

# Newsletter

Global Environmental and  
Chemical Regulations, Policies,  
and Standards

October 2023

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# NEWSLETTER

*Global Environmental and Chemical Regulations, Policies, and Standards  
October 2023*



## WHO IS IAEG?

The International Aerospace Environmental Group ([IAEG](#)) is a non-profit organization of global aerospace companies created to collaborate on and share innovative environmental solutions for the industry. The group works to promote the development of voluntary consensus standards and provide accessible solutions for key environmental issues.

Members of IAEG recognize that there are currently a wide variety of different laws and regulations impacting health and the environment in place worldwide. The complexity and variability of requirements and guidance has led to an increased burden for the industry and its supply chain.

IAEG work groups address such issues as chemical material declarations and reporting requirements, the development of alternative technologies and greenhouse gas reporting and management. They create a forum for diverse and often competitive businesses to come together and share information on industry-wide opportunities for the promotion and adoption of global environmental requirements. In addition, IAEG provides opportunities for wider education on environmental issues and the supply chain via its meetings agendas and bespoke seminars.

## IAEG WORK GROUP 9 NEWSLETTER

The Aerospace and Defense (AD) industry is committed to developing an approach to help the AD industry evaluate emerging global environmental and chemical regulations and their impact on compliance and potential operational risk for companies and their supply chain. The objectives are to:

- » Maintain a list of global regulations, policies and standards considered and to be considered, including executive summaries of those regulations.
- » Develop a method to evaluate designated emerging regulations potential impact on compliance and/or operational risk, business continuity and/or impact on supply chain.
- » Develop summaries of the associated timeline for regulations (e.g., deadlines) and highlight the specific impacts.
- » Develop communication materials and conduct informational webinars, as appropriate, for member companies and/or AD supply chain companies, as appropriate.

This Newsletter summarizes environmental and chemical regulations relevant to the AD industry. Contact Lisa Brown at [myrna.l.brown@lmco.com](mailto:myrna.l.brown@lmco.com) or Lindsey Bean at [lindsey.bean@ngc.com](mailto:lindsey.bean@ngc.com) for any questions on this Newsletter. For general assistance on IAEG matters, contact Michele Lawrie-Munro at [mlawriemunro@iaeg.com](mailto:mlawriemunro@iaeg.com) or Amanda Myers at [amanda.myers@sae.org](mailto:amanda.myers@sae.org).

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## GLOBAL

### The tenth revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (published)

The tenth revised edition (ST/SG/AC.10/30/Rev.10) of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was released in 2023. The GHS is a United Nations-developed system aimed at standardizing the classification and labelling of chemicals worldwide to enhance human health and environmental protection by providing crucial information on chemical hazards to workers, consumers, and emergency responders. It serves as a reference point for companies as they create GHS labels and safety data sheets (SDSs) for their products.

Key updates and provisions in the tenth revised edition of the GHS include:

- » classification procedure for desensitized explosives; the GHS introduces a novel classification procedure for desensitized explosives – this procedure considers standardized test results, the desensitization process, and the intended use of the explosive
- » non-animal testing methods for health hazards; encouraging the use of non-animal testing methods, especially for classifying health hazards like skin corrosion/irritation, serious eye damage/irritation, and respiratory or skin sensitization – this aligns with the global shift towards reducing animal testing (3Rs: replacement, reduction, and refinement)
- » rationalization of precautionary statements; the GHS streamlines precautionary statements to enhance user comprehension while maintaining usability for labelling practitioners – this involves consolidating and simplifying some precautionary statements, fostering consistency across different hazard classes
- » review of Annexes 9 and 10; Annexes 9 and 10 went through a review to ensure alignment with the classification strategy, guidance, and tools for metals and metal compounds, specifically in terms of long-term aquatic toxicity classification – this alignment fosters consistent and harmonized classification and labelling of metals and metal compounds

Apart from these significant changes, the tenth revised edition of the GHS incorporates several minor updates and clarifications to enhance clarity and consistency, making it easier for users to implement. This edition plays a crucial role in maintaining the GHS as an effective tool for enhancing chemical safety globally.

These changes will now be added to the different regional/national implementations of GHS by the relevant national authorities; there is no specified deadline for this.

Penalties for non-compliance with GHS labelling and SDS requirements vary based on local regulations and enforcement mechanisms.

More information can be found [here](#).

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## AFRICA

### South Africa

#### Revisions to regulations governing the Control of the Import or Export of Waste, 2019 (consultation)

On 2 October 2023, the Minister of Forestry, Fisheries, and the Environment, in accordance with the National Environmental Management Waste Act 59 of 2008 (NEMWA), introduced proposed amendments to the regulations governing the Control of the Import or Export of Waste, 2019. NEMWA aims to reform waste management laws, protect health and the environment, prevent pollution, promote sustainable development, and establish standards for waste management. It covers various aspects such as institutional arrangements, planning, licensing, and more.

The proposed amendments impact the following sections:

- » Definitions
- » Objectives of the Regulations
- » Scope of Application of the Regulations
- » General Prohibitions
- » Mandatory Requirements for Importing Hazardous Waste
- » Mandatory Requirements for Importing Non-Hazardous Waste
- » Mandatory Requirements for Exporting Hazardous Waste
- » Mandatory Requirements for Exporting Non-Hazardous Waste
- » Mandatory Requirements for the Transit of Hazardous Waste
- » Decision-Making Processes
- » Record-Keeping Procedures
- » Offences and Violations

These amendments reflect the government's commitment to enhancing waste management and environmental protection. Public comments on the proposed changes were due on 1 November 2023.

More information can be found in this [notice](#) form the Government Gazette.



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## ASIA

### India

#### Launch of ChemIndia, a chemical inventory for India (announced)

On 10 October 2023, the Indian Department of Chemicals and Petro-chemicals launched ChemIndia, a chemical inventory for India, with the objective of collecting, compiling, and analyzing real time data from the chemical industry. It is hoped that the new platform will make data more readily available, helping both industry and policymakers to make informed decisions regarding the Indian chemical industry.

Companies can access the database and use the stored data to ensure compliance and save time gathering data themselves. The site itself includes geographic information systems dashboards, links to publications, as well as search functions for substances via CAS number.

More information can be found [here](#).

### Israel

#### Draft Climate Law (published)

The Ministry of Environmental Protection (MEP) had an initial reading of its Climate Law in the Knesset on 12 September 2023. The law introduces a national goal of reducing greenhouse gas emissions by 30% by 2030, aiming for emissions to be 70% of 2015 levels. Ultimately, the law envisions achieving net-zero emissions by 2050.

This landmark legislation is a response to the pressing need to address climate change and its adverse effects. It is designed to safeguard public health and well-being from the repercussions of climate change, particularly for future generations. Additionally, the law seeks to promote sustainable development in Israeli society and the environment by protecting public health, natural resources, food safety, ecological systems, and biodiversity. Below are key highlights of the Climate Law:

- » the law sets ambitious greenhouse gas emission reduction targets for 2030, aiming for a 30% reduction from 2015 levels
- » governmental ministries and relevant entities are mandated to formulate climate change preparation plans, build resilience, and report biennially – these measures aim to reduce climate risks and enhance Israel's preparedness for the effects of climate change
- » a Climate Cabinet, led by the Prime Minister, is tasked with coordinating climate-related policies and actions across government ministries, improving the government's response to climate-related crises
- » a Climate Council, comprising representatives from relevant governmental ministries and stakeholder groups (including industry and environmental organizations), formulates and implements Israel's climate policy, ensuring a comprehensive and informed approach
- » the law requires the assessment of climatic risk for plans significantly impacting greenhouse gas emissions or susceptible to climate change effects, integrating climate considerations into decision-making processes

- » within six months of the law's enactment, an interdisciplinary experts' committee will be appointed to provide expert advice on climate-related matters and policy implementation
- » a report and supervision service will be established to monitor the government's adherence to the law's requirements and transparency in long-term policy decisions

The Climate Law gains increasing significance as Israel reports rising greenhouse gas emissions and experiences extreme climate events. It provides certainty for businesses, industries, and investment entities as they transition towards sustainable alternatives and a low-carbon, zero-emission economy, aligning with international climate goals. The law responds to the urgent need to reduce emissions and mitigate the escalating climate crisis, emphasizing the necessity of a 45% emissions reduction within this decade.

There is no penalty associated with this regulation.

Information can be in English in this [notice](#) from the MEP. The narrative for the draft law can be here [in English](#) and [in Hebrew](#). Additional information can be found in English in this [release](#) from the MEP.

