

Current US TSCA Policies That Have An Effect On Hazard Communication

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In this session, we will discuss the OCSPP implementation of policies that effect hazard communication, especially in SDS with specific warnings and PPE recommendation. We are witnessing an increase in restrictions with respect to hazard communication as an outcome from more conservative risk characterizations for new substances. In addition, the OCSPP is implementing new chemical bands may change the way you communicate with your downstream user and their suppliers. Some of you who thought you were exempt from the TSCA may need to take a more active role in ensuring compliance.



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Background



Background TSCA Reform

- Toxic Substances Control Act (TSCA) from 1976 to 2016
- Some NGOs believed that there was weak federal oversight
- States were acting - Regions were enacting Labeling acts; hazard warning (Proposition 65)
- Interrupting commerce
- The 2016 TSCA Reform was to create a strong Federal system to instill confidence





One way to make the TSCA stronger is to increase and enforce Penalties

Penalties for TSCA violations usually emanate for non-compliance for the following sections:

- § 5 requires manufacturers or importers to notify the EPA of any new substance in commerce.
- § 8 requires manufacturers or importers to keep records and report information, mainly to do with suspected, but not known risks.
- § 12(b) rule requires chemical exporters to submit information about certain chemicals.
- § 13 rule requires chemical importers to submit certification statements concerning shipments of chemical substances.

Depending on the nature of the non-compliance there may be:

- Injunctive actions to stop the non-complying action;
- Monetary actions as paying a penalty (\$25,000/day/violation; and/or
- Criminal actions as prison terms (1 year).
- Publicity

02

The New Administration – Policy, Cases, Budget



TSCA



- The latest TSCA Inventory is February 2022
- As of August 2021, the Inventory contained 86,607 chemicals of which 41,953 are active in U.S commerce.
- As of February 2022, the Inventory contains 86,631 chemicals of which 42,039 are active.
- Conservative risk assessments and characterizations.

Cases:

- Some are open from 2012
- No updates for cases after November of 2021
- There are 311 active cases

TSCA

Budget

- The new chemicals division continues to review its processes and procedures to find additional efficiencies, the agency added, but the program "is operating under limited resources and has to balance support for these other goals with its obligation to conduct PMN reviews in a manner that is both protective and timely".
- The total number of employees is less than they had prior to the Reform



03

Hazard Communication and the TSCA





Facility Information Availability:

- The EPA is proposing to reimpose certain safety requirements that apply to facilities to better protect communities from chemical accidents, and advance environmental justice for communities that have been disproportionately impacted.
- Does promulgating information increase security concerns?
- The new rule addresses security concerns by limiting information availability to people who live within 6 miles of a facility.
 - Including new requirements of a community notification system set up to warn people when chemical releases threaten the community.



PPE assumptions

- With respect to PPE, the EPA's revised approach reflects that it "does not believe it is appropriate to assume as a general matter that an applicable [Occupational Safety and Health Administration] (OSHA) under the Department of Labor, requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied."
- "Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers."

Assistant Administrator of the Office of Chemical Safety and Pollution Prevention (OCSPP) Michal Freedhoff



PPE assumptions – Cont'd

- Industry urges nuanced PPE assumptions in TSCA risk evaluations
- Worker advocates and environmental organizations support the EPA's position that PPE should be viewed as a risk management tool and not factor into risk determinations at the evaluation stage.
- Revised approach to PPE - no longer assume in its evaluations that PPE is always provided and used appropriately. The shifted stance reflects the EPA's recognition "that unreasonable risk may exist for subpopulations of workers that may be highly exposed", including for those not covered by, or out of compliance with, OSHA standards.
- Trade groups and companies that submitted industrial hygiene (IH) information to the EPA say this policy runs counter to the TSCA requirement to "take into consideration [reasonably available] information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use".
- The Chemical Users Coalition (CUC) said the agency "has not provided a reasonable basis for discounting or simply ignoring" submitted information on PPE use, in contravention of the section 26 requirement to consider such data. The CUC represents the National Electrical Manufacturers Association (NEMA) and major IT and aerospace firms such as Sony and Raytheon.
- The Halogenated Solvents Industry Alliance (HSIA) added that "recognition of standard work practices and reliance on reasonable and realistic exposure data are critical to meet the statutory requirements of TSCA".



