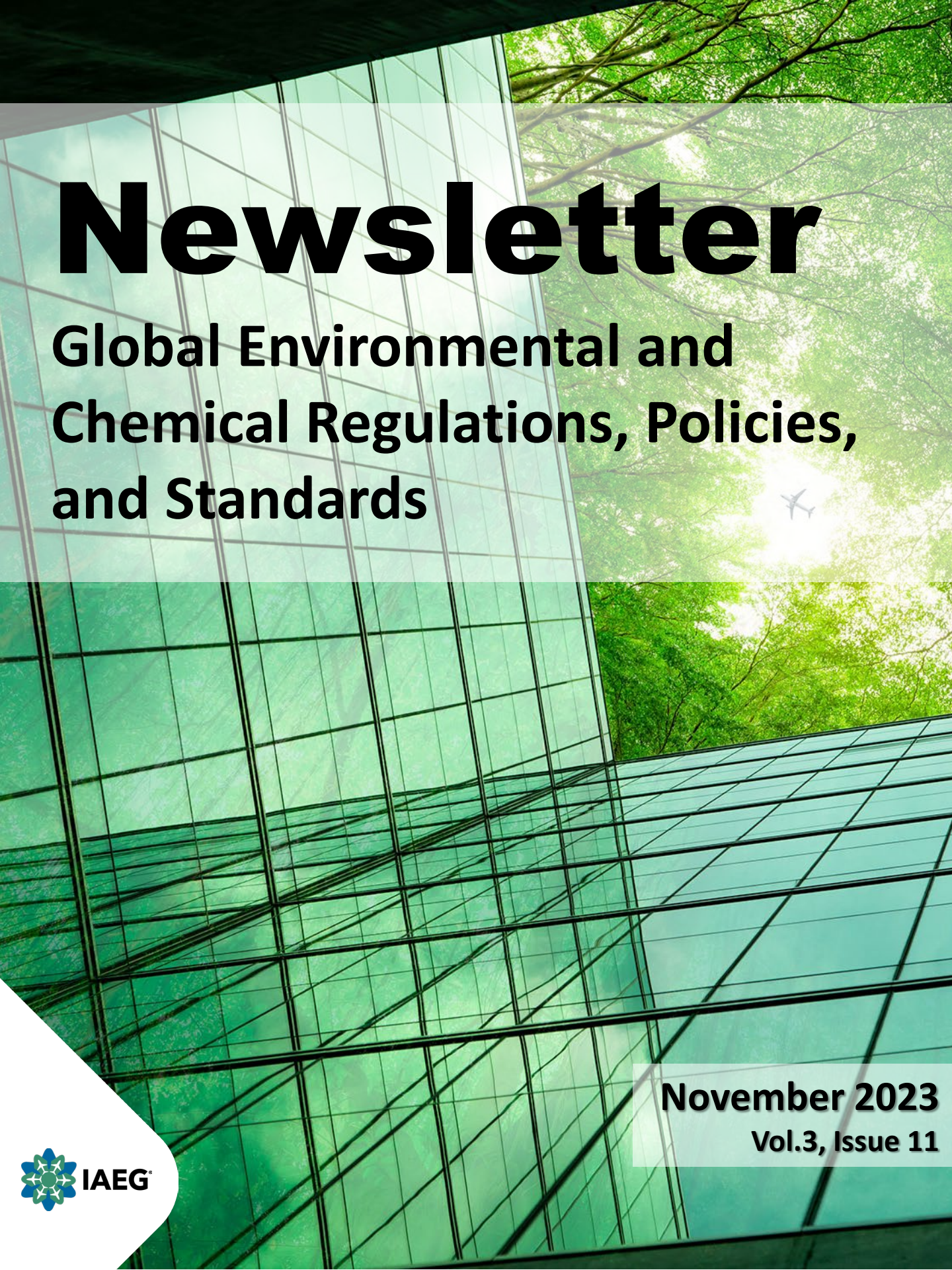

Newsletter

Global Environmental and Chemical Regulations, Policies, and Standards

November 2023
Vol.3, Issue 11

IAEG

NEWSLETTER

Global Environmental and Chemical Regulations, Policies, and Standards
November 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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AFRICA

South Africa

Amendments to the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade (consultation)

On 24 October 2023, the Ministry of Forestry, Fisheries, and Environment proposed amendments to South Africa's regulation implementing the Rotterdam Convention on the (prior informed consent (PIC) procedure for certain hazardous chemicals and pesticides in international trade. The purpose of the Rotterdam Convention is to facilitate informed decision-making by countries with regard to trade in hazardous chemicals, requiring importers to submit consent forms and receive approval before introducing certain chemicals to countries party to the Convention.

The regulation applies to the banned or severely restricted chemicals listed in Annex I. It establishes that importing or exporting chemicals in South Africa necessitates obtaining consent under this regulation, particularly for chemicals listed in Annex I. Anyone intending to import and/or export chemicals must submit a notification per sub-regulation (2) to the South Africa Designated National Authority. Additionally, importers and exporters of chemicals are obligated to maintain accurate records and issue a declaration. The draft amendment updates the previous implementing regulation to add recent amendments to the Convention.

Non-compliance with the regulation can lead to penalties, including fines up to five million Rands and imprisonment for up to five years for a first offence, and fines up to ten million Rands and imprisonment for up to ten years for subsequent offences, or a combination for both. The amendment is expected to enter into force 300 days from the date of its publication in the Government Gazette. A consultation on these amendments was open until 23 November 2023.

More information can be found in this notice from the Government Gazette.

