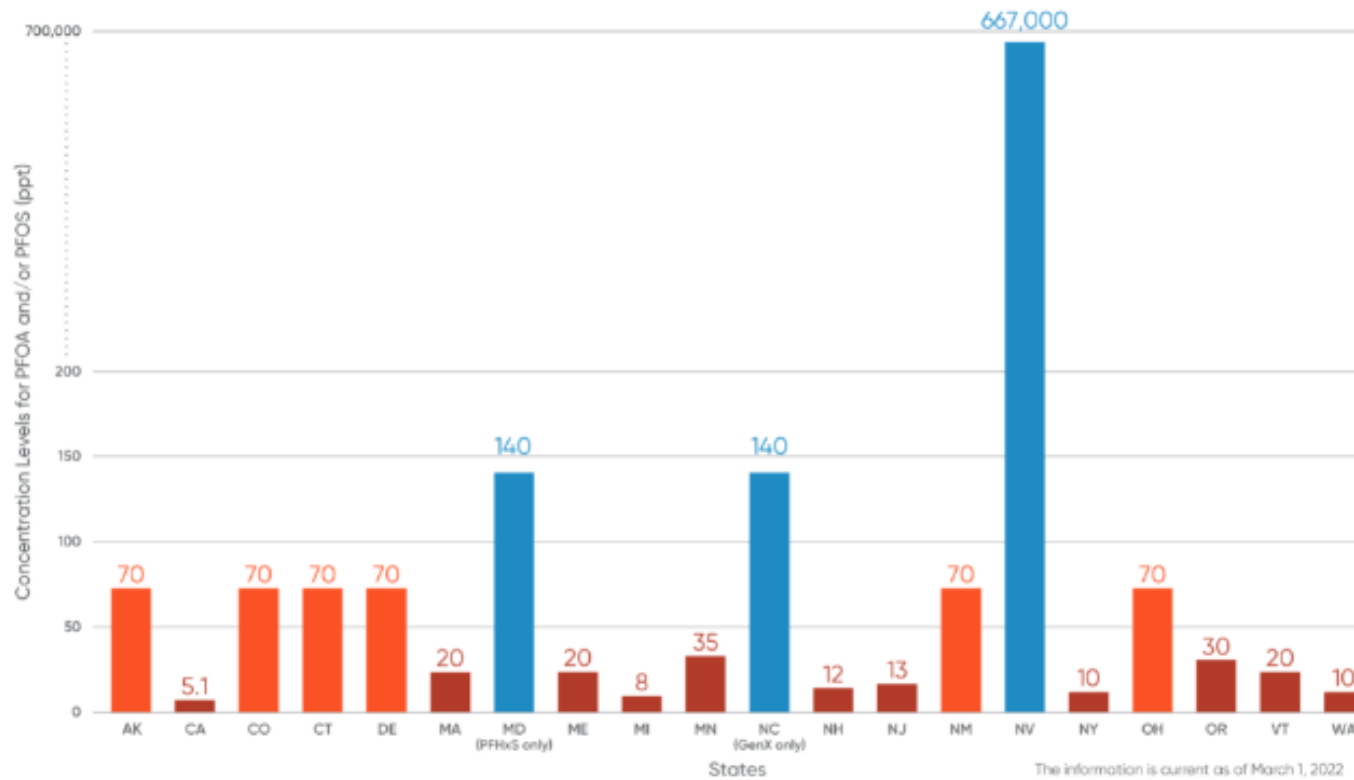


- Real variability on form and nature of the standards established. For example:

States	Type	Chemicals	Standards
Massachusetts	Drinking Water Regulation (MCL)	PFOA; PFOS; PFHxS; PFNA; PFHpA, PFDA	20 ppt (summed across all six)
Vermont	Drinking Water Regulation (MCL)	PFOA; PFOS; PFHxS; PFHpA; PFNA	20 ppt (summed across all five)
Michigan	Drinking Water Regulation (MCL)	PFNA; PFOA; PFHxA; PFOS; PFHxS; PFBS; HFPO-DA	PFOA: 8 ppt PFOS: 16 ppt
Minnesota	Health-based Guidance Values for Drinking Water	PFBS; PFHxS; PFOS; PFBA; PFPeA; PFHxA; PFOA	PFOA: 35 ppt PFOS: 15 ppt
Ohio	Guidance Action Levels for Drinking Water	PFOA; PFOS; GenX; PFBS; PFHxS; PFNA	PFOA/PFOS: >70 ppt GenX: > 21 ppt PFBS: >2,100 ppt PFHxS: > 140 ppt PFNA: > 21 ppt