PPE assumptions – Nuanced Approach

- Rather than assuming that PPE is ‘always’ or ‘never’ used in the workplace, the American Chemistry Council (ACC) said, the EPA should factor in information businesses provide about current work practices and their efficacy.
- The Household and Commercial Products Association (HCPA) said making risk determinations without accounting for standard PPE could cause "significant workplace confusion", including concern from workers that their employers’ safety measures might not be protective.
- The HCPA suggested the EPA identify in its evaluations whether there is unreasonable risk both without PPE and with known PPE, in order to receive "more robust and targeted comments during risk management and more effectively communicate the risks to stakeholders and the public".
- The ACC added that risk management requirements, in turn, "should also be targeted, depending on whether they apply to OSHA-regulated businesses or non-OSHA regulated businesses". For example, the EPA could consider establishing a federally enforceable training and certification programs for those who fall outside OSHA regulations.
- NGO coalition that includes Earthjustice and Safer Chemicals Healthy Families. The practice "lacks any legal basis, departs from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to unsafe chemicals".

04

PBT and Articles





- TSCA section 6(h) requires EPA to take expedited regulatory action under TSCA section 6(a) for certain PBT chemicals identified in the 2014 Update to the TSCA Work Plan for Chemical Assessments.
- EPA has determined that prohibiting the use of the five PBT is reasonably foreseen to reduce exposures to the extent practicable. EPA interprets this requirement as generally directing the Agency to consider such factors as achievability, feasibility, workability, and reasonableness without the need for a risk assessment.
- Environmental Justice. These final rules may increase the level of protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population.
- The proposed rule provided a 60-day public comment period, with a 30-day extension provided. The comment period closed on October 28, 2020.

PBT and Articles



Substance Identity	Rule Summary	Use
Decabromodiphenyl Ether (DecaBDE) CASRN 1163–19–5	Prohibits all distribution containing products or articles	Used as a flame retardant in televisions, computers, textiles and other applications;
Phenol, Isopropylated Phosphate (3:1) (PIP 3:1) CASRN 68937-41-7	Prohibits distribution containing products, with specified exclusions, and prohibits the release to water. EPA proposed downstream notification in sections 1 and 15 of the safety data sheets (SDS).	Used as a flame retardant in consumer products, as a plasticizer and as a lubricant and hydraulic fluid;

PBT and Articles



Substance Identity	Rule Summary	Use
2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3)	Prohibits distribution of products containing concentrations above 0.3%,	A reactant in processing that is also used as an additive in fuels and lubricants;
Hexachlorobutadiene (HCBd) (CASRN 87-68-3)	Prohibits all distribution in commerce and containing products or articles, recognizing that there is unintentional production of HCBd as a byproduct	Used as a solvent and as a hydraulic, heat transfer or transformer fluid, and can be produced as a byproduct during the manufacture of chlorinated hydrocarbons.
Pentachlorothiophenol (PCTP) (CASRN 133-49-3)	Prohibits distribution in commerce and products and articles containing PCTP above 1% by weight.	Used to make rubber more pliable



PBT and Articles

- In March 2021, EPA announced a 60-day public comment period to collect additional input on these final rules.
- Additionally, EPA issued a temporary 180-day “No Action Assurance” indicating that the agency will exercise its enforcement discretion regarding 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 in order to ensure that the supply chain of these important articles is not interrupted while EPA continues to collect the information needed to best inform subsequent regulatory efforts.
 - Once PIP (3:1) is identified, a suitable alternative or replacement component may need to be tested for industry safety or performance standards.
 - PIP was not regulated in other jurisdictions.
 - September 3, 2021, EPA announced its intent to initiate a new rulemaking and anticipates proposing new rules for five PBT chemicals that are the subject of final risk management rules under TSCA.
 - The electronics industry called for a longer period for the electronics industry to transition to alternatives for PIP (3:1), with exemptions for de minimis volumes, spare and replacement parts, research and development (R&D) and in monitoring and control instruments. - EPA attorney-advisor Cindy Wheeler