ASIA

India

The Department of Chemicals and Petrochemicals postponed the quality control orders for polyethylene, ethylene vinyl acetate, and maleic anhydride (published)

India's Department of Chemicals and Petrochemicals has postponed the implementation of mandatory quality control orders (QCO) for three substances:

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- polyethylene (CAS No. 9002-88-4) – used in moulding and the production of bottles, bags, and food grade packaging material – the new entry into force of the QCO is 5 January 2024
- ethylene vinyl acetate (CAS No. 24937-78-8) – used in specialized low-density polyethylene (LDPE) food contact materials, adhesives, coatings, and resins – the new entry into force of the QCO is 3 April 2024
- maleic anhydride (CAS No. 108-31-6) – used in bathroom fixtures, fiberglass, food additive, paints, and coatings – the new entry into force of the QCO is 24 April 2024

This delay is due to concerns about potential disruptions to trade. To manufacture or trade these substances, businesses need certification from the Bureau of Indian Standards (BIS). The BIS delayed the implementation in the interest of the public, as inspections of overseas manufacturing plants supplying imported materials are not yet complete and immediate enforcement could lead to trade disruptions.

QCOs are gazette orders issued pursuant to Section 16 of the BIS Act, 2016. They are issued by the government 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/articles (objects whose function is determined by their shape, surface, or design to a greater degree than their chemical composition). 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 covered by the QCO - 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, 2016. Penalties for non-compliance include fines of up to five lakh rupees.

More information can be found in the Gazette of India.

Sodium cyanide Quality Control Order (draft law)

The Department of Chemicals and Petrochemicals (DCP) has issued a draft order of implementation for a Quality Control Order (QCO) for sodium cyanide (CAS No. 143-33-9). QCOs indicate what standards products in India need to comply with, and any exemptions or additional requirements that might apply to these products, to ensure the quality and safety of products placed on the Indian market.

The draft order will not apply to sodium cyanide meant for export. Manufacturer and importer of sodium cyanide must ensure the conformity to the Indian Standard 11782:1986 bearing the title of Indian Standard 'Specification for Sodium Cyanide' and ensure their products bear the standard mark. The draft order will enter into force six months from the day it is published on the official Gazette of India.

More information can be found in this announcement from the DCP.

Japan

Amendment to the GHS classification of six substances (amendment)

On 25 September 2023, Japan's National Institute of Technology and Evaluation (NITE) amended the globally harmonized system (GHS) classifications of six substances. The GHS system provides a standardized approach to classifying and labelling

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chemicals to communicate their hazards and risks to users. The Ministry of Economy, Trade, and Industry (METI), the Ministry of Health, Labor, and Welfare (MHLW), and the Ministry of Environment (MoE) are responsible for classifying the substances, which companies then refer to when preparing GHS labels and safety data sheets (SDSs). NITE publishes the list on their behalf. The six substances are:

- titanium (III) chloride (CAS No. 7705-07-9)
- hexane, 2,5-dimethyl-2,5-bis(t-butylperoxy) (CAS No. 78-63-7)
- ronnel (CAS No. 299-84-3)
- 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(S)-1-methoxypropan-2-yl]acetamide (CAS No. 87392-12-9)
- dimethyl terephthalate (CAS No. 120-61-6)
- 2,4-dichloro-1-nitrobenzene (CAS No. 611-06-3)

Stakeholders using those six substances shall prepare GHS labels and safety data sheets according to the new classification.

Additional Information can be here in Japanese and in English.

Schedule for manufacturing/import applications for new chemical substances with low production volumes and small quantities (published)

On 13 October 2023, Japan's Ministry of Economy, Trade, and Industry (METI) along with the Ministry of Environment (MoE) and Health, Labor, and Welfare (MHLW) issued notices outlining the schedule for manufacturing and importing applications concerning new substances characterized by low production volumes and new substances with small quantities. The provided schedules also include submission timelines for gaining access to the Electronic Information Processing System, which is the designated platform for all reports and applications related to manufacturing and import.

Manufacturers and importers intending to deal with new substances featuring low production volumes or small quantities are required to submit applications and obtain approval before engaging in manufacturing and import activities. The deadlines for each application batch have been clearly specified, with approval anticipated to be granted approximately one month after the deadline.

Penalties are not specified in the update.

Additional Information can be found in Japanese regarding the schedule for manufacturing and importing applications concerning new substances characterized by low production volumes and new substances with small quantities as well as the submission timelines for gaining access to the Electronic Information Processing System.

Malaysia

Amendments to the Industry Code of Practice for Chemicals Classification and Hazard Communication (consultation)

Malaysia is in the process of consulting on amendments to its mandatory Industry Code of Practice (ICOP) for Chemicals Classification and Hazard Communication, which assists companies in adhering to the nation's regulations regarding hazardous chemicals. The consultation period ended on 10 November 2023. These proposed amendments are intended to bring the ICOP in line with global standards and include modifications to various hazard classifications and definitions. The

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ICOP serves to help businesses comply with the Classification, Labelling, and Safety Data Sheet (CLASS) of Hazardous Chemicals regulations of Malaysia that are governed by the Occupational Safety and Health Act 1994 (OSHA).

The proposed amendments to the ICOP encompass several areas, such as changes to definitions and classification methods for physical, health, and environmental hazard classes. Additionally, there will be new requirements for safety data sheets (SDSs), including guidance on first aid measures, suitable fabric for personal protective clothing for emergency responders, air monitoring procedures, physical and chemical properties content, and bulk transportation guidance. The amendments will also add further details to the ICOP appendix covering carcinogens, precautionary statements for labelling, label contents models, substance and mixture model labels, and examples of fold-out labels. These changes are intended to align Malaysia with the eighth revised edition of the United Nations' Globally Harmonized System for chemical classification and labelling.

More information can be found here.

