

Newsletter

Global Environmental and
Chemical Regulations, Policies,
and Standards

August 2023

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NEWSLETTER

Global Environmental and Chemical Regulations, Policies, and Standards
August 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 or Lindsey Bean at lindsey.bean@ngc.com for any questions on this Newsletter. For general assistance on IAEG matters, contact Michele Lawrie-Munro at mlawriemunro@iaeg.com or Amanda Myers at amanda.myers@sae.org.

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ASIA

China

Amendment to the “Restricted Substances in Electrical and Electronic Products – Substance Limit Requirements” National Standard No. 1 (draft)

On 19 May 2023 by the National Environmental Standardization Technical Committee for Electrical and Electronic Products and Systems Hazardous Substance Testing Method Sub-Technical Committee (SAC/TC 297/SC 3) had a technical review meeting on the amendment of the "Restricted Use in Electrical and Electronic Products - Substance Limit Requirements" National Standard No.1. The review experts from various institutions and companies reviewed the drafting group's report on the revision process, content, and materials, as well as the technical content and text format of the revision sheet. They unanimously agreed to pass amendment and recommend submitting approval materials to the National Standards Committee for approval and implementation. Subsequently on 29 May 2023, a notice stating that the amendment on the subject has passed the expert review was issued.

The Ministry of Industry and Information Technology compiled a revision sheet to control hazardous substances in electrical and electronic products. Phthalates were added to the list. The goal is to standardize China's hazardous substance management and control, aligning with global standards, and promoting the country's "going out" development strategy in the electronics manufacturing industry.

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

India

Delay in Quality Control Orders for twelve substances (published)

On 21 June and 21 July 2023, India's Department of Chemicals and Petrochemicals (DCPC) announced the postponement of the enforcement of two and ten mandatory quality control orders (QCOs), respectively. Entities intending to produce or trade substances subject to these QCOs must obtain certification from the Bureau of Indian Standards (BIS). This delay was implemented to avoid trade disruption due to a backlog in certification applications. The existing regulations will remain in effect until the new implementation dates for the QCOs. The revised implementation dates are as follows:

Chemical Name	CAS Number	New Date	Typical Uses
n-butyl acrylate	141-32-2	22 December 2023	textiles, leather finishing, paints, adhesives, and rubber production
toluene	108-88-3	22 December 2023	textiles, leather finishing, paints, adhesives, and rubber production
Morpholine	110-91-8	1 February 2024	Optical brighteners, rubber production, waxes, and polishes

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Acetic acid	64-19-7	3 February 2024	production of cellulose acetate, acetic anhydride, plastics, dyes, and solvents
Methanol	67-56-1	3 February 2024	Base material for acrylic plastics, synthetic fibers, adhesives, and paints
Aniline	62-53-3	3 February 2024	Antioxidant in dyes, photographic chemicals, explosives, petrochemical refining, herbicides, and fungicides
Pyridine	110-86-1	13 March 2024	Paints, dyes, rubber products, and adhesives
Gamma picoline	108-89-4	13 March 2024	Rubber, resins, and dyes
Beta picoline	108-99-6	13 March 2024	Solvents
Potassium carbonate	584-08-7	13 March 2024	Glass production, soaps, fire suppressants, and household cleaning products
Acetone	67-64-1	13 March 2024	Denatured alcohol, varnish removal, and the production of plastics and textiles
Sodium tripolyphosphate	7758-29-4	13 March 2024	Paints and varnishes

QCOs are issued pursuant to Section 16 of the BIS Act of 2016 to announce that relevant standards prescribed by the BIS concerning certain products will be mandatory effective from the date specified in the QCO. QCOs apply to products/articles¹. These orders require anyone handling the products/articles, including companies manufacturing or importing and downstream users, to comply with the requirements set out in the QCOs or face a ban. The requirements may be included from Indian Standards (IS) covered by the QCO such as handling, packaging, and marking requirements and sampling methods and tests for substances contained in products/articles. By the issuance of QCOs, the use of Standard Mark under a license or a certificate of conformity from BIS is mandated.

Penalties will be applied under the BIS Act. Penalties for non-compliance include fines of up to 5 lakh rupees.

More information can be found the Gazette of India in the [21 June 2023](#) and the [21 July 2023](#) announcements.

[Israel](#)

[Amendment to the Hazardous Substances Bill \(published\)](#)

On 24 July 2023, Israel published a bill amending the Hazardous Substances Bill. The 1993 Hazardous Substances Law requires anyone dealing with a hazardous material to obtain a Toxins Permit from the Ministry of Environmental Protection. The Ministry grants a Toxins Permit after an inspection, a site visit to the factory, and a risk assessment. This amendment bill adds the requirement to include the contact number of the National Institute for Poison Information on the packaging of poisonous substances. The aim is to improve the treatment of injuries caused by these substances. The Israel Poison Information Center provides expert advice on poisonings to the healthcare system and the general public.

Penalties for non-compliance under the 1993 Hazardous Substances Law include fines and/or imprisonment.

More information can be found the Gazette of India in Hebrew in this [notice](#) and in English [here](#).

¹ Defined as objects whose function is determined by their shape, surface, or design to a greater degree than their chemical composition.

Japan

Investigation of toxicity of 149 chemical substances in accordance with the Industrial Safety and Health Act (published)

On June 27, 2023, the Ministry of Health, Labor, and Welfare (MHLW) published the names of 149 substances in the Official Gazette, and their serial numbers ranged from 30748 to 30895, in accordance with Article 57-4, paragraph 3 of the Industrial Safety and Health Act. The purpose of this action is to investigate the toxicity of these new chemical substances and prevent health problems for workers. Businesses in Japan that manufacture or import 100 kilograms or more of such substances are required to promptly take necessary measures to protect their workers from suffering health hazards due to exposure to them.

In Japan, new chemical substances manufactured or imported are required to be notified under the Industrial Safety and Health Act (ISHL) and the Chemical Substances Control Law. Under the ISHL, manufacturers and importers of substances classified as existing chemical substances do not need to notify the MHLW as new chemical substances. Substances are added to the ISHL inventory one year after they have been notified to the MHLW as new chemical substances. The ISHL inventory applies to substances manufactured in or imported to Japan for workplace use, and it is intended to protect workers from harm.

The update does not mention penalties for non-compliance.

More information can be found in Japanese in this [inventory update notice](#) and the [MHLV chemicals database](#).

Updated classification list based on the United Nations Globally Harmonized System (published)

On 29 June 2023, Japan's National Institute of Technology and Evaluation (NITE) released an updated classification list for substances based on the sixth revised edition of the United Nations Globally Harmonized System (GHS) for chemical classification and labelling. The published updated classification list contains 3,327 substances, comprising 46 newly classified substances and 125 reclassified substances. The GHS system provides a standardized approach to classifying and labelling chemicals to communicate their hazards and risks to users. The updated list serves as a reference point for companies as they create GHS labels and safety data sheets (SDSs) for their products.

The Ministry of Economy, Trade, and Industry (METI), the Ministry of Health, Labor, and Welfare (MHLW), and the Ministry of Environment (MoE) oversee the classification process for these substances. The aim is to ensure consistency and accuracy in hazard communication, thereby enhancing safety for workers, consumers, and the environment.

The updated classification list is a resource for companies to align their products' hazard communication with international standards. The collaborative involvement of METI, MHLW, and MoE reflects the government's commitment to promoting safety and ensuring accurate chemical hazard communication.

As this update involves important changes for businesses preparing GHS labels and safety data sheets (SDSs), companies are encouraged to review and adapt their practices accordingly. Businesses are required to ensure accurate classification and labelling to maintain compliance and uphold safety standards. Penalties for non-compliance with GHS labelling and SDS requirements vary based on local regulations and enforcement mechanisms.

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

Philippines

Ban on all imports of waste (draft act)

On 23 May 2023, the House of Representatives of the Republic of the Philippines proposed an act banning all imports of waste into the country. Over the past two decades, the country has witnessed numerous incidents of toxic waste disposal. The act is proposed to enter into force 15 days after it is published in the Official Gazette.

The proposed act establishes that any individual, group, business, corporation, or government office is prohibited from importing, using, treating, processing, recycling, or storing any type or quantity of waste, processed waste materials, or waste by-products, regardless of whether they are organic or inorganic, in any form such as solid, liquid, liquefied, gaseous, or any combination thereof. The Implementing rules and regulations will be established within 60 days of the enactment of the act.

An Environmental Protection Desk will be established at every port of entry into the country to enforce the act. Transport vessels importing waste, either having declared them or not, will not be allowed to offload and will be immediately ordered to depart and return the wastes to their port of origin. If they refuse, the vessel will be seized and returned to its port of origin. Moreover, all the vessel's officers, crew, and the responsible consignee may face immediate arrest.

Violations of the act will be subject to the relevant penal provisions of environmental and customs law. These penalties may include, but are not limited to, the enforcement of the following laws:

- » Ecological Solid Waste Management Act of 2000 (Republic Act No. 9003)
- » Philippine Clean Air Act of 1999 (Republic Act No. 8749)
- » Philippine Clean Water Act of 2004 (Republic Act No. 9275)
- » Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990 (Republic Act No. 6969)
- » Customs Modernization and Tariff Act (Republic Act No. 10863)

Information can be found in this [explanatory note](#) from the House of Representatives. More information can be found [here](#).

Russia

Approval of regulations outlining the requirements and composition of an action plan for preventing and mitigating environmental pollution (announced)

The Government of the Russian Federation has approved the regulations outlining the requirements and composition of an action plan for preventing and mitigating environmental pollution caused by the operation of a specific production facility. The regulation specifically applies to hazardous production facilities classified as hazard classes I and II, excluding coal mines. It addresses individual hazardous production facilities falling under these classes. The regulations are effective from 1 September 2023 until 1 September 2029.

The action plan includes measures such as land reclamation, conservation or liquidation procedures, and graphical representations of the territory boundaries where environmental impact reduction actions are implemented. The action plan does not encompass measures related to the liquidation of the production facility if it already includes conservation measures. The composition of the action plan is tailored to each specific production facility, allowing the consideration of

relevant technologies and technical methods described in information and technical reference books on best available technologies.

Penalties for non-compliance are not specified in the provided information.

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

South Korea

Amendments to the Enforcement Decree of the Persistent Pollutant Control Act (in force)

On 7 June 2023, the South Korean Ministry of Environment published amendments to the Enforcement Decree (the Decree) of the Persistent Pollutant Control Act that aims to prescribe matters delegated under the Residual Pollutants Control Act and matters necessary for its implementation. The amendments entered into force on 11 June 2023.

According to the Decree, the Minister of Environment appoints i) a specialized agency in measurements and analysis to systematically manage measurement and ii) analysis agencies responsible for tasks such as measurement agencies for persistent pollutants and impact assessments in the environment. The provisions allowing for incorrect or fraudulent changes and appointments have been amended to include the cancellation or suspension of appointments made through incorrect or fraudulent means. Entities aspiring to be designated as specialized organizations in the measurements and analysis of persistent pollutants must establish standards for facilities, equipment, and technical personnel.