PBT - Difficulties in Managing PBTs

- PIP 3:1 EPA issued a Pre-Publication Notice extending the compliance dates from 8 March 2021 to 8 March 2022
 - Articles: must maintain ordinary business records, such as invoices and bills-of-lading, starting 8 March 2022. (previously 8 March 2021).
 - This is not for the substance itself
- EPA proposed a rule to extend until October 31, 2024, the timeline for complying with a TSCA prohibition on the use of the flame retardant PIP (3:1) in articles, offering time to phase out the substance's use.
 - Not as long as industry (electrical) says they need
 - EPA will consider whether further extensions are required when it begins broader rulemaking in 2023 to potentially amend all five of the PBT rules. October 2024. It made the extension official on 4 March.
 - To avoid significant disruption in the supply chains for important articles
- A wide array of industries – including producers of electronics, appliances, vehicles and equipment – requested anywhere from 2.5 to 15 years to comply with the PIP (3:1) prohibition, after discovering the wide array of applications where the substance may appear as a flame retardant or plasticizer.
- Even if the electronics industry doesn't oppose the deadline, they may press to allow for using existing stock

PBT - Difficulties in Managing PBTs

- Industries said they had been unaware, but were now discovering, that the substance is used in thousands of products, ranging from computers and clothes dryers to manufacturing equipment and military supplies.
- PIP is not regulated in other countries
- EPA focused on production process – not in finished articles
- “Inconsistent” with TSCA requirements for expedited action on PBTs





Practical Points to consider Now!

DO YOU MANUFACTURE, IMPORT, PROCESS OR DISTRIBUTE?

- Is there an alternative?
- Assurances from supplier?
- Normally start small...
- It might be good to look at a few of the restricted substance requirements holistically so you can implement practical and sustainable solutions.
- Risk based approach?
- Need Expertise:
 - Regulatory;
 - Supplier Engagement Team;
 - Testing resources; and
 - Software

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PFAS





Per- and Polyfluoroalkyl Substances

- All PFAS contain a chain of carbon atoms bonded to fluorine atoms. Some also have a functional group at the end of the chain. These structures are the basis for different chemical properties and different chemical names.
- Some examples:
 - Perfluorooctane sulfonic acid (PFOS),
 - Perfluorooctanoic acid (PFOA)
 - Polytetrafluoroethylene (PTFE) is a synthetic fluoropolymer of tetrafluoroethylene - Teflon
- There are over 1300 different structures.

Per- and Polyfluoroalkyl Substances

- Fluoropolymers impart strength, durability, heat and chemical resistance, and high-performance electrical insulation.
- Extending the lifespan of components, improves fire safety, increases data transmission speeds, and enables the creation of the smaller, more powerful, more integrated electronic products.
- They are resistant to heat, oil and water- contain a non-polar or hydrophobic portion of the molecule which will repel water.



PFAS



PFAS are prevalent in a wide range of consumer and industrial products including:

- food packaging, such as microwave popcorn bags and fast food wrappers;
- stain-resistant carpets, rugs, and furniture;
- protective coatings in non-stick cookware;
- outdoor gear with a “durable water repellent” coating;
- aerospace, medical (dental floss), and automotive applications;
- firefighting foams used in aviation, military and air force bases;
- ski wax, and industrial applications;
- waterproof fabrics, shoes, textiles, leather, mattress;
- pesticide containers;
- fabric softeners;
- household paints;
- industrial catalysts;
- batteries and solar thermal energy systems;
- chrome plating, electronics;
- Etc,



Challenges are to moving away from PFASs (from NGO Chem Sec)

- A lack of available alternatives (71% of respondents);
- The cost of alternatives (43%);
- A lack of knowledge of PFASs and their uses (43%); and
- Inadequate performance of alternatives (29%).

