CDX Newsletter May 2023

Regulatory updates

Contents

North America

United States

Enhancing Battery Safety: Proposed New Rule for Warning Labels and Packaging

The Consumer Product Safety Commission has proposed a new rule that would require companies manufacturing, importing, or distributing button cell or coin batteries, as well as consumer products containing these batteries, to comply with warning label requirements and packaging standards. This rule is a result of Reese's Law being enacted and aims to improve battery safety. Additionally, companies would need to provide technical and performance data concerning the safety of these batteries at the point of sale, both online and in stores.

To adhere to the rule, companies must ensure that their packaging includes a warning label clearly stating the hazards of ingesting the batteries and advising consumers to seek immediate medical attention if ingestion occurs. The packaging must also indicate that the batteries should be kept away from young children. The comment period for this proposed rule closed on March 13, 2023.

For further information, we encourage you to use this link.

Final Risk Determination for 1-Bromopropane (1-BP) Released by EPA

Companies engaged in the manufacture, processing, import, or use of 1-Bromopropane (1-BP) should be aware that the U.S. Environmental Protection Agency (EPA) has released its final risk determination for this chemical. The determination states that 1-BP poses an unreasonable risk to health under certain conditions of use, such as importing, manufacturing, processing, and use as an industrial solvent. However, the assessment does not consider distribution and use as insulation as contributing factors to 1-BP's unreasonable risk.

If a company handles 1-BP, it may be necessary to provide additional personal protective equipment (PPE) to employees in accordance with the EPA's risk determination. While the EPA's final risk determination does not directly impose requirements on companies, it should be noted that the EPA will issue risk management plans in the future. It is advisable for companies to carefully review the final revisions to 1-BP's risk determination to ensure compliance with the necessary requirements.

Compliance with Proposed HFC Regulations by the EPA

Companies involved in the manufacturing, import, export, packaging, sale, or distribution of products that use or are intended to be used with hydrofluorocarbons (HFCs) are required to comply with the proposed regulations set forth by the U.S. Environmental Protection Agency (EPA). The objective of these regulations is to gradually reduce HFC production by placing restrictions on their usage in specific sectors, introducing technology transitions petitions, and implementing recordkeeping and reporting obligations.

If a company engages in the manufacturing of electronic products or products designed for use with HFCs, it must adhere to the amendments outlined in the Phasedown of Hydrofluorocarbons regulation. This includes implementing on-product labeling, maintaining proper recordkeeping, fulfilling reporting requirements, and submitting technology transitions petitions where necessary.

Please note that strict adherence to these regulations is of utmost importance to avoid penalties and potential legal consequences. It is essential for companies to ensure full compliance with the proposed EPA regulations concerning the use of HFCs.

New Regulations for Shipping Lithium Ion Batteries by Air

Effective from January 20, 2023, companies involved in shipping lithium ion batteries via air transportation are required to adhere to additional regulations established by the U.S. Department of Transportation (DOT). These regulations introduce specific measures, including the prohibition of transporting lithium ion cells on passenger aircraft, the imposition of a maximum state of charge of 30 percent for batteries shipped on cargo-only aircraft, and the implementation of labeling requirements for smaller batteries.

Business impact:

- It is essential to maintain lithium ion cells and batteries below a state of charge of 30 percent when transporting them by air.
- Compliance is necessary with authorized quantity limits, accurate descriptions, certifications, and markings for the transportation of hazardous materials by air.
- The final rule now includes both lithium metal and lithium ion cells and batteries, whereas previous restrictions only applied to lithium metal. Smaller lithium ion cells must display the "LITHIUM ION BATTERIES--FORBIDDEN FOR TRANSPORTATION ABOARD PASSENGER AIRCRAFT" or "CARGO AIRCRAFT ONLY" marking.
- Exceptions are granted for medical devices that use up to two lithium cells or batteries, subject to approval from the Associate Administrator.

For comprehensive details regarding this amendment, please refer to the Enhanced Safety Provisions for Lithium Batteries Transported by Aircraft.

Canada

Screening Assessment: Ethers Group Substances under CEPA

The Department of the Environment and the Department of Health have recently conducted a screening assessment of four substances collectively referred to as the Ethers Group. These substances, namely dimethyl ether (CAS No. 115-10-6), diethyl ether (CAS No. 60-29-7), diphenyl ether (CAS No. 101-84-8), and dipropylene glycol methyl ether (CAS No. 34590-94-8), were evaluated under the Canadian Environmental Protection Act.

Based on the assessment, it has been determined that these substances do not meet the criteria outlined in section 64 of the Act, indicating that they are not harmful to the environment or human health. Consequently, no further action is proposed by the Minister of the Environment and the Minister of Health.

The Ethers Group substances find application in various industries, including automotive, aircraft, transportation, cleaning, fuels, oil and gas, and paints. It is important to note that these substances do not raise any concerns related to non-compliance.