Below is a summary of the changes the Decree:

- » Article 2 has been deleted
- » In Article 15, the title "permissible daily exposure" in Article 15 has been amended to "human exposure safety standard," and "permissible daily exposure amount" has been changed to "human exposure safety standard per day"
- » Articles 21-2, 21-3, and 21-4 have been added to Chapter 3
 - Article 21-2 outlines designation criteria for institutions specializing in measurement and analysis of persistent pollutants
 - Article 21-3 sets out the requirements for change of designations for organizations specialized in measurement and analysis – application to make such changes must be submitted to the Minister of Environment in accordance with the Ordinance of the Ministry of Environment
 - Article 21-4 states that the suspension of business of an institution specializing in measurement and analysis shall be in accordance with the requirements set out in Table 4-3
- » additional Annexes 4-2 and 4-3 have been created as attached pages
- » in the title of Annex 5, "related to Article 28" has been changed to "related to Article 27"

Chapter 6 of the Decree sets out the penalties for non-compliance and these include fines of up to 10 million won.

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

Taiwan

Inclusion of perfluorohexane sulfonic acid, its salts, and related compounds in the “Scheduling of Toxic Chemical Substances and Operation Management Items” (published)

On 11 July 2023, the Environmental Protection Agency, in response to the Stockholm Convention on Persistent Organic Pollutants, revised the "Scheduling of Toxic Chemical Substances and Operation Management Items" to include perfluorohexane sulfonic acid (PFHxS; CAS No. 355-46-4), its salts, and related compounds as toxic chemical substances in Taiwan. PFHxS, its salts, and related compounds are listed as toxic chemical substances due to their persistence, long-distance migration, and bioaccumulation, posing risks to living organisms. The amendment aligns with the Stockholm Convention's efforts to eliminate, limit, and reduce persistent organic pollutants for human health and environmental protection. The control concentration of these substances is set at 0.01% of the full concentration. The regulation requires licensing, labeling, transportation, and the involvement of professional personnel for handling these chemicals. A buffer period of six months to one and a half years is provided for phased implementation in the industry.

Penalties for non-compliance are not mentioned in the notice.

More information can be found in Chinese [here](#). General description of the draft amendment and comparison table of announcement of the amendment draft can be found [here](#) in Chinese.

Revisions to the "Toxic and Concern Chemical Substances Permit Registration and Approval Management Measures" (consultation)

On 11 July 2023, the Environmental Protection Administration (EPA) of the Executive Yuan in Taiwan announced revisions to the "Toxic and Concern Chemical Substances Permit Registration and Approval Management Measures." This is to complete regulations related to the review of permits, registration documents, and approval documents for toxic and concerned chemical substances and to promote the integration of various environmental protection permits. The amendments aim to improve the review process for applications related to 341 toxic chemical substances and 18 chemical substances of concern. Permits, registration documents, or approval documents are currently required for the manufacture, import, export, sale, use, storage, transportation, and disposal of these substances. Comments were due on 10 August 2023.

The revisions state that the scope of review for these permits will only cover the application items or content and will not extend to other matters or impose additional obligations beyond the regulations. The time limit for issuing permits after completion of the review will not be increased to improve management efficiency. The review process should also not extend beyond the application items or content and must not impose additional obligations not specified in regulations.

The major proposed amendments include:

- » Application Materials:
 - manufacturers or users of toxic and concerned chemical substances must provide a comprehensive diagram showing the flow of waste air, wastewater, pollutants, and substances within the entire plant – the diagram will be used in the regulatory authority's review of permit/registration/approval applications, as well as modifications or extensions of these documents
 - applications for environmental permits must be submitted concurrently with other permits for stationary pollution sources
- » Review Scope and Time Limit:

- municipal and county (city) regulatory agencies will limit their review scope to applications, modifications, or extensions of permits/registration/approval documents without imposing any new obligations beyond the regulation's specifications
- the time limit for issuing permits/registration/approval documents will be set at 14 days after the applicant has publicly provided the necessary information as per the regulation
- » Storage Requirements: Concerned chemical substances not designated as "hazardous" must provide the required documents for storage in commercial storage facilities, self-managed storage sites, and storage sites serving as warehouses for loading and unloading unspecified toxic and concerned chemical substances, whether through maritime transport or air cargo

More information can be found in Chinese in this [press release](#).



EUROPE

European Union

Regulation (EU) 2023/1608 amends Annex I to Regulation (EU) 2019/1021 regarding the listing of perfluorohexane sulfonic acid, its salts, and its related compounds (in force)

On 8 August 2023, the European Union (EU) published a Commission Delegated Regulation (EU) 2023/1608 (the Regulations) that amends Annex I to the Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorohexane sulfonic acid (PFHxS), its salts, and PFHxS-related compounds. Regulation (EU) 2019/1021 was established to protect human health and the environment by eliminating or restricting the production and use of persistent organic pollutants (POPs) as defined in the Stockholm Convention on Persistent Organic Pollutants.

The amendment, which enters into force on 28 August 2023, aims to strengthen the application and enforcement of Regulation (EU) 2019/1021 and contribute to the reduction of persistent organic pollutants. The Regulation establishes limits for PFHxS and its related compounds in various substances, mixtures, and articles to ensure their safe use and minimize their environmental impact. It sets concentration limits for these substances as follows:

- » the allowed concentration for PFHxS or any of its salts must be equal to or below 0.025 milligrams per kilogram (mg/kg) when present in substances, mixtures, or articles
- » the sum of concentrations of all PFHxS-related compounds must be equal to or below 1 mg/kg when present in substances, mixtures, or articles
- » the allowed concentrations of PFHxS, its salts, and PFHxS-related compounds are equal to or below 0.1 mg/kg when present in concentrated firefighting foam mixtures intended for use or used in the production of other firefighting foam mixtures – the European Commission will review and assess this exemption no later than 28 August 2026

Penalties for non-compliance under Regulation (EU) 2019/1021 vary by Member States.

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

Amendment to Directive 2011/65/EU regarding an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions (in force)

On 11 July 2023, the European Commission (EC) published an amendment to Annex IV of the 8 June 2011 Directive 2011/65/EU concerning the restriction of certain hazardous substances in electrical and electronic equipment (EEE). The amendment is for a new exemption for mercury in melt pressure transducers for capillary rheometers under extreme conditions used as monitoring and control instruments. The amendment entered into force on 31 July 2023 and applies from 1 February 2024.

Directive 2011/65/EU requires Member States to ensure that EEE placed on the market does not contain the hazardous substances listed in Annex II to the directive. Directive 2011/65/EU applies to the categories of EEE listed in Annex I and mercury is a restricted substance listed in Annex II. However, the restriction does not apply to certain exempted applications listed in Annex IV to the directive. Thus, in Annex IV to Directive 2011/65/EU, the following entry is added: Mercury in melt pressure transducers for capillary rheometers at temperatures over 300 °C and over 1,000 bar pressures. It applies to Category 9 and expires on 31 December 2025.

By January 31, 2024, Member States are required to enact and make public the necessary laws and regulations to comply with this amendment. Additionally, Member States are required to inform the EC about the key provisions of their national laws related to the subject matter of this amendment. Penalties for non-compliance to Directive 2011/65/EU are determined by the Member States as stated under Article 23 of the directive.

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

Classification, Labeling, and Packaging 19th and 20th Adaptation to Technical Progress (in force)

The European Union has published Classification, Labeling and Packaging (CLP) 19th and 20th Adaptation to Technical Progress (ATPs). ATPs are issued yearly by the European Commission and update the CLP regulation to include all harmonized classification and labeling decisions taken during the previous year. In 2023, the updates have been divided into two regulations.

The 19th ATP implements the opinions taken by the Committee for Risk Assessment (RAC) regarding the classification covering a group of substances based on 2-ethylhexanoic acid (CAS No: 149-57-5) and its salts, and to the classification of reproductive toxicity for boron compounds and 2-ethylhexanoic acid and its salts. The 19th ATP amends Part 1 of Annex VI to CLP, which contains all harmonized entries, to include three new notes:

- » X has been added to section 1.1.3.1 notes relating to the identification, classification, and labeling of substances:
 - “The classification for the hazard class(es) in this entry is based only on the hazardous properties of the part of the substance which is common to all substances in the entry. The hazardous properties of any substances in the entry also depend on the properties of the part of the substance which is not common to all substances in the group. The latter must be evaluated to assess whether more severe classification(s) (i.e., a higher category) or a broader scope of the same classification (additional differentiation, target organs and/or hazard statements) might apply for the hazard class(es) in the entry.”
- » note 11 has been added to section 1.1.3.2 notes relating to the classification and labeling of mixtures:
 - “The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is $\geq 0,3\%$.”
- » note 12 has been added to section 1.1.3.2 notes relating to the classification and labeling of mixtures:

- “The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual substances covered by this entry in the mixture as placed on the market is equal to, or above, the applicable generic concentration limit for the assigned category, or a specific concentration limit given in this entry.”

The 20th ATP amends Part 3 of Annex VI by updating a series of entries, mainly to include references to the new notes introduced in the 19th ATP:

- » entry 005-007-00-2: boric acid (CAS No: 10043-35-3)
- » entry 005-008-00-8: diboron trioxide (CAS No: 1303-86-2)
- » entry 005-011-00-4: tetraboron disodium heptaoxide, hydrate (CAS No: 12267-73-1); disodium tetraborate, anhydrous (CAS No: 1303-96-4); orthoboric acid, sodium salt (CAS No: 13840-56-7); disodium tetraborate decahydrate (CAS No: 1303-96-4); disodium tetraborate pentahydrate (CAS No: 1303-96-4)
- » entry 607-230-00-6: 2-ethylhexanoic acid and its salts (with the exception of those specified elsewhere in this Annex)

The new classification and labeling requirements introduced by the 20th ATP apply from 1 February 2025. However, suppliers can start classifying, labeling, and packaging substances and mixtures according to the 20th ATP from 31 July 2023. Penalties for non-compliance are not specified in the provided information.

More information can be found here on the [19th ATP](#) and the [20th ATP](#).

Harmonized classification and packaging updates for N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine, thymol, 2-bromo-2-nitropropane-1,3-diol, and 4,4'-methylenediphenol (consultation)

The European Chemicals Agency has opened two harmonized classification and labeling (CLH) consultations for N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine (6PPD; CAS no. 793-24-8) and thymol (CAS no. 89-83-8). The deadline for comments was 1 September 2023.

N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine is used as an anti-degradant (antioxidant and antiozonant) added to tire rubber to protect the rubber polymer from reaction with oxygen (O₂) and ozone (O₃). The proposed harmonized classification is:

- » acute toxicity 4, H302
- » skin sensitization 1A, H317
- » reproductive toxicity 1B, H360FD
- » aquatic acute 1, H400, aquatic acute 1, M-factor = 10 000
- » aquatic chronic 1, H410, aquatic chronic 1, M-factor = 10
- » oral acute toxicity estimate (ATE) = 890 milligrams per kilogram

Thymol is used in plant protection products as a fungicide. The proposed harmonized classification is:

- » acute toxicity 4, H302
- » skin sensitization 1, H317
- » skin corrosion 1, H314
- » STOT SE² 3, H336
- » eye damage 1, H318
- » aquatic chronic 3, H412

² specific target organ toxicity arising from single exposure.

