

# CHEMICALS AND CLIMATE:

Where We Stand in 2023 and the Future Trends We're Tracking



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New chemical and climate-related regulations and guidances are continually being adopted by nations around the world, and existing legislation and regulations continue to evolve. Much like trying to hit a moving target, chemical manufacturers and end users need to keep a close eye on legislative and regulatory action if they wish to remain in compliance.

In 2020, scientists created a global inventory that lists more than 350,000 chemicals and mixtures of chemicals registered for commercial production and use. In a study promoting the global inventory, published in *Environmental Science & Technology* in February 2020, researchers estimated the total number of chemicals on the global market was nearly 2.5 times the upper range of previous estimates. ("Toward a Global Understanding of Chemical Pollution: A First Comprehensive Analysis of National and Regional Chemical Inventories," *Environmental Science and Technology*. 2020, DOI: 10.1021) Each year since, hundreds of additional chemicals have been added to global inventories.

Although hundreds of new and existing chemical- and climate-related regulations are under scrutiny around the world at any given time, some stand out. For example, as foreseen in the European Union's (EU) Chemical Strategy for Sustainability, efforts to limit, ban, or phase out production of per- and polyfluoroalkyl substances (PFAS) was a dominant regulatory issue in 2022 and 2023 and likely will continue to be of interest in 2024 and beyond. The concept of extended producer responsibility (EPR) also is of interest to chemical manufacturers. EPR is a mandatory policy requiring manufacturers to take responsibility for their products and packaging through all life cycle stages. This responsibility extends to the post-consumer stage of a product's life cycle. EPR shifts responsibility for any lasting environmental or health impact (physically and/or economically; fully or partially) back to the producer and away from end users. The goal is to have producers take environmental considerations into account when designing their products. Some European countries also adopted additional plastic taxes that include plastic packaging.

### **EPR** is a mandatory policy requiring manufacturers to take responsibility for their products and packaging through all life cycle stages.

In the United States, the Biden Administration proposed changes to the Clean Air Act, which are related to climate change and could also have a significant impact on chemical manufacturing in the United States, as well as changes to the Clean Water Act.

While many regulations impact the chemical industry, experts cited PFAS, EPR, and new air pollution and emissions standards as trending regulatory changes globally and in the United States. Here is a breakdown of just some of the current and proposed regulations that impact chemical manufacturers and end users.





## UNITED STATES Federal

Dozens of U.S. Environmental Protection Agency (EPA) regulations related to chemicals, clean air, and clean water are on the Spring 2023 regulatory agenda. In total, the EPA's spring regulatory agenda featured 147 actions, many of which impact the use and distribution of chemicals. Regulatory action designating perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Hazardous Substances is in the final rule stage at EPA.

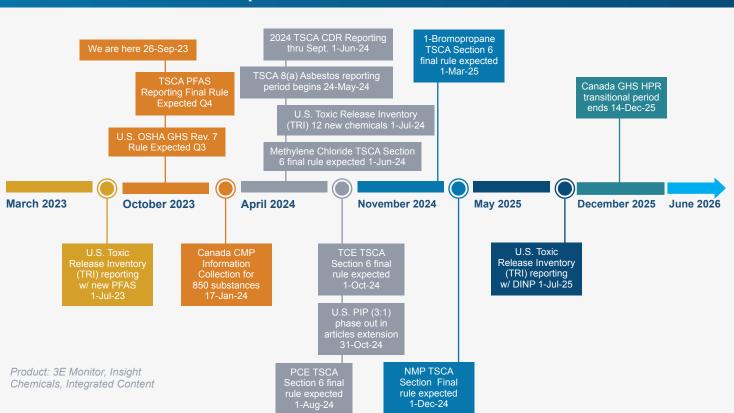
The agency has more than 85,000 chemicals listed on its inventory of substances that fall under the Toxic Substances Control Act (TSCA), which requires the EPA to review the potential risks of new chemicals before they enter the U.S. market and, when necessary, put safeguards in place to protect human health and the environment from any risks. Learn more about the EPA's review process for new chemicals.

Prior to the 2016 amendments to TSCA, EPA issued risk determinations for approximately 20% of new chemical submissions. In 80% of cases, the EPA "dropped" the

chemical from further review and allowed it to go to market. Following the 2016 amendments to TSCA, the EPA is required to make an affirmative risk determination on 100% of new chemical notices submitted under TSCA section 5, an approximately five-fold increase in workload for the agency.