South Korea

Announcement of hazards and risks of fifty-five new chemical substances in the third quarter of 2023 (amendment)

In the third quarter of this year, South Korea's Ministry of Employment and Labor (MoEL) published risk management information on fifty-five newly imported chemicals including their names, hazards, risks, and measures to prevent health hazards to workers. This announcement aims to ensure the safety of workers handling these substances and is in accordance with the Korean Occupational Safety and Health Act (K-OSHA). K-OSHA's goals involve promoting the safety and health of workers, encouraging efficient business to prevent industrial accidents, and motivating business proprietors into joining them, contributing to the improvement of economic development.

The MoEL requires manufacturers and importers of new chemicals to submit an investigation report, including safety data sheets, toxicity test data, manufacturing and handling methods, and process charts before they manufacture or import. The assessment of potential hazards and risks is conducted based on this information and communicated to the rest of the industry and the public.

Among the fifty-five new chemicals disclosed, twenty have been identified as potentially hazardous to workers. These chemicals exhibit characteristics such as acute toxicity, skin and eye irritation, skin sensitivity, and harm to the aquatic environment. Employers dealing with these substances must take measures to protect workers, including the installation of ventilation systems and the provision of personal protective equipment, such as respiratory protection and protective goggles.

The list of newly imported chemicals was published on 26 September 2023. The notification requires that employers and manufacturers comply with health and safety measures. Penalties for non-compliance are not specified in the announcement.

Information and the list of chemicals can be found here in Korean and in English.

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Revisions to the Act on Registration and Evaluation of Chemical Substances (announced)

The South Korea Ministry of Environment (MoE) is revising the Act on Registration and Evaluation of Chemical Substances to revise requirements related to priority control substances, including the procedures and fees for the transfer of ownership of chemical substance registrations. The MoE has published a draft and a notice detailing the proposed changes.

The purpose of this Act is to prescribe the matters for chemical registration, evaluation assessment of hazard risks of chemical substance and product containing hazardous chemical substance, designation of hazardous chemical substance, and to protect public health and environment by producing and utilizing the information of chemical substance.

The key changes proposed in this update include the possibility of transferring the registration ownership to foreign companies, parent companies, etc., to simplify the process and the documentation requirements. For the transfer of registration ownership, there is no longer a requirement to submit risk data and the registration/report status will be recorded instead of report numbers to best protect confidential information.

This update also aims to introduce reporting requirements for changes to the status of priority control substances. When the proportion of a priority control substance is increased by 50% or more, this composition change needs to be reported. However, if the proportion is below 30% of the total composition, changes do not need to be reported.

The reporting fee for priority control substance will be reduced from 50,000 won to 20,000 won, while the ownership transfer reporting fee will be set at 15,000 won for registration and 2,000 won for reporting the change. Detailed standards for imposing fines for non-compliance are also established, with penalties ranging from six million won to ten million won depending on the number of violations.

These draft revisions are planned to take effect on 4 January 2024. Penalties for non-compliance include fines ranging from six million won to ten million won depending on the number of violations.

Information on the proposal can be found here in Korean and in English. More information on the revisions can be found here in Korean and in English.

EUROPE

European Union

REACH updates: Restriction intentions, opinions, and calls for comments (published)

The number of applications for authorization for the use of certain hexavalent chromium [Cr(VI)] substances has far exceeded the expected amounts at the time of inclusion of the substances in REACH Annex XIV, and the regulatory approach is no longer appropriate to control the risks. As such, ECHA is preparing a restriction dossier regarding a possible restriction of at least two Cr(VI) substances: chromium trioxide (entry 16 in Annex XIV; CAS No. 1333-82-0; EC No. 215-607-8) and chromic acid (entry 17 in Annex XIV; CAS No. 7738-94-5; EC No. 231-801-5). The expected date of submission is 4 October 2024. Stakeholders are requested to provide relevant information to the dossier submitter.

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Norway has registered a new substance of very high concern (SVHC) intention for bis(α,α-dimethylbenzyl) peroxide (CAS No. 80-43-3; EC No. 201-279-3) proposing it should be identified as an SVHC and listing an expected date of submission of 1 February 2024 for the SVHC dossier. The scope of the restriction regards the substance's properties as toxic for reproduction under Article 57c.

ECHA has published the combined opinion on medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17. MCCPs were previously identified as SVHCs due to their persistent, bio-accumulative, and toxic (i.e., PBT) and very persistent and very bio-accumulative (i.e., vPvB) properties. ECHA has published the final consolidated opinion from both the risk assessment (RAC) and socio-economic analysis committees, supporting ECHA's proposal to restrict MCCPs, and suggesting that substances that may contain MCCP constituents/congener groups could be considered to meet the REACH Annex XIII criteria for a PBT or vPvB substance if these constituents are present in a concentration greater than or equal to 0.1 % w/w. A two-year transition period is supported within this opinion. Notably, the RAC does not support a derogation for the metalworking fluid uses of MCCPs, stating that the diversity of metalworking operations means it is not possible to identify specific risk management measures that would be applicable.

ECHA called for comments on the draft screening report for Bis(2-methoxyethyl) ether (diglyme) (CAS No. 111-96-6; EC No. 203-924-4). Diglyme was included in the Authorization List (REACH Annex XIV) on 14 August 2014 and had a sunset date of 1 March 2023 for the use of the substance in the production of spare parts where alternatives are not available. Now the sunset date has passed, ECHA needs to consider if risks from the use of the substance are adequately controlled. The call for evidence is to gather information on the use of diglyme in articles such as plastic products, vehicles, and electronic components, as well as the potential use of diglyme as an electrolyte in batteries. Information on alternatives and waste management for diglyme is also sought. The closing date for submission of comments was 22 November 2023.

Penalties are determined by each Member State.