Substitutes for industrial uses:

- Shorter chain-length PFAS telomeric substances;
- Gen X short-chain organofluorine chemical compound, the ammonium salt of hexafluoropropylene oxide dimer acid (HFPO-DA) fluoride;
- nonfluorinated chemicals;

For grease-resistant grades, food wrap, fry scoops or microwave paper:

- High-charged cationic (positively charged) natural polymers (starches); and
- Sourced from plants like waxy maize and tapioca.



Withdrawing Compliance Guide on PFAS SNUR

Issued in January 2021, weakened the July 2020 SNUR. Among other things, the July 2020 SNUR prohibits companies from importing certain long-chain PFAS as part of a “surface coating” on articles without prior EPA review and approval.

The EPA deems the compliance guide limits what would be considered a “surface coating” subject to the SNUR and determined that the guide inappropriately narrowed the scope and weakened the prohibitions included in the SNUR.

Additional PFAS to be added to the TRI

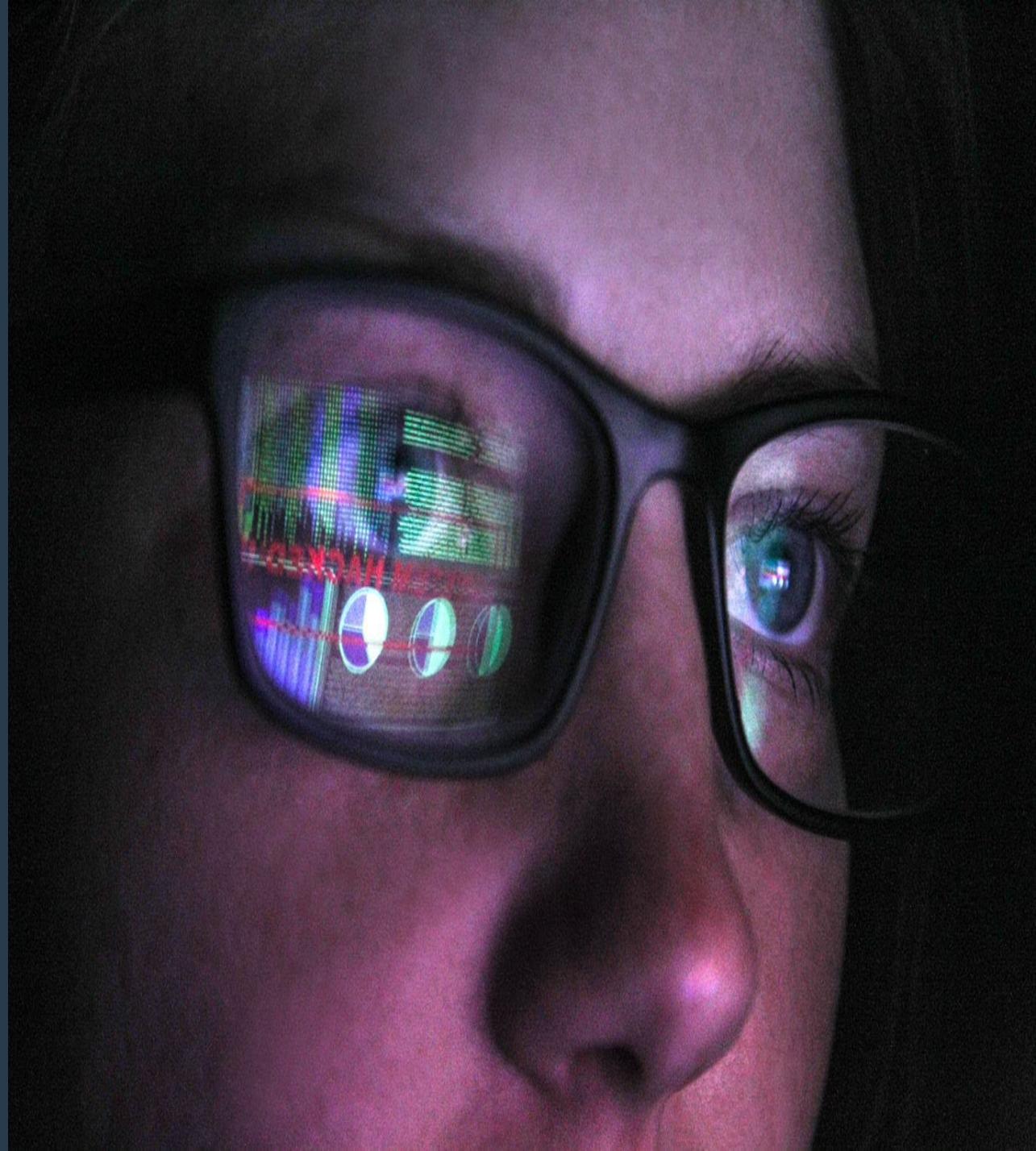
For Toxics Release inventory (TRI) Reporting Year 2021 (reporting forms due by July 1, 2022), three new PFAS have been added to the TRI list because they are now subject to a SNUR under TSCA.