## Amendments to Aviation Regulations (Operation of Aircraft and Flight Rules) (draft)

The Ministry of Transportation and Road Safety (MTRS), the regulator of the aviation industry in Israel, outlined proposed amendments to Aviation Regulations (Operation of Aircraft and Flight Rules), specifically focusing on safety equipment requirements for aircraft operating in general international operation. These amendments are driven by the need to align Israeli aviation standards with international norms set by the International Civil Aviation Organization (ICAO), which Israel is committed to following.

The proposed amendments primarily target safety equipment, including surface warning and awareness systems, firefighting equipment, rescue equipment for flying over water, and systems for detecting stormy weather. These requirements are derived from ICAO's Annex 6 to the Chicago Convention and aim to enhance flight safety and the potential for saving lives in emergencies. Annex 6 of the Chicago Convention specifies international standards and recommended practices for airplanes used in international commercial air transport operations carrying passengers or freight.

The amendment also emphasizes the legal framework for implementing these changes, highlighting relevant sections of the Aviation Law and Pilot Law that grant the MTRS the authority to establish these regulations. It mentions the need for consent from the Minister of Internal Security, but it does not entail criminal punishment for non-compliance, only financial penalties.

In summary, the proposed amendments seek to bring Israeli aviation regulations in line with international standards, focusing on safety equipment requirements for various types of aircraft operating in general international operation. These changes are expected to take effect one year after publication to allow operators and aircraft owners time to comply.

The draft aviation regulations amendment can be found here [in English](#) and [in Hebrew](#). The amendment explanatory notes can be found here [in English](#) and [in Hebrew](#).

## Japan

### Additions to the list of substances requiring Safety Data Sheets and Global Harmonized System of Classification and Labeling based labels (in force)

On 31 August 2023, an update was made by the Ministry of Health, Labor, and Welfare (MHLW) updated the list of substances that require Safety Data Sheets (SDSs) and Global Harmonized System of Classification and Labelling (GHS) based labels. The update is in line with Japan's Industrial Safety and Health Act (ISHA) that aims to improve transparency of hazard information across the supply chain. The scope of ISHA covers the safety and health of workers in workplaces, facilitating comfortable working environments by having comprehensive and systematic counter measures for prevention of industrial accidents.

The updated list contains 667 substances (provided in Japanese and English) including their cut-off values. The cut-off value shows the concentration threshold of a chemical substance in a product. Manufacturers are exempted from providing SDSs and GHS-based labelling if a listed chemical falls below this threshold.

Penalties for non-compliance include fines.

More information can be found [here](#) in Japanese.

### Revision to Order for Enforcement of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances, etc. (amendment)

In September 2023, Japan revised the Order for Enforcement of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances, etc. ([Cabinet Order No. 202 of 1974](#)). This order is a Japanese law that oversees the manufacturing, importing, and usage of chemical substances, with a primary objective of protecting human health and the environment from the detrimental impacts of these substances. The order encompasses a range of chemical substances, specifically focusing on Perfluoro (hexane-1-sulfonic acid) (PFHxS; CAS No. 355-46-4), its isomers, or these salts. Furthermore, it extends its jurisdiction to various products that incorporate PFHxS, its isomers, or these salts in their composition, including but not limited to:

- » water-repellent textiles and oil-repellent textiles
- » etching agents used for metal processing
- » etchants used in the manufacture of semiconductors
- » surface treatment agents for plating or such preparation additives
- » antireflection agents used in semiconductor manufacturing
- » resists for semiconductors
- » water repellent, oil repellent, and fabric protection agents
- » fire extinguishers, fire-extinguishing agents, and fire-extinguishing foam
- » water-repellent clothes and oil-repellent clothes
- » water-repellent floor coverings and oil-repellent floor coverings

Under Order No. 202 of 1974, all new chemical substances must undergo evaluation by the Ministry of Economy, Trade, and Industry (METI) before they can be manufactured or imported into Japan. METI's evaluation process considers various factors, including the chemical properties of the substance, its potential for causing harm to humans and the environment, and its intended purpose. If a new chemical substance is deemed safe by METI, a manufacturing or import license is

granted. Conversely, if it's considered unsafe, METI may either deny the license or impose restrictions on its manufacturing or import. Additionally, the law also governs the use of certain existing chemical substances. For example, it prohibits the use of specific chemicals in food and cosmetics and mandates warnings on labels for certain hazardous substances.

The recent revision of Order No. 202 of 1974 designates PFHxS, its isomers, or these salts as Class I Specified Chemical Substances, requiring authorization for manufacturing or importing, as outlined in Articles 17 and 22 of the Act on the Regulation of Manufacture and Evaluation of Chemical Substances. Furthermore, products that contain PFHxS, its isomers, or these salts are prohibited from being imported under Article 24 of the Act, encompassing the items listed above.

This amendment is driven by the urgent need to prevent environmental pollution caused by PFHxS, its isomers, or these salts, which possess characteristics such as non-biodegradability, high bioaccumulation potential, and chronic toxicity. These substances have been identified as potentially hazardous based on decisions made at the 10th Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants in 2022.

The amendment does not specify any particular dates related to this law.

Information on the revision of the order can be found [here](#) in English.

## Proposal to revise the Industrial Safety and Health Act (draft)

On 21 June 2023, the Ministry of Health, Labor, and Welfare (MHLW) published a draft proposal to revise Japan's Industrial Safety and Health Act (ISHA) to implement the chemical classification system established by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Article 18 of the ISHA Enforcement Order (Cabinet Order No. 318 of 1972) sets out the dangerous and harmful substances whose names, labelling, etc. should be displayed on their container and be notified (Article 18-2) when transferring or providing such chemical substances. Hence, suppliers of hazardous chemical substances listed in Table 9 (related to Article 18 and Article 18-2) of Cabinet Order No. 318 of 1972 of the ISHL are obligated to create and provide Safety Data Sheets (SDS) and labels to customers.

According to the Department of Environment and Safety at the Japan Chemical Industry Association, the revised policy is based on the recommendations of the review committee report titled "How to Manage Chemicals in the Workplace" that was released on 19 July 2021. The revision is in line with the idea of expanding the number of substances that require notification. The report suggests that the list of substances subject to notification will be gradually expanded in the future. Additionally, the proposal adds as many as 1,550 substances to the list, which currently contains 674 substances.

The enforcement date for promulgation of some provisions is scheduled for 1 April 2025. There will be a grace period of one year for companies to comply with any new labelling or SDS requirements.

Revisions to the order can be found here [in English](#) and [in Japanese](#). The Ministerial ordinance draft overview can be found here [in English](#) and [in Japanese](#).

## Notification of the schedule for manufacturing and importing of new chemical substances in 2024 (published)

On 8 September 2023, Japan's Ministry of Health, Labor, and Welfare, Ministry of Economy, Trade, and Industry, and Ministry of Environment together published a notice about the schedule for manufacturing and import of new chemical substances in 2024. Japan's Law concerning the Evaluation of Chemical Substances and Regulation of their Manufacture,

etc. (Law No. 117 of 1973) aims to establish a system for evaluating the properties of new chemical substances before their manufacture or import and for implementing necessary regulations with respect to their manufacture, import, use, etc. to protect human health and environment. Article 3(1), Article 5(1,7) of the law mentions that a manufacturer or importer of new chemical substances must notify the ministry in charge of the new substance, after which the substance is required to undergo an examination.

The newly published schedule for receipt of new notifications in 2024 states the available reception dates for the submission of materials for preliminary examination and for the submission of notification form. The dates range between from 6 October 2023 till 29 November 2024 in twelve reception periods. If a submission is late, then the information will have to be resubmitted during the next submission period.

More information can be found here [in English](#) and [in Japanese](#).

## [Saudi Arabia](#)

### [Amendment to standard regarding 12V lead-acid started batteries intended for use in road vehicles \(consultation\)](#)

On 18 September 2023, the Saudi Standards, Metrology, and Quality Organization (SASO) opened a consultation (till 17 November 2023) on proposed standard SASO/DS/IEC 60095-1:2019/AMD1:2023, amending SASO/DS/IEC 60095-1:2019 regarding 12V lead-acid starter batteries intended to be used in road vehicles. The proposed amendment includes some significant modifications such as:

- » charging modes and functions (such as code date)
- » water consumption test
- » summary of requirements

Information can be found in English in this [notice](#) from the World Trade Organization and in this [SASO Standard](#).