As a result, the TSCA new chemicals program has been operating with insufficient resources to meet all the requirements under the amended law. To maximize the impacts of its limited resources, the EPA takes into account a variety of factors in prioritizing new chemical submissions for review including:

- The date of receipt of submission (e.g., EPA generally strives for a first-in-first-out approach, absent extenuating circumstances).
- Statutory and regulatory deadlines.
- The extent to which the submitter has provided additional information during the review period – subsequent to the original submission – and the level of effort needed to potentially rework some or all of the risk assessment as a result.
- Applicability of new innovative approaches the EPA has developed to standardize reviews for certain new chemicals (e.g., biofuels, mixed metal oxides (MMO)/ cathode active materials (CAMs), etc.).



#### **Compliance Timeline North America**





In the last few years, the EPA has received an average of about 350–500 TSCA section 5 notices and other applications each year. This includes pre-manufacture notices (PMNs), significant new use notices (SNUNs), and microbial commercial activity notices (MCANs) – all of which must be reviewed within 90 days. One of the difficult parts of PMNs is that there is no required dataset. Manufacturers are asked to provide data that supports the safety of the product. While a submitter only intends to use a product one way, the EPA might want to examine other ways to use the chemical and requests a lot more info. This can slow down the process as well.

Currently, according to the American Chemistry Council

(ACC), there are 392 TSCA new chemicals under review. Of the 392 new chemicals under TSCA review, only 23 -6% – have been reviewed within the required 90 days. In a 2022 survey of ACC member companies, 70% of respondents reported that they have decided to introduce new chemicals outside of the U.S. due to uncertainties and challenges with the EPA's New Chemicals Program.

The agency's total <u>new chemicals workload</u> also includes applications for exemptions from the full PMN review process (e.g., low volume (LVE), low release and low exposures (LoREX), test market (TME), etc.). These applications represent over 50% of annual applications, have between 30- and 60-day review periods, and are also reviewed by the EPA.

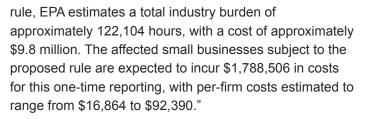
As an indication of how ubiquitous the chemical industry is in the United States, on 4 August 2023, the EPA published preliminary Toxics Release Inventory (TRI) data about chemical waste management, including releases and pollution prevention activities that occurred during 2022 at more than 20,000 industrial and federal facilities across the country. All states and many cities are impacted by chemical risk management.

Terry Wells, Senior Manager, Regulatory Research for North America, 3E Co., noted that of all the proposed regulations and amendments, a few stood out for her in terms of their impact on 3E customers.

"The existing chemical risk assessments will have a big impact because they will involve banning some activities and implementing a workplace chemical protection program (WCPP) and the existing chemical exposure limit (ECEL), which have traditionally been in the Occupational Safety and Health Administration's (OSHA's) purview. The TSCA 8(a)7 PFAS reporting rule will impact both chemical and discrete manufacturers, spans a long timeframe, and will affect so many small businesses."

The final rule for TSCA 8(a)7, Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, is scheduled for publication in September 2023 and identifies reporting and recordkeeping requirements PFAS. The EPA proposes to require companies that manufacture (including import) or have manufactured these chemical substances in any year since 1 January 2011 to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards. (See the proposed rule here.)

According to Wells, the economic impact on businesses, particularly smaller ones, could be significant. According to the EPA, "The industry is expected to incur one-time burdens and costs associated with rule familiarization, form completion, CBI claim substantiation, recordkeeping, and electronic reporting activities. Under the proposed



Another important regulatory action from the EPA, according to Wells, is related to the detection of certain PFAS in some public water supplies, which has generated public concern and a number of state regulatory actions.

The EPA is responding to PFAS using Safe Drinking Water Act (SDWA) authorities. In March 2021, the agency finalized a positive regulatory determination (RD) to develop SDWA regulations for the two most frequently detected PFAS, PFOA and PFOS (86 Federal Register 12272). On 29 March 2023, the EPA proposed a national primary drinking water regulation (NPDWR) for PFOA and PFOS and issued a preliminary positive RD and a proposed NPDWR for several other PFAS (88 Federal Register 18638). Under SDWA, the agency is required to finalize the rule within 18 months of the proposal, and it has a proposed publication date for the final rule of January 2024.