For further details, we recommend consulting the published screening assessment decision for more comprehensive information.

New Regulations for Sulfonic Acids, Sodium Salts: Compliance and Environmental Obligations

Commencing from December 28, 2022, manufacturers and importers of sulfonic acids, specifically branched alkane hydroxy and branched alkene, sodium salts (CAS RN 18520-7), are required to comply with Ministerial Condition No. 21338. This regulation introduces usage restrictions and record-keeping obligations for the first time. If your company is

involved in the manufacturing or importation of sulfonic acids, branched alkane hydroxy and branched alkene, sodium salts (CAS RN 18520-7), please take note of the following requirements:

- Import Restrictions: Importation is only permitted for the purpose of injecting the substance into petroleum reservoirs for oil production operations. This restriction also applies to household cleaning and dishwashing products containing the substance.
- Recordkeeping and Reporting: Manufacturers or users of the substance must provide comprehensive information to the Minister of the Environment at least 120 days prior to manufacturing. This information includes transportation and storage details, as well as container specifications.
- Environmental Responsibility: Prevent spills and promptly report any incidents to the Minister of the Environment to prevent further releases.
- Record Maintenance: Maintain records for a period of five years, including quantities manufactured and imported, specific uses, and recipient names.
- Waste Management: Ensure proper disposal of any waste generated by the substance, following local regulations, through incineration or hazardous waste landfill facilities.

Sulfonic acids, branched alkane hydroxy and branched alkene, sodium salts (CAS RN 18520-7) are commonly found in laundry detergents, dishwashing products, household cleaners, personal care items, textiles, leather, cosmetics, and various manufacturing processes.

For more information, please refer to the Ministerial Condition No. 21338.

Exemption from Reporting Requirements for Substances Added to DSL

Companies engaged in the manufacturing, importing, or use of specific substances listed in Part 1 of the Domestic Substances List (DSL) are now exempt from reporting requirements as mandated by the Canadian Environmental Protection Act 1999 (CEPA). This exemption applies to substances such as CAS RN 128446-60-6, CAS RN 245678-22-2, and CAS RN 2180952-57-0.

Effective from January 23, 2023, companies that utilize or import any of the five substances listed in Part 1 of the Domestic Substances List (DSL), including CAS RN 1462343-28-7, for their own use are no longer obligated to report under the DSL. These substances find common applications in products such as paint and varnish, automotive brakes, laminating and rubber compounding resins, surface coatings, and epoxy resins.

For more information visit Order 2023-87-02-01 Amending the Domestic Substances List.

Australia and Oceania

Australia

Australian Government Implements Changes to IChEMS Register for Eight Chemicals

The Australian government has recently implemented changes to the Industrial Chemicals Environmental Management Standard (IChEMS) Register for eight chemicals. These changes were made following a public consultation period that concluded on December 7, 2022. The IChEMS Register establishes a consistent nationwide approach to the management of chemical use, storage, handling, and disposal, simplifying the process for industries to select less harmful chemicals.

Among the eight chemicals listed, three are classified as persistent organic pollutants (POPs) and are included in Schedule 7. As per this schedule, their importation, manufacture, and use in Australia are prohibited due to their high environmental risk. Two chemicals are listed in Schedules 3 and 2, respectively, while one chemical is listed in Schedule 1. Each schedule outlines specific controls and requirements for the listed substances. The most recent decisions regarding the scheduling of these chemicals can be accessed on the IChEMS Online Register, which provides comprehensive information on the environmental risks associated with the listed chemicals, as well as the corresponding control measures. It is important to note that this update does not specify non-compliance penalties.

Europe

European Union

RoHS Regulation Amendment: Hexavalent Chromium Exemption for Gas Absorption Heat Pumps

On January 26, 2023, an amendment to the European Union (EU) Restriction of Hazardous Substances (RoHS) Regulation was published in the EU Official Journal. This amendment pertains to the use of hexavalent chromium as an anticorrosion agent in gas absorption heat pumps. The RoHS Regulation governs the presence of hazardous substances in electrical and electronic equipment (EEE), and Annex III of the regulation provides a list of exemptions for restricted substances.

The newly introduced exemption, referred to as "Entry 9 (a)-III," permits the use of up to 0.7% hexavalent chromium by weight as an anticorrosion agent in the working fluid of the carbon steel sealed circuit of gas absorption heat pumps used for space and water heating. This exemption is specifically applicable to Category 1 EEE, which includes large household appliances, and it will remain valid until December 31, 2026.

To ensure compliance, EU Member States are required to incorporate this exemption into their national legislation by August 31, 2023. Companies operating within these member states must adhere to the relevant provisions starting from September 1, 2023. It is important to note that there are no specified non-compliance provisions associated with this update, meaning that no penalties or sanctions will be imposed for non-compliance.

