



Global Environmental and Chemical Regulations, Policies, and Standards February 2024

#### 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 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 <a href="mailto:mlawriemunro@iaeg.com">mlawriemunro@iaeg.com</a> or Amanda Myers at <a href="mailto:mamnda.myers@sae.org">mmanda.myers@sae.org</a>.

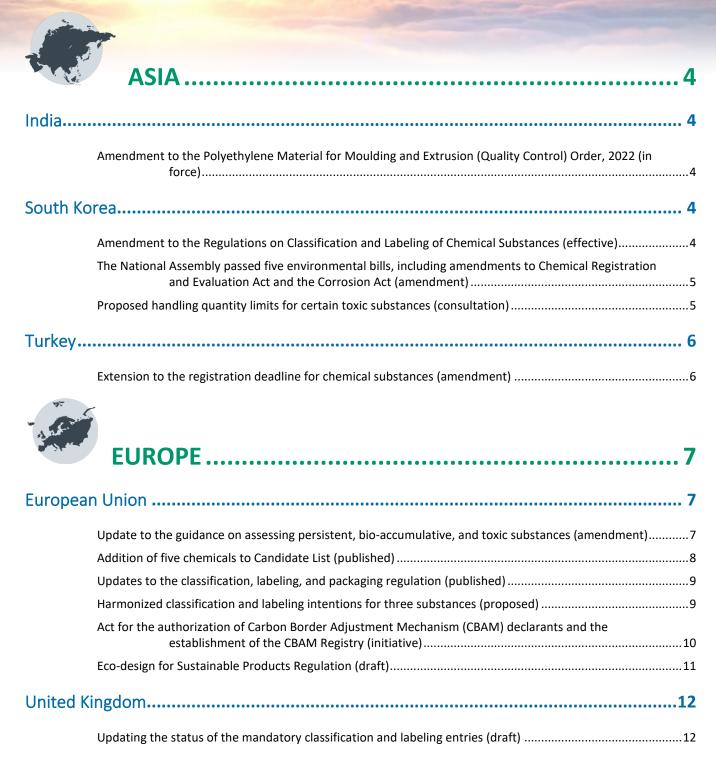
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### India

# Amendment to the Polyethylene Material for Moulding and Extrusion (Quality Control) Order, 2022 (in force)

On 4 January 2024, the Central Government, after consulting the Bureau of Indian Standards, published an Order to amend the Polyethylene Material for Moulding and Extrusion (Quality Control) Order, 2022 (QCO) according to the provision of the Bureau of Indian Standard Act (BIS), 2016. BIS 2016 is an act that aims to provide for the establishment of a national standards body for the harmonious development of the activities of standardization; conformity assessment; quality assurance of goods, articles, processes, systems, and services; and for matters connected therewith or incidental. The QCO was originally planned for implementation in April 2022 but was deferred by the Department of Chemical and Petrochemicals (DCPC) several times following industry requests.

The amendment order exempts the following materials from the QCO:

- » low-density polyethylene extrusion (LDPE) coating
- » LDPE film grades (blown/cast) or pharma
- » linear LDPE butene grades
- » linear LDPE hexene/octene grades
- » metallocene polyethylene grades
- » base resins of power cable, jacketing and other applications
- » compounds for cable jacketing/sheathing/polyethylene-80 and polyethylene-100 (black and pigmented)/reinforcement fillers

The amendment entered into force on 4 January 2024. Penalties for non-compliance include fines and imprisonment.

### South Korea

#### Amendment to the Regulations on Classification and Labeling of Chemical Substances (effective)

The National Institute of Environmental Research (NIER) published <u>Notice No. 2024-4</u> on 10 January 2024 announcing an amendment to the Regulations on Classification and Labelling of Chemical Substances. The amendment, effective immediately, adds new substances, deletes one substance, and includes Unique Numbers (UN), division groups, and hazard classes in the hazardous chemicals labeling list table in Appendix 4. The amendments detailed are as follows:

- » hazard classifications acute toxicity-dermal (3.1), reproductive toxicity (3.7), and specific target organ (3.9) are added to tetraalkyl lead (CAS No. 78-00-2) listed in serial number 97-1-296
- » hazard classifications carcinogenicity (3.6), reproductive toxicity (3.7), and specific target organ (3.9) are added to cobalt lithium manganese nickel oxide (CAS No. 182442-95-1) listed in serial number 2014-1-718