Wells highlighted additional proposed regulations as of particular importance to 3E customers and chemical manufacturers, importers/exporters, and end users. Here is the list of chemicals – mainly organohalogen compounds used as solvents – along with the proposed dates for the publication of the final rules:

- Methylene Chloride Final Rule 6/24
- 1 Bromopropane Final Rule 3/25
- Trichloroethylene Final Rule 10/24
- Perchloroethylene Final Rule 8/24
- N-Methylpyrrolidone 12/24

#### **States**

Using data from 2011, 2015, 2019, 2021, and 2023, Wells identified state regulatory trends in several key areas, among them PFAS, EPR, cosmetics, and climate change. Her analysis of state regulatory changes shows there has been a significant uptick in state regulations. In addition to more recent state regulatory interest in PFAS, regulatory changes also were noted for occupational exposure limits (OELs), right to know laws, volatile organic chemicals (VOCs), and chemical release reporting.

In a six-month period in 2023, Maryland, Oregon, Washington, California, Maine, Vermont, Hawaii, New York, Colorado, and Minnesota have acted on PFAS. These actions range from banning them in various products and product packaging to hazard disclosures and product notifications. (See graphic that highlights six months of state regulatory action around PFAS.)



## EUROPE

#### **European Union/EMEA**

**EU** <u>REACH</u> (Registration, Evaluation, Authorization, and Restriction of Chemicals) – EU REACH is not only impactful in the European Union (EU) but also around the world in various forms. Adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, REACH also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

In principle, REACH applies to all chemical substances, not just those used in industrial processes. It includes chemicals found in cleaning products, paints, clothing, furniture, cosmetics, and electrical appliances. Therefore, REACH impacts most companies across the EU, which must identify and manage the risks linked to the substances they manufacture, import, and market in the EU. They must demonstrate to the European Chemicals Agency (ECHA) how the substance can be safely used and communicate the risk management measures to the users.

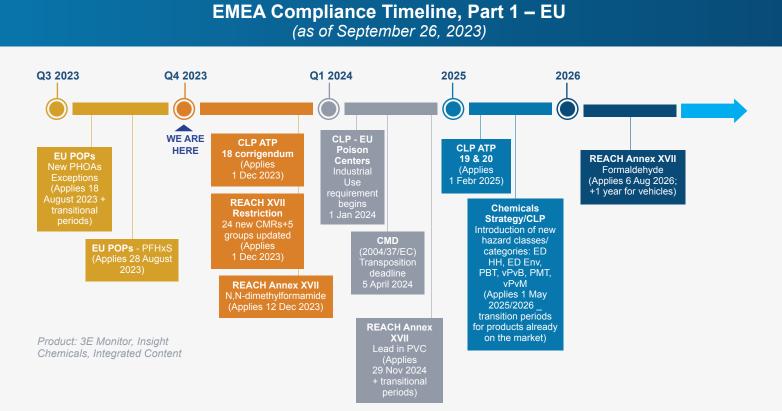
While EU REACH came into force on 1 June 2007, new regulations continue to be added and existing regulations and policies are expanded and amended. Most recently,

on 6 August 2023, REACH Annex XVII, entry 77 – Formaldehyde and Formaldehyde Releasing Substances – came into force. No. 77 in REACH Annex XVII prohibits placing on the market the following articles if they release formaldehyde above the specified concentrations:

- Indoor furniture and wood-based articles: 0.062 mg/m<sup>3</sup>
- Other articles (including toys): 0.080 mg/m<sup>3</sup>
- Road vehicles (in the interior of the vehicle): 0.062 mg/m<sup>3</sup>