Regulation on preventing plastic pellet losses to reduce microplastic pollution (draft law)

On 16 October 2023, the European Commission adopted a proposed regulation on preventing plastic pellet losses to reduce microplastic pollution. A feedback period is open until 4 January 2024 and is being extended every day until the adopted proposal is available in all European Union (EU) languages. This proposal was developed through the Microplastics Pollution Initiative, which previously aimed to address synthetic textiles, tires, and plastic pellets. The proposed regulation now only includes plastic pellets since it was determined that plastic pellet losses from textiles and tires could be more appropriately managed through other measures. The proposal aims to complement the Annex XVII REACH restriction on intentionally added microplastics, which was published on 27 September 2023.

The proposed regulation applies to economic operators handling plastic pellets in the EU in quantities above five tonnes in the previous calendar year, in addition to EU carriers and non-EU carriers transporting plastic pellets in the EU. The proposal aims to further develop existing voluntary approaches pioneered by industry via Operation Clean Sweep, under which companies recognize the importance of making zero pellet losses and commit to adopting best practices.

Key obligations under Article 3 of the proposal are:

- economic operators, EU carriers and non-EU carriers shall ensure that plastic pellet losses are avoided and where losses occur, take immediate action to clean-up those losses
- notification requirements for economic operators and EU carriers:

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- notifying the competent authority of each installation they operate and when engaging in the transport of plastic pellets, as applicable
- notifying the competent authorities of the Member State in which they are established of any significant change in their installations and activities related to handling of plastic pellets, including of any closure of an existing installation

Further obligations include risk assessment plans, self-declarations of conformity and under Annex III, actions to be taken by EU carriers and non-EU carriers during loading and unloading operations, transport journeys, and cleaning and maintenance operations. There are also obligations on mandatory staff training and record-keeping, and a regulatory system requiring the entire supply chain to adhere to best practices to prevent pellet losses, which includes certification by an accredited, independent certifier. Moreover, Article 9 details measures to be taken in the event of an incidental or accidental loss of plastic pellets significantly affecting human health or the environment. A regulatory system of liability and compensation obligations to remediate environmental damage caused by pellet losses is also outlined in the proposal.

The proposed regulation will apply 18 months after its entry into force. However, the obligation to avoid losses and take immediate clean-up measures (in the event of any losses) under Article 3(1) applies from the date of entry into force.

Penalties for non-compliance shall be laid down by Member States and will include fines proportionate to the turnover or income of the person committing the infringement, as per Article 15.

Information on annexes to the proposed regulation can be found here.

Amendment to RoHS Directive to add two exemptions for cadmium in LED semiconductor chips (draft amendment)

On 20 October 2023, the European Union published a draft amendment to Annex III to Directive 2011/65/EU, the RoHS Directive, adding two exemptions for cadmium (Cd) in LED semiconductor chips (with comments due on 19 December 2023). The RoHS Directive aims to prevent the risks posed to human health and the environment related to the management of electronic and electrical waste. It does this by restricting the use of certain hazardous substances in electrical and electronic equipment (EEE) that can be substituted by safer alternatives.

Annex III to the RoHS Directive is amended to add the following exemptions:

- cadmium selenide in downshifting Cd-based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0.2 micrograms [µg] Cd per square millimeter [mm²] of display screen area) – this exemption will expire for all EEE categories eighteen months after the entry into force of the amendment
- Cd in downshifting semiconductor nanocrystal quantum dots directly deposited on LED semiconductor chips for use in display and projection applications (< 5 µg Cd per mm² of light emitting LED chip surface) with a maximum amount per device of 1 milligram – this exemption will expire for all EEE categories on 31 December 2027

Additional information can be found in the WTO notification, EC Directive, and its annex.

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France

National law on green industry (published)

On 24 October 2023, France published Law No. 2023-973 (the Law) as its national law on green industry. This aims to ensure that France becomes the leader for green industry in Europe and follows European Union (EU) regulations, proposed in March 2023 relating to green technologies. Chapter III of the Law intends to develop the circular economy in France and includes obligations relating to waste management and reuse.

Under Chapter III, France aims to develop its recycling procedures. In particular, it aims to simplify the use of recycled waste as a raw material and ensure that production residues are reused within industrial platforms. Chapter III amends Article L. 541-4-3 of the French Environmental Code that establishes whether substances or objects produced in a production facility fall under the status of waste. The amendments are as follows:

Using recycled waste as a raw material: Substances or objects produced in a production facility that uses all or part of waste as raw material do not have the status of waste if the substance or object is similar to that which would have been produced without using waste, This is provided that the operator of the production facility complies with the conditions below and submits justification to the competent authority, including tests for waste that is likely to be a dangerous raw material:

- the substance or object is used for specific purposes
- there is a demand for such a substance or object, or it responds to a market
- the substance or object meets the technical requirements for the specific purposes and complies with the legislation and standards applicable to the products
- its use will not have any overall harmful effects on the environment or human health

Reuse of production residues within industrial platforms: Substances or objects produced within an industrial platform[1] and whose production was not the primary aim of the production process do not acquire the status of waste if the following conditions are met:

- it is certain that the substance or object will be used within the same industrial platform
- the substance or object has no overall harmful impact on the environment or human health, with the operator of the production installation obliged to provide such justification to the competent authority, in particular the tests carried out when the substance or object is likely to be dangerous

Chapter III also amends sanctions under the French Environmental Code, which aim to ensure that irregular transfers of waste are more severely punished. Penalties for non-compliance include fines up to five times the cost of processing the waste concerned by the illicit transfer. Fines cannot be imposed more than three years after illegal transfers have been noted.

Within one year from the promulgation of this Law, the government will present measures on the minimum quality and traceability requirements for textiles to ensure that they will be reused and not treated as waste.