The three substances are Perfluorooctyl iodide (507–63–1), Potassium perfluorooctanoate (2395–00–8), and Silver(I) perfluorooctanoate (335–93–3).

Further complicating the PFAS compliance area, is the fact that these federal actions are being implemented while many States are enacting their own PFAS phase out regulations.

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CBI





What is CBI?

- According to the EPA, Confidential Business Information (CBI) is the proprietary information, considered confidential to the submitter, the release of which would cause substantial business injury to the owner.

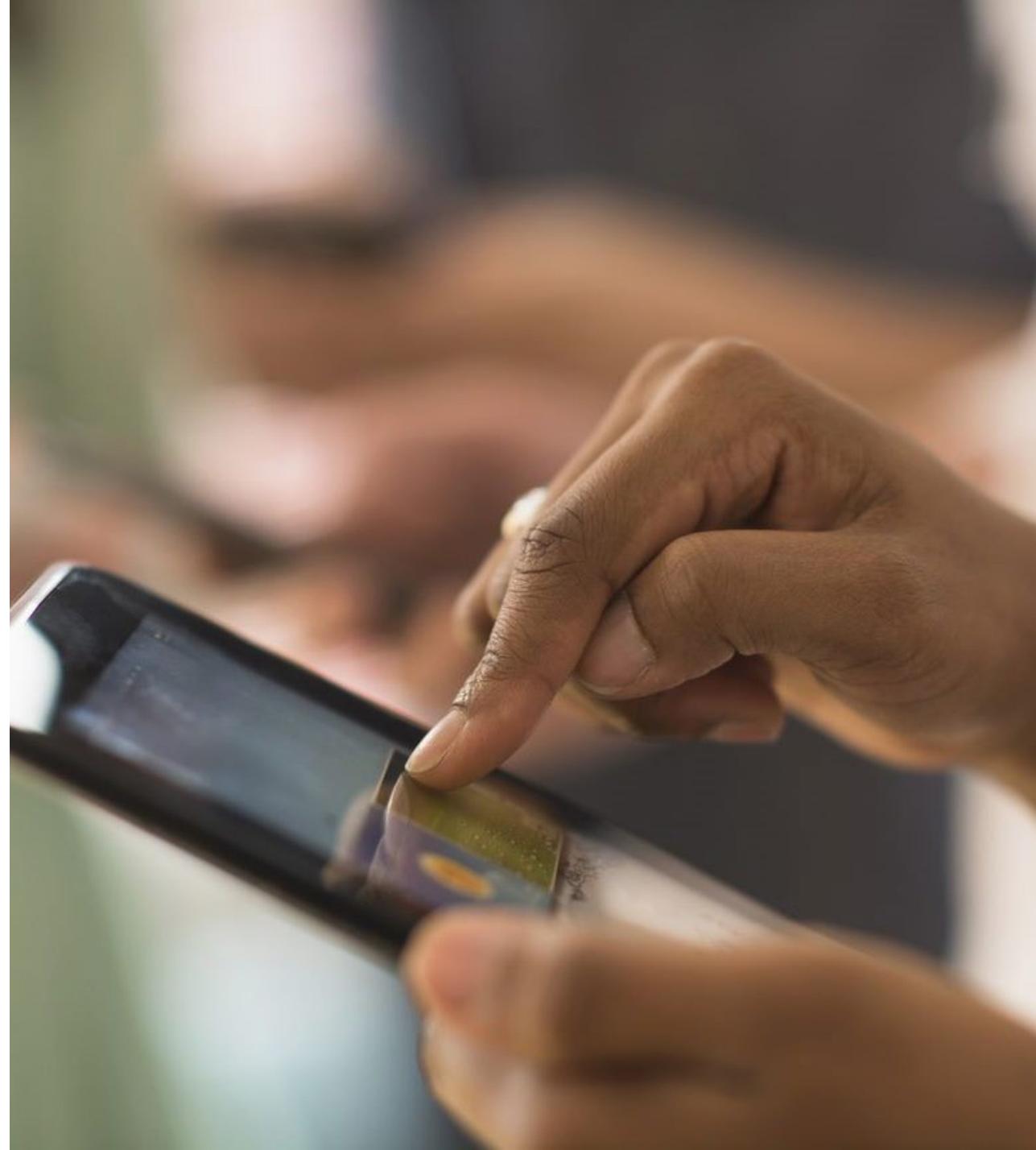
Section 14 of the TSCA

- Requires up front and more substantiation of confidential business information (CBI)
- Many CBI claims sunset after ten years
- Broadens who may access TSCA CBI

TSCA CBI

CBI Claim Review

- EPA must review initial CBI claims (excluding presumptive CBI) within 90 days and requests for CBI extensions within 30 days - If claim denied, EPA shall provide written statement of the reasons –this is
- EPA must review all CBI chemical identity claims
- EPA must review at least 25 percent of all other CBI claims
- EPA failure to make a decision on CBI claim shall not have the effect of denying the claim





- Companies wishing to maintain the confidential identity of substances under the inventory reset originally were asked to provide substantiation by November 2020. But the EPA said in January it was considering reopening that process after it became clear that many of them did not fully understand the regulatory requirements.
- In October 2021, however, the EPA said it was giving industry more time to review the list, following requests from the American Chemistry Council and BASF. The timeline for their release has now apparently shifted back, as well.