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- » hazard classification serious eye damage/eye irritation (3.3) is added to 1,2-dichloropropane (CAS No. 78-87-5) listed in serial number 2017-1-763
- \* the CAS numbers of strontium chromate (CAS No. 7789-06-2) and sodium chromate (CAS No. 7775-11-3) are corrected among the list of substances in serial number 97-1-271
- the column for acetic anhydride (CAS No. 108-24-7) in the serial number 2023-1-1147 is deleted
- » serial numbers 2023-1-1174 through 2023-1-1212 are newly established with new chemical substances and hazard classes added
- » division group 1B is added to tetrafluoroethylene (CAS No. 116-14-3) listed in serial number 72 in Appendix 4 (accident preparation materials)
- » UN no. 1250 is added to trichloromethylsilane (CAS No. 75-79-6) listed in serial number 92 in Appendix 4

By 1 January 2025, anyone required to label hazardous chemicals according to the updated regulations must ensure that the labeling complies with Article 16 of the Chemicals Control Act. Penalties are not mentioned in the update.

The Regulations on Classification and Labelling of Chemical Substances can be found here in Korean.

# The National Assembly passed five environmental bills, including amendments to Chemical Registration and Evaluation Act and the Corrosion Act (amendment)

The South Korean Ministry of Environment published a <u>press release</u> announcing that five environmental bills, including amendments to the Chemicals Registration and Evaluation Act and the Chemicals Control Act were passed during the National Assembly plenary session on 9 January 2024.

The amendments to the Chemicals Registration and Evaluation Act primarily focus on aligning the registration criteria for new chemical substances with international standards and enhancing transparency in chemical management. Key amendments include:

- » adjustment of the registration criteria for new chemical substances from an annual limit of 0.1 tons to 1 ton
- » introduction of a new procedure for reviewing the adequacy of government-reported data to minimize safety concerns
- » classification of toxic substances into three categories based on their harmful effects

The amendments to the Chemicals Control Act aim to improve the management of hazardous substances and enhance safety measures in chemical handling facilities. Key amendments include:

- » restructuring of the toxic substance designation system to differentiate inspection and diagnosis obligations for handling facilities based on the quantity of chemicals handled and the risk of accidents
- » adjustment of regulations to exclude unnecessary application of handling standards for consumers
- » implementation of a system to convert from permits to notifications for handling chemicals with low quantities or low risks

#### Proposed handling quantity limits for certain toxic substances (consultation)

On 23 January 2024, South Korea's Ministry of Environment (MoE) issued a notice to solicit comments on the proposed handling quantity limits for certain toxic substances (comments due on 12 February 2024). This is a proposed amendment to the Regulation on the Designated Quantities of Hazardous Substances, Restricted Substances, Prohibited Substances, and Permitted Substances, which details hazardous substances that require preparation for accidents. This proposal seeks to



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establish appropriate limits for safe management and control of these substances within South Korea. The affected substances were newly designated on 17 November 2023 with unique numbers from "2023-1-1119" to "2023-1-1174" via the National Institute of Environmental Research Notice (NIER) Notice No. 2023-64.

Under the Korean Chemicals Control Act, a chemical accident prevention management plan must be submitted if the prescribed handling limits are exceeded. If the upper handling limit is exceeded, a Grade 1 chemical accident prevention management plan is required. If the lower handling limit is exceeded, a Grade 2 chemical accident prevention management plan is required.

Additional information can be found here in Korean.

### Turkey

#### Extension to the registration deadline for chemical substances (amendment)

On 23 December 2023, an amendment to KKDIK<sup>1</sup> (Turkey REACH) was officially published. The amendment extends the registration deadlines for chemical substances in Turkey for substances above 1,000 tonnes, longer for other tonnage bands, to address concerns that the chemical industry raised.

KKDIK regulates the administrative and technical procedures and principles regarding the registration, evaluation, permission, and restriction of chemicals to ensure a high level of protection for human health and the environment from harmful chemicals, including the promotion of alternative methods for assessing hazards arising from substances. Manufacturers, importers, and downstream users are responsible for this by ensuring that the production, placing on the market, or use of certain substances has no adverse effect on human health or the environment.