More information can be found here.

[1] industrial platforms are defined in Article L. 515-48 of the French Environmental Code as groupings of "factories, workshops, depots, construction sites and, in general, installations operated or owned by any natural or legal person, public or private, which may present dangers or inconveniences either for the convenience of the neighborhood, either for public health, safety, sanitation, or for agriculture, or for the protection of nature, the environment and landscapes, or for the economical use of natural, agricultural or forestry, either for the rational use of energy, or for the conservation of sites and monuments as well as elements of archaeological heritage."

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United Kingdom

Updates to the Great Britain mandatory classification and labeling list (in force)

On 20 October 2023, the Health, and Safety Executive (HSE) published the updated Great Britain[2] mandatory classification and labeling (GB MCL) list. A total of sixty-seven already classified substances had their classifications updated while thirty-six previously not classified substances were assigned new classifications. The update includes HSE's the first recommendation to ministers on new or revised entries for ninety-eight substances. The GB MCL entries are the equivalent of the European Union's Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures.

Within this update, Great Britain has adopted HSE's recommendation for new or revised entries for ninety-eight chemical substances. This follows a consultation on the ninety-eight substances, which ended on 4 June 2023. The GB MCL list has been updated to reflect this decision, in addition to correcting a number of reported errors (editorial issues, typos, and transcription errors). Summaries of the GB MCLs have been published in the GB CLP publication table. The legally binding mandatory classification and labeling of the substances is included in the GB MCL List.

The updated GB MCL list entered into force on 20 October 2023 and compliance is mandatory from 20 April 2025. Penalties for non-compliance with GB CLP include fines (up to an unlimited amount) and/or up to 2 years imprisonment.

More information can be found in this announcement from HSE.

Update to guidance on conformity assessment marking (published)

The United Kingdom (UK) has updated its guidance on UK Conformity Assessment (UKCA) marking. Currently, certain products that meet European Union (EU) requirements, including CE (i.e., European Conformity) marking, can be placed on the Great Britain (GB) market until 31 December 2024. However, the UK is planning to pass a new law to extend this recognition indefinitely.

This extension will allow specific EU-compliant products to be sold in the GB market after 31 December 2024 with no end-date. These changes specifically affect the eighteen regulations that fall under the Department for Business and Trade (DBT), meaning the following A&D relevant products are affected:

- simple pressure vessels
- electromagnetic compatibility
- non-automatic weighing instruments
- measuring instruments
- measuring container bottles
- lifts
- equipment for potentially explosive atmospheres
- radio equipment
- pressure equipment
- personal protective equipment
- gas appliances
- machinery
- equipment for use outdoors

[2] i.e., England, Wales, and Scotland.

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- aerosol dispensers
- low voltage electrical equipment

Other specific rules apply to construction products, civil explosives, marine equipment, cableways, eco-design, transportable pressure equipment, and hazardous substances (RoHS).

Some conformity assessment procedures permit manufacturers to self-declare conformity, while others, particularly for products with higher risk profiles, might necessitate third-party conformity assessment.

Information on technical documentation regarding record keeping and the UK Declaration of Conformity was updated on 3 October 2023. There are no penalties associated with this update.

More information can be found in this guidance.

Draft socio-economic opinion on lead in ammunition restriction (consultation)

The United Kingdom Health and Safety Executive (HSE) has opened a 60-day consultation regarding the draft socio-economic opinion on lead (CAS No. 7439-92-1) in ammunition restriction proposals (comments due by 10 December 2023)[3]. After a previous consultation and published opinion on risk assessment for lead in ammunition, HSE is now required to seek comments on the published draft socio-economic opinion.

The draft opinion finds that there are risks to the environment and consumer of game meat that are not adequately controlled and additional measures are recommended. The draft socio-economic assessment details i) the expected cost to manufacturers, ii) climate impact, iii) enforcement costs, iv) the expected shooter substitution costs, and v) the projected benefits of the restrictions.

NORTH AMERICA

Canada

Addition of ten substances into the Domestic Substances List (in force)

On 11 October 2023, Canada issued Order 2023-87-09-01 (the Order) announcing the addition of ten substances in the Domestic Substances List (DSL). Evaluation of these substances determined that they fulfill the criteria outlined in the Canadian Environmental Protection Act, 1999 (CEPA), thus warranting their addition to the DSL. The Order enters into force on 27 September 2023.

[3] Comments on risk factors are not being sought as this consultation has already been conducted.

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The DSL functions as a record of substances produced or imported in Canada on a commercial scale. It undergoes revisions twelve times a year to accommodate the addition, modification, or removal of substances. Substances not listed in the DSL are categorized as new to Canada and require notification.

- Part 1 of the DSL has been amended by adding the following substances:
  - magnesium acrylate (CAS No. 5698-98-6)
  - oxirane, 2-methyl-, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, oxirane and 2-[[3-(triethoxysilyl)propoxy]methyl]oxirane, polyethylene-polypropylene glycol mono-Bu ether monoether with propylene oxide-2-[[3-(triethoxysilyl)propoxy]methyl]oxirane polymer- and polypropylene glycol mono-Bu ether-blocked) (CAS No. 1815601-65-0)
  - no name (CAS No. 2763070-25-1)