- In March 2022, the US EPA has dropped the confidentiality status for 377 substances, making their chemical identities available to the public.
- Substances with the status make up around 8,000 of the nearly 42,000 chemicals listed as active in US commerce on the TSCA inventory. Those designated as confidential business information (CBI) are not directly identified, but instead given a generic name and accession number.



- After a review of the original list of 390 substances, the EPA said 13 were found to already be on the public inventory or were reported using an invalid accession number.
- The remaining 377 chemicals "were reported as non-confidential by one or more manufacturers" during one or more of the quadrennial chemical data reporting (CDR) submission periods in 2012, 2016 or 2020, the agency said. "Therefore, these substances are no longer eligible for continued confidential inventory status."
- That broader list included substances companies had reported as non-confidential in a CDR submission, as well as those flagged during the 2017-18 inventory reset process, in which they had to identify chemicals that were manufactured, imported or processed in the US during a ten-year 'look-back' period.



January 2022

- An interagency review has begun on a proposal to bring in "new and amended" procedures for making and maintaining confidentiality claims under TSCA.
- The US EPA sent the proposed rule to the White House's Office of Management and Budget (OMB) on 20 January, presaging its public release in the coming months. Once issued, the proposal will probably invite discussion on a range of issues, including what substantiation will be needed to withhold proprietary information and the processes around renewing claims before they expire.
- Upcoming topics corrections to the inventory!!