The amendment pushes the registration deadline to December 2026 for substances above 1,000 tonnes, December 2028 for those between 100-1,000 tonnes, and December 2030 for 1-100 tonnes. Carcinogenic, mutagenic, and reprotoxic substances and those very toxic to aquatic life are also subject to the 2026 deadline. In addition, the period for preregistrations has been extended until the end of 2030.

The amendment is relevant to all industries carrying out manufacture, import and use of substances falling under KKDIK. There are no additional penalties associated with this amendment, though penalties for non-compliance with KKDIK after the relevant registration deadlines include fines and legal action.

More information can be found here in Turkish.

<sup>&</sup>lt;sup>1</sup> KKDIK is an acronym in Turkish for Registration, Evaluation, Authorization and Restriction of Chemical



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### **EUROPE**

### **European Union**

Update to the guidance on assessing persistent, bio-accumulative, and toxic substances (amendment)

The European Chemical Agency (ECHA) published on 17 January 2024 an <u>announcement</u> regarding an update to the <u>guidance on assessing persistent, bio-accumulative, and toxic (PBT) substances</u> and included an <u>example of weight of evidence assessment</u>. The guidance describes the information requirements under REACH with regard to properties of substances, exposure, use and risk management measures, and the chemical safety assessment. The guidance aims to help all stakeholders with their preparation for fulfilling their obligations under REACH. This covers detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The update to the guidance aims to reflect the latest scientific developments, revised REACH information requirements, and adaptations from the recent changes to REACH annexes on ecotoxicological information, including recently adopted or revised Organization for Economic Cooperation and Development (i.e., OCED) test guidelines. The main changes are as follows:

- » update of R.11.3.2.2 to provide clarification on the procedure for the inclusion of substances in the Candidate List of Substances of Very High Concern
- » revision of R.11.4.1 on the "Standard Approach" including the weight-of-evidence determination, benchmarking, and reporting of the analytical methods as part of the environmental fate studies
- » R.11.4.1.1 on "Persistence Assessment" and of the corresponding integrated testing strategy described in Section R.11.4.1.1 and Figure R.11-3
- » update of the R.11.4.1.1.3 regarding the degradation half-life derivation
- » update of Section R.11.4.1.2 on "Bioaccumulation Assessment" and of the corresponding integrated testing strategy described in Section R.11.4.1.2.1 and Figure R.11-4
- » introduction in section R.11.4.1.2.2 of text regarding the use of aquatic invertebrate tests (hyalella azteca bioconcentration test)
- » introduction of new section R.11.4.1.2.4 on in vitro biotransformation data and in vitro in vivo extrapolation
- » introduction of new section R.11.4.1.2.8 regarding the assessment of bio-accumulation in air-breathing organisms
- » introduction of the new section R.11.4.2.1.3 regarding volatile substances
- » introduction of the new section R.11.4.2.1.4 regarding substances with nanoforms
- wupdate of the R.11.4.2.2.3 regarding the toxicity assessment for UVCBs<sup>2</sup>
- » deletion of the section of the Appendix R.11—1 regarding indicators for limited bioconcentration for PBT assessment
- » deletion of the Appendix R.11—1 Annex 3 (Examples-use of the indicators for limited bioaccumulation)
- » deletion of the Appendix R.11—2 (Assessment of substances requiring special consideration during testing)

<sup>&</sup>lt;sup>2</sup> Unknown or variable composition, complex reaction products or of biological materials.



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- » introduction of the new Appendix R.11-4 (Approach on NER<sup>3</sup> quantification and characterization in persistence assessment)
- » introduction of the new Appendix R.11- 5 (Comparison of HPLC⁴ and KowWIN⁵ v1.68 QSAR generated log Kow values)
- » introduction of the new Appendix R.11- 6 (Relevance and scientific justification of correction for growth dilution when deriving BCF)
- » introduction of the new Appendix R.11-7 (Volatilization correction approaches for the kinetic analysis of simulation studies)
- » update of cross-references and links to the revised sections of Chapters R.7b, R.7c and the appendices for substance in nanoform

Examples of weight of evidence in PBT assessment were further added. These examples were taken from the Candidate List that explained the basis for the weight of evidence on selected endpoint(s).

Penalties are not mentioned in the update.