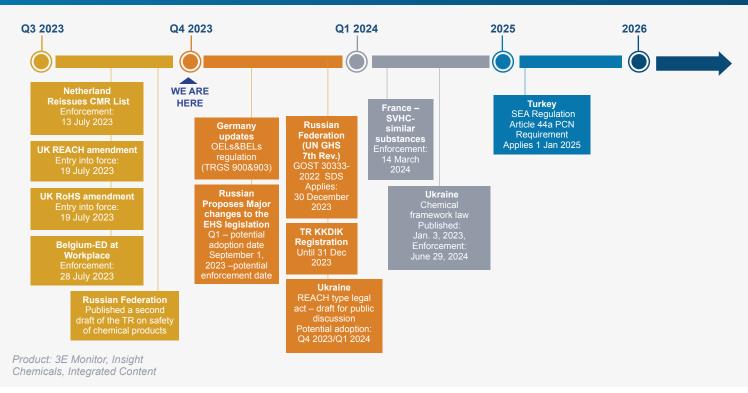
Companies have until 6 August 2026 (indoor furniture, wood-based articles, other consumer articles) and 6 August 2027 (interior of road vehicles) to meet these requirements.

**Restrictions Roadmap** – On 25 April 2022, the European Commission published the <u>Restrictions Roadmap</u>, which prioritizes group restrictions for the most harmful chemicals to human health and the environment that are still found in consumer products. Critics, like the European Environmental Bureau (EEB), are calling it "the road to nowhere," claiming, "Despite the Commission's legal obligation, strong political mandate of the Chemicals Strategy for Sustainability, and powers to ensure broad and rapid bans, it [the roadmap] allows and even contributes to slow and weak regulation." The EEB is a









network of environmental citizens' organizations in Europe. It currently consists of over 180 member organizations in 40 countries, including a growing number of networks, and represents some 30 million individual members and supporters.

**Supply Chain Transparency** – One major regulatory trend in Europe aims at making the supply chains transparent in an effort to enable a circular economy, according to Miriam Schoepel, Senior Chemical Regulatory Compliance Consultant, Regulatory Consulting, EMEA region, 3E Europe GmbH. "This is especially challenging as supply chains have not been designed to be transparent, based on the fear of giving away too much information and losing competitive advantage," she says, adding, "A vital part of this will be the introduction of a Digital Product Passport, as introduced by the Ecodesign for Sustainable Products Regulation. The passport will enable the setting of performance and information requirements for almost all categories of physical goods placed on the EU market."

**PFAS** – As in the United States, legislation that bans or restricts PFAS is trending in Europe, says Schoepel. Many jurisdictions worldwide address PFAS as a group after

regulating certain bellwether PFAS substances individually. PFAS is believed to include around 10,000 individual substances, although it is unclear how many have been used commercially. The so-called fluoropolymers are subject to proposed and enacted legislation, similar to those for polytetrafluoroethylene (PTFE, commonly known by the brand name Teflon).

Fluoropolymers are used in industrial and commercial products whenever extreme durability, resistance, and inertness are needed. "Currently, only limited alternatives are available; the industry is skeptical about restricting this subgroup," says Schoepel. "Next to actual restrictions/ bans, much of the PFAS legislation also includes certain reporting obligations, such as TSCA 8(a)7, Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances in the United States, that create considerable challenges surrounding data collection."

She also mentioned alternative feedstocks to gas and oil for chemical production processes are another trend. These feedstocks can be either recycled materials (mechanical and chemical recycling) or bio-based, renewable feedstocks.



The Ukraine/Russian conflict is obviously having a huge impact on Eastern Europe, says Emilia Vassileva, Senior Regulatory Research Analyst, Regulatory Research, Eastern Europe, 3E Co. Both countries are making changes to their regulatory policies around chemical risk management.

"Ukraine is continuing the process of aligning its chemical legislation with the EU," says Vassileva. On 18 October 2022, the Ukrainian Parliament passed on its first reading the draft Law on Chemical Safety and Management of Chemical Products. The law is the first of numerous acts aimed at bringing Ukrainian chemicals legislation into the 21st century and aligning it further with European chemical legislation, according to Vassileva. The goals of the legislation include:

- Build a national system for management of chemical substances according to the European model.
- Implement basic technical regulations like REACH and CLP.
- Introduce the international classification of hazardous chemicals and create a single database of such substances.
- Introduce mechanisms for restrictions and bans of products containing carcinogens, mutagens, bioaccumulative substances, and environmental hazards.