State Regulation of PFAS

- In the absence of established federal drinking water levels, states have taken an array of different approaches. As of Spring 2022:



- States are also regulating PFAS in a variety of other contexts:
 - **Massachusetts**
 - PFOS, PFOA, and related PFAS are considered “hazardous materials” subject to regulation under the Massachusetts Contingency Plan (MCP).
 - Land application of biosolids requires quarterly PFAS monitoring.
 - **Vermont**
 - Restricts PFAS found in firefighting foam and equipment; food packaging; rugs, carpets, and aftermarket stain and water-resistant treatments; and ski wax.
 - Requires manufacturers of certain PFAS that are of high concern to children to report information to the Health Department.
 - **New York**
 - PFOA-acid, PFOA-salt, PFOS-acid, and PFOS-salt were added to the list of hazardous substances.
 - Firefighting foam containing PFAS was phased out in 2017.
 - **California:**
 - Sept. 29, 2022 laws banning the manufacture and sale of clothing and textile items and restricting PFAS in cosmetics.
 - Vetoed law that requiring platform to annually register PFAS products.

- **TSCA is central to the future regulation of PFAS**
 - TSCA Chemical Substance Inventory (Section 8(a)(7))
 - EPA has identified 1,364 PFAS that may be potentially covered.
 - 669 Commercially Active PFAS; 695 Commercially Inactive PFAS.
 - June 8, 2021: EPA proposed to require those who manufacture (including import) or have manufactured PFAS in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.
 - Per the Strategic Roadmap, a final rule is expected winter 2022.
- **TSCA Compliance Notification Letter**
 - March 2022: EPA released an open letter notifying manufacturers, processors, distributors, users, and those that dispose of fluorinated HDPE containers and similar plastics (i.e. fluorinated polyolefins) that the presence of PFAS formed as a byproduct in these containers may be a violation of TSCA.

- **EPA finalized a new PFAS SNUR in July 2020.**
 - Applicable to long-chain perfluoroalkyl carboxylate and perfluoroalkyl sulfonate chemical substances (LCPFAC).
 - 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 or certain substance in carpets.
- **July 2022:** Because EPA did not following docketing procedures, the public was not notified of changes to the final Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances SNUR.
 - EPA agreed to tighten policies for revising rules following OIG investigation.
- **September 2022:** EPA released 8 SNURs involving PFAS covering chemicals it first reviewed in 2009.
 - Environmental groups argued limits should be much stricter than 2009; EPA declined to revisit them.
- **Future Action:** EPA is developing a SNUR for certain uses of Inactive Inventory PFAS. An NPRM was expected last month, with a final rule in June 2023.

■ Looking Forward

- Establish another PFAS Voluntary Stewardship Program challenging industry to reduce overall releases of PFAS (missed Spring 2022 deadline).
- Use TSCA authority to require manufacturers to conduct and fund studies and toxicity testing for approximately 24 PFAS (granted petition in December 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 enforcement of requirements in SNURs – particularly PFAS.
- “Close the door” on new uses of PFAS (missed Summer 2022 deadline).
- Finalize new PFAS reporting under TSCA Section 8 to collect more data (Expected final Dec. 2022).
- (FIFRA) Sept. 1, 2022: Proposing to remove 12 PFAS from the current list of inert ingredients approved for use in pesticides.

- **EPA committed to prioritizing protection of disadvantaged communities in its Strategic Roadmap.**
- **EJ has been at the forefront of the Biden Administration's efforts:**
 - Issuance of Executive Orders 14008 (Tackling Climate Crisis) and 13990 (Public Health and Environment) directly address EJ concerns.
 - 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.
 - EPA launched a new national office in Sept. 2022: Office of EJ and External Civil Rights with more than 200 staff across 10 regions.
- **EJ concerns with PFAS have focused on drinking water:**
 - PFAS have been confirmed to be in the drinking water of approx. 3,000 communities - impacting more than 200 million Americans.
 - Studies have found that low income, people of color, and indigenous communities are more likely to have elevated PFAS in drinking water, based on research in California and New Jersey.