- Part 3 of the List is amended by adding the following in numerical order:
  - 19489-7 N[4]: fatty acids, plant-based oil, conjugated, maleated
  - 19670-8 N-P[5]: 2-propenoic acid, 2-methyl-, alkyl ester, polymer with dodecyl * 2-methyl-2-propenoate, 2-hydroxyethyl 2-methyl-2-propenoate and methyl 2-methyl-2-propenoate
  - 19671-9 N: alkanoic acid, 12-hydroxy-, compound with heteromonocycle polymer with N1-(2-aminoalkyl)-1, alkylamine, 12-hydroxyoctadecanoic acid, 2-oxepanone and tetrahydro-2H-hetermonocycle
  - 19674-2 N-P: 2-propenoic acid, 2-methyl, alkyl ester, polymer with butyl 2-propenoate, 2-hydroxyethyl 2-methyl-2-propenoate, 2-hydroxyethyl 2-propenoate and methyl 2-methyl-2-propenoate
  - 19676-4 N-P: 2-propenoic acid, polymer with 2-hydroxyalkyl 2-propenoate and α-(alkylalkenyl)-ω-hydroxypoly(oxy-1,2-ethanediyl), graft
  - 19677-5 N-P: 2-ethyl-2-(hydroxymethyl)propane-1,3-diol polymer with 2,2-dimethylpropane-1,3-diol, benzene-1,4-dicarboxylic acid and ethane-1,2-diol, 2-hydroxy-3-[(alkanoyl)oxy]propyl ester

Incorporation into the DSL implies that these elements are now exempt from the New Substances Notification Regulations (Chemicals and Polymers). Consequently, the Order is anticipated to simplify businesses' access to these substances, as they are no longer bound by the obligations outlined in subsection 81(1) or 106(1) of CEPA.

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

More information can be found in the Canada Gazette.

Hazardous Substance Assessments for six substances (published)

On 28 September 2023, Health Canada released hazardous substance assessments (HSAs) for six substances:

- 4,4'-methylenediphenyl diisocyanate (CAS No. 101-68-8)

[4] N flag indicates that the substance was reported and evaluated as a novel material following 1 July 1994 and subsequently appended to the DSL based on its production or import into Canada.
[5] P flag signifies that the material was included in the DSL because it satisfied the polymer criteria for Reduced Regulatory Requirements (RRR). Any variant of the substance that fails to meet these RRR polymer standards necessitates advance notice prior to importing or manufacturing.

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- diethylene glycol (CAS No. 111-46-6)
- d-limonene (CAS No. 5989-27-5)
- EDTA tetrasodium salt (CAS No. 10378-23-1)
- Morpholine (CAS No. 110-91-8)
- Toluene (CAS No 108-88-3)

HSAs serve as informative tools to aid in the creation of compliant Safety Data Sheets and labels for hazardous products. They provide insights into how Health Canada classifies each substance concerning the physical and health hazard classes outlined in the Hazardous Products Regulations (HPR). Each HSA contains a thoroughly referenced assessment supporting the classification of the respective hazardous substance, utilizing publicly available data. To support suppliers during the three-year HPR transition, these new HSAs reflect the requirements of both the former and amended HPR.

Penalties are not mentioned in the update.

More information can be found in this workplace hazardous program newsletter and the hazardous products regulations.

Assessment of thirteen titanium-containing substances group listed under the Domestic Substances List (draft)

On 28 October 2023, Canada published the summary of the draft assessment of thirteen titanium-containing substances group (consultation open until 27 December 2023). This group is listed under the Domestic Substance List (DSL) and was assessed to determine if they pose a significant enough risk to health and the environment. The substances included in the group are:

- 2-propanol, titanium(4+) salt (CAS No. 546-68-9)
- 1-hexanol, 2-ethyl-, titanium(4+) salt (CAS No. 1070-10-6)
- rutile (CAS No. 1317-80-2)
- titanium oxide (CAS No. 1344-54-3)
- titanium oxide (CAS No. 13463-67-7)
- 1-butanol, titanium(4+) salt (CAS No. 5593-70-4)
- titanium tetrachloride (CAS No. 7550-45-0)
- titanium chloride (CAS No. 7705-07-9)
- titanate, barium (1:1) (CAS No. 12047-27-7)
- titanate, strontium (1:1) (CAS No. 12060-59-2)
- titanium, oxo[sulfato(2-)-O,O']- (CAS No. 13825-74-6)
- titanate(2-), hexafluoro-, dipotassium, (OC-6-11)- (CAS No. 16919-27-0)
- titanium hydroxide (Ti(OH)4), (T-4)- (CAS No. 20338-08-3)

It was concluded that these thirteen substances do not meet the criteria under paragraph 64(c) of CEPA, as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. Therefore, the draft assessment proposes to take no further regulatory action.

More information can be found in the Canada Gazette.

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Amendment to the Domestic Substances List to add the letter "P" to the identifiers of 145 polymers that meet the requirement of reduced regulations (proposed)

On 16 September 2023, the Minister of the Environment announced its intention to amend the Domestic Substances List (DSL) by the assignment of the letter "P" to certain substances deemed polymers. The DSL is an inventory of substances manufactured in or imported into Canada on a commercial scale. A substance not on the DSL is therefore a new substance in Canada. Under Canadian Environmental Protection Act, 1999 (CEPA), no new substances can be imported into or manufactured in Canada above the prescribed thresholds before an assessment of their potential impacts on human health and the environment has been performed. The DSL contains five different flags for substances; some flags are used for governmental tracking purposes and others indicate that notification requirements may apply. The onus is on the notifier to identify and comply with obligations resulting from any applicable flags or regulations imposed on a substance.

The letter "P" after a substance identifier indicates that the substance, which was subject to subsection 81(1) or 81(2) of CEPA, was assessed and added to the DSL on the basis that it met the Reduced Regulatory Requirement (RRR) polymer criteria; as such it is of low concern, which allows for fewer regulatory information requirements. The purpose of the P flag is also to indicate that any person who intends to manufacture in or import into Canada the flagged polymer in a form that is not considered RRR in a quantity above prescribed thresholds must submit a non-RRR schedule New Substances Notification (NSN).