#### Addition of five chemicals to Candidate List (published)

On 23 January 2024, the European Chemicals Agency (ECHA) added <u>five new chemicals</u> to the <u>Candidate List</u> of substances of very high concern (SVHC), bringing the total number of entries to 240. Substances that may have serious and often irreversible effects on human health and the environment can be identified as SVHCs. These substances may be placed on the Authorization List in the future. Inclusion on the Authorization List will mean that the use of the substances will be prohibited unless a company receives authorization from the European Commission to continue its use.

The five newly added chemicals are:

- » 2,4,6-tri-tert-butylphenol (CAS No. 732-26-3) added due to being toxic for reproduction and as persistent, bio-accumulative and toxic (PBT) has previously been used in the formulation and manufacture of other substances as well as in fuel products
- » 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol (CAS No. 3147-75-9) added due to its very persistent and very bio-accumulative (vPvB) properties – has been used in coating products, adhesives, and sealants, as well as in washing and cleaning products
- » 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (CAS No. 119344-86-4) added due to being toxic for reproduction has been used in inks and toners
- » bumetrizole (CAS No. 3896-11-5) added due to its vPvB properties used in coating products, adhesives, sealants, and washing and cleaning products
- » oligomerization and alkylation reaction products of 2-phenylpropene and phenol (CAS No. not available) added due to vPvB properties used in adhesives, coating products, modeling clay, and polymers

With the substances being listed on the Candidate List, there are certain obligations:

» article suppliers must notify SVHCs to ECHA's SCIP (i.e., Substances of concern in articles as such or in complex objects [Products]) database under the Waste Framework Directive

<sup>4</sup> High performance liquid chromatography

<sup>&</sup>lt;sup>3</sup> Non-extractable residues.

<sup>&</sup>lt;sup>5</sup> KowWIN method estimates the log octanol-water partition coefficient, log KOW, of chemicals using an atom/fragment contribution method



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- any supplier of articles containing a Candidate List substance above a concentration of 0.1 % (weight by weight) has to give sufficient information to their customers and consumers to allow safe use
- » suppliers of these substances have to provide their customers with a safety data sheet

In addition to the aforementioned obligations, importers and producers of articles had to notify ECHA if their article contains the mentioned substances by 14 December 2023.

Penalties for non-compliance vary by Member State.

#### Updates to the classification, labeling, and packaging regulation (published)

In December 2023, four Harmonized Classification and Labeling (CLH) intentions were withdrawn after the dossier submitter withdrew the intention or a compliance check was required. CLH intentions for <u>silver copper zeolite</u> (CAS No. 130328-19-7), <u>silver zeolite</u> (CAS No. 130328-18-6) and <u>silver sodium zirconium hydrogenphosphate</u> (CAS No. 155925-27-2) have been withdrawn. Sweden submitted the three substances as active substances in biocidal products but withdrew the intentions due to a change of priority.

Also withdrawn was the CLH intention for thiourea/thiocarbamide (CAS No. 62-56-6), submitted under "Chemical registered under REACH" regulatory program. This substance is used as a flame retardant for nylon-based products, as an intermediate in pesticides and fungicides, in ammonia-based fertilizer, and in textile processing. The CLH intention was listed as withdrawn after the need for a compliance check was revealed. The decision on the compliance check required a screening for reproductive/developmental toxicity testing in rates and a prenatal developmental toxicity study with a deadline of 26 April 2023. The resumption of the CLH proposal is dependent on these results.

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

Penalties for non-compliance have not been specified.

#### Harmonized classification and labeling intentions for three substances (proposed)

The latest updates on classification, labeling, and packaging (CLP) harmonized classification and labeling (CLH) proposals include the submission of intentions for three substances:

- » perhydro-1,3,5-trinitro-1,3,5-triazine (EC No. 204-500-1; CAS No. 121-82-4)
- » octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine (EC No. 220-260-0; CAS No. 2691-41-0)
- » mono- and di-phthalate esters with linear and/or branched alkyl moieties with at least one longest continuous carbon chain counted from the ester function corresponding to C4-C6 and/or with C6 cyclic saturated carbon chains and/or with unsaturated hydrocarbyl moieties (mono- and di-phthalate esters etc.; EC and CAS Nos. not available)

Perhydro-1,3,5-trinitro-1,3,5-triazine and Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine are used by professional workers in explosives products, mining and building work, construction work, and for the manufacture of fabricated metal products. There are no registered uses found for mono- and di-phthalate esters etc. The proposed classifications for each substance are below.