The public discussion phase for the draft of the Ukrainian Technical Regulations for the Classification of Hazards, Labeling, and Packaging of Chemical Products (CLP) ended in April 2023. <u>The second draft</u>, published 6 September 2023, implements some of the main rules of the EU REACH (1907/2006) and establishes a national registration scheme, mandatory SDS requirements, procedure for establishing restrictions on the production, use or supply on the market in Ukraine of chemical products that pose uncontrolled risks to human health and/ or the environment, etc. Together, the Law on Chemical Safety and Management of Chemical Products and the CLP will change the Ukrainian chemical regulatory landscape, says Vassileva. Once approved by the Ukrainian National Assembly, manufacturers and importers must comply with the newly introduced legal requirements for the classification and labeling of chemical products once the act is adopted and enforced.

Russia is accelerating the adoption of its own legal act (Russian TR on safety of chemical products) "that will change the existing regime of regulation of chemicals in Russia, [separating] the Russian legislation from the Eurasian Economic Union (EAEU) (until the EAEU Technical Regulation (TR) will be enforced), and will make the compliance with the UN GHS, 7th rev. ed. mandatory," says Vassileva. The new Russian TR can potentially change the status of the Russian safety data sheet (SDS) the classification and labeling of chemicals in Russia.

Public discussion of the new draft (second draft) ended on 28 August 2023. This regulation will be enforced six months from the publication date, although there is no official information about the publication and enforcement dates. The first draft, which is no longer valid, listed September 2024 as a potential enforcement date.





"What is the connection between the EAEU TR on safety of chemical products and the Russian TR on safety of chemical products? They are almost identical as text, but the EAEU TR is superior (trumps any Russian legal act)," says Vassileva. "The expectations are that the Russian TR will most probably be enforced first and aims to fill the chemical regulatory gap in Russia until the EAEU TR on safety of chemical products is enforced."

#### UK

Under the European Union (Withdrawal) Act 2018, the EU REACH Regulation was brought into UK law on 1 January 2021 and is known as UK REACH. REACH, and related legislation, were replicated in the UK with the changes needed to make it operable in a domestic context. The REACH Statutory Instruments that made these changes can be found on <u>legislation.gov.uk</u>. The key principles of the EU REACH Regulation were retained in UK REACH.

In the UK, the big news is that the Health and Safety Executive (HSE) issued a draft amending the <u>Great Britain</u> <u>Mandatory Classification and Labeling List</u> (GB MCL) by adding 26 hazardous chemical substances. Comments can be submitted to HSE until 24 October 2023. Once finalized, the amendment is scheduled to be adopted and enter into force for voluntary implementation in the first quarter of 2024. Manufacturers, importers, and distributors are mandated to apply this harmonized classification by the third quarter of 2025.

#### Germany

#### The Act on Corporate Due Diligence Obligations in

<u>Supply Chains</u> (Gesetz über die unternehmerischen Sorgfaltspflichten in Lieferketten (LkSG)) took effect in January 2023 and imposes new obligations on companies with 3,000 or more employees to ensure their suppliers have high standards regarding safety and environmental health. In January 2024, it will be expanded to include companies with 1,000 or more employees.

The act requires companies to conduct comprehensive risk analyses and introduce or enhance risk management systems. They must check their entire supply chain for violations of human rights and environmental concerns. If a company identifies any risks in its supply chain, it must take preventative or remedial measures to mitigate the risks, depending on the point in the process the risks are uncovered. The act also requires a policy statement on the company's own strategy, which specifies in more detail how the new obligations are to be handled. As part of their comprehensive documentation and reporting obligation, companies must publish and submit annual business reports related to their obligations under the Act on Corporate Due Diligence Obligations in Supply Chains.

It is expected that the German supply chain act will serve as a template of sorts for similar EU legislation, which will cover the same measures. The goal is to level the playing field for ESG initiatives and the people throughout the supply chain.

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On 14 June 2023, the Federal Ministry for Economic Affairs and Climate Action (BMWK) initiated the departmental vote on the draft of the <u>Climate Protection Act</u> (KSG) and the <u>Climate Protection Programme 2023</u> (KSP). Taken as a package, the climate protections set higher national emissions reduction targets for 2030 (at least 65%) and 2040 (at least 88%), with the goal of achieving net greenhouse gas neutrality by 2045 (five years earlier than the EU). In order to achieve these ambitious targets, Germany has set up annual CO2 emission budgets for six individual industry sectors until 2030, along with a monitoring and policy adjustment mechanism.