07

What to Look for



SNURs



Use of SNURs

- EPA will stop issuing determinations of “not likely to present an unreasonable risk” based on the existence of proposed SNURs.
- Rather than excluding reasonably foreseen conditions of use from EPA’s review of a new substance by means of a SNUR, Congress anticipated that EPA would review all conditions of use when making determinations on new chemicals and, where appropriate, issue orders to address potential risks.
- Going forward, when EPA’s review leads to a conclusion that one or more uses may present an unreasonable risk, or when EPA lacks the information needed to make a safety finding, the agency will issue an order to address those potential risks.
- More PPE language in the SDS

Whole-chemical approach

- The 2016 amendments to TSCA require the EPA to assess each substance's 'conditions of use' when conducting a risk evaluation.
- Stakeholders have been divided, however, on whether an ultimate finding of unreasonable risk should be presented on a comprehensive "whole-chemical" basis, or on a use-by-use basis.
- For the First 10 Risk Assessments for the high priority chemicals, in 2021 the EPA moved from use by use to a substance-as-a-whole determination.





Whole-chemical approach – Cont'd

- EPA estimates they will not publish for at least 2 more years - timelines significantly behind its statutory deadlines. (proposed publications from November 2023 thru January 2025)
- Will this move be applied to the PMNs?
- Does the EPA have the authority?
 - The preamble to the final risk evaluation 'framework' rule, states: "EPA will make individual risk determinations for all uses identified in the scope."
- More required language in the SDS

Fees



2021 saw the agency update its fee schedule for the first time since its 2018 adoption, by imposing a 18.9% inflation increase.

A more comprehensive overhaul of the fee structure, however, was pushed to the current year.

- to ensure "fee amounts capture up to 25% of the actual costs of TSCA activities, fees are distributed equitably, and fee payers are identified through a transparent process."
- October 2018
 - PMN/SNUN from \$2500 to \$16,000, LVE \$0 to \$4700
 - Small Business - PMN \$100 to \$2800 LVE \$0 to \$940
- January 2022
 - PMN/SNUN \$19,020, LVE \$5590
 - Small Business \$ 3330 LVE \$1120



TSCA – What to look for

Articles- EPA appears to be using its TSCA authority to regulate and require reporting on chemicals in articles.

- TSCA regulations require the EPA to use its risk management authority on them ‘only to the extent necessary’ to address identified unreasonable risk.
- Stakeholders must advocate with sound science.

Enforcement of the TSCA is becoming more conservative and evaluation of uses are broadening.

- Robust debate expected around the US EPA's approaches to risk management

Timelines for action on existing chemicals highly uncertain

- Rework of ten risk evaluations for High Priority (some Whole Chemical Assessment);
- Long timelines also affect the EPA’s effort to refine risk management rules for five PBT

New chemicals to continue to be closely scrutinized under a lengthier review process, with a trend towards increased transparency in the program

- Industry concerns for the pace
- NGO concerns for lack of transparency



TSCA – What to look for – Cont'd

- In March, it introduced a multiyear research initiative to enhance and expedite TSCA section 5 premarket reviews with in vitro **new approach methodologies (NAMs)**, updated data processes and greater transparency. While some business entities approve of the project, several NGOs question the accuracy of NAMs and believe the agency should instead focus on boosting the new chemicals program's transparency and scientific integrity.
- Meanwhile, firms have repeated calls for the EPA to quicken premarket assessments and adhere to TSCA's 90-day mandate, asking the agency to better communicate information needs and improve the productivity of pre-submission meetings
- In response, it launched an **outreach campaign** in June targeting premanufacture notice (PMN) submitters, explaining common problems that can hinder assessments. To further clarify the review process, the agency is readying a procedural rule proposal scheduled for February.



Globally – What to Look for

- UN concerns global chemicals, waste and pollution trends include circular economy
- Endocrine Disruptors
- PBT and PM Persistent and Mobile
- Latin America Regulatory Cooperation Forum and its efforts to ensure that national regulations within the region are as close as possible.
- Industry-led Asean Regulatory Cooperation Forum to align proposed and existing rules on chemical inventories
- India Chemical Management Legislation

Keep Calm But Take Action



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