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#### Perhydro-1,3,5-trinitro-1,3,5-triazine

- » explosive
- acute toxicity
- » skin corrosion/irritation
- » serious eye damage/eye irritation
- » carcinogenicity
- » reproductive toxicity
- » specific target organ toxicity single exposure
- » specific target organ toxicity repeated exposure

#### Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine

- » explosive
- acute toxicity
- » skin corrosion/irritation
- » serious eye damage/eye irritation
- » carcinogenicity
- » reproductive toxicity
- » specific target organ toxicity single exposure
- » specific target organ toxicity repeated exposure

#### Mono- and di-phthalate esters etc.

- » reproductive toxicity
- » endocrine disruptor for human health
- » endocrine disruptor for the environment

If these proposed classifications are approved, new labeling and packaging requirements might apply to these substances and products containing them.

# Act for the authorization of Carbon Border Adjustment Mechanism (CBAM) declarants and the establishment of the CBAM Registry (initiative)

In January 2024, the European Commission announced the commencement of an initiative, currently in the preparatory phase, aimed at drafting an upcoming act for the authorization of Carbon Border Adjustment Mechanism (CBAM) declarants. This initiative seeks to establish clear procedures and conditions for obtaining authorization as a CBAM declarant, defining communication and processes involving applicants, competent authorities, and the European Commission. Specific details, including the format, deadlines, and rules for identifying CBAM declarants engaged in electricity importation, will be delineated. Simultaneously, another initiative is underway, focusing on the establishment of the CBAM Registry.

CBAM, introduced by Regulation (EU<sup>6</sup>) 2023/956 published on 16 May 2023, and in force since 17 May 2023, imposes a carbon border tariff on carbon emissions during the production of certain carbon-intensive goods listed in Annex I to the regulation, when imported into the EU customs territory. However, third countries and territories outlined in Annex III to the regulation are exempted. CBAM also applies to products held offshore within the ocean territory of an EU Member State and extends to processed items derived from goods manufactured through the inward processing procedure

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<sup>&</sup>lt;sup>6</sup> European Union.



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mentioned in Article 256 of Regulation (EU) No 952/2013, even if the processed products are not listed in Annex I. These items are subject to CBAM upon import into the EU's customs territory or while held offshore within a Member State's ocean territory.

The primary objective of CBAM is to prevent carbon leakage, particularly in cases where consumers purchase substitutes for EU-produced goods from non-EU countries with lower or no carbon pricing, or if companies shift production activities to such countries with lax standards. Covered goods, deemed most susceptible to carbon leakage, include but are not limited to iron, steel, aluminum, hydrogen, and electricity.

The European Commission plans to adopt the forthcoming CBAM act in the third quarter of 2024, following a feedback period that allows interested parties to submit comments and opinions.

#### Eco-design for Sustainable Products Regulation (draft)

The European Parliament and the Council have reached a provisional agreement on the <u>Eco-design for Sustainable Products</u> <u>Regulation</u> aiming to make sustainable products the norm in the European Union (EU). The regulation targets improved product durability, energy and resource efficiency, easier repair and recycling, reduced use of harmful substances, and increased recycled content.

The European Commission (EC), through the new law, will progressively set performance and information requirements for key products in the EU market, prioritizing impactful products such as textiles, furniture, iron, steel, aluminum, tires, paints, lubricants, chemicals, energy-related products, ICT<sup>7</sup> products, and electronics. The regulation covers aspects like product durability, reusability, upgradability, repairability, chemical substances affecting reuse, energy and resource efficiency, recycled content, carbon and environmental footprints, and a Digital Product Passport<sup>8</sup> (DPP). The regulation also addresses the destruction of unsold consumer products, introducing bans, disclosure requirements for large companies, and measures to prevent wasteful practices. It emphasizes providing better information to consumers through tools like the DPP, making sustainability characteristics easily accessible.

The draft regulation takes into account the special requirements affecting products in both the aerospace and defense sectors and acknowledges that eco-design requirements in these industries need to consider the security needs and expected performance needs of these products. The provisional agreement requires formal approval by the European Parliament and Council, after which the regulation will enter into force. The EC will adopt its first working plan within nine months, indicating product groups to be regulated. Delegated acts will specify product-specific requirements with individual transition periods.