## [Turkey](#)

### [Guide for the implementation of the Regulation on the Export and Import of Certain Harmful Chemicals \(published\)](#)

Turkey released a guide for implementing the Regulation on the Export and Import of Certain Harmful Chemicals (the Regulation), which was published on 28 January 2023 and came into effect in June 2023. The primary goals of the Regulation are to safeguard human health and the environment from the adverse effects of harmful chemicals, promote environmentally responsible usage of such chemicals, facilitate the exchange of information regarding these chemicals, and encourage shared responsibility and cooperation. The Regulation applies to industrial chemicals. The released guide is intended to assist a variety of stakeholders, including the Ministry of Environment, Urbanization, and Climate Change (the Ministry), as well as exporters, importers, and industrialists, in effectively implementing the regulation.

The main focus of the guide is on the responsibilities of exporters, while responsibilities for importers are primarily governed by other national regulations. According to the guide, the summary of exporter obligations includes:

- » notifying the Ministry before the planned export date for the chemical (substance/mixture)

- » complying with the import decisions of importing countries regarding Annex-2 chemicals<sup>1</sup>
- » avoiding the export of chemicals listed in Annex-6<sup>2</sup>
- » properly packaging and labelling the chemicals intended for export
- » providing safety data forms
- » informing the Ministry about the amount exported in the first quarter of each year (i.e., by 31 March each year)
- » providing additional information upon request

The guide discusses importer responsibilities under the Rotterdam Convention. The chemicals covered by the Rotterdam Convention include pesticides and industrial chemicals that have been prohibited or heavily restricted by the parties to the convention due to health or environmental concerns. Chemicals subject to prior notified acceptance under the Rotterdam Convention are listed in Annex III of the convention. When a prohibited or heavily restricted chemical is exported from its territory, the party must notify the importing country. The convention also establishes a mechanism for adding other chemicals to Annex III.

While the Regulation does not contain detailed provisions on import restrictions or prohibitions, it governs the procedures and principles for the Ministry to make and evaluate import decisions regarding chemicals within the scope. Importers are required to provide information on the quantities of chemicals imported and placed on the market.

There are no penalties for non-compliance associated with this update.

Information can be found here [in English](#) and [in Turkish](#).

## Vietnam

### Guidelines for measurement, reporting, appraisal of greenhouse gas emission mitigation and greenhouse gas inventory in the industry and trade sector (consultation)

The Ministry of Industry and Trade (MIT) is inviting comments regarding the draft Circular that establishes guidelines for the measurement, reporting, and evaluation of greenhouse gas emission mitigation, as well as the greenhouse gas inventory within the industry and trade sector. The due date for comments was 7 November 2023. Circular adoption date is planned for 2024.

The Circular contains general provisions regarding the regulation of greenhouse gas (GHG) inventory and the technical processes for Measuring, Reporting, and Appraising (MRA) to mitigate GHG emissions within the Industry and Trade sector. This Circular applies to organizations and individuals involved in GHG inventory activities and measurement, reporting, and appraisal (MRA) of GHG emission mitigation in the industry and trade sector.

The greenhouse gas inventory and MRA processes must adhere to several key principles:

- » completeness – the inventory and MRA activities should cover all sources of greenhouse gas emissions, and data collection should be continuous and uninterrupted
- » consistency – the MRA activities should be carried out continuously over time, maintaining consistency in monitoring plans, calculation data, and greenhouse gas inventory methods

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<sup>1</sup> chemicals subject to the special admission procedure and open acceptance procedure.

<sup>2</sup> substances showing persistent organic pollutants.

- » transparency – all documents, data, assumptions, operational data, application coefficients, calculation methods, and greenhouse gas inventories must be transparent and accessible for appraisal by competent agencies and independent units upon request
- » accuracy - GHG emission calculations should strive for the highest possible accuracy based on the selected method, aiming to minimize deviations
- » continuous improvement – the reporting and calculation system for GHG emissions should be subject to continuous improvement based on appropriate recommendations from appraisal agencies

The sector-level greenhouse gas inventory will focus on activities within the domain of energy and industrial processes under the authority of the MIT. This inventory will include:

- » GHG inventory for the energy sector:
  - measurement of GHG emissions resulting from fuel combustion activities
  - assessment of GHG emissions stemming from fuel emission activities
- » GHG inventory for industrial processes and product use:
  - evaluation of GHG emissions originating from the chemical industry
  - estimation of GHG emissions related to the metallurgical industry
  - assessment of GHG emissions associated with the utilization of substitutes for ozone-depleting substances

Establishments will be required to submit reports on GHG emission mitigation results together with reports on appraisal of GHG emission mitigation results to MIT and the Ministry of Natural Resources and Environment before March 31 of each year starting in 2027.

Information can be found [here](#) in Vietnamese.



## EUROPE

### European Union

#### Amendment to REACH regarding synthetic polymer microparticles (published)

On 27 September 2023, the European Commission (EC) published an amendment to Annex XVII of REACH regarding synthetic polymer microparticles. ECHA defines microplastics as solid plastic particles composed of mixtures of polymers and functional additives; they may also contain residual impurities. Microplastics can be unintentionally formed when larger pieces of plastic wear and tear, like car tires or synthetic textiles, but they are also deliberately manufactured and added to products for specific purposes, such as exfoliating beads in facial or body scrubs.

Tiny fragments of synthetic or chemically modified natural polymers are insoluble in water, degrade very slowly, and can easily be ingested by living organisms since they are found in drinking water and food. As such, and given their ubiquitous presence, they accumulate in the environment and contribute to microplastic pollution. This raises concerns about microplastics general impact on the environment and on human health, which has made the EC adopt measures that restrict microplastics that are intentionally added to products. The new rule prevents approximately 500,000 tonnes of

microplastics from being released to the environment, prohibits the sale of microplastics as such and of products to which microplastics have been added intentionally, and restricts the release of those microplastics when used.

The restriction covers a wide definition of microplastics such as all synthetic polymer particles below 5 millimeters that are organic, insoluble, and resist degradation, to reduce emissions of intentional microplastics from as many products as possible.

Manufacturers, importers, and industrial downstream users of products containing synthetic polymer microparticles are to provide to competent authorities, upon their request, specific information enabling the unequivocal identification of the polymers in the scope of this restriction contained in their products and the function of those polymers in the product. But, if they claim that certain polymers in their products are excluded from the designation of synthetic polymer microparticles on grounds of degradability or solubility, information proving those properties should be provided to competent authorities upon their request. Industrial downstream users who do not have the required information should request it from their suppliers first. Products used at industrial sites or not releasing microplastics during use are derogated from the sale ban, but their manufacturers will have to provide instructions on how to use and dispose of the product to prevent microplastics emissions.

To start, the ban on loose glitter and microbeads began to apply on 17 October 2023. In other cases, the sale ban will apply after a longer period to give affected stakeholders the time to develop and switch to alternatives. Synthetic polymers microparticles, on their own or in mixtures, which have been placed on the market before 17 October 2023 may continue to be placed on the market. That rule is not needed for uses of synthetic polymers microparticles subject to transitional periods.

There are no penalties for non-compliance associated with this update.

Information can be found in this [press release](#). Additional information can be found in this [regulation narrative](#) and in ECHA's [definition of microplastics](#).

## Final screening report of trixylyl phosphate use in articles (published)

On 19 September 2023, the European Chemicals Agency (ECHA) published its final screening report<sup>3</sup> that found that the use or presence of trixylyl phosphate (TXP; EC No. 246-677-8; CAS No. 25155-23-1) in articles poses a risk to human health that is not adequately controlled. The report also concludes that the proposed restriction in the European Union (EU) is the most appropriate measure.

TXP is used in vehicles, plastic articles, electric and electronic devices, textiles, and leather and was added to the Authorization List, Annex XIV to REACH, with a sunset date of 27 May 2023. For substances on the Authorization List, once the sunset date has passed, ECHA must assess if the risks from the use of these substances in articles are adequately controlled. If ECHA concludes that the risk is not controlled and the use of these substances poses a risk to human health or the environment, then ECHA must prepare an Annex XV restriction dossier.

Annex XV sets out the general principles for preparing dossiers to propose and justify the identification of substances that are carcinogenic, mutagenic, or toxic for reproduction; persistent, bio-accumulative, and toxic (PBT); very persistent and

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<sup>3</sup> The consultation on the draft screening report was held from 28 June 2023 to 9 August 2023.



very bio-accumulative; or a substance of equivalent concern. It also sets out the rules for restriction dossiers on the manufacture, placing on the market or use of a substance within the EU.