Additionally, the following hazard classes are open for commenting regarding thymol:

- » explosives
- » flammable solids
- » self-reactive substances and mixtures
- » pyrophoric solids
- » self-heating substances or mixtures
- » substances or mixtures which in contact with water emit flammable gases
- » oxidizing solids
- » corrosive to metals
- » acute toxicity
- » skin corrosion/irritation
- » serious eye damage/eye irritation
- » skin sensitization
- » germ cell mutagenicity
- » carcinogenicity
- » reproductive toxicity
- » specific target organ toxicity — single exposure
- » specific target organ toxicity — repeated exposure
- » aspiration hazard
- » hazardous to the aquatic environment
- » hazardous for the ozone layer

ECHA also opened two harmonized classification and labeling consultations for bronopol; 2-bromo-2-nitropropane-1,3-diol (bronopol; EC No. 200-143-0; CAS No. 52-51-7) and 4,4'-methylenediphenol (bisphenol F; EC No. 210-658-2; CAS No. 620-92-8). The deadline for comments is 29 September 2023.

Bronopol is used as a microbiocide/microbiostat in oil field systems, air washer systems, air conditioning/humidifying systems, cooling water systems, papermills, absorbent clays, metal working fluids, printing inks, paints, and adhesives. The proposed new classification is as follows:

- » acute toxicity 3, H301
- » acute toxicity 4, H312
- » acute toxicity 3, H331
- » skin irritation 2, H315
- » eye Damage 1, H318
- » STOT SE 3, H335
- » aquatic acute 1, H400, M=100
- » aquatic chronic 1, H410, M=10
- » oral: ATE = 193 mg/kg
- » dermal: ATE = 1600 mg/kg
- » inhalation: ATE = 0.588 milligrams per liter (dust/mist)

Additionally, the following hazard classes are open for comment in the consultation:

- » explosives
- » flammable solids
- » self-reactive substances and mixtures
- » pyrophoric solids
- » self-heating substances and mixtures
- » substances which in contact with water emit flammable gases
- » oxidizing solids
- » organic peroxides
- » corrosive to metals
- » desensitized explosives
- » carcinogenicity
- » germ cell mutagenicity
- » reproductive toxicity
- » acute toxicity – inhalation
- » acute toxicity - dermal
- » acute toxicity - oral
- » specific target organ toxicity – single exposure
- » specific target organ toxicity – repeated exposure
- » skin corrosion/irritation
- » serious eye damage/eye irritation
- » skin Sensitization
- » hazardous to the aquatic environment

Bisphenol F is used as a monomer in polycarbonate and epoxy resins (intermediate use), which are in turn used in coatings, lacquers, pipe linings, industrial floors, road and bridge deck toppings, adhesives, plastics, water pipes, dental sealants, and food packaging. It is also used as an additive in thermal paper, and it has been identified as a component used in leather tanning processes. The proposed new classification is reproductive toxicity 1B, H360F.

If these new harmonized classifications are approved, companies trading these substances or products containing these substances will have to update their labeling and ensure their packaging still complies with the substance's risk level.

More information can be found here related to [N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine](#), [thymol](#), [bonopol](#), and [bisphenol F](#).

Harmonized classification and labeling for four substances (consultation)

On 24 July 2023, the European Chemicals Agency (ECHA) opened a consultation on a proposal for harmonized classification and labeling (CLH) for the following substances:

- » 3-p-cumenyl-2-methylpropionaldehyde; 2-methyl-3-(4-isopropylphenyl)propanal (CAS No. 203-161-7)
- » 3-(p-cumenyl)propionaldehyde; 3-(4-isopropylphenyl)propanal (CAS No. 231-885-3)
- » 4-isopropylbenzaldehyde; cuminic aldehyde (CAS No. 204-516-9)
- » 4-isopropylbenzoic acid; cuminic acid (CAS No. 208-642-5)

The substances are used in cleaning and washing agents, polish and wax blends, rinsing agents for textiles, and air care products. The deadline for comments is 22 September 2023.

Further details are available in this [announcement](#) from ECHA and this [CLH report](#).

Proposal to add three substances to Annex B to the Stockholm Convention on Persistent Organic Pollutants (consultation)

On 15 June 2023, the European Chemicals Agency (ECHA) opened a consultation window on a proposal to add octamethylcyclotetrasiloxane (D4; CAS No. 556-67-2), decamethylcyclopentasiloxane (D5; CAS No. 541-02-6), and dodecamethylcyclohexasiloxane (D6; CAS No. 540-97-6) to Annex B to the Stockholm Convention on Persistent Organic Pollutants. Annex B lists the restricted substances whose production and use need to be reduced. The deadline for comments was 10 August 2023.

D4, D5, and D6 are widely used in various sectors, including automotive and electronics, and have been identified as high-production volume chemicals. They are substances of concern due to their persistence, bioaccumulation, and potential adverse effects. These substances are registered under the EU REACH and have been identified as substances of very high concern. Restrictions on their use in certain products are already in place.

The proposal addresses the information requirements of Annex D to the Stockholm Convention. It highlights the environmental risks associated with D4, D5, and D6 and the need for further control measures. Additionally, a REACH restriction proposal is currently ongoing at the European Commission.

Information can be found in this [announcement](#) from ECHA.

Evaluation of the Waste Electrical and Electronic Equipment Directive (consultation)

The Waste Electrical and Electronic Equipment (WEEE) Directive in the European Union is being evaluated to determine its effectiveness and relevance in addressing the growing challenges of WEEE management. The directive was initially adopted in 2002 and revised in 2012 to address the environmental and health impacts of WEEE.

This evaluation aims to assess the implementation of the directive, including challenges in separate collection of WEEE, meeting collection targets, ensuring proper treatment, and combatting illegal activities. It will consider aspects such as legal coherence, environmental impact, economic factors, and technological developments. The evaluation will include public consultation and targeted consultations with stakeholders. The evaluation will cover the period from the entry into force of the current directive (13 August 2012) onwards. A synopsis report summarizing the consultation results will be included in the evaluation report.

The purposes of the consultation are to:

- » validate the topics and issues covered by the evaluation
- » gather information, data, and experience on the implementation of the directive
- » solicit views and opinions of stakeholders on the extent to which this directive has met, or is on track to meet, its objectives
- » gather views on the directive's relevance taking into account developments impacting electrical and electronic equipment and the generation of waste.

Commission adoption is planned for the second quarter of 2024. The deadline for comments is 22 September 2023.

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

Screening report on the presence and risk of trixylyl phosphate in articles (consultation)

On 28 June 2023, the European Chemicals Agency (ECHA) opened a consultation on the draft screening report for the presence and risk of trixylyl phosphate (TXP; CAS No. 25155-23-1) in articles. TXP, which is used in vehicles, plastic articles, electric and electronic devices, and textiles and leather, was added to Annex XIV to the REACH Authorization List with a sunset date of 27 May 2023.

For substances in 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 risks are not controlled and the use of these substances poses a risk to human health or the environment, then ECHA must initiate a restriction proposal.

ECHA has published the draft [screening report](#) assessing the risk of TXP. The draft report concludes that TXP poses a risk to human health and, therefore, that a restriction proposal should be initiated. Additionally, the draft report also recommends that the restriction proposal considers the risks from other organophosphorus flame retardants given their structural similarity with TXP. The public consultation, which was open until 9 August 2023, sought to gather information on:

- » the type of articles containing TXP
- » TXP transfer (migration) and/or release from material matrixes or articles
- » waste handling and end-of-life of articles containing TXP
- » availability of suitable alternatives

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

On per- and polyfluorinated substances ban in firefighting foams (consultation)

On 22 June 2023, the European Chemicals Agency's (ECHA) Committee for Socio-Economic Analysis (SEAC) adopted its final opinion on the restriction proposal for per- and polyfluorinated substances (PFAS) in firefighting foams. The proposal aims to prohibit the use of PFAS in firefighting foam concentrates where the concentration of total PFASs is greater than 1 part per million.

In an ECHA announcement, SEAC agrees that this proposal is the most appropriate European Union-wide measure to address the risks posed by the presence of PFAS in firefighting foams. However, SEAC recommends lengthening the transition period:

- » from 5 to 10 years for firefighting foams used at offshore installations in the oil and gas industry
- » from 3 to 5 years for uses in civilian shipping
- » from 6 to 18 months for placing certain types of portable fire extinguishers on the market

Additionally, SEAC suggests that a review of available fluorine-free alternatives for sites that produce, treat, or store dangerous substances and those neighboring them is carried out before the end of the ten-year transition period, to ensure that effective alternatives exist.

ECHA will now prepare the opinion for publication and send it together with the restriction proposal to the European Commission for the final steps in the restriction process.

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

Amendments to the 23 May 2023 proposal for regulation establishing a framework for setting eco-design requirements for sustainable products (proposal)

On 12 July 2023, the European Parliament adopted some amendments to the text of the proposal for a new regulation establishing a framework for setting eco-design requirements for sustainable products. This proposal, which was published on 23 May 2023, sits under the European Green Deal that aims to transform the European Union (EU) market into a climate-neutral and circular economy model.

Currently, there is no general eco-design requirements regulation at the EU level, instead only having a few eco-design requirement regulations focused on specific products and product groups. This has led to some Member States publishing national regulations to set eco-design requirements for other products, which means that the EU internal market is unbalanced as these national regulations are different from each other and only apply in certain countries. To ensure the integrity of the internal market and achieve the objectives of the European Green Deal, the European Commission (EC) has decided to create a harmonized regulatory framework to progressively introduce eco-design requirements for products across the internal market. This proposal provides a framework by making the eco-design approach, initially set out in Directive 2009/125/EC to establish a framework for energy-related products, applicable to the broadest possible range of products.

The approved amendments mainly focus on clarifying and further detailing the text. However, some new articles have been introduced that establish rules and requirements that are not present in the original proposal to address the items below.

NEWSLETTER

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



Planned obsolescence

The framework will consider design measures responsible for planned obsolescence and take measures against them in future delegated regulations.

Second-hand products

The framework will establish that second-hand products, especially those that have been refurbished or repaired, should not be considered as new products, and thus will not have to comply with eco-design requirements – this will generally not apply to second-hand products from third countries, but exemptions might be given under certain conditions.

Reparability

This framework will introduce a reparability score to enable end-users to easily compare the performance of products. The methodology to assess the reparability of products shall be developed according to the specificities of product categories and laid down in the relevant delegated act. Additionally, more information on reparability and other ecological aspects of a product will be required to be available to consumers than what is currently available.

Product destruction

While the prohibition of destroying unsold products existed in the original proposal, these amendments establish a concrete application date of one year after the date of entry of the regulation for textiles and footwear, and electrical and electronic equipment (exemptions might apply).

Comparison platform

This framework will introduce a publicly accessible online tool allowing stakeholders to compare information included in the product passports stored by the economic operator.

Additionally, the amendments specify that for the period between 2024 and 2027, the EC shall consider prioritizing the following product groups in the first working plan to establish delegated acts implementing the framework:

- » iron, steel
- » aluminum
- » textiles, notably garments and footwear
- » furniture, including mattresses
- » tires
- » detergents
- » paints
- » lubricants
- » chemicals
- » energy related products, the implementing measures for which need to be revised or newly defined
- » ICT products and other electronics

This new text was referred for interinstitutional negotiations to the responsible committee, meaning that further changes to the text might be approved. The final text is expected to be approved by the end of 2023 or the beginning of 2024.