"In almost all sectors, i.e. in the energy sector, transport, industry, the building sector, waste management, agriculture and land use and forestry, there is an urgent need for action in the coming years in view of the inadequate emission reductions in the past and the therefore foreseeable failure to meet the German and European climate protection targets," notes the draft program. Emission reductions will need to double or triple in some cases if the targets of reducing greenhouse gas emissions by 65% (compared to 1990 levels) by 2030 and achieving climate neutrality by 2045 are to be reached.

More than €80 billion has been targeted to provide funding for measures to achieve the new climate targets. Based on a rationale that underlies the Climate Action Programme 2030, initial financial support for the transition to climatefriendly technologies will gradually be replaced by incentives and rules.



#### **Asia Pacific/ASEAN**

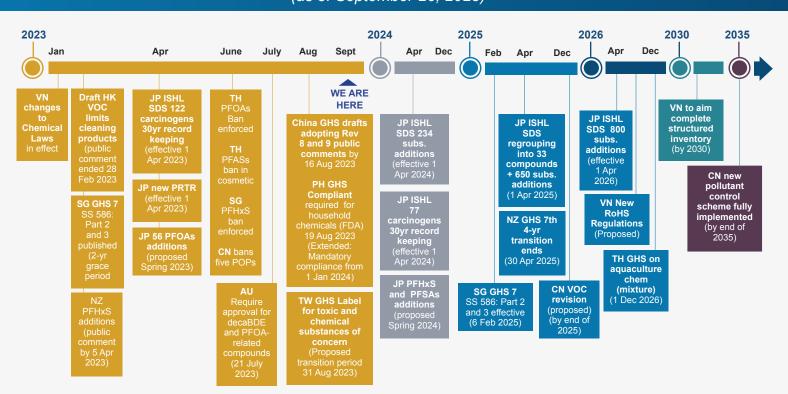
The Regional Comprehensive Economic Partnership (RCEP) Agreement entered into force in January 2022, covering 10 members of the Association of Southeast Asian Nations (ASEAN)—Brunei, Burma (Myanmar), Cambodia, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand, and Vietnam—and five ASEAN free trade agreement (FTA) partners—Australia, China, Japan, New Zealand, and South Korea. All ASEAN countries other than the Philippines and Myanmar have formally ratified the RCEP.

A free trade agreement among the largest economies in Asia, the RCEP potentially could have a huge impact on the chemical industry. Under the RCEP, more than 90% of the trade of goods in the region will eventually achieve zero tariffs. With more than 1,000 tariff numbers related to the chemical industry, the RCEP should facilitate the import and export trade of chemicals.

As part of RCEP coverage, most of the countries, including China, have adopted GHS classification and labeling systems, which requires the SDS and labels of chemicals to comply with the GHS-related regulations and standards of each country and region.

In fact, many regulatory changes and updates are impacting companies operating in the Asia Pacific (AP) region. Continuing to stay aligned with global trends of chemical management such as REACH and GHS, the AP region has adopted a more rigorous and holistic approach in controlling chemical substances and products introduced or circulated in the market, says Kristyn Hong, Associate Director, Asia Pacific, 3E Co., who lists REACHlike management systems as a top trend in the region. As the head of the AP team for 3E Co., Hong oversees the team of regulatory analysts who are responsible for regulatory management, research, and analysis in the region.

According to her, REACH or REACH-like management of chemical substances has been fully or partially implemented by several countries (K-REACH in Korea, Taiwan REACH, etc.) and likely will expand to more jurisdictions. India's REACH-like management system, so far, is the next most visible regulation, and



#### Asia Pacific Compliance Timelines, except Korea (as of September 26, 2023)



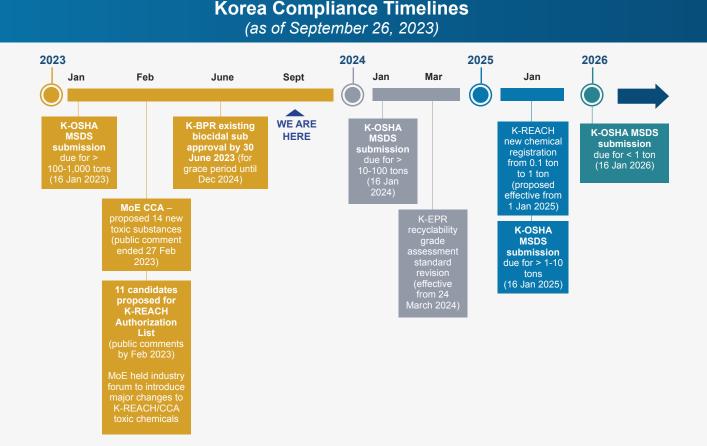
many companies around the globe are waiting on its development to understand detailed compliance requirements. One of the unique REACH-like implementations in the AP region, different from EU REACH, is the continuation of existing chemical inventory management. "Adopting chemical inventories to distinguish existing chemicals from new ones and differentiate restrictions based on inventory status continues to be a dominant measure as we see more jurisdictions develop chemical inventories," says Hong.