The final report recommends that the restriction proposal considers the risks from other organophosphorus flame retardants, not currently on Annex XIV, given their structural similarity with TPX. ECHA also recommends that other endpoints, such as endocrine disruption or PBT, are considered in the restriction proposal, in addition to repro-toxicity. The timing of the restriction dossier development will be identified in the Restrictions Roadmap under the Chemicals Strategy for Sustainability, considering other priorities.

There are no penalties for non-compliance associated with this update.

More information can be found in the [final screening report](#) and in ECHA's [completed activities on restriction](#).

## Amendment to Regulation (EU) 2017/852 on mercury-added products subject to manufacturing, import, and export prohibitions (published)

On 29 September 2023, the European Union (EU) published an amendment to Regulation (EU) 2017/852 of the European Parliament and of the Council (the Regulation) on mercury-added products subject to manufacturing, import, and export prohibitions. The Regulation establishes measures and conditions concerning (i) the use, storage of, and trade in mercury, mercury compounds, and mixtures of mercury; (ii) the manufacture and use of and trade in mercury-added products, and (iii) the management of mercury waste in order to ensure a high level of protection of human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds.

Annex II to the Regulation, which sets out the mercury-added products that are prohibited from export, import, and manufacturing in the EU from the dates specified therein, has been amended. Entries 3a and 6a have been inserted respectively to include:

- » compact fluorescent lamps with an integrated ballast for general lighting purposes that are  $\leq 30$  watts with a mercury content not exceeding 2.5 milligrams per lamp burner
- » cold cathode fluorescent lamps and external electrode fluorescent lamps of all lengths for electronic displays, which are not included in Entry 6

Additionally, Entries 10 and 11 have been added to include:

- » electrical and electronic measuring devices except those installed in large-scale equipment or those used for high precision measurement where no suitable mercury-free alternative is available:
  - melt pressure transducers
  - melt pressure transmitters
  - melt pressure sensors
- » other mercury-added products:
  - mercury vacuum pumps
  - tyre balancers and wheel weights
  - photographic film and paper
  - propellant for satellites and spacecraft

The export, import, and manufacturing of the newly included mercury-added products are prohibited in the EU starting 31 December 2025. The amendment entered into force on 19 October 2023.

Penalties for non-compliance with the Regulation are determined by Member States.

More Information can be found [here](#).

## Registry of Classification and Labeling update (amendment, consultation, intention)

The CLP Regulation aims to ensure that hazardous chemicals are correctly identified and classified. It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package hazardous chemicals appropriately before placing them on the market.

### Amendments:

A Registry for Classification and labeling (CLH) intention has been submitted for [resorcinol; 1,3-benzenediol](#) (CAS No. 108-46-3; EC No. 203-585-2). This substance is used in rubber products, chemicals, plastic products, cosmetics and personal care products, wood, and wood products. The proposed classification is:

- » acute tox. 4\*, H302
- » skin irrit. 2, H315
- » eye irrit. 2, H319
- » ED HH 1, EUH380
- » aquatic acute 1, H400

A CLH intention has been submitted for [melamine](#) (CAS No. 108-78-1; EC No. 203-615-4). This substance is used in articles such as flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper/cardboard products, electronic equipment, by professional workers (widespread uses), in formulation or re-packing, at industrial sites, and in manufacturing. The proposed classification is:

- » carc. 2, H351
- » STOT RE 2, H373
- » reproductive toxicity
- » persistent, mobile, toxic/very persistent, very mobile

Penalties for non-compliance have not been specified.

### Consultations:

Consultations for [\[ethylenebis\[nitrilobis\(methylene\)\]tetrakisphosphonic acid, sodium salt](#) (CAS No. 22036-77-7; EC No. 244-742-5), [\[ethylenebis\[nitrilobis\(methylene\)\]tetrakisphosphonic acid, potassium salt](#) (CAS No. 34274-30-1; EC No. 251-910-1) and [\[ethylenebis\[nitrilobis\(methylene\)\]tetrakisphosphonic acid, calcium sodium salt](#) (CAS No. 85480-89-3; EC No. 287-370-9) opened from 25 September 2023 to 24 November 2023. These substances are used in water softeners, air care products, fillers, putties, plasters, modelling clay, polishes and waxes, washing and cleaning products, and cosmetics and personal care products. The proposed classification for the three substances is:

- » carc. 1B, H350
- » carc. 1B; H350: C ≥ 1 %

A consultation for [\[ethane-1,2-diylbis\[nitrilobis\(methylene\)\]tetrakisphosphonic acid](#) (CAS No. 1429-50-1; EC No. 215-851-5) opened from 25 September 2023 to 24 November 2023. This substance is used in water softeners, air care products, fillers,

putties, plasters, modelling clay, polishes and waxes, washing and cleaning products, and cosmetics and personal care products. The proposed classification is:

- » carc. 1B, H350
- » carc. 1B; H350: C ≥ 1 %

A consultation for [fluazaindoline \(ISO\); 8-chloro-N-\[\(2-chloro-5-methoxyphenyl\)sulfonyl\]-6-\(trifluoromethyl\)imidazo\[1,2-a\]pyridine-2-carboxamide](#) (CAS No. 1254304-22-7) was open from 11 September 2023 to 10 November 2023. This substance is planned to be used as an active substance in plant protection products. The proposed classification is:

- » acute tox. 4, H302
- » TOT RE 2, H373
- » aquatic chronic 2, H411

A consultation for [dichloromethane](#) (CAS No. 75-09-2; EC No. 200-838-9) opened from 18 September 2023 to 17 November 2023. This substance is used in adhesives and sealants, plant protection products, washing & cleaning products, biocides (e.g., disinfectants, pest control products), and coating products. The proposed classification is:

- » muta. 2, H341
- » carc. 1B, H350

A consultation for [silver nitrate](#) (CAS No. 7761-88-8; EC No. 231-853-9) opened from 11 September 2023 to 10 November 2023. This substance is used in biocidal products. The proposed classification is:

- » ox. sol. 1, H271
- » acute tox. 2, H300, ATE = 29 mg/kg by weight
- » skin corr. 1A, H314
- » skin sens. 1, H317
- » muta. 2, H341
- » repr. 1B, H360FD
- » STOT RE 2, H373 (nervous system)
- » aquatic acute 1, H400, M factor=1000
- » aquatic chronic 1, H410, M-factor=100
- » EUH071

A consultation for [acetophenone](#) (CAS No. 98-86-2; EC No. 202-708-7) opened from 2 October 2023 to 1 December 2023. This substance is used as a cleaning agent, intermediate, solvent, and in polymer manufacturing and processing, in air care products, fillers, putties, plasters, modelling clay, cleaning and care products, lubricants, greases, release products, coatings and paints, thinners, paint removers, and finger paints. The proposed classification is:

- » eye irrit. 2, H319
- » repr. 1B, H360FD
- » STOT SE 3, H336

A consultation for [2-pyrrolidone; pyrrolidin-2-one](#) (CAS No. 616-45-5; EC No. 210-483-1) opened from 16 October 2023 to 15 December 2023. This substance is used in ink and toners, coatings, imaging and printing mixtures, and as a laboratory chemical. It is also used as a catalyst in polymerization. The proposed classification is: repr. 1B, H360D.

If these proposed new classifications are approved, new risk management, labeling, and packaging requirements might apply.

## Intentions:

The CLH Intentions Until Outcome records submissions to the European Chemicals Agency (ECHA) for proposed harmonized classifications and labeling of substances. These proposals come from EU Member State authorities, manufacturers, importers, or downstream users. It plays a key role in standardizing hazard communication for chemicals in the EU. The latest updates on Classification, Labeling, and Packaging (CLP) proposals published by ECHA are summarized below:

A new CLH intention was submitted for [sodium chlorite](#) (CAS No. 7758-19-2; EC No. 231-836-6) on 2 October 2023 and updated on 17 October 2023. This substance is used in washing and cleaning products, textile treatment products and dyes, and in the manufacture of leather and fur. The proposed classification is:

- » ox. sol. 1, H271
- » met. corr. 1, H290
- » acute tox. 3, H301
- » acute tox. 2, H310
- » skin corr. 1, H314
- » eye dam. 1, H318
- » muta. 2, H341
- » STOT RE 2, H373
- » hazardous to the aquatic environment

The CLH intention submitted for [cinnamaldehyde](#) (CAS No. 104-55-2; EC No. 203-213-9) was updated on 2 October 2023. This substance is used in air care products, fragrances, polishes and waxes, and washing and cleaning products. The proposed classification is:

- » eye irrit. 2, H319
- » skin sens. 1A, H317
- » aquatic acute 1, H400
- » aquatic acute 1, M-factor=1
- » aquatic chronic 2, H411