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

Two proposals to amend Regulation (EU) 2017/852 regarding mercury-added products subject to manufacturing, import, and export prohibitions (adopted)

On 14 July 2023, the European Commission (EC) adopted two proposals to amend the Regulation (EU) 2017/852 that implements the Minamata Convention on mercury and establishes measures and conditions at a European Union (EU) level for activities relating to mercury, mercury compounds, mercury mixtures, and mercury-added products. The amendments would expand the list of mercury-added products subject to manufacturing, import and export prohibitions. This is intended to address the remaining uses of mercury in the EU. In addition, the amendments aim to ensure coherence

between the Regulation (EU) 2017/852 and RoHS Directive 2011/65/EU, which restricts the use of certain hazardous substances in electrical and electronic equipment.

Per the adopted proposals, the import, export, and manufacture of the following products will be banned as of 31 December 2025:

- » compact fluorescent lamps with an integrated ballast for general lighting purposes that are ≤ 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
- » the following 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
 - tire balancers and wheel weights
 - photographic film and paper
 - propellant for satellites and spacecraft

The amendments shall enter into force on the twentieth day following that of its publication in the Official Journal of the EU.

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

Regulation concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (adopted)

On 10 July 2023, the Council of the European Union (EU) adopted a new regulation that strengthens sustainability rules for batteries and waste batteries. The regulation has received the signature of the European Parliament and European Council but has not yet been published in the Official Journal. The regulation aims to create a harmonized regulatory framework for the entire life cycle of batteries placed on the EU market. It is part of circular economy commitments under the European Green Deal and builds on the Waste Framework Directive. In addition, it will repeal the current EU Battery Directive (Directive 2006/66/EC), two years after entry into force.

The Regulation sets out rules on sustainability, safety, storage, labeling, marking, and information to allow the placing on the market or putting into service of batteries, as well as minimum requirements for the extended producer responsibility, collection and treatment of waste batteries, and for reporting. The requirements will apply to all categories of batteries, namely portable batteries, starting, lighting and ignition batteries, light means of transport (LMT) batteries³, electric vehicle batteries and industrial batteries. Batteries designed to be or incorporated into or added to products are also in scope.

³ LMT batteries as those that are sealed and weigh below or equal to 25 kilograms, are designed to provide electric power for the traction to wheeled vehicles that can be powered by an electric motor alone or by combination of motor and human power and are not electric vehicle batteries.

Article 6 and Annex I set out restrictions for mercury, cadmium, and lead in certain categories of batteries. The substance restrictions are in Annex I as follows:

- » 0.0005% mercury (EC No. 231-106-7; CAS No. 7439-97-6) and its compounds – expressed as mercury metal by weight in batteries, whether or not incorporated into appliances, light means of transport, or other vehicles
- » 0.002% cadmium (EC No. 231-152-8; CAS No. 7440-43-9) and its compounds – expressed as cadmium metal by weight in portable batteries, whether or not incorporated into appliances, light means of transport, or other vehicles
- » from 12 months after entry into force: 0.01% lead (EC No. 231-100-4; CAS No. 7439-92-1) and its compounds – expressed as lead metal by weight in portable batteries, whether or not incorporated into appliances; this does not apply until 60 months after entry into force for portable zinc-air button cells

Article 6 enables the European Commission (EC) to amend substance restrictions in the event of an unacceptable risk to human health or the environment. The EC can also initiate further restrictions for substances used in the life cycle of batteries, as per Article 86. Some key obligations for companies are set out below.

Chapter II and Annex XII - sustainability and safety requirements:

- » recycled content of industrial batteries specified in Article 8: 16% cobalt, 85% lead, 6% lithium, and 6% nickel (96 months after entry into force); 26% cobalt, 85% lead, 12% lithium, and 15% nickel (156 months after entry into force)
- » minimum recycling efficiencies and levels of recovered materials are specified in Annex XII
- » batteries must be readily removable and replaceable by any time during the lifetime of the product that incorporates portable batteries, with accompanying instructions and safety information on the use, removal and replacement of the batteries – this only applies to entire batteries, not to individual cells or other parts included in the batteries (Article 11)

Economic operators must also adopt, and clearly communicate to suppliers and the public, a company due diligence policy for batteries, concerning raw materials indicated in Annex X, point 1 and associated social and environmental risk categories indicated in Annex X, point 2 (Article 49).

Chapter III and Annex VI - labeling, marking and information requirements:

- » from 24 months after entry into force, all batteries shall be marked with the “separate collection symbol” in Part B of Annex VI – the symbol shall cover at least 3 % of the area of the largest side of the battery up to a maximum size of 5 × 5 centimeters (Article 13.4)
- » all batteries containing more than 0.002 % cadmium or more than 0.004 % lead shall be marked with the chemical symbol for the metal concerned: Cd or Pb (Article 13.5)
- » from 42 months after entry into force, all batteries shall be marked with a QR code in accordance with Part C of Annex VI (Article 13.6)

Chapter VIII - management of waste batteries:

- » producers shall be obliged to register in each Member State where they make a battery available on the market for the first time (Article 55)
- » producers shall apply for an authorization from the competent authority on the fulfilment of their extended producer responsibility obligations (Article 58)

Chapter IX - digital battery passport

- » required from 42 months after entry into force for each LMT battery, each industrial battery with a capacity greater than 2 kWh, and each electric vehicle battery placed on the market or put into service

Affected regulations:

- » 24 months after it enters into force, this regulation repeals Directive 2006/66/EC, subject to the transitional provisions in Article 95 - Annex XV outlines how this regulation corresponds to Directive 2006/66/EC
- » Regulation (EU) 2019/1020, on the market and surveillance of products from third countries, is amended to include batteries and economic operators affected by this regulation
- » Directive 2008/98/EC, the Waste Framework Directive, is amended to ensure that extended producer responsibility schemes established before 4 July 2018 apply to batteries in scope of this new regulation

Penalties for non-compliance shall be determined by the Member States and must be laid down within two years after the regulation enters into force.

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

Adding undecafluorohexanoic acid, its salts, and its related substances to REACH Annex XVII (consultation)

The European Union (EU) has published a World Trade Organization (WTO) notification announcing a draft amendment that will add a new entry to REACH Annex XVII for undecafluorohexanoic acid⁴ (PFHxA; CAS No: 307-24-4), its salts, and PFHxA-related substances. The comment period ended on 18 August 2023.

REACH Annex XVII lists all substance restrictions applicable in the EU for substances, mixtures, and articles. The Annex XV report concluded that a proposal to restrict the market placement of PFHxA, its salts, and related substances was necessary due to their environmental and health risks. These substances have properties such as oil, dirt, and water repellency, and they are used in fire-fighting foams, textiles, food contact materials, cosmetics, semiconductors, and more.

The proposed restriction would apply to PFHxA, its salts, and PFHxA-related substances having a linear or branched perfluoropentyl group with the formula C₅F₁₁ directly attached to another carbon atom as one of the structural elements or having a linear or branched perfluorohexyl group with the formula C₆F₁₃.

The following substances are excluded from this designation:

- » perfluorohexane (CAS No. 355-42-0)
- » C₆F₁₃-C(=O)OH, C₆F₁₃-C(=O)O-X' or C₆F₁₃-CF₂-X' (where X' = any group, including salts)
- » any substance having a perfluoroalkyl group C₆F₁₃ directly attached to an oxygen atom at one of the non-terminal carbons

Additionally, the restriction specifies that “for the purposes of this entry, PFHxA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to PFHxA.”

The proposed restriction would restrict the placing on the market and use of these substances in a concentration equal to or greater than 25 parts per billion (ppb) for the sum of PFHxA and its salts, or 1,000 ppb for the sum of PFHxA-related substances, measured in homogeneous material, in the following products:

- » fire-fighting foams for training and for testing (except functional testing of the firefighting systems), fire-fighting foams for municipal fire services, and fire-fighting foams for civil aviation
- » textiles, leather, furs, and hides for the general public

⁴ Also known as perfluorohexanoic acid.

- » footwear for the general public
- » paper and cardboard used as food contact materials within the scope of Regulation (EC) No 1935/2004
- » mixtures for the general public
- » cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009

Different dates of application will apply to different products, to ensure that alternatives are found before phasing-out the substances, and derogations will apply for products placed on the market before a certain date. Dates have not yet been finalized.

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

First set of European Sustainability Reporting Standards (adopted)

On 31 July 2023, the European Commission adopted the first set of European Sustainability Reporting Standards (ESRS). This includes a package of standards that aim to ensure that companies across the European Union (EU) report comparable and reliable sustainability information. The ESRS apply to all companies in the scope of the EU Corporate Sustainability Reporting Directive (CSRD; Directive (EU) 2022/2464) that requires large and listed companies to report on sustainability. These are:

- » large groups that meet at least 2 of the following conditions:
 - more than 250 employees
 - more than €40 million net turnover
 - assets of at least €20 million
- » non-EU companies with a turnover above €150 million
- » from 2026, all SMEs, except for micro-enterprises – companies qualify as small if they exceed at least 2 of the following conditions:
 - more than 10 employees
 - more than €700,000 net turnover
 - assets of at least €350,000

The ESRS in this first set are not sector specific. Sector-specific standards, proportionate standards for listed small and medium size enterprises (SMEs), and standards for non-EU companies will be adopted by June 2024.

The ESRS are detailed in the annex to the adopted regulation. These must be used by businesses to comply with sustainability reporting obligations under Articles 19a and 29a of Directive 2013/34/EU. Under Article 19a, companies must include information regarding their impact on sustainability matters (environmental, social and human rights, and governance factors) within a dedicated section of their management report, in addition to information on how such matters affect the company's development, performance and position. Under Article 29a, the same obligation applies for consolidated management reports prepared by parent undertakings of large groups. The ESRS only apply to material impacts, risks, and opportunities. A sustainability matter is material when it pertains to actual or potential, positive or negative impacts on people or the environment over the short-, medium- or long-term.

Two cross-cutting standards will apply to all sustainability matters, in addition to another ten standards on environmental, social, or governance matters. These include:

- » cross-cutting standards
 - ESRS 1 – General Requirements
 - ESRS 2 – General Disclosures

- » environmental standards
 - ESRS E1 – Climate Change
 - ESRS E2 – Pollution
 - ESRS E3 – Water and Marine Resources
 - ESRS E4 – Biodiversity and Ecosystems
 - ESRS E5 – Resource Use and Circular Economy.

The timeline for compliance is as follows for financial years starting on or after:

- » 1 January 2024: companies previously subject to the Non-Financial Reporting Directive (NFRD) (large EU and non-EU listed companies with more than 500 employees) are required to start reporting under the ESRSs (first sustainability statement published in 2025)
- » 1 January 2025: other large EU and non-EU companies covered by the CSRD must report under the ESRS (first sustainability statement published in 2026)
- » 1 January 2026: listed EU and non-EU SMEs must report under the ESRS (first sustainability statement published in 2027) – listed SMEs may opt out of the reporting requirements until 1 January 2028 – the last date for a listed SME to start reporting is financial year 2028 (first sustainability statement published in 2029)
- » 1 January 2028: non-EU companies that generate over €150 million per year in the EU and that have (in the EU) either a branch with a turnover exceeding €40 million or a subsidiary that is a large company or a listed SME must report on sustainability impacts at the group level of that non-EU company from financial year 2028 (first sustainability statement published in 2029) – separate standards will be adopted for this case

Penalties for non-compliance with Directive 2013/34/EU are determined by the Member States.

Further details are available in this [announcement](#) and these suggested [links](#) from the EC.