Part 1 of the DSL is proposed to be amended by adding the letter "P" to 118 substance identifiers. Part 3 of the DSL is proposed to be amended by adding the letter "P" to twenty-seven substance identifiers. These 145 substances have been found to meet the requirements of the reduced regulation in polymer criteria, allowing the letter "P" identifier to be added.

Comments can be made within 120 days of publication of the notice (until 14 January 2024) which will be taken into consideration during the development of the final Order.

More information can be found in the Canada Gazette.

Amendments to regulations on transboundary regulations of electronic waste (consultation)

Canada is proposing to amend certain regulations to comply with changes made to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (the Convention). These changes amended annexes II, VIII and IX, imposing controls on the transboundary movement of all electronic waste (e-waste). The proposed amendments are aimed at enhancing the environmentally sound management of e-waste while facilitating the Convention's implementation (consultation open until 29 November 2023). The amendments do not introduce changes to movements between provinces. A strategic environmental assessment conducted in 2023 concluded that the proposed amendments align with the objectives of the Federal Sustainable Development Strategy. These objectives include ensuring clean and safe water, reducing waste, and strengthening partnerships to promote sustainable development.

The amendments include changes such as incorporating e-waste that does not contain certain components (e.g., circuit boards) into the regulations, thus requiring permits for its transboundary movement. They also prohibit the export of most hazardous waste to non-Organization for Economic Cooperation and Development[6] countries to adhere with the

[6] The Organization for Economic Co-operation and Development (OECD) is a unique forum where the governments of 37 democracies with market-based economies collaborate to develop policy standards to promote sustainable economic growth.

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Convention's amendments. Other changes clarify the requirement for permits to move waste, enable interim operations before disposal or recycling, and expand the definitions of hazardous waste based on certain characteristics.

More information can be found in the Canada Gazette.

United States

Changes to reporting requirements for per- and polyfluoroalkyl substances (published)

The Environmental Protection Agency (EPA) is making changes to reporting requirements for per- and polyfluoroalkyl substances (PFAS) under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act in response to the National Defense Authorization Act for Fiscal Year 2020. PFAS with a lower reporting threshold of 100 pounds will be added to the list of "Chemicals of Special Concern." This means they will be subject to the same reporting requirements as other chemicals of special concern, eliminating certain reporting exemptions and limiting range reporting, providing a more comprehensive picture of PFAS releases and waste management.

The EPA is also removing the de minimis exemption for Supplier Notification Requirements for all chemicals on the list of chemicals of special concern, ensuring that purchasers are informed about the presence of these chemicals in products. This action aims to collect more data on PFAS, benefiting the public, including communities with environmental justice concerns and public water utilities. It will inform future EPA actions under various environmental regulations.

Overall, the goal is to increase data collection on PFAS and other chemicals of special concern, providing more information to the EPA and the public on waste management of these substances. These changes will apply to the reporting year beginning on 1 January 2024.

Penalties are not mentioned in the update.

More information can be found in the Federal Register.

Revamping the "Break Free from Plastic Pollution Act" to hold corporations accountable for the complete lifecycle of their plastic products (published)

On 25 October 2023, U.S. lawmakers reintroduced the "Break Free from Plastic Pollution Act" (the Act), a revamped version of the 2020 and 2021 versions. This legislation aims to combat plastic pollution within the United States, safeguarding both the population and the environment from the adverse effects of corporate pollution. Distinguished from its predecessors, the Act introduces essential policy measures to hold corporate polluters accountable for the complete lifecycle of their plastic products, spanning from production to disposal. The Act implements the "Protecting Communities from Plastics Act," therefore, covered facilities and products are as mentioned in section 204(a) of the same act.

It is not expected that the Act will be enacted into law. If it does, the Act will mandate producers of packaging, containers, and food-service products to spearhead waste and recycling programs, taking charge of design, management, and financing. It will implement a nationwide beverage container refund program to elevate recycling rates and prohibit certain non-recyclable single-use plastic products. Additionally, the Act will outlaw single-use plastic carryout bags, introducing a fee for the remaining bags, a strategy proven effective at the state level. It will enforce minimum recycled content

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requirements for beverage containers, packaging, and food-service products, directing significant investments into U.S. domestic recycling and composting infrastructure.

The legislation will also forbid the export of plastic waste to developing countries and safeguard state and local governments adopting stricter standards. The US Environmental Protection Agency (EPA) will be mandated to collaborate with the National Academies of Science for a comprehensive study on the environmental and public health impacts of incinerators and plastic chemical recycling facilities.

Furthermore, the Act will impose a temporary halt on permitting new and expanded plastic production facilities while the EPA formulates and updates regulations to protect frontline and fence line communities. It aims to broaden the definition of toxic chemicals, prevent their inclusion in covered products, and encourage greater reuse by tracking reusable packaging rates and initiating pilot programs for reuse and refill technology.

Penalties are not explicitly mentioned in the update.

More information can be found in this announcement.

Guidance and instructions for reporting requirements for asbestos and per- and polyfluoroalkyl substances under the Toxic Substances Control Act (published)

In October 2023, the US Environmental Protection Agency (EPA) released guidance and instructions aimed at assisting companies in complying with recently adopted reporting requirements under the Toxic Substances Control Act (TSCA) for asbestos and per- and polyfluoroalkyl substances (PFASs). These rules, in contrast to typical TSCA reporting requirements, do not include common exemptions. Consequently, a broader range of companies, many of which may not be familiar with the intricacies of data submission under this statute, will be subject to these reporting obligations.