The CLH intention submitted for [L-p-mentha-1\(6\),8-dien-2-one](#) (CAS No. 6485-40-1; EC No. 229-352-5) was updated on 9 October 2023. This substance is used in air care products, polishes and waxes, fragrances, and washing and cleaning products. The proposed classification is:

- » skin sens. 1B, H317
- » repr. 2, H361d
- » asp. tox. 1, H304
- » aquatic chronic 3, H412

The opinion of the Risk Assessment Committee (RAC) has been adopted and published for the CLH intention regarding [3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate](#) (CAS No. 4098-71-9; EC No. 223-861-6), agreeing with the proposed new classification. This substance is a raw material used for the industrial manufacture of resins/hardeners for coating materials, adhesives, sealants, elastomers, and polyurethanes. The proposed classification is:

- » acute tox. 1, H330
- » skin corr. 1, H314
- » eye dam. 1, H318
- » resp. sens. 1, H334
- » skin sens. 1A, H317
- » aquatic chronic 2, H411

The proposed specific concentration limits are:

- » inhalation: ATE = 0.031 milligrams per liter (dust/mist)
- » resp. sens. 1; H334: C ≥ 0.5 %
- » skin sens.1A; H317: C ≥ 0.05 %

If the proposed new classifications are approved, new risk management, labeling and packaging requirements might apply.

## Amendments to the proposal for a regulation on fluorinated greenhouse gases (draft law)

On 27 September 2023, the European Parliament adopted a series of amendments to the proposal for a regulation on fluorinated greenhouse gases (F-gases) amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 on F-gas. Directive (EU) 2019/1937 provides protection to those who report breaches of European Union (EU) law, whilst Regulation (EU) No 517/2014 was adopted to reverse the increase in F-gas use and emissions.

This proposal has been developed under the European Green Deal, which aims to protect the health and well-being of citizens from environment-related risks and impacts. It aims to ensure that the EU complies with its obligations under the Kigali Amendment to the Montreal Protocol since emission savings envisaged by 2030 are unlikely to be achieved under Regulation (EU) No 517/2014.

The proposed Regulation aims to set quantitative limits for the placing of hydrofluorocarbons (HFCs) – often used in refrigeration, air-conditioning, building insulation, and aerosols – on the market. The regulation applies to all F-gases listed in Annexes I, II, and III of the proposal, either alone or in a mixture. Some of the adopted amendments are below.

Article 2 has been amended to clarify that the proposed regulation applies to products and equipment that contain or need F-gases to function either partly or entirely. Article 3, which contains definitions, has been amended to further clarify the meaning of “operator”, “placing on the market”, and “feedstock”.

Article 4 of the proposal outlines the obligations of manufacturers and operators to prevent the intentional and unintentional emission of F-gases. Paragraph 5 - subparagraph 2<sup>4</sup> has been amended to clearly state the supporting documentation needed alongside the declaration of conformity. In addition, Paragraph 6a has been added stating that operators must ensure sulfuric fluoride is captured and recovered by qualified persons after fumigation, and the evidence of destruction must be provided to the competent authorities.

Article 5 makes provisions for leak checks. Paragraph 1 - subparagraph 3 provides the conditions to which hermetically sealed residential equipment should not be checked for leaks. Point c of the subparagraph has been deleted via the adopted amendments document. In addition, paragraph 2 - subparagraph 1 - point (e) has been amended to include vans and ships.

Article 6 makes provisions for leakage detection systems. Paragraph 2 has been amended to include "For the purposes of Article 5(2), point (g), the leakage detection system shall have a higher sensitivity than a pressure- or density-monitoring device." Article 8 sets out provisions for recovery and destruction of F-gases. Paragraph 1 - subparagraph 1 and subparagraph 2 - point (b) have been amended respectively, to include vans and ships.

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<sup>4</sup> It sets out the obligation to provide evidence that any trifluoromethane produced as a by-product during the manufacturing process, including during the manufacturing of feedstock for their production, has been destroyed or recovered for subsequent use, using the best available techniques.

Article 9 - paragraph 1 has been amended to require that by 31 December 2027, extended producer responsibility schemes are established for the recovery, recycling, reclamation, or destruction of fluorinated greenhouse gases listed in Annexes I and II, considering already applicable producer responsibility schemes.

Article 11 details the restrictions on the placing on the market and sale of F-gases and products or equipment that contain them. Paragraph 1 - subparagraph 3<sup>5</sup> has been amended, replacing the two years with six months. Article 11a that sets out restrictions on the export of certain products and equipment containing fluorinated greenhouse gases, has been added to the proposed regulation.

Several amendments have also been made to the Annexes. The proposed regulation has not yet been published.

More information can be found [here](#).

## Netherlands

### Addition of eighty substance to the list of substances of very high concern (published)

On 4 September 2023, the Netherlands National Institute for Public Health and the Environment (RIVM) announced that amendments have been made to its list of substances of very high concern (ZZS). The amendment adds over 80 substances to the [ZZS List](#), taking the total number of entries to over 2,200.

ZZS are substances that are dangerous to humans and the environment. The government aims to reduce the presence of these substances in the living environment as far as possible. To do this, ZZS are identified using the same hazard criteria as substances of very high concern (or SVHCs) in Article 57 of EU REACH. The ZZS List therefore consolidates priority hazardous substances from EU REACH, the European Water Framework Directive, the European POP Regulation<sup>6</sup>, and the OSPAR Convention<sup>7</sup>. The ZZS List itself is not legally binding but is used by local and regional authorities to issue environmental permits.

At least twice a year, the RIVM updates the ZZS List in response to changes in EU legislation and United Nations conventions. The second review of 2023 added more than 80 substances to the List. The new substances include, but are not limited to:

- » bis(4-chlorophenyl) sulfone (CAS No. 80-07-9)
- » diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (CAS No. 75980-60-8)
- » hydrocarbons, C10-C13, aromatics, <1% naphthalene
- » kerosene (CAS No. 8008-20-6)
- » kerosene (petroleum), direct fractionation, wide cut (CAS No. 92045-37-9)
- » tellurium, snails
- » diaminotoluene, mixture of isomers of 2,4-toluenediamine and 2,6-toluenediamine
- » several cadmium, mercury and chromium (VI) compounds

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<sup>5</sup> It specifies that after two years from the dates in Annex IV, supplying or making available products or equipment in the EU will only be allowed if evidence is provided that they were lawfully placed on the market before the specified date.

<sup>6</sup> The European POPs Regulation bans or severely restricts the production and use of persistent organic pollutants in the European Union.

<sup>7</sup> Convention for the Protection of the Marine Environment of the North-East Atlantic.

- » disodium 4-amino-5-hydroxy-6-[[4'-[(4-hydroxyphenyl)azo][1,1'-biphenyl]-4-yl]azo]-3-[(4-nitrophenyl)azo] naphthalene-2,7-disulfonate (CAS No. 4335-09-5)
- » chips, chemicals
- » 3-bromobiphenyl (CAS No. 2113-57-7)
- » 4,4'-dibromobiphenyl (CAS No. 92-86-4)
- » 4-bromobiphenyl (CAS No. 92-66-0)
- » nonabromo-1,1'-biphenyl (CAS No. 27753-52-2)
- » tetrabromo(tetrabromophenyl)benzene (CAS No. 27858-07-7)
- » mixture of 5-[(2R)-butan-2-yl]-2-[(1R,2R)-2,4-dimethylcyclohex-3-en-1-yl]-5-ethyl-1,3-dioxane and 5-[(2R)-butan-2-yl]-2-[(1R,6R)-4,6-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2S)-butan-2-yl]-2-[(1R,2R)-2,4-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2S)-butan-2-yl]-2-[(1S,2R)-2,4-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane and 5-[(2S)-butan-2-yl]-2-[(1S,6R)-4,6-dimethylcyclohex-3-en-1-yl]-5-methyl-1,3-dioxane

Companies are obliged to avoid discharges and emissions of ZS into air and water, as per the [Environmental Management Activities Decree](#) (EMAD). If this is not feasible, the minimization obligation applies, whereby emissions must be reduced as much as possible. Obligations for companies who must acquire permits for ZS substances are outlined in Article 2.4 of the EMAD. This requires companies to submit an avoidance and reduction program to the competent authority every five years, which must detail the ZS emissions and the opportunities for emission reduction and their feasibility.

There are no penalties for non-compliance detailed in this update.

More information can be found in Dutch in this [announcement](#).