More Information can be found in this <u>proposal</u> from the EC.

<sup>&</sup>lt;sup>7</sup> ICT covers any product that will store, retrieve, manipulate, transmit or receive information electronically in a digital form. For example, personal computers, digital television, email, robots.

<sup>&</sup>lt;sup>8</sup> A Digital Product Passport is a tool for collecting and sharing product data throughout its entire lifecycle used to illustrate a product's sustainability, environmental and recyclability attributes.



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### **United Kingdom**

Updating the status of the mandatory classification and labeling entries (draft)

The Health and Safety Executive (HSE) published on 11 January 2024 a proposal to update the status of the Great Britain's Mandatory Classification and Labeling (GB MCL) list for 90 substances. These substances were originally included in the GB MCL list, as they were part of the European Union's (EU) 14th and 15th Adaptations to Technical Progress (ATPs) when the United Kingdom left the EU. However, they ended up not being retained in GB law at the end of the transition period on 31 December 2020. The GB MCL is the equivalent of the EU Classification, Labeling, and Packaging (CLP) List of hazard classifications, both aiming to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures, and articles.

The HSE has now carried out an assessment of these substances and of their EU classification and is proposing to update the GB MCL list according to this assessment. The HSE agrees with the EU classification for 62 of the substances. A final decision now needs to be made by the Ministers. It is expected that, if approved, the entry into force of the updated GB MCL will be April 2024.

More information can be found in this ebulletin and opinion from HSE.

#### Inclusion of diisohexyl phthalate in the UK REACH Authorization List (Annex 14) (recommendation)

The Health Safety Executive (HSE), under Article 58(3) of the United Kingdom (UK) REACH regulation, recommended priority substance diisohexyl phthalate (EC: 276-090-2 and CAS No: 71850-09-4) for inclusion in Annex 14 of UK REACH (i.e., the Authorization List). The draft recommendation for was published in September 2023, with the commenting period closing in December 2023. Under Article 58(3) of UK REACH, the HSE is required to recommend priority substances for inclusion in the UK REACH Authorization List from the UK candidate list of substances of very high concern. The final decision on the inclusion will be made by the Department for Environment, Food & Rural Affairs (Defra) - Secretary of State and the Scottish and Welsh Ministers.

More information can be found in this recommendation and announcement from HSE.

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<sup>&</sup>lt;sup>9</sup> England, Wales, and Scotland.



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### **NORTH AMERICA**

### **Canada**

Final decision on the assessment of calcium naphthenate and naphthenic acids (published)

On 27 January 2024, the Department of Environment (DE) and the Department of Health (DH) in Canada released a <u>final assessment on calcium naphthenates and naphthenic acids</u> (CAS Nos. 61789-36-4 and 1338-24-5, respectively) in accordance with paragraphs 68(b) and (c) of the Canadian Environmental Protection Act, 1999 (CEPA). The CEPA is designed to prevent pollution, safeguard the environment, and protect human health by addressing risks associated with toxic and harmful substances.

The DE and DH determined that these substances do not meet any of the criteria outlined in Section 64 of CEPA. Specifically, they are not entering the environment in quantities or concentrations, nor under conditions, that pose or may pose a danger in Canada to human life or health. Consequently, the DE and DH propose to take no further action on these substances at this time under Section 77 of CEPA.

Penalties are not mentioned in the update.

More information can be found in the Canada Gazette.

Updated assessments for N-methylpyrrolidinone, N-ethylpyrrolidinone and fifteen substances in the Substituted Phenols Group (consultation)

On 27 January 2024, the Department of Environment (DE) and the Department of Health (DH) published updated <u>draft assessments</u> for N-methylpyrrolidinone (NMP, CAS No. 872-50-4) and N-ethylpyrrolidinone (NEP, CAS No. 2687-91-4) under Section 77 of the Canadian Environmental Protection Act (CEPA). A sixty-day consultation period (deadline of 27 March 2024) has been initiated for feedback on the proposed actions and measures outlined in the draft assessments, as well as on the scientific rationale behind these proposals.

NMP, a highly polar organic solvent, is used in a wide variety of applications, including coatings, inks and resins, and lithiumion battery production. NEP, possessing similar properties, is used as a replacement for NMP in many industries including electronics industries.