Rules for the application of Directive 2003/87/EC regarding the content and format of climate-neutrality (consultation)

On 4 August 2023, the European Commission (EC) published and opened a consultation window on a draft regulation laying down rules for the application of Directive 2003/87/EC as regards the content and format of climate-neutrality plans. Directive 2003/87/EC establishes a scheme for greenhouse gas emission allowance trading within the European Union community to promote reductions of greenhouse gas emissions in a cost-effective and economically efficient manner. The deadline for comments was 1 September 2023. According to the update, the regulation is expected to be adopted in the fourth quarter of 2023.

This draft regulation establishes what content the climate-neutrality plans need to include in its Annex (see provided link), this content includes general information on the installation, historical emissions, milestones, and targets, planned measures and investments, etc. Article 3 specifies that the included measures, milestones, and targets must be specific, measurable, achievable, relevant, and time bound.

According to the draft, the EC will make available a climate-neutrality plan, electronic template, or specific file format that companies will have to use. However, Member States can also develop their own templates, in which case companies will have to use these where relevant.

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

Three initiatives related to greenhouse gas (consultation)

The European Commission (EC) has opened consultation windows on three initiatives related to greenhouse gas (GHG) emissions.

Published on 28 July 2023, the first initiative – European Union (EU) emissions trading system (ETS), update of emission allowances auctioning rules – aims to publish a new delegated act to replace Regulation (EU) No 1031/2010 on the timing, administration, and other aspects of auctioning of greenhouse gas emission allowances pursuant to Directive 2003/87/EC. Directive 2003/87/EC sets up the EU ETS and was recently updated to include emissions from maritime transport in the ETS scheme and to set up a parallel emissions trading system to be applied to fuels used for combustion in the buildings and road transport sectors as well as in additional sectors of industrial activities not covered by its Annex I. Thus, Regulation (EU) No 1031/2010 needed to be updated to reflect these changes; however, the EC decided that it is more efficient to replace it with a new regulation.

This proposed new regulation will maintain the architecture of Regulation (EU) No 1031/2010 and its auctioning process. It will take into account the new changes to Directive 2003/87/EC and also address changes necessary for the implementation of the auctions for [REPowerEU](#) in accordance with Article 10e of Directive 2003/87/EC and for the Social Climate Fund established by Regulation (EU) 2023/955, as well as for the functioning of the Innovation Fund, established pursuant to Article 10a(8) of Directive 2003/87/EC. Additionally, this new regulation will clarify certain aspects of Regulation (EU) No 1031/2010.

Published on 31 July 2023, the second initiative – EU ETS, update of the Registry Regulation – aims to amend Delegated Regulation (EU) 2019/1122, which details the functioning of the Union Registry mentioned in Directive 2003/87/EC. As mentioned before, Directive 2003/87/EC has been updated. Therefore, Regulation (EU) 2015/757 needed to be updated to take into account these changes, as well as to simplify some of the processes.

Published on 2 August 2023, the third initiative – shipping emissions, rules on monitoring and reporting – aims to amend Regulation (EU) 2015/757, on the monitoring, reporting, and verification of carbon dioxide emissions from maritime transport. Regulation (EU) 2015/757 was recently updated to add it to the ETS scheme, and to add the monitoring, reporting, and verification of methane and nitrous oxide to the regulation.

As such, parts of Regulation (EU) 2015/757's annexes need to be amended to properly reflect the recent changes. The proposed draft regulation under this initiative updates the rules for monitoring greenhouse gas emissions and other relevant information from maritime transport by amending Annex I and Parts A and B of Annex II, also adding a new Part C, on data management and control, to this Annex II.

The deadlines for comments on the three initiatives were 25 August, 28 August, and 30 August 2023, respectively.

More information can be found here on the [update of emission allowances auctioning rules](#), [the update of the Registry Regulation](#), and [rules on monitoring and reporting](#).

Spain

Order JUS/877/2023 modifies Order JUS/288/2021 to regulate the procedure of notification of chemical substances and mixtures to the National Institute of Toxicology and Forensic Sciences (in force)

On 27 July 2023, the Ministry of Justice in Spain issued an Order JUS/877/2023 (the Order) regulating the procedure for notifying chemical substances and mixtures to the National Institute of Toxicology and Forensic Sciences (NITFS), the appointed Poison Centre for Spain, in line with European regulations. The Order entered into force on 28 July 2023 as it amends Order JUS/288/2021 of March 25, which regulates the notification procedure of chemical substances and mixtures to the NITFS.

The main changes are as follows:

- » the notification of product commercialization cessation can be submitted directly through the harmonized procedure established by the European Chemicals Agency (ECHA) (Article 5.2 of Order JUS/288/2021 has been amended to reflect this change)
- » the requirement for the Toxicological Information Service to issue an acknowledgment of receipt is removed; instead, companies can download the submission report confirming that the information has been received by Spain directly from the ECHA database – this ensures companies can market their products more quickly after completing the harmonized notification procedure (Article 8.2 of Order JUS/288/2021 has been amended to reflect this change)

The modified Order adheres to the principles of good regulation, necessity, effectiveness, proportionality, legal certainty, and transparency. It operates under the protection of relevant laws and regulations. Penalties for non-compliance are not mentioned in the update.

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

United Kingdom

Indefinite extension to use CE marking for businesses (published)

On 1 August 2023, the Department for Business and Trade (DBT) in the United Kingdom (UK) announced an indefinite extension to use CE marking for businesses. The initial deadline for the use of CE marking was 31 December 2024 (or until the end of the issued CE marking certificate). However, according to this announcement, businesses are allowed to continue to use the CE marking on Great Britain (i.e., England, Scotland, and Wales) market beyond the initial set date, and this applies to the following 18 regulations that fall under the DBT:

- | | |
|--|--|
| » toys | » lifts |
| » pyrotechnics | » equipment for potentially explosive atmospheres (ATEX) |
| » recreational craft and personal watercraft | » radio equipment |
| » simple pressure vessels | » pressure equipment |
| » electromagnetic compatibility | » personal protective equipment (PPE) |
| » non-automatic weighing instruments | » gas appliances |
| » measuring instruments | » machinery |
| » measuring container bottles | |

- » equipment for use outdoors
- » low voltage electrical equipment
- » aerosols

A CE mark on a product confirms that the manufacturer or importer has complied with the relevant European Union (EU) legislation, so the product can be sold throughout the European Economic Area. However, the UK Conformity Assessed marking (UKCA marking) became statutory in Great Britain on the EU exit day (31 December 2020) with the coming into force of "The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019" that was published on 27 March 2019. The regulation amended some EU legislation related to product safety and metrology, enforcing the UKCA marking to ensure mandatory product compliance with the UK legislation following the EU exit. Thus, the UKCA marking applies to most products eligible for CE marking, thereby providing continuity and certainty for businesses and maintaining consumer confidence in the safety and accuracy of the relevant products.

Following extensive engagement between the DBT and industries, the indefinite extension to the use of CE marking for businesses was announced to cut business costs and time required to place products on the market and benefit consumers. The extension will give businesses flexibility and choice to use the UKCA or CE approach to sell products in Great Britain.

Penalties for non-compliance are not mentioned in the announcement.

More information can be found in this [press release](#).

Extension of UK REACH submission deadlines for transitional registrations (amendment)

Great Britain (GB, which comprises England, Scotland, and Wales) proposed to extend the UK REACH submission deadlines for transitional registrations in November 2022. It has now approved and published the final amendment to the submission deadlines. The UK REACH Regulation contains transitional provisions that allow companies to submit initial "notification" data in order to continue trading and then subsequently provide the full registration data. The transitional provisions apply to those that were registrants, downstream users, or distributors under EU REACH before UK REACH came into effect. The original deadlines raised concerns around the cost to businesses, so the UK government decided to amend them.

Article 41(5) of UK REACH has been amended to extend the periods during which that Article requires the Health and Safety Executive to carry out compliance checks on minimum percentages of certain types of registration dossiers to the following:

- » until 27 October 2027, not less than 20% of the registration dossiers received for substances referred to in Article 127P(4B)(a)
- » until 27 October 2030, not less than 20% of the registration dossiers received for substances referred to in Article 127P(4B)(b)
- » until 27 October 2035, not less than 20% of the registration dossiers received for substances referred to in Article 127P(4B)(c)

Article 127P(4B) of the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 has been amended to define that relevant post-IP completion period means the period beginning with the day after that on which IP completion day falls and ending with:

- » 27 October 2026 in respect of:
 - substances included on the candidate list by virtue of Article 59(1A) or added to the candidate list referred to in Article 59(1) on or before 31 December 2023
 - substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, in accordance with Regulation (EC) No 1272/2008 and manufactured in Great Britain or imported, in

- quantities reaching one tonne or more per year per manufacturer or importer, at least once after implementation period (IP) completion day
- substances classified as aquatic chronic category 1 (very toxic to aquatic life with long lasting effects) or aquatic acute category 1 (very toxic to aquatic life) in accordance with Regulation (EC) No 1272/2008 and manufactured in Great Britain or imported, in quantities reaching 100 tonnes or more per year per manufacturer or importer, at least once after IP completion day
- substances manufactured in Great Britain or imported, in quantities reaching 1,000 tonnes or more per year per manufacturer or importer, at least once after IP completion day
- » 27 October 2028 in respect of:
 - substances added to the candidate list referred to in Article 59(1), other than by virtue of Article 59(1A), during the period beginning with 1 January 2024 and ending with 27 October 2026
 - substances manufactured in Great Britain or imported, in quantities reaching 100 tonnes or more per year per manufacturer or importer, at least once after IP completion day
- » 27 October 2030 in respect of substances manufactured in Great Britain or imported, in quantities reaching 1 tonne or more per year per manufacturer or importer, at least once after IP completion day

This extends the period within which information must be submitted to the Health and Safety Executive under Articles 127B, 127L and 127M, and in which a “protected transitional import” can be made under Article 127E(2) to October 2026, October 2028, or October 2030.

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

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

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2023 (in force)

On 14 June 2023, the government of the United Kingdom published "The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2023" (the Regulations). The Regulations amend exemptions in Schedule A2 to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (S.I. 2012/3032, “the RoHS Regulations”). The amendment entered into force on 17 July 2023 and applies to Great Britain (i.e., England, Scotland, and Wales).

The RoHS Regulations restrict the use of hazardous substances in electrical and electronic equipment (EEE). The amendment revises Schedule A2 of the RoHS Regulations, which lists applications exempt from the restrictions on using certain hazardous substances in EEE. Entries 1 to 9 in Table 1 have been replaced with new entries 1 to 9.4 – these relate to exemptions for mercury in different types of lighting.

The amended entries have the effect of renewing or revoking exemptions from the restriction. Those that have been renewed will remain valid until the date specified in column 6 of Table 1, whilst the revoked exemptions will expire on 1 February 2024. The amendments also modify the specific conditions of some exemptions, including allowable mercury levels. Some exemptions have been amended so they now apply to all categories of EEE.

The amended entries align with decisions made by the European Commission in respect of corresponding exemptions under the European Union law.

Penalties for non-compliance with the RoHS Regulations include fines.

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

The Retained European Union Law (Revocation and Reform) Bill signed into law (published)

The Retained European Union (EU) Law (Revocation and Reform) Bill received Royal Assent on 29 June 2023 and has been signed into law. Now known as the Retained EU Law (Revocation and Reform) Act, it aims to provide the United Kingdom (UK) government with the power to revoke and amend retained EU legislation. The Act also enables the UK courts to interpret laws differently than the EU.