## Sweden

### Amendments to Ordinance (1998:944) on prohibitions etc. in connection with the handling, importation, and exportation of chemical products (published)

On 29 August 2023, amendments to the Ordinance (1998:944) on prohibitions etc. in certain cases in connection with the handling, importation, and exportation of chemical products was published in the Swedish Code of Statutes via SFS 2023:521. These amendments entered into force on 1 October 2023.

A summary of the amendments is as follows:

- » Section 14f of the Ordinance, which states that "Dishwasher detergents containing phosphates may not be sold or handed over to consumers for individual use, if the total phosphorus content in the detergent exceeds 0.5% by weight" shall cease to apply
- » the heading immediately after section 14d shall be deleted
- » Section 15, which outlines chemical products or goods that may not be sold or transferred, was amended to include that the ban on the sale and transfer of methanol in car care products applies only if a corresponding ban does not already follow from Regulation (EC) No. 1907/2006

Information can be found here [in English](#) and [in Swedish](#).

## [United Kingdom](#)

### [Rolling Action Plan for UK REACH 2023-2025 \(amendment\)](#)

Great Britain (GB) has published its latest Rolling Action Plan (RAP) for the period 2023-2025. The RAP is an Action Plan under UK REACH to prioritize the substances that need to be further evaluated to decide if further regulatory management options should be considered, such as restrictions. In this latest plan, the Health and Safety Executive (HSE) has prioritized:

- » N-butylbenzenesulphonamide (CAS No. 3622-84-2; EC No. 222-823-6) to be evaluated in 2023
- » per- and polyfluoroalkyl substances (i.e., PFAS) to be evaluated in 2024
- » a substance to be agreed by 31 May 2025 and to be evaluated in 2025

There are no non-compliance provisions associated with this update.

More information can be found in this [announcement](#) from HSE.

### [Call for evidence to support assessing hazardous properties of N-butylbenzenesulphonamide and its use \(consultation\)](#)

On 9 October 2023, the Health and Safety Executive (HSE) initiated a 60-day call for evidence to support the evaluation of N-butylbenzenesulphonamide (BBSA) (CAS No. 3622-84-2; EC No. 222-823-6) in Great Britain. This evaluation aims to assess the hazardous properties of BBSA and its use. The deadline for comments is 8 December 2023.

BBSA is plasticizer of polyamide and cellulose resin, used in adhesives, printing inks, and surface coatings. HSE identified certain substances for evaluation and included them in the Rolling Action Plan (see entry above). BBSA is among these substances, as it is suspected to be persistent and environmental monitoring data suggest widespread distribution.

The evaluation's primary focus is to understand the hazardous properties and usage patterns of BBSA in Great Britain. Its purpose is to determine if any of its applications pose risks to human health or the environment and whether further actions are needed to manage these identified risks. To support this evaluation, HSE is inviting interested parties to provide general information and specific details. HSE is particularly interested in:

- » information related to the use, exposure, and disposal of BBSA in GB
- » details regarding its manufacture and import, including any use in imported articles
- » insights into potential alternative substances and technologies

HSE is also inquiring whether respondents are open to being contacted by HSE and the Environment Agency to discuss the information they have submitted.

More information can be found in this [announcement](#) and [call for evidence](#) from HSE.

### [Recommendation to include diisohexyl phthalate in Annex 14 of UK REACH \(consultation\)](#)

On 18 September 2023, the Health and Safety Executive (HSE) published a draft recommendation for the inclusion of diisohexyl phthalate (CAS No. 71850-09-4; EC No. 276-090-2) in Annex 14, the Authorization List, to UK REACH. In addition to the publication of the draft recommendation, HSE has published information about the approach it has taken to identify priority substances for inclusion in its recommendations.



Diisohexyl phthalate is classified as toxic for reproduction, category 1B, H360F. It is currently not registered under UK REACH, but the HSE considers that there is potential for this substance to be used in the place of other phthalates that have been added to Annex 14. Therefore, the HSE is recommending to also add this substance to Annex 14 to avoid it being used as a substitute.

HSE is required to submit its recommendation to the appropriate authorities after inviting comments from interested parties over a three-month period. HSE will update its recommendation, particularly when it comes to exemptions, taking account of any comments received. The consultation ends on 18 December 2023.

Additionally, the HSE has published the UK REACH approach to prioritization of substances for recommendation to Annex 14. This approach consists of three steps:

- » initial ranking, which follows the European Chemicals Agency's methodology
- » further refinement by taking into account regulatory effectiveness considerations
- » final adjustment, which focuses on substitution risks

More information can be found in the [draft recommendations](#) and the [approach to Annex 14 prioritization](#).



## NORTH AMERICA

### Canada

#### Amendment to the Domestic Substances List to add the letter “P” to 145 polymers that met the reduced regulatory requirement criteria (consultation)

Canada's Department of the Environment issued a [notice](#) on 16 September 2023 that the Minister of the Environment, pursuant to the Canadian Environmental Protection Act, 1999 (CEPA), plans to amend the [Domestic Substances List](#) (DSL) by adding the letter “P” to the identifiers of the polymers referred to in the [annexed proposed Order](#), as the form of these 145 polymers met the reduced regulatory requirement (RRR) polymer criteria after being assessed.

The DSL is an inventory of substances manufactured in or imported into Canada on a commercial scale. A substance not on the DSL is therefore a new substance in Canada. Under CEPA, no new substances can be imported into or manufactured in Canada above the prescribed thresholds before an assessment of their potential impacts on human health and the environment has been performed. The DSL contains five different flags for substances; some flags are used for governmental tracking purposes, and others indicate that notification requirements may apply. The onus is on the notifier to identify and comply with obligations resulting from any applicable flags or regulations imposed on a substance.

Three regulatory flags indicate to notifiers that notification requirements may apply prior to manufacturing, importing, or using the substance. These flags are The S flag, The S' flag, and The P flag. The P flag connotes that the letter “P” after a substance identifier indicates that the substance, which was subject to subsection 81(1) or 81(2) of CEPA, was assessed and added to the DSL on the basis that it met the RRR polymer criteria and are therefore of low concern, which allows for fewer regulatory information requirements.

The purpose of the P flag is also to indicate that any person who intends to manufacture in or import into Canada the flagged polymer in a form that is not considered RRR in a quantity above prescribed thresholds must submit a Non-RRR Schedule New Substances Notification.

The annexed proposed Order includes the CAS Numbers or the Confidential Substance Identity Numbers of the polymers at issue. The 145 polymers have been found to meet the requirements of the reduced regulation (the regulation requirements can be seen in the provided link) in polymer criteria and therefore, the letter “P” identifier will be added. The Order would come into force on the day on which it is registered.

Any person may provide comments within 120 days of publication of the notice (i.e., until 14 January 2024). If there is any objection to the addition of the letter “P” to the identifiers of one or more of those polymers, it should indicate clearly in the comment the identifier it pertains to.

## Assessment of 1-hexanol, 2-ethyl-, reaction products with 1,6-diisocyanatohexane (in force)

In accordance with paragraph 84(1)(a) of the Canadian Environmental Protection Act (CEPA), 1999, the Ministers of the Environment and Health have assessed 1-hexanol, 2-ethyl-, reaction products with 1,6-diisocyanatohexane, (CAS No. 197393-84-3). As a result, the Minister of the Environment permits the manufacture or import of this substance, subject to specific conditions. These ministerial conditions were published on 23 September 2023 and took effect on 12 September 2023.

The conditions include definitions, restrictions on the import and manufacture of the substance for consumer products, requirements for environmental release control, and record-keeping obligations. According to the update, a “notifier” means the person who has, on 25 April 2023, provided to the Minister of the Environment the prescribed information concerning the substance, in accordance with subsection 81(1) of CEPA.

The notifier is permitted to manufacture or import the substance but must adhere to certain restrictions, including:

- » not importing the substance if it is present in a consumer product regulated by the Canada Consumer Product Safety Act (CCPSA)
- » not using the substance to manufacture a consumer product subject to the CCPSA
- » only transferring the substance to someone who agrees to use it in compliance with these restrictions

Penalties for non-compliance under CEPA include fines of up to \$1 million a day for each day an offence continues, imprisonment for up to three years or both.

More information can be found in the [Canada Gazette](#).

## United States

### Finalization of the reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (in force)

The Environmental Protection Agency (EPA) has finalized the reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS) under the Toxic Substances Control Act (TSCA). The new rules require manufacturers of PFAS, including importers, who have manufactured these substances at any point since 1 January 2011 to submit information

regarding the amounts, uses, disposal, and existing information on health and environment effects to the EPA. This rule applies to both PFAS and articles that contain PFAS. The purpose of this rule is to allow the EPA to characterize the sources and volumes of manufactured PFAS in the United States.