For further information, we encourage you to use this link.

Addition of Nine Hazardous Chemicals to the REACH Candidate List

On January 17, 2023, the European Chemicals Agency (ECHA) updated the Candidate List of substances under the REACH Regulation by adding nine hazardous chemicals. These substances are classified as substances of very high concern (SVHC). The newly added substances, along with their CAS numbers, are as follows:

- 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (CAS No. 37853-59-1)
- 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (CAS No. 79-94-7)
- 4,4'-sulphonyldiphenol (CAS No. 80-09-1)

- barium diboron tetraoxide (CAS No. 13701-59-2)
- bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof (CAS No. not available)
- isobutyl 4-hydroxybenzoate (CAS No. 4247-02-3)
- melamine (CAS No. 108-78-1)
- perfluoroheptanoic acid (CAS No. 375-85-9) and its salts
- reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (CAS No. not available)

These substances have various applications, including as flame retardants, in paints and coatings, inks and toners, coating products, plasticizers, and in the manufacture of pulp and paper. SVHCs are substances that can have significant and often irreversible effects on human health and the environment. It is possible that these substances may be included in the "Authorisation List" in the future, which would prohibit their use unless authorized by the European Commission.

The inclusion of these substances on the Candidate List entails certain obligations, which include:

- Article suppliers must notify ECHA's SCIP database under the Waste Framework Directive for SVHCs present in articles.
- Suppliers of articles containing any Candidate List substance above a concentration of 0.1% must provide sufficient information to ensure safe use by their customers and consumers.
- Suppliers of these substances must provide their customers with a safety data sheet.
- Importers and producers of articles must notify ECHA if their articles contain any of the nine substances by July 17, 2023, which is six months from the date of inclusion on the Candidate List.

Penalties for non-compliance vary by Member State. It is crucial to ensure compliance with the respective obligations imposed by the regulations.

For more detailed information, please click on the provided link.

Per- and polyfluoroalkyl substances restriction proposal

National authorities from Denmark, Germany, the Netherlands, Norway, and Sweden have submitted a proposal to the European Chemicals Agency (ECHA) under the EU's chemicals regulation, REACH, for the restriction of per- and polyfluoroalkyl substances (PFASs). The purpose of the proposal is to address the risks associated with the manufacturing, market placement, and use of PFASs. On February 7, 2023, ECHA published the proposal, which will undergo evaluation by the RAC and SEAC committees in March 2023.

The proposal encompasses over 10,000 PFAS substances and offers two options: a complete ban without derogations or a time-limited derogation based on specific uses. Starting on March 22, 2023, a six-month consultation period will commence, allowing stakeholders to provide feedback and input. Additionally, an online information session will be held on April 5, 2023, to further discuss the proposal and address any questions.

For more detailed information, including the list of chemicals covered by the proposal, please refer to the provided link.

Consultation on Proposed Amendment to Regulation (EU) 2019/1021

The European Commission launched a consultation on February 9, 2023, regarding a proposed amendment to Regulation (EU) 2019/1021. This regulation focuses on persistent organic pollutants (POPs) and implements the Stockholm Convention within the European Union. The proposed amendment introduces a new entry in Annex I, specifically addressing perfluorohexane sulfonic acid (PFHxS), its salts, and PFHxS-related compounds. Stakeholders were invited to provide comments on the proposal by March 9, 2023.

PFHxS, its salts, and PFHxS-related compounds are commonly used in various applications, such as paint additives, stain and water-resistant materials, and fire-fighting foams. These substances fall under the broader category of per- and polyfluoroalkyl substances (PFAS). The proposed entry specifies that it encompasses different isomers of PFHxS, its salts, and any substance containing the chemical moiety C6F13S- as a structural element, which degrades to PFHxS, as defined by the Stockholm Convention.

Exceptions to the prohibition of manufacturing, use, and placing on the market apply only to unintentional trace contaminants of these substances. Concentrations of PFHxS or its salts equal to or below 0.025 mg/kg, as well as the sum of concentrations of all PFHxS-related compounds equal to or below 1 mg/kg, are permitted in substances, mixtures, or articles. In concentrated firefighting foam mixtures used in the production of other firefighting foam mixtures, concentrations of PFHxS and PFHxS-related compounds equal to or below 0.1 mg/kg are allowed. Please note that the consultation period has ended, and the information provided is subject to any subsequent updates or revisions by the European Commission.

For more detailed information, please refer to the official website of the European Union, which provides comprehensive information on this topic.

Proposal of New EU Rules on Batteries: Towards a Sustainable and Circular Economy

The European Union (EU) Permanent Representatives Committee has endorsed new regulations on batteries and waste batteries, aligning with the circular economy goals of the European Green Deal. These regulations establish a harmonized framework for the entire life cycle of batteries placed on the EU market, encompassing sustainability, safety, storage, treatment, labeling, and information requirements.