■ EPA is preparing to update its Strategic Roadmap

- Sept. 28, 2022: Draft recommendations by EPA's National Environmental Justice Advisory Council (NEJAC) PFAS Workgroup were approved.
- The focus was on emergency response actions for communities:
 - Adding “resource” and “respond” to the strategy's current three “R's” – “research, remediate and restrict.”
 - Forming a PFAS response program and creating an interagency PFAS emergency response plan.
 - Compiling best practices to provide emergency responses.
 - Prioritizing efforts to address PFAS contamination in disadvantaged communities over research.
 - Overarching recommendation that EPA needs to ensure it has the internal resources to actually implement the PFAS roadmap.

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)



Regulation of PFAS: CERCLA



Lianne Mantione

■ **Proposed Hazardous Substances Determination:**

- September 6, 2022: EPA proposal to add PFOS and PFOA to the hazardous substances list under CERCLA (the “Superfund” law).
- Proposed rule finds the substances may present “substantial danger” to public health or welfare or the environment when released.
- EPA interpreted CERCLA to preclude it from considering cost in making this designation.

■ **Public Comment:**

- November 7, 2022: Public comment period closes.
- Summer 2023: Anticipated final rule.
- Robust public comment is expected, both from supporters and challengers. 70+ comments already posted – with many commenters requesting more time.
- EPA stated its intent to further outreach and engagement with impacted communities, wastewater utilities, businesses, and other potentially impacted parties during the consideration of the proposed rule.

- **Possible Impacts of Hazardous Substances Designation:**
 - Expansion or reopening of ongoing remediation
 - Identification of new sites based on historical PFAS releases
 - Potentially expansive identification of potentially responsible parties (PRPs)
 - Widened scope of environmental due diligence for transactions
 - New state cleanup requirements
 - Reporting requirements for releases of a reportable quantity

- **Ongoing Uncertainties:**
 - Number of contaminated sites/magnitude and extent of contamination
 - Remedial standards that must be met
 - Indirect cleanup costs
 - Technologies for assessing and remediating contaminated media and their associated costs

■ Potentially Responsible Parties - Widespread Risk

- The designation of PFAS as hazardous substances under CERCLA could mean a significant number of parties being identified as PRPs
 - Manufacturers and importers of PFOA or PFOS
 - Entities that use or manufacture products containing PFOA or PFOS
 - Solid waste or wastewater facilities that handle such products
 - Prior to restrictions on use, PFAS use was near-ubiquitous in many segments of manufacturing industry

- **Identification as a PRP:**
 - Heightened risk of private litigation
 - Multiple parties may be held jointly and severally liable for 100% of the cleanup costs
 - Could be identified as a PRP for historical releases or very small releases
 - Could lead to additional governmental enforcement
 - Even if ultimately not found to be a PRP, there are risks and costs associated with defending claims, as well as possible negative public scrutiny

■ Possible Effects on State Regulation:

- CERCLA has often served as a model for state remediation statutes
- Many states incorporate CERCLA hazardous substance list by reference and would thus include PFOA and PFOS if the rule is finalized
- State cleanup requirements may vary from those imposed by CERCLA; differences could include scope, defenses, statutes of limitation, or other provisions
- Could lay groundwork for more uniform and predictable application of PFAS policy

■ Possible Designations of Additional PFAS Substances:

- EPA has said it anticipates issuing another notice seeking comment on designating other PFAS chemicals as hazardous substances
- Continued research on various PFAS substances, including human and animal health studies and environmental studies, will provide EPA with information needed to support further designations
- EPA is likely to use feedback on the current proposed rule to inform future PFAS rulemakings under CERCLA

Questions and Answers



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For those of you who require CLE credits please note the following states have been approved or pending for 1.50 hour of general MCLE in AZ, CA, NJ, NY, OH, PA and TX

Please write down the following affirmation code [PFAS1013]

After today's session you will receive an email with ***uniform certificate of attendance*** and ***program evaluation*** to complete and SUBMIT to my colleague, Robin Hallagan at robin.hallagan@squirepb.com.