At the end of 2023 (sunset date), the Act automatically revokes EU-derived subordinate legislation and retains direct EU legislation, allowing them to be replaced with UK-only regulations. A total of 587 EU regulations, including some that are no longer in use, will be revoked on 31 December 2023.

Schedule 1 of the Act provides the full list of revoked regulations and the extent to which they will be revoked. However, the Act does allow for additional regulations to be revoked in the future. Schedule 1 is divided as follows:

- » Part 1 - Subordinate Legislation
- » Part 2 - Retained Direct EU Legislation; this includes regulations relating to biocidal products, the PIC Regulation concerning the export and import of hazardous chemicals, and implementation of the Stockholm Convention on persistent organic pollutants

Under Part 2 of Schedule 1, the UK government plans to repeal Annex VIII to the Classification, Labeling and Packaging (CLP) Regulation. Annex VIII to CLP Regulation details the information requirements and notification format for poison center notifications. A voluntary scheme for poison center notifications is currently under consideration by the UK government. There are no other significant changes to transposed EU laws listed.

No penalties are detailed in the Act, though the Act does allow national authorities to impose penalties for specific regulations, similar to those in revoked EU law.

More information can be found here on [the Act](#) and [the schedule of retained EU law](#).

Applications seeking authorization for the use of chromium trioxide (consultation)

On 31 July 2023, the Health and Safety Executive (HSE) opened public consultations for several applications seeking authorization for the use of chromium trioxide (EC No. 215-607-8, CAS No. 1333-82-0) in various contexts. The applications and their specific uses are as follows:

- » AFA046-01 – use of chromium trioxide for functional chrome plating of aircraft components for civil and military sectors and hydraulic components for military vehicles
- » AFA048-01 – use of chromium trioxide for the surface treatment of engineering components in the aerospace and defense sector to create coatings with specific performance characteristics
- » AFA049-01 – use of chromium trioxide for hard (functional/engineering) chromium electroplating of engineering components to achieve specific performance characteristics
- » AFA050-01 – use of chromium trioxide for hard (functional/engineering) chromium electroplating of engineering components within an in-house production facility to meet specific performance characteristics

- » AFA051-01 – use of chromium trioxide for the surface treatment of engineering components in the aerospace and defense sector to create coatings with specific performance characteristics

Additionally, Article 64 of the UK REACH Regulation allows HSE to gather and use additional information about potential alternatives during the decision-making process.

HSE invites interested parties to provide scientific and technical information on possible alternatives or technologies related to these applications. Parties are encouraged to submit relevant information using the provided commenting webform and templates. Non-confidential comments will be made public on HSE's website. The deadline for comments is 22 September 2023.

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



NORTH AMERICA

Canada

Bill S-5 amends the Canadian Environmental Protection Act, 1999 and the Food and Drug Act, and repeals the Perfluorooctane Sulfonate Virtual Elimination Act (in force)

Bill S-5, an act to amend the Canadian Environmental Protection Act, 1999 (CEPA), to make related amendments to the Food and Drugs Act, and to repeal the Perfluorooctane Sulfonate Virtual Elimination Act received Royal Assent and entered into force on 13 June 2023. This amendment recognizes the right to a healthy environment in the preamble and requires that the government protects this right. Within two years, an implementation framework must be developed to set out how that right will be considered in the administration of Bill S-5.

Bill S-5 also introduces changes and new requirements for chemical management under CEPA. Principally, it establishes that, within two years, the Ministers must develop, consult on, and publish a Plan of Chemicals Management Priorities with timelines, which sets out i) a multi-year, integrated plan for the assessment of substances already in commerce in Canada, ii) the activities and initiatives that support chemicals management, such as information-gathering, risk management, risk communications, research, and monitoring, and iii) a strategy to promote the development and timely incorporation of scientifically justified alternative methods and strategies in the testing and assessment of substances to replace, reduce, or refine the use of vertebrate animals. Further, this amendment reinforces the use of a risk-based approach to assessing substances, accounting for the properties of a substance as well as exposure to the substance and several other factors, such as cumulative effects and the impact on vulnerable populations. It establishes that the Minister must publish and maintain a list, known as the “Watch List”, of substances of potential concern. A new provision allows any person to request that the Ministers assess a substance to determine whether it is toxic or capable of becoming toxic.

When developing pollution prevention (P2) plans, the Minister can require that the plan prioritizes the identification, development, or use of safer or more sustainable alternatives, and that written progress reports be submitted to prove the implementation of a P2 plan.

CEPA's schedule 1 containing the list of toxic substances is divided into 2 parts:

- » Part 1 includes substances that are either persistent and bio-accumulative and inherently toxic; carcinogenic, mutagenic, or toxic for reproduction (CMR); or otherwise found to pose the highest risk
- » Part 2 includes all other toxic substances

For substances in Part 1, risk management will prioritize their prohibition above other options where possible. New regulations and criteria are to be developed to better define toxic substances that pose the highest risk and to establish additional thresholds for CMR and any other relevant circumstances or conditions.

In the case of significant new activity information, the Minister can vary elements of a significant activity notice or order, such as the data or information that needs to be submitted for evaluation prior to undertaking the activity, as well as the timelines for submitting that information. The amendment also gives the Minister power to add and remove substances to the Domestic Substance List from the Revised In-Commerce List.

There are no penalties associated with this amendment.

More information can be found in this [news release](#), in the [Bill S-5 text](#), and in this [summary](#) of Bill S-5.

Notice to provide information regarding certain substances to determine if such substances are or have the potential to be toxic (consultation)

On 24 June 2023, the Canadian Environmental Protection Agency issued a notice stating that the Minister of the Environment requires certain individuals to provide information regarding substances listed in Schedule 1 of this [notice](#) in the Canada Gazette. This information is necessary to determine if the substances are toxic or have the potential to become toxic, and to assess the need for control measures. Individuals described in sections 2 and 3 of the notice are expected to provide the required information outlined in sections 5 to 10. The deadline for submitting this information is January 17, 2024.

To comply with this notice, interested parties must respond by submitting the required information to the Minister of the Environment. This must be done through the online reporting system provided by Environment and Climate Change Canada's Single Window platform.

This notice applies to entities who:

- » manufactured a total quantity greater than 100 kilograms (kg) of a substance listed in Part 1 or Part 4 of Schedule 1, or manufactured a total quantity greater than 1000 kg of a substance listed in Part 2 of Schedule 1
- » imported a total quantity greater than 100 kg of a substance listed in Part 1 or Part 4 of Schedule 1, or imported a total quantity greater than 1000 kg of a substance listed in Part 2 of Schedule 1 under certain conditions specified in subparagraphs (i), (ii), and (iii)
- » imported a total quantity greater than 100 kg of a substance listed in Part 3 of Schedule 1, under certain conditions specified in subparagraph (i) and (ii)
- » used a total quantity greater than 100 kg of a substance listed in Part 1 or Part 4 of Schedule 1, or used a total quantity greater than 1,000 kg of a substance listed in Part 2 of Schedule 1, in the manufacturing process of a mixture, product, or manufactured item
- » used a total quantity greater than 100 kg of a substance listed in Part 3 of Schedule 1 in the manufacturing process of a mixture, product or manufactured item described by one or more associated application codes in Part 3 of Schedule 1

- » used a total quantity greater than 100 kg of a substance listed in Part 4 of Schedule 1 in activities other than the manufacturing of a mixture, product, or manufactured item

Additionally, this notice applies to any person or class of persons who is the successor or assign of the person identified in subsection 2(2).

New requirements for certain human health hazards of concern in consumer chemical products under the Canada Consumer Product Safety Act (consultation)

Health Canada has opened a consultation on a proposed regulatory initiative to introduce requirements for certain human health hazards of concern (HHHOCs) in consumer chemical products under the Canada Consumer Product Safety Act (CCPSA). These products include household cleaning products, adhesives, and lubricants.

Before 2001, no harmonized classification criteria for HHHOCs had been established. At the international level, the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals was being developed parallel to the Consumer Chemicals and Containers Regulations (CCCR), 2001. CCCR under the CCPSA aims to protect Canadians from certain acute human health and physical hazards associated with consumer chemical products, through prohibitions and restrictions on dangerous consumer chemical products, information disclosure requirements, and container requirements.

The acute human health and physical hazards that the CCCR currently addresses are:

- » acute toxicity (lethal or serious but non-lethal effects)
- » corrosivity (chemical burns and eye damage)
- » flammability (chemicals that catch fire)
- » pressurized containers (containers that may explode if heated or punctured)
- » quick skin-bonding adhesives (adhesives that bond skin instantly or nearly instantly)

Many substances in consumer chemical products are linked to HHHOCs, including those that may cause adverse health effects from long-term or intermediate exposure. However, the CCCR does not include requirements that help mitigate the risks for the following HHHOCs:

- » carcinogenicity (induction of cancer)
- » germ cell mutagenicity (heritable gene mutations)
- » reproductive toxicity (adverse effects on sexual function, fertility, or developmental toxicity in offspring)
- » specific target organ toxicity (adverse effects on target organs after single or repeated exposure)
- » respiratory or skin sensitization (allergic reactions or hypersensitivity)

To address concerns, the Government of Canada intends to introduce requirements for HHHOCs. In addition, it plans to strengthen the disclosure of chemicals on labels for consumer products.

Health Canada proposes to introduce the following requirements for consumer chemical products under the CCPSA:

- » classification criteria for HHHOCs based on those set out in the GHS
- » information disclosure requirements for HHHOCs based on GHS label elements, including hazard symbols, signal words (i.e., "Danger" or "Warning"), hazard statements (e.g., "May cause cancer"), precautionary statements (e.g., instructions for safe use and first aid), and ingredient disclosure requirements
- » additional protections, such as prohibitions, restrictions, or child-resistant container requirements, where deemed necessary

Health Canada will use the input received through this pre-consultation to inform next steps, which may include a cost-benefit analysis of the proposal and future consultations. Any future regulatory proposal would be pre-published in the Canada Gazette, Part I for further stakeholder consultation.

The deadline for comments is 9 October 2023.

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

United States

Reporting and recordkeeping requirements for asbestos under the Toxic Substances Control Act (TSCA) (published)

On 25 July 2023, the Environmental Protection Agency (EPA) published a rule establishing new reporting and recordkeeping requirements for asbestos under the Toxic Substances Control Act (TSCA). The rule becomes effective from 24 August 2023. The affected asbestos fibers include:

- » asbestos (CAS No. 1332–21–4)
- » chrysotile (CAS No. 12001–29–5)
- » crocidolite (CAS No. 12001–28–4)
- » amosite (CAS No. 12172–73–5)
- » anthophyllite (CAS No. 77536–67–5)
- » tremolite (CAS No. 77536–68–6)
- » actinolite (CAS No. 77536–66–4)
- » libby amphibole asbestos (CAS No. not applicable), mainly consisting of tremolite (CAS No. 77536–68–6), winchite (CAS No. 12425–92–2), and richterite (CAS No. 17068–76–7)

This rule applies to manufacturers, importers, and/or processors of asbestos and asbestos-containing articles (including as an impurity), who worked with asbestos in the four years before 25 July 2023 (date of publication of rule). Affected parties must electronically report certain exposure-related information including the presence, types, and quantities of asbestos (including asbestos that is a component of a mixture) and asbestos-containing articles that were manufactured (including imported) or processed, types of use, and employee data.