Key highlights of the regulations include:

- Sustainability and Safety Requirements: The regulations introduce sustainability and safety requirements for batteries, including compliance with substance restrictions and specified recycled content for industrial batteries.
- Design Requirements for Portable Batteries: Design requirements are established for portable batteries used in electronic devices to enable easy removal and replacement by end-users. This promotes user convenience and faciliates proper battery management.
- Company Due Diligence Policies: The regulations require companies to adopt due diligence policies addressing raw materials and associated social and environmental risks. This encourages responsible sourcing and supply chain management.
- Labelling, Marking, and Information Requirements: The regulations impose labelling, marking, and information requirements for batteries. This includes the use of symbols indicating separate collection and specific chemical symbols for batteries containing certain metals. These measures promote proper handling and recycling of batteries
- Waste Management Obligations: The regulations establish waste management obligations, including producer registration and the fulfillment of extended producer responsibility. These measures ensure that producers take responsibility for the collection, treatment, and recycling of waste batteries.

The regulations apply to all categories of batteries placed on the EU market, regardless of their origin, and cover batteries designed to be incorporated into products or added to products. They will replace Directive 2006/66/EC and amend Regulation (EU) 2019/1020. Through the implementation of these regulations, the EU aims to foster sustainability, enhance the circular economy, and ensure the responsible management of batteries throughout their lifecycle.

For further details, please refer to the full text of the regulations.

Compliance with Regulation (EC) No 1005/2009 on substances that deplete the ozone layer

Regulation (EC) No 1005/2009 establishes rules for substances that deplete the ozone layer. This regulation covers various activities, including the production, import, export, market placement, use, recovery, recycling, reclamation, and destruction of

ozone-depleting substances (ODS), as well as the import, export, market placement, and use of products and equipment containing these substances. It specifically applies to companies involved in refrigeration, air conditioning, heat-pump, and fire extinguishing equipment.

Companies engaged in these activities must fulfill several obligations under the regulation to ensure compliance, including:

- Import/Export Licenses: Companies must obtain the necessary import/export licenses for controlled substances and products covered by the regulation.
- Leakage and Emissions: Companies are required to address any leakage or emissions of controlled substances, implementing measures to prevent and minimize their release.
- Recordkeeping: Companies must maintain accurate records of controlled substances, including quantities produced, imported, and exported.
- Inspections and Maintenance: Qualified personnel must conduct regular inspections and maintenance of equipment containing controlled substances to ensure proper functioning and minimize leakage.
- Annual Reports: Companies are obligated to submit annual reports detailing their activities related to controlled substances, including quantities handled and any actions taken to prevent and control emissions.
- Prevention of Release: Companies must take measures to prevent the release of ozone-depleting substances in existing buildings and equipment.

For companies planning to produce or import controlled substances for laboratory, analytical, or critical purposes in 2024, registration with the ODS licensing system is required by May 22, 2023. Additionally, they must apply for production or import quotas through the ODS Licensing System by June 22, 2023. It's important to note that these deadlines do not apply to previously registered companies.

Non-compliance with Regulation (EC) No 1005/2009 can result in significant fines and legal consequences. Therefore, companies must ensure full compliance with the regulation's requirements to avoid penalties and meet their obligations in protecting the ozone layer.

Protecting Health and the Environment: Updates on Persistent Organic Pollutants Regulation

Regulation (EU) 2019/1021, effective from June 20, 2019, implements the Stockholm Convention and the UNECE Protocol on persistent organic pollutants (POPs). This regulation aims to protect human health and the environment by restricting and phasing out the production, use, and market placement of POPs. Key updates and requirements of the regulation are as follows:

1. Scope and Requirements:

- The regulation applies to companies engaged in manufacturing, making substances available on the EU market, and/or using substances listed in Annex I (e.g., aldrin, chlordane, DDT, and PCBs) and Annex II.
- Companies must refrain from producing, placing on the market, and using substances listed in Annex I, while complying with defined conditions for substances in Annex II.
- Holders of stockpiles containing prohibited substances must manage them as waste.
- Holders of permitted stockpiles above 50kg are required to provide information on the nature and size of the stockpile to the competent authority of the Member State by July 15, 2020, and subsequently annually.
- Companies must avoid contamination of waste with substances listed in Annex IV and ensure proper disposal or recovery of waste containing POPs.

2. Restricted Substances and Deadlines:

- From September 7, 2025, the manufacture and market placement of perfluorooctane sulfonic acid and its derivatives (PFOS) as a mist suppressant for non-decorative hard chromium (VI) plating in closed-loop systems are prohibited.
- From July 4, 2025, the use of PFOA, its salts, and PFOA-related compounds is banned in specific applications such as semiconductor manufacturing, photographic coatings, medical devices, and fire-fighting foam