Concerning asbestos, the EPA introduced guidance and instructions regarding reporting under TSCA section 8(a)(1). This reporting regulation, finalized in July 2023, applies to entities engaged in the manufacturing, importation, or processing of asbestos between 2019 and 2022, provided their annual sales exceeded $500,000. Notably, this reporting rule covers products containing asbestos, whether it is present as an impurity or part of a mixture. The comprehensive 54-page guidance and instructions outline the scope of the rule, including potential exemptions or reduced reporting requirements. They also provide details on the information that must be submitted, procedures for substantiating claims of confidential business information, and an explanation of the 'known to or reasonably ascertainable' reporting standard. The reporting period for asbestos will run for three months, commencing on 24 February 2024, and concluding on 24 May 2024.

Concurrently, the EPA released a small business compliance guide and instructions to facilitate compliance with the recently implemented reporting rule for PFASs under TSCA section 8(a)(7). This rule mandates that manufacturers and importers of over a thousand distinct PFASs must submit information covering a 12-year period from 2011 to 2022. Unlike several other TSCA reporting requirements, this rule offers no exemptions for small businesses, imported articles, de minimis quantities, byproducts, impurities, polymers, non-isolated intermediates, or research and development compounds. The PFAS instructions specify the entities subject to the rule and provide guidance on potential eligibility for "streamlined" reporting. Additionally, they detail the types of information that companies must provide during the reporting period.

Data submissions will be made via a rule-specific reporting tool on the EPA's central data exchange. This tool offers guidance through the electronic submission process and includes functionality to identify whether certain information has been previously reported to the EPA, thereby preventing duplication of data. Nonetheless, the EPA recommends that

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companies carefully review the reporting requirements for this PFAS rule, even if they have reported under the TSCA chemical data reporting (CDR) rule in the past or were exempt from CDR reporting, to ensure accurate compliance.

Companies have a total of 18 months, until 13 May 2025, to gather the requisite data before a six-month reporting period commences. Small businesses reporting solely on imported articles will receive an additional six months to respond, extending their deadline to 13 November 2025.

Penalties are not mentioned in the updates.

More information can be found in TSCA 8a7 small entity compliance guide and TSCA 8a7 reporting instruction 9-28-23.

Amendment to rule outlining the framework for conducting risk evaluations under the Toxic Substances Control Act (draft)

On 19 October 2023, the US Environmental Protection Agency (EPA) announced a proposal to amend the rule outlining the framework for conducting risk evaluations under TSCA. The risk evaluation process is the second step in EPA's chemical process under TSCA, with the objective of determining whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use. Comments will be accepted until 15 December 2023 following publication at docket EPA-HQ-OPPT-2023-0496.

As required by TSCA amendments made in 2016, EPA finalized a risk evaluation framework rule in 2017, though this was challenged in court and EPA was required to reconsider several provisions of the framework. The 2023 proposed rule includes revisions as per the court's ruling, as well as provisions regarding considering disproportionate harm to overburdened communities, ensuring risks to workers are appropriately evaluated, and a clear requirement for risk evaluations to arrive at a single determination rather than on individual chemical uses. While the majority of amendments proposed apply to EPA's activities in performing risk evaluations, manufacturers and importers will be impacted by the changes when requesting an EPA-conducted TSCA risk evaluation.

More information can be found in this announcement from EPA.

Proposal to ban use of trichloroethylene under the Toxic Substances Control Act (draft)

On 31 October 2023, the United States Environmental Protection Agency (EPA) published a proposal to ban Trichloroethylene (TCE) under the Toxic Substances Control Act (TSCA) with comments due by 15 December 2023. TCE is widely used as a solvent in various industrial, commercial and consumer applications, including for hydrofluorocarbon (HFC) production, vapor, and aerosol degreasing, and in lubricants, greases, adhesives, and sealants.

The EPA recommends the prohibition of all applications of TCE, including manufacture (including import), processing, and distribution in commerce. The TSCA section 6(a) proposed rule aims to address "unreasonable risk" identified in a 2020 risk evaluation by eventually eliminating all of TCE's 54 existing consumer and commercial conditions of use. Considering the health risks to human health proposed by the EPA, TCE will not be allowed to be used, and TSCA will pursue a comprehensive ban on this solvent.

More information can be found in the Federal Register and this proposed rule from EPA.

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OCEANIA

New Zealand

Adjustments to regulations on lead levels in paints (consultation)

The Environmental Protection Authority (EPA) is seeking input from the public regarding potential adjustments to regulations governing lead levels in paints, as well as art materials like chalk, crayons, and felt-tip pens. The primary objective of these proposed updates to group standards[7], which pertain to these products, is to enhance the protection of people's health by reducing the permissible lead levels in paint.

At elevated levels, lead can cause severe health problems, including permanent damage to the brain and nervous system, anemia, and kidney damage. Additionally, it is toxic to plants, animals, and microorganisms. The risk of lead poisoning from currently available paints and graphic materials is already quite low. The proposal to update the group standards is primarily a precautionary measure to ensure that regulations remain as robust as possible and are in alignment with similar international regulatory standards.

The current lead level limit for paint is 0.1% (1000 parts per million/ppm). The proposed changes would reduce this to 0.009% (90 ppm), in line with countries including Australia, Canada and the United States. Further proposed measures include:

- add lead limits to the Corrosion Inhibitors Group Standards
- require evidence of compliance with lead levels where relevant
- update element migration (leaching) limits in graphic materials
- remove the notification requirement from the Graphic Materials Group Standard

The changes will take effect six months after they are officially announced in the Gazette. Any products that do not comply with the new requirements must be disposed of within six months from the date the changes come into effect.

More information can be found in this notice and call for feedback from EPA.

[7] Group standards are essentially sets of approvals and guidelines for handling a category of hazardous substances that share common characteristics, functions, or uses.

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DISCLAIMER