This rule uses the reporting standard used for certain other TSCA section 8(a) reporting requirements, including chemical data recording. This standard requires that manufacturers (including importers) and processors report information to the extent that the information is known to or reasonably ascertainable by the manufacturer (including importer) or processor. It requires that submitters conduct a reasonable inquiry within the full scope of their organization and may also entail inquiries outside the organization to fill gaps in the submitter's knowledge.

The collected information will be used in EPA's "TSCA Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos". Additionally, EPA and other federal agencies will use the reported information to decide if future actions, such as risk evaluation and risk management activities, are needed.

The reporting period will start six months following the effective date of this rule (24 February 2024) and will last for three months, until 24 May 2024. Penalties for non-compliance are not mentioned in the update.

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

Final rule to add diisononyl phthalate as a new category of toxic chemicals (published)

On 14 July 2023, the Environmental Protection Agency (EPA) published a final rule which aims to enhance chemical reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA) by adding a new category of toxic chemicals - diisononyl phthalate (DINP). The final rule became effective on 12 September 2023.

The DINP category consists of branched alkyl di-esters of 1,2 benzenedicarboxylic acid with alkyl ester moieties containing nine carbons. This addition is in response to the EPA's evaluation of the potential health risks posed by DINP, which has been found to meet the EPCRA chronic human health effects toxicity criterion. According to EPA assessments, chemicals within the DINP category can reasonably be anticipated to cause serious or irreversible reproductive dysfunctions, as well as various chronic human health effects in humans, including developmental, kidney, and liver toxicity.

Facilities that manufacture, process, or utilize chemicals falling within the DINP category are now subject to annual reporting requirements. They must disclose information about environmental releases, waste management practices, and pollution prevention measures related to these chemicals. The EPA has provided a list of North American Industrial Classification System codes to help determine whether specific facilities fall under the reporting obligations.

The addition of DINP to the EPCRA toxic chemical list was triggered by a petition, and the EPA has undergone a thorough review of toxicity data to ensure the validity of this decision. As part of the EPA's commitment to transparency and public engagement, the agency has provided updated supporting materials for this regulatory action. These materials include a hazard assessment for DINP, titled the "2022 Technical Review of DINP." The EPA can add or delete chemicals from the EPCRA toxic chemical list based on certain criteria. In response to a petition, EPA is adding DINP to the list due to its health effects. The finalized addition is based on EPA's review of toxicity data, showing that DINP can cause serious or irreversible reproductive dysfunctions and chronic human health effects.

Penalties for non-compliance are not specified in the update.

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

Final rule to establish methodology to allocation hydrofluorocarbons production and consumption allowance for 2024 through 2028 (published)

On 20 July 2023, the U.S. Environmental Protection Agency (EPA) published a final rule that amended existing regulations to implement some provisions of the American Innovation and Manufacturing Act, which authorizes the phase down hydrofluorocarbons (HFCs) by 85% by 2036. The amendment, which becomes effective on 18 September 2023, establishes the methodology for allocating HFC production and consumption allowances for the calendar years of 2024 through 2028, adjusts the consumption baseline, and makes other modifications to support the phasedown provisions. Amendatory instructions 3 and 13 become effective on 1 October 2024. The incorporation of certain publications is approved as of 20 July 2023, and others as of 1 October 2024.

HFCs are greenhouse gases commonly used in a wide variety of applications, including refrigeration, air-conditioning (AC), building insulation, fire extinguishing systems, and aerosols. HFCs have high global warming potential (GWP), raising concern about their impacts as they become increasingly used as replacements for ozone-depleting substances (ODS), and as economic growth spurs demand for new equipment, especially in the refrigeration/AC sector.

The allocation of allowances will be based on entities' market shares, calculated from the average of their three highest years of production and consumption of regulated substances between 2011 and 2019. Entities eligible for general pool allowances must have produced or imported bulk regulated substances in 2021 or 2022. Furthermore, the EPA has adjusted to the consumption baseline, updating it from 303,887,017 metric tons of exchange value equivalent (MTEVe) to 302,538,316 MTEVe, considering verified revisions from entities for 2011 through 2013 and internal review of baseline calculation methodologies.

The rule also introduces revisions to facilitate compliance with the allowance program. Allowances must be expended at the time of import, with only the importer of record authorized to expand them. Entities must adhere to revised recordkeeping and reporting requirements, including providing advance notification and quarterly reports for shipments. Sampling and testing requirements for regulated substances have been clarified, with additional verification measures established.

The EPA has also included additional changes based on lessons learned during the HFC phasedown program's implementation. These changes specify features on labels and markings, prohibit repackaging or relabeling by parties other than the importer of record, and allow related companies to expend allowances without transfers.

Penalties for non-compliance are not specified in the update.

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

Draft revision to the risk assessment of 1,4-dioxane (consultation)

On 26 July 2023, the Environmental Protection Agency (EPA) published a notice seeking public input on a draft revision to the risk assessment of 1,4-dioxane (CAS No. 123-91-1), following a previous evaluation under the Toxic Substances Control Act (TSCA). 1,4-Dioxane is a solvent used in various industries and can be a byproduct in manufacturing processes, appearing in products like soaps, detergents, antifreeze, and plastics.

EPA evaluated 1,4-dioxane risks in 2020, identifying potential exposure through work, consumer products, and environmental contact, with effects including liver toxicity, olfactory issues, and cancer risk. EPA sought to revise risk assessments to consider more pathways of human exposure, particularly related to byproduct production and general population exposure via air and water. The 2023 draft supplement to the risk evaluation and the 2023 draft revised unreasonable risk determination were developed based on these considerations. This new revision reflects policy changes made in June 2021, aiming to ensure public safety based on scientific and legal grounds. The revision indicates that 1,4-dioxane poses an unreasonable health risk under its usage conditions.

In addition to the risks identified in the 2020 risk evaluation, this 2023 draft supplement found:

- » cancer risk estimates higher than 1 in 10,000 for a range of occupational exposure scenarios associated with 1,4-dioxane produced as a byproduct
- » cancer risk estimates higher than 1 in 1 million for a range of general population exposure scenarios, including to fence line communities associated with drinking water sourced downstream of release sites and for air within 1 kilometer of releasing facilities

The revised assessment acknowledges that not all workers consistently use personal protective equipment (PPE) and considers cases where workers might lack adequate protection due to various factors. Once finalized, this revision will replace previous risk assessments and declare 1,4-dioxane an overall substance of unreasonable risk.

The EPA will consider feedback from the public and peer review to finalize the risk determination. The deadline for comments was 8 September 2023.

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

Proposed rule to address potential risk of injury presented by carbon tetrachloride (consultation)

On 28 July 2023, the United States Environmental Protection Agency (EPA) published a proposed rule to address potential risk of injury to human health presented by carbon tetrachloride (CTC) under its conditions of use. The Toxics Substances Control Act (TSCA) Section 6 requires EPA to address unreasonable risks of injury to health or the environment posed by existing chemical substances in the TSCA inventory under the conditions of use. The deadline for comments was 11 September 2023.

Following the 2020 Risk Evaluation and 2022 Revised Unreasonable Risk Determination, EPA has determined that CTC presents an unreasonable risk of injury to health due to cancer from chronic inhalation and dermal exposures and liver toxicity from chronic inhalation, chronic dermal, and acute dermal exposures in the workplace.

CTC is a volatile, organic compound primarily used as a feedstock (i.e., processed as a reactant) in making products such as refrigerants, aerosol propellants, and foam-blowing agents. To address the identified unreasonable risk, EPA is proposing under TSCA to establish workplace safety requirements for most conditions of use, prohibit the manufacture (including import), processing, and distribution in commerce, and establish recordkeeping and downstream notification requirements.

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

Workplace safety requirements for carbon tetrachloride (consultation)

The U.S. Environmental Protection Agency (EPA) has announced a proposal to better protect workers from carbon tetrachloride (CTC; CAS No. 56-23-5) exposure. This proposal aims to minimize exposures and ban uses that have already ceased. In its 2020 risk evaluation, EPA determined that CTC presents an unreasonable risk to health, including liver toxicity and cancer from chronic inhalation and dermal exposures, primarily to workers and occupational non-users (workers nearby but not in direct contact with this chemical). Comments were due on 1 September 2023.

If finalized, the rule would require a workplace chemical protection program with strict controls, including inhalation exposure limits and dermal protections for manufacturing (including importing) CTC, processing, and other industrial or commercial uses. The workplace chemical protection program would cover uses related to the phasedown of climate pollutants under the American Innovation and Manufacturing Act, the production of chlorine and caustic soda, the manufacture of agricultural products, and repackaging for use as a laboratory chemical, recycling, and disposal. EPA is also proposing workplace controls and establishing downstream notification and recordkeeping requirements.

More information can be found in this [news release](#) from EPA.

White Paper on quantitative human health approach in risk evaluation of asbestos (consultation)

On 3 August 2023, the US Environmental Protection Agency (EPA) published a notice seeking public input on a white paper titled "Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2—Supplemental

Evaluation including Legacy Uses and Associated Disposals of Asbestos." The paper outlines a quantitative human health approach for assessing health risks associated with asbestos. The paper covers cancer and non-cancer hazards and aims to gather expert opinions on the proposed approach. This initiative is in line with the Toxic Substances Control Act (TSCA) and focuses on refining risk evaluation methodologies for asbestos. The deadline for comments is 2 October 2023.

The paper introduces a systematic review framework for identifying studies relevant to dose-response analysis, evaluating cancer risk and non-cancer effects, and proposing exposure thresholds for asbestos. The aim is to enhance risk assessment procedures for asbestos. The paper addresses the historical context of an asbestos risk evaluation under TSCA, incorporating legacy uses and disposal issues that were excluded in prior assessments. It outlines how the EPA has gathered epidemiological data and proposes a quantitative approach for cancer and non-cancer health hazards, considering both inhalation and other exposure routes.

This update affects various stakeholders, including those involved in asbestos manufacturing, processing, distribution, and disposal. The paper conclusions may impact risk assessments, safety protocols, and regulatory compliance measures within these industries.

The peer review process, which evaluates the quantitative approach proposed in the paper, will take place between 25 October 2023 and 24 November 2023. Feedback from this review will influence the development of Part 2 of the risk evaluation for asbestos.

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

Regulations pertaining to designating per- and polyfluorinated alkyl substances as hazardous waste (consultation)

On 13 April 2023, the United States Environmental Protection Agency (EPA) issued a notice to seek public input and data to assist in its consideration of the development of potential future regulations pertaining to designation as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for certain per- and polyfluorinated alkyl substances (PFAS) – comments were due on 11 August 2023:

- » seven PFAS, besides perfluorooctanoic acid (PFOA; CAS No. 335-67-1) and perfluorooctane sulfonic acid (PFOS; CAS No. 1764-23-1), their salts and structural isomers, or some subset thereof:
 - perfluorobutanesulfonic acid (PFBS; CAS No. 375-73-5)
 - perfluorohexanesulfonic acid (PFHxS; CAS No. 355-46-4)
 - perfluorononanoic acid (PFNA; CAS No. 375-95-1)
 - hexafluoropropylene oxide dimer acid (HFPO-DA; CAS No. 13252-13-6)
 - perfluorobutanoic acid (PFBA; CAS No. 375-22-4)
 - perfluorohexanoic acid (PFHxA; CAS No. 307-24-4)
 - perfluorodecanoic acid (PFDA; CAS No. 335-76-2)
- » precursors to PFOA, PFOS, and other PFAS listed above
- » categories of PFAS.