This draft assessment proposes that NMP meets one or more of the criteria set out in Section 64 of CEPA, specifically under paragraph 64(c), that NMP is entering or may enter 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, further risk management measures should be taken. The DE and DH propose to add NMP to Part 2 of Schedule 1 to CEPA.

Conversely, the DE and DH propose that NEP does not meet any of the criteria under Section 64 of CEPA. As such they recommended to take no further action on NEP at this time, though options are being considered for follow-up activities to track changes in exposure to NEP.



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On 13 January 2024, the DE and DH published an assessment of fifteen substances referred to collectively, under the Chemicals Management Plan, as the <u>Substituted Phenols Group</u> specified on the Domestic Substances List (DSL; Section 77 of CEPA). The assessment concludes that four substances meet one or more of the criteria set out in Section 64 of CEPA. A risk management scope document was released for these substances to initiate discussions with stakeholders on the development of risk management options. These substances are:

- » phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)- (CAS No. 118-82-1)
- » phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- (CAS No. 128-37-0)
- » benzenepropanoic acid, 3-(1,1-dimethylethyl)-4-hydroxy-5-methyl-, 1,2-ethanediylbis(oxy-2,1-ethanediyl) ester (CAS No. 36443-68-2)
- » phenol, styrenated (CAS No. 61788-44-1)

The DE and DH propose that the remaining eleven substances do not meet any of the criteria set out in Section 64 of CEPA, which led them propose no further action on these eleven substances. Comments on the assessments are due on 13 March 2024.

### **United States**

#### New chemicals significant new uses notices and rules (published)

On 22 January 2024, the Environmental Protection Agency (EPA) published findings in the <u>Federal Register</u> of EPA's review of submissions concerning new chemical substances or significant new uses; the reviews confirm the absence of unreasonable risks to human health or the environment. The statements encompass various submissions, including premanufacture notices, significant new use notices, and microbial commercial activity notices submitted in November 2023.

Under the authority granted by the Toxic Substances Control Act (TSCA) Section 5(a)(3), EPA evaluates submissions to determine potential risks posed by new chemical substances or significant new uses. The agency's duty, as mandated by TSCA Section 5(g), necessitates the publication of findings in the Federal Register when it concludes that a new chemical substance or significant new use does not likely present an unreasonable risk of injury to health or the environment. This regulatory framework ensures transparency and accountability in safeguarding public health and the environment.

Penalties are not mentioned in the update.

# New significant new use rule for 329 per- and polyfluoroalkyl chemical substances that are designated as inactive (published)

On 11 January 2024, the Environmental Protection Agency (EPA) published a <u>significant new use rule</u> (SNUR) that strengthens the regulation of 329 per- and poly-fluoroalkyl substances (PFAS) that are designated as inactive on the Toxic Substance Control Act (TSCA) inventory. As such, the new SNUR requires that EPA be notified at least 90 days before commencing any manufacture (including import) or processing of these substances for any use. The EPA exempted from the notice requirement PFAS present as impurities, any byproducts that are not used for commercial purposes, and the importing or processing of inactive PFAS-containing articles "because notification for the commercial activity designation (as active or inactive) on the TSCA Inventory is not required for such substances". Also exempt are PFAS manufactured or



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processed in small quantities solely for research and development, for test marketing purposes, as non-isolated intermediates, or solely for export from the United States, as described in 40 CFR 720.30(e).

PFAS are a group of man-made chemicals that can be found in cleaners, textiles, leather, paper and paints, fire-fighting foams, and wire insulation. They have been used in industry and consumer products since the 1940s because of their useful properties, such as water and stain resistance. Many PFAS break down very slowly and can build up in humans, animals, and the environment over time. Exposure at certain levels to specific PFAS can adversely impact human health and other living things.

This new rule will enter into force from 11 March 2024. Violations of the new SNUR constitute a violation of TSCA and are subject to the associated sanctions and penalties.

More information can be found in the Federal Register and this announcement.

### Mexico

#### Article 283 Bis regarding restrictions on use of asbestos (published)

On 14 November 2023, Elva Agustina Vigil Hernández from the MORENA parliamentary group presented an initiative proposing the addition of Article 283 Bis to the General Health Law. The initiative addresses the health risks associated with asbestos (CAS No. 132207-32-0) exposure, highlighting its historical uses, health hazards, and the need for regulation. The initiative aims to reduce health risks and promote a safe work environment by banning all forms of asbestos in Mexico, emphasizing the substance's carcinogenic properties and the global move towards its prohibition. The initiative outlines asbestos's properties, uses, health risks, and current regulations, advocating for comprehensive measures to eliminate asbestos-related diseases.