TSCA provides EPA with authority to require reporting, record-keeping, testing requirements, and restrictions relating to chemical substances and/or mixtures. The TSCA Inventory contains 86,685 chemicals of which 42,170 are active in US commerce. Additionally, the TSCA Inventory now includes commercial activity data, unique identifiers, and regulatory flags (e.g., significant new use rules and test orders).

Parties that have manufactured or imported PFAS since 1 January 2011 will have 18 months from the effective date of this rule – 13 November 2023 – to report the necessary data on PFAS to the EPA. Small entities, as defined at 40 CFR 704.3, will have 24 months from the effective date to report their data. The data required by the EPA includes the common or trade name, chemical identity and molecular structure of each relevant substance or mixture, as well as their proposed uses. Manufacturers will need to submit data on the amount of PFAS produced or processed, the descriptions of the by-products generated over the substance's lifecycle, including use and disposal, and all existing information on the hazards of the substances and the likelihood of exposure to individuals. The method of disposal for each substance or mixture should also be included. The reporting standard for this rule is “information known to or reasonably ascertainable by the manufacturer,” the same standard used in other TSCA section 8 rules.

The full list of affected PFAS will be posted to the EPA’s [CompTox Chemicals Dashboard](#). While there are no new penalties for non-compliance, the general regime for TSCA regulations is enforced, along with the associated penalties.

More information can be found in this [announcement](#) from EPA and in the [Federal Register](#).

## Amendment to the general provisions for the National Emission Standards for Hazardous Air Pollutants (consultation)

On 13 September 2023, the United States Environmental Protection Agency (EPA) published a proposed rule (with comments due on 13 November 2023) that would amend the general provisions for National Emission Standards for Hazardous Air Pollutants (NESHAP). NESHAP are stationary source standards for hazardous air pollutants that are known or suspected to cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental effects. Therefore, entities that may be impacted by this proposal include sources that emit pollutants that are added to the hazardous air pollutants (HAP) list.

This amendment is aimed at addressing issues related to applicability and compliance that have arisen due to the addition of 1-bromopropane (CAS no. 106-94-5) to the HAP list in 2022 in response to a petition. The EPA identified three issues which include:

- » whether already promulgated NESHAPs would apply to a newly listed HAP
- » consideration of the permitting implications for facilities that become major sources under Section 112 solely due to the addition of a new pollutant to the HAP list
- » if a major source due to listing triggers the applicability of a major source NESHAP – what is the determination of the applicable emission standards (i.e., is the source subject to standards for new sources or existing sources) and compliance deadlines for the new NESHAP requirements?

The proposed rule does not make any changes to the Title V Permit regulations regarding the addition of a new pollutant to the Section 112 HAP list. However, the EPA has stated its intention to clarify the applicability of previously established NESHAP rules when it adds a new pollutant to the HAP list, which will be achieved by revising 40 C.F.R. 63.64, Subpart C.

Additionally, the EPA is proposing initial notifications, several alternatives to address applicable emission standards and compliance deadlines for Major Source Due to Listing facilities by revising 40 CFR, subpart A.

More information can be found in the [Federal Register](#).

## Proposed changes to emission rules to ensure that emissions cannot increase when transitioning from a “major source” to an “area source” (consultation)

The U.S. Environmental Protection Agency (EPA) is proposing to strengthen the 2020 Clean Air Act rule to ensure that industrial facilities emitting significant hazardous air pollution cannot increase their emissions when transitioning from a "major source" to an "area source." Comments to EPA were due on 13 November 2023.

The proposed amendments to the "Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act" rule would require facilities choosing to reclassify to establish federally enforceable permit conditions. These conditions must prevent emissions from increasing beyond the limits allowed under major source emission standards set by the Clean Air Act. This ensures that facilities maintain emission reductions after reclassification while still having flexibility to adopt innovative pollution-reduction technologies. The proposal applies to all sources that choose to reclassify, including those that have reclassified since 25 January 2018.

The EPA's proposal addresses concerns about hazardous air pollutant emissions increases following reclassification, with the goal of protecting communities from air toxics. It strengthens the 2020 rule and ensures that limits taken to reclassify are federally enforceable, providing a level playing field for compliance enforcement.

More information can be found in this [Announcement](#) from EPA and in the [Federal Register](#).



## OCEANIA

### [Australia](#)

#### Four chemicals added to the Australian Inventory of Industrial Chemicals (published)

Four new industrial chemicals have been added to the Australian Inventory of Industrial Chemicals (AIIC) in accordance with section 82 of the Industrial Chemicals Act 2019 (IC Act) because five years have passed since the assessment certificates for the industrial chemicals were issued:

- » zinc, bis(5-oxo-L-prolinato- $\kappa$ .N1, $\kappa$ .O2)-, (T-4)-, (CAS No. 15454-75-8)
- » cesium tungsten oxide (CAS No. 52350-17-1)
- » benzaldehyde, 2-hydroxy-3-methyl-, oxime, 5-(C9-rich C8-10-branched alkyl) derivs. (CAS No. 1643677-98-8)
- » ethanone, 1-(2-hydroxy-3-methylphenyl)-, oxime, ar-(C9-rich C8-10-branched alkyl) derivs. (CAS No. 1643678-01-6)

The AICC is a searchable database consisting of around 40,000 chemicals that are being manufactured or imported into Australia for industrial use. Chemical substances that are listed in the AICC can be introduced by any registered introducers (manufacturer or importer). According to the IC Act, which regulates the manufacture and import of industrial chemicals<sup>8</sup>, introducers shall apply for registration before introducing an industrial chemical to Australia. For chemicals not listed in the AICC, introducers shall apply to the Executive Director for an assessment certificate for their introduction.

All added substances are subject to obligations to provide information. Importers and manufacturers must inform the authorities within 28 days if the circumstances of importation or manufacture (introduction) are different to those in the assessment.

Penalties for non-compliance include fines.

More information can be found [here](#).

## Evaluations for twenty single chemicals or group of chemicals open for comments under the Australia Industrial Chemicals Introduction Scheme (consultation)

The Australian Government's Department of Health and Aged Care has published twenty draft evaluations for public comment (due by 27 November 2023) under the Australian Industrial Chemicals Introduction Scheme (AICIS). These provide safety information about the use, import or manufacture of 1996 industrial chemicals.

Each evaluation could be for a single chemical or a group of chemicals. The evaluations are part of Australia's Evaluations Roadmap and are listed in the accompanying Rolling Action Plan, which is a work plan for prioritizing chemicals for evaluation based on their risk to human health and/or the environment. Evaluations are completed under the Industrial Chemicals Act 2019 (IC Act), which regulates the manufacture and import of industrial chemicals<sup>8</sup>. The uses include adhesive and sealants, paints and coatings, plastic and polymer products, personal care products, paper products, and uses as chemical intermediates.

The draft evaluation statement for 2-methoxyethyl methacrylate (CAS No. 6976-93-8) and 2-ethoxyethyl methacrylate (CAS No. 2370-63-0) proposes an Australian Inventory of Industrial Chemicals listing variation under Section 86 of the IC Act to add a specific requirement to provide information. This will require those who introduce or use the chemicals to inform the Executive Director of the volume of introduction, use, and end use of the chemical within 20 working days if the chemical is being introduced for consumer end use, except uses in articles. Both chemicals are used as chemical intermediates in chemical synthesis and for the manufacturing of polymers used in cosmetics (including hair products) and food contact materials.

More information can be found [here](#).

## Four proposed chemical management standards for certain brominated flame-retardant chemicals or articles (consultation)

The Australian Department of Climate Change, Energy, the Environment, and Water invited stakeholders to provide feedback on the four proposed standards to manage polybrominated diphenyl ethers (PBDEs) and other brominated flame-retardant chemicals. The standards would manage the environmental risks posed by deca- (CAS No. 1163-19-5), nona- (CAS

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<sup>8</sup> chemicals used for purposes other than agriculture, veterinary or therapeutic purposes, or in food or feed.

No. 63936-56-1), octa- (CAS No. 32536-52-0), hepta- (CAS No. 68928-80-3), hexa- (CAS No. 36483-60-0), penta- (CAS No. 32534-81-9), and tetra- (CAS No. 40088-47-9) bromodiphenyl ethers (BDEs) as well as hexabromocyclododecane (HBCDD, CAS No. 25637-99-4), all of which are included in the scope of the Stockholm Convention on Persistent Organic Pollutants. Comments were due on 23 October 2023.

The proposed standards prohibit the manufacture, import, export, and use of these brominated flame-retardant chemicals or articles containing them unless exempt or authorized, and places restrictions on the disposal and waste management of these substances and articles in which they are included. Importers and manufacturers who are authorized to introduce these substances must provide information on the concentration of these substances, details of their safe disposal, and the justification of their use, and keep this information up to date.

The proposed dates of entry into force of these proposed standards are 1 July 2024 for octa-, hepta-, hexa-, penta- and tetra-BDEs as well as for HBCDD, and 1 July 2025 for deca- and nona-BDE. There are no penalties associated with this update.

More information can be found here on [deca- and nonaBDE](#); [octa-, hepta-, and hexaBDE](#); [penta- and tetraBDE](#); and [HBCDD](#).

## Changes to categorization, reporting, and record keeping in the 2019 Industrial Chemicals (General) Rules and the Industrial Categorization Guidelines (consultation)

On 15 September 2023, the Department of Health and Aged Care opened a consultation about changing categorization, reporting, and record keeping. Its purpose is to ensure protection of human health and the environment or clarify the intent of certain requirements. This consultation is organized into topics, each explaining proposed changes to the 2019 Industrial Chemicals (General) Rules and the Industrial Chemicals Categorization Guidelines, including the reasons for these changes and their practical implications. Interested parties can review these materials offline or online and offer feedback on any or all of the proposed revisions.

These proposals were formulated with a risk-based regulatory approach suitable for each situation. Key proposals in this consultation include simplifying compliance by replacing written comments with records, increasing the use of INCI names for reporting, adjusting categorization criteria to assist various industries, and strengthening health and environmental protection requirements. Importantly, these proposals do not follow the Industrial Chemicals Act of 2019 and aim to potentially reduce regulatory burdens for introducers while upholding regulatory goals.

More information can be found [here](#).



## SOUTH AMERICA

### Brazil

#### Establishment of the National Inventory of Chemical Substances (draft)

The Brazilian Chamber of Deputies has approved the final draft for Bill PL 6120/2019 that aims to establish a National Inventory of Chemical Substances and further regulate the manufacture, use, and import of chemical substances in Brazil.

This law will not apply to:

- » radioactive substances
- » chemical substances under development
- » chemical substances intended exclusively for research
- » non-isolated reaction intermediates
- » substances usable in national defense
- » waste
- » chemical substances, mixtures, and articles subject to customs supervision, which are not subject to any type of treatment or transformation
- » substances resulting from an unintentional chemical reaction during the storage of another substance, mixture, or article, as well as if they are a consequence of exposure of another substance or article to environmental factors
- » products subject to control within the scope of specific legislation such as food, medicines, cosmetics, fertilizers, etc.
- » the following substances, except those that are chemically modified, contain, consist of, or are made up of substances classified as dangerous to health or the environment, in accordance with the Globally Harmonized System (GHS):
  - ores and their concentrates, as well as other rocks and minerals, including coal and coke, crude oil, gas natural gas, liquefied petroleum gas, natural gas condensate, gases, and components of mineral production processes
  - natural substances
  - fats, essential oils, and fixed oils extracted by grinding, pressing, or bleeding, even when purified, as long as they result in products with characteristics identical to the original
  - glass, frit, and ceramics
- » narcotic, psychotropic, and immunosuppressive substances
- » substances used exclusively as ingredients in tobacco and derivatives
- » metallic alloys in the form of plates, sheets, strips, billets, ingots, beams, and other similar materials for structural purposes
- » explosives and their accessories

All substances placed in the Brazilian market which are manufactured or imported in quantities equal or above one tonne per year will have to be submitted to the National Inventory of Chemical Substances (NICS). The submitted information will have to include:

- » the identity of the manufacturer or importer
- » the annual manufactured or imported quantities of the substance

- » the identity of the substance, including CAS or IUPAC number
- » GHS classification
- » recommended uses of the substance

The following are exempt from being submitted to the NICS:

- » mixtures (however the individual substances in the mixture need to be submitted)
- » articles
- » monomeric units when they are part of polymers and additives added to preserve the stability of the polymers
- » low concern polymers

There will be a three-year period for the submission of existing substances to the NICS from the date the NICS is opened. Once this period has passed, new substances will have to be submitted by 31 March of the following year from their introduction. Any changes to the information will also have to be submitted by 31 March of the following year.

Substances in the NICS will undergo risk assessments to decide if they need to be further regulated, for example by establishing restrictions and bans or additional labelling requirements, etc. The risk assessment process will be similar to that of REACH, where substances will be prioritized based on their hazard classification, a committee will be responsible for the assessment, and stakeholders will have the chance to take part in the assessment by submitting information and taking part in consultations, a set of recommendations will be submitted by the committee, recommending or not additional regulatory measures, and these will be approved by the Minister/Head of State as relevant. Foreign companies will need to designate an Only Representative in Brazil to carry out the obligations that importers need to comply with.

Administrative penalties, including fines, requisition and/or destruction of goods, etc., will apply to non-compliance with this regulation and to the submission of false information.

This proposal was originally introduced in 2019, has now been fully approved by the Chamber of Deputies, and will be sent to the Senate for final approval, after which it will be published in the Official Journal. The proposal might still undergo changes if the Senate does not agree with the current text. Once the law is published, the government will have 180 days to prepare and publish any needed enforcement regulations, and three years to create the NICS platform.

More information can be found in Portuguese in the [approval process](#) and in the [final draft](#).

## Bill No. 412 of 2022 establishes the Brazilian Greenhouse Gas Emissions Trading System and regulates the Brazilian Emissions Reduction Market (announced)

On 4 October 2023, the Brazilian Senate passed Bill No. 412 of 2022 (the Bill) that will regulate the Brazilian Emissions Reduction Market (MBRE). The Bill's main objective is to establish the Brazilian Greenhouse Gas Emissions Trading System (the SBCE). The SBCE aims to:

- » harmonize and coordinate the available legal instruments to achieve the goals of the National Policy on Climate Change
- » comply with the relevant international agreements and conventions that Brazil is a party to
- » increase the transparency, predictability, and legal certainty
- » reduce, and eventually end, national emissions of greenhouse gases in a fair and cost-effective manner
- » promote sustainability and climate equity
- » guarantee the rights of indigenous and traditional populations



To achieve this, the SBCE will establish a new framework for the measurement and reporting of emissions. It will set reduction objectives and quotas, implementing these gradually, and setting economic incentives for compliance with these. A Central Registry will be established to collect and make available all relevant information on greenhouse gas emissions.

The SBCE will be implemented in five phases:

- » Phase I – period of twelve months, extendable for another twelve months counting from the Bill’s entry into force
- » Phase II – period of one year for the set-up of the instruments for reporting emissions
- » Phase III – period of two years, in which operators will only be subject to the duty to submit a monitoring plan and present an emissions and greenhouse gas removals report to the SBCE management body
- » Phase IV – publication of the first National Allocation Plan, with distribution not onerous of Brazilian Emission Quotas and implementation of the SBCE asset market
- » Phase V – full implementation of the SBCE, at the end of the first National Plan of Allocation

This Bill has been unanimously approved by the Senate; however, appeals could have been submitted until 16 October 2023. It is expected that this Bill will be published in 2024.

More information can be found in Portuguese in the [final text of the bill](#) and in this [announcement](#).

## Bill PL 2726/2023 to regulate per- and polyfluoroalkyl substances (draft)

Brazil is currently in the process of approving a Bill PL 2726/2023 (the Bill) to regulate per- and polyfluoroalkyl substances (PFAS). The proposed law was first introduced on 22 May 2023 to the Brazilian Deputy Chamber and is currently awaiting the opinion of the Commission for Environment and Sustainable Development.

The proposed Bill will set a framework of actions, measures and instruments for control, monitoring, surveillance, prevention, and remediation of environmental and health effects associated with PFAS. These will include monitoring and regulating emissions; setting allowed concentration limits in water, soil, and foods; monitoring and regulating the manufacture; use and disposal of PFAS; and promoting alternatives to PFAS. Companies manufacturing and/or using PFAS will be required to monitor and report annually their use of these substances, as well as develop and implement management plans to reduce their use and progressively eliminate them.

It is expected that once the Bill is published, further delegated regulations specifying the measure, requirements, and processes will be published. No expected date of publication has been announced, but it is likely that approval and publication will happen in 2024.

The draft text can be found here [in English](#) and [in Portuguese](#). More information can be found in Portuguese in the [approval process](#).

# NEWSLETTER

*Global Environmental and Chemical Regulations, Policies, and Standards  
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