PFAS are a large group of man-made substances, which are used in various products such as firefighting foams, paints and coating, phosphate ester-based brake and hydraulic fluids, wires and cables, and lubricant for turbine engines, jet engine, and satellite instrumentation.

CERCLA provides a Federal "Superfund" to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other emergency releases of pollutants and contaminants into the environment. Through CERCLA, EPA was given the power to seek out those parties responsible for any release and assure their cooperation in the cleanup.

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

Draft IRIS toxicological review of perfluorohexane sulfonic acid and related salts (consultation)

On 24 July 2023, the U.S. Environmental Protection Agency (EPA) announced the release of the IRIS toxicological review of perfluorohexane sulfonic acid (PFHxS; CAS No. 355-46-4) and related salts for a 60-day public comment period and external peer review. PFHxS is a PFAS used in water- and stain-protective coatings for consumer products such as carpets, textiles, paper, packaging, textiles, and electronics. It has been used industrially as a surfactant to make fluoropolymers, for cleaning and polishing products, and in other industrial fluids or water-proofing agents. It may also be present unintentionally as an impurity from industrial production processes. PFHxS has also been used in aqueous film-forming foam for fire suppression. Concerns about PFHxS and other per- and polyfluorinated alkyl substances (PFAS) stem from the resistance of these compounds to hydrolysis, photolysis, and biodegradation, which leads to their persistence in the environment.

The deadline for comments is 22 September 2023.

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



OCEANIA

[Australia](#)

Requirement for annual authorization for decabromodiphenyl ether and perfluorooctanoic acid (published)

The Australian government has announced that from 21 July 2023, Australian importers and exporters of the following chemicals must receive annual authorization from the Australian Industrial Chemicals Introduction Scheme (AICIS):

- » decabromodiphenyl ether (decaBDE; CAS No. 1163-19-5)
- » perfluorooctanoic acid (PFOA; CAS No. 335-67-1) and its salts
- » PFOA-related compounds
 - any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C₇F₁₅- directly attached to another carbon atom as one of the structural elements
 - any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C₈F₁₇- as one of the structural elements

The following exceptions (chemicals that do not require annual import or export authorization from AICIS) apply:

- » introductions of decaBDE, PFOA, its salts, or PFOA-related compounds solely for the purpose of research or analysis at volumes of 100 kilograms or less in an AICIS registration year (30 August to 1 September)
- » the following fluorinated chemicals:
 - C8F17-X, where X = F, Cl, Br
 - C8F17-C(=O)OH
 - C8F17-C(=O)O-X' (where X' = any group, including salts)
 - C8F17-CF2-X' (where X' = any group, including salts)

The AICIS helps protect Australians and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use. Penalties for non-compliance are not mentioned in the update.

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

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

On 19 June 2023, the Australian government announced the addition of four chemicals to the Australian Inventory of Industrial Chemicals (AIIC) in accordance with Section 82 of the Industrial Chemicals (IC) Act 2019. The IC Act states that the Executive Director must list an industrial chemical on the AIIC if five years have passed since the assessment certificate was issued. The four chemicals are:

- » linseed oil, polymer with bisphenol A, p-tert-butylphenol, formaldehyde, maleic anhydride and tung oil (CAS No. 2922740-42-7)
- » poly(oxy-1,4-butanediyl), .alpha.-hydro-.omega.-hydroxy-, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane (CAS No. 39378-01-3)
- » soybean oil, polymer with pentaerythritol, phthalic anhydride and polymd. soybean oil (CAS No. 68152-88-5)
- » nickel sulfide (CAS No. 12035-72-2)

The AIIC is a searchable database consisting of around 40,000 chemicals that are manufactured or imported into Australia for industrial use. Chemical substances listed in the AIIC can be introduced by any registered introducers (manufacturer or importer). According to the IC Act, which regulates the manufacture and import of industrial chemicals (chemicals used for purposes other than agriculture, veterinary or therapeutic purposes, or in food or feed), introducers shall apply for registration before introducing an industrial chemical to Australia. For chemicals not listed in the AIIC, introducers shall apply to the Executive Director for an assessment certificate for their introduction.

Penalties for non-compliance include fines.

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

Confidential business information approval revoked for proper names of two substances (published)

On 8 June 2023, the Australian government announced that the confidential business information (CBI) approval for the proper names of the following two substances in the Australian Inventory of Industrial Chemicals (AIIC) has been revoked by the Australian government:

- » formaldehyde, polymer with N1-(2-aminoethyl)-N2-[2-[(2-aminoethyl)amino]ethyl]-1,2-ethanediamine, 2,2'-[1,4-butanediylbis(oxyethylene)]bis[oxirane], 4,4'-[1-methylethylidene]bis[phenol] and 2,2'-[(1-

methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane], reaction products with 1-[[2-[(2-aminoethyl)amino]ethyl]amino]-3-phenoxy-2-propanol and Bu glycidyl ether, acetates (salts) (CAS No. 2919023-46-2)

- » 2,5-pyrrolidinedione, 3-C15-18-branched 2-alkenyl derivs. (CAS No. 2256059-74-0)

The AIIC is a searchable database consisting of around 40,000 chemicals manufactured or imported into Australia for industrial use. Chemical substances that are listed in the AIIC can be introduced by any registered introducers (manufacturer or importer). According to the Industrial Chemicals Act 2019, which regulates the manufacture and import of industrial chemicals (chemicals used for purposes other than agriculture, veterinary or therapeutic purposes, or in food or feed), introducers shall apply for registration before introducing an industrial chemical to Australia. For chemicals not listed in the AIIC, introducers shall apply to the Executive Director for an assessment certificate for their introduction.

Penalties for non-compliance include fines.

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

Australian government seeks input on effective strategies for environmental managements of per- and polyfluorinated alkyl substances and pentachlorobenzene (consultation)

On 21 July 2023, the Australian government initiated a public consultation to gather feedback on proposed scheduling decisions that pertain to the management of per- and polyfluoroalkyl substances (PFAS) and pentachlorobenzene (PeCB; CAS No. 608-93-5) under the Industrial Chemicals Environment Management Standard (IChEMS). Comments were due on 1 September 2023.

PFAS chemicals include perfluorooctanoic acid (PFOA; CAS No. 335-67-1), perfluorooctanesulfonic acid (PFOS; CAS No. 1763-23-1), and perfluorohexanesulphonic acid (PFHxS; CAS No. 355-46-4). These substances are categorized as Persistent Organic Pollutants. The consultation process, referred to as "Have Your Say," aims to encourage input from stakeholders and the public to aid in formulating effective strategies for the environmental management of these chemicals. The government's proposal is in line with international efforts to address the risks posed by PFAS and PeCB.

IChEMS is a nationwide framework established to regulate the import, use, and disposal of industrial chemicals in Australia. It ensures consistent and practical guidelines for chemical management while promoting the adoption of less harmful chemicals within industries. The IChEMS framework aligns with the existing environment, health, safety, and duty of care obligations.

The public consultation is accessible through the government's consultation hub, where stakeholders and individuals can provide their feedback on the proposed scheduling decisions. The feedback received will contribute to refining the approach for managing these chemicals and mitigating their potential environmental risks.

The public consultation process emphasizes the government's commitment to evidence-based decision-making and stakeholder engagement. By inviting input from a wide range of participants, including industry stakeholders and the public, the Australian government aims to implement effective measures for managing PFAS chemicals and PeCB. The feedback gathered will likely influence the final scheduling decisions and the strategies for their implementation.

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

New Zealand

Submissions about a proposed infringement scheme for hazardous substances (consultation)

The New Zealand Ministry for the Environment and the Environmental Protection Authority (EPA) are calling for submissions about a [proposed infringement scheme for hazardous substances](#). The government is requesting general feedback on the proposed scheme, the list of infringement offences, and the fees that go with them. The current range of enforcement tools for hazardous substances is limited to warning letters, compliance orders, or prosecution. An infringement scheme will provide an intermediate enforcement tool.

The scheme will let enforcement officers respond to lower-level offences in a way that is more efficient and proportional to the offending. Access to appropriate enforcement tools in a timely and efficient manner will support improved compliance and deter future non-compliance. Improved compliance will reduce the risk of harm to people and the environment. Proposed infringement fees range from \$200 to \$3,000, depending on the nature of the offence. Prosecution would continue to be available for more serious offending.

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



SOUTH AMERICA

Brazil

Amendment to standards for the classification and labeling of chemicals (published)

On July 3, 2023, the Brazilian authorities published an amendment to its standard for the classification and labeling of chemicals via ABNT NBR 14725:2023. The amendment, which will enter into force on 4 July 2025, consolidates all the information of the four-part standard into one and implements version 7 of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in Brazil. The updated standard establishes:

- » terms adopted on the classification of the chemical hazards, in the labeling of hazardous chemicals and in the Safety Data Sheets (SDS)
- » purpose, scope, and application of the GHS
- » criteria for the classification of physical hazards, human health, and the environment of a chemical
- » information on safety, health, and environment related to the chemical to be included on the labels
- » information on how to prepare an SDS
- » confidentiality and comprehensibility of information and training within GHS

These changes will affect existing SDSs, labels, and classifications. Companies are required to review these amendments and implement the necessary changes to remain compliant. Penalties for non-compliance are not specified in the provided information.

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

New Recommended Practice – ABNT PR 2060 – for companies to demonstrate carbon neutrality (published)

On 21 July 2023, Brazil published ABNT PR 2060, a new Recommended Practice (RP) in Brazil that provides clear and reliable guidelines for companies to demonstrate carbon neutrality. The practice aligns with international ISO standards on GHG emission reduction.

ABNT PR 2060 outlines the requirements for achieving carbon neutrality by quantifying, reducing, and offsetting greenhouse gas (GHG) emissions from a specified object. This RP is intended for various entities, including governments, organizations, communities, families, and individuals. It is applicable to activities, products, services, buildings, projects, cities, and events. It aims to provide security to organizations seeking carbon neutralization goals and adds value to Brazilian production by following certified parameters. It clarifies measures necessary for carbon neutralization, preventing greenwashing and promoting sustainable practices. The RP provides two levels of communication:

- » a primary level involving a statement of commitment to carbon neutrality
- » a declaration level requiring proof of reductions and offsetting

Entities can also use a consumer-friendly "representative statement" for promotional purposes, but this is in addition to the formal statement. The RP allows for the validation of carbon neutrality claims by the entity itself or third parties hired for this purpose. To claim compliance, entities must satisfy all relevant requirements specified in the RP.

Annex A contains admissible declarations related to carbon neutrality, including a unified declaration for future commitments. Annex B provides a checklist for completing the Qualified Explanatory Statement for each statement. Annex C includes examples of widely accepted standards and methodologies for quantifying and offsetting GHG emissions. However, other standards meeting the principles can also be used, provided they are confirmed by the assessing entity. External documents listed in Annex C are essential for the successful application of this RP, and compliance with their requirements is integral to complying with this RP.

The update does not mention penalties for non-compliance.

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

NEWSLETTER

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



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