Asbestos is a naturally occurring mineral that has been used for thousands of years due to its unique properties, such as heat resistance, corrosion resistance, and durability. However, it has been discovered over time that asbestos poses serious health risks to humans, leading to its prohibition or regulation in many countries. This initiative seeks to reduce health risks and foster a suitable work environment for workers and all inhabitants of the national territory against the risks posed by exposure to asbestos, which is harmful to both public and individual health in any of its forms or presentations.

A detailed analysis is presented on what asbestos is, its types, historical uses, health risks, and current regulations. Asbestos is a generic term referring to a group of fibrous minerals composed mainly of magnesium silicates. The most common types of asbestos include chrysotile, also known as white asbestos, which is the most common and least dangerous type and has been used in products such as asbestos-cement and pipe gaskets. Amphibole asbestos types include crocidolite, amosite, actinolite, anthophyllite, and tremolite, which are more dangerous to health and have been used in applications such as insulation materials and automobile brakes.

The proposal calls for the prohibition of exploiting, producing, importing, exporting, commercializing, or distributing any variety of asbestos and products made with it throughout the national territory. This proposal is in line with the recommendations of international health and labor organizations, such as the World Health Organization and the International Labor Organization, which have advised countries to prohibit all production, work processes, and products



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containing asbestos to eradicate diseases associated with its exposure, such as lung cancer and malignant pleural mesothelioma.

More information can be found here in Spanish.



#### Australia

Changes to the list of chemicals with high hazards for categorization (consultation)

The Australian government opened a consultation period for <u>proposed changes to the list of chemicals with high hazards for categorization</u>. Comments were due on 22 February 2024. This list is a compilation of substances from national and international sources considered to be highly hazardous to human health or the environment. The List, first issued in 2020, provides guidance to manufacturers and importers (introducers) to i) categorize hazard classes for their chemicals based on known information, and ii) prevent any high concern chemicals being categorized as exempted.

Some key changes include:

- removing some information sources from the list
- » removing some entries from the list
- » removing the current requirement to check for esters and salts based solely on the list
- » defining any exceptions that apply for the esters and salts



### **SOUTH AMERICA**

### **Brazil**

Normative Instruction No. 29 sets import controls on hydrofluorocarbons (in force)

On 21 December 2023, the Brazilian Institute of Environment and Renewable Natural Resources (i.e., IBAMA) published Normative Instruction No. 29 that sets the import controls for hydrofluorocarbons (HFCs), in line with Brazil's obligations under the Kigali Amendment to the Montreal Protocol. This Normative Instruction establishes the requirements and procedures related to the import control of HFCs, including mixtures containing HFCs, as well as establishing their respective maximum annual import quotas in tons of carbon dioxide equivalent. Companies importing HFCs will need to submit a valid Certificate of Regularity, as established in IBAMA Normative Instruction No. 13 of 2021, and its successors.



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The import quotas are established in Annexes I and II and the requirements and process for import requests are detailed in articles 4 to 21.

From 1 January 2024, the total stock of HFCs in the country will be divided into a "performance quota", or 90% of total imports. A "technical reserve", or 10% of the annual imports, will also be established for companies that do not have records of import activities between 1 January 2020 and 31 December 2022, while a "specific quota" will be assigned to companies that have imported at least one of the substances listed in Groups I and II of Annex F of the Montreal Protocol in the allotted period.

To use the performance quota or technical reserve, the import request must be registered with IBAMA and the Single Foreign Trade Portal. IBAMA must be informed of annual import activities by 30 April of the subsequent year. Information must also be sent to IBAMA within one month of cancellation if an import is cancelled. There are no exemptions listed for aerospace or defense industries and, as such, all companies importing HFCs into Brazilian territory must comply with this instruction.

The requirements entered into force on 2 January 2024. Failure to comply with the rules established in this Normative Instruction is subject to administrative penalties in addition to other civil and criminal sanctions provided for in current legislation.

Further details can be found in Portuguese in the Official Diary of the Union.



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