PFAS-focused chemical control is another trending issue, according to Hong, who says it has become one of the highest priority objectives. "We see increasing regulatory updates in banning or restricting PFAS-containing products from manufacture, import or export, distribution, sale, use, or discharge into the environment, and the trend will only grow in 2024 or beyond," she says.

As the AP region moves forward with a risk assessment approach, departing from conventional hazard testing, she expects to see more Chemicals of Concern (CoC)-types of publication, calling the implications of an implementation of management of CoC "staggering" in terms of the futureoriented chemical control strategies under consideration by Asia Pacific authorities. For example, the changes to the substances of ISHL (Industrial Safety and Health Law) SDS and Risk Assessment List have been planned out up to 2026 (including the grace period, until 2027) and published by Japan's Ministry of Health, Labor, and Welfare (MHLW).

The final trend mentioned by Hong is the technical and administrative support offered by Asia Pacific authorities to industry to manufacture greener chemical products. Government strategies for technical and scientific data and/or financial support for industry for green chemistry innovation include things like tax reduction and increased publication of recommended substitute chemical lists for industry. Hong recommends manufacturers take advantage of these substitute chemical lists for ecodesign of their products.

As noted earlier, the regulatory landscape for chemicals is constantly shifting. Trends appear to target supply chains and the responsibility for the life cycle of chemical substances that are thought to be harmful to humans, animals, or the environment, particularly those that have been characterized as "forever chemicals."



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"Chemical manufacturers have been navigating an escalating level of regulatory burden on U.S.-based operations, which threatens to erode competitiveness and hold back growth," said Emily Sanchez, American Chemistry Council Director for Economics and Data Analytics in a <u>blog post</u> on the ACC web site.

"The most recent [Economic Sentiment Index] reading of rising compliance and opportunities costs related to regulations is concerning," Sanchez added. "Chemical companies are challenged in an increasingly unfavorable business environment."

As noted by Alan L. Johnson, Managing Director, Chemical and Workplace Safety, 3E Co., we live in an interconnected world where business operations transcend borders. As such, "the importance of maintaining chemical compliance across global operations cannot be overstated." He adds that as companies expand their reach and impact, "the need to adhere to consistent and rigorous chemical compliance standards becomes a critical component of both environmental stewardship and business success." Calling adherence to chemical global chemical regulations "a non-negotiable imperative," Johnson points out the vital importance to the triple bottom line — people, environment, and corporate reputation and performance of maintaining compliance and staying on top of industry trends. That said, he admits it's not easy but offers hope for the future for companies that can successfully navigate the regulatory roadmap.

"Navigating the complex web of global chemical regulations is like running a business with a map that keeps changing its terrain. Each new regulation represents a hurdle, a shifting landscape, and a constant challenge to maintain compliance. Yet, in this dynamic environment, successful businesses not only adapt but also find opportunities amid the complexity, ensuring that safety, sustainability, and innovation go hand in hand."

#### ABOUT 3E

#### Intelligent compliance. Sustainable progress. A safer world.

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Our unmatched Environmental Health and Safety and Sustainability (EHS&S) and product compliance expertise empowers our clients to improve chemical and workplace safety, product safety and stewardship and supply chain transparency.

We equip customers to capture market opportunity while proactively meeting regulatory obligations and ensuring the safety of their people and products. Clients can accelerate the development and launch of products designed with safety from the start. We provide actionable intelligence that increases the sustainability of products and business processes and improves Environmental, Social and Governance (ESG) performance.

We are deeply committed to serving our more than 5,000 customers worldwide, including many of the world's leading chemical manufacturers, retailers and pharmaceutical companies.

Together we are building a safer world and a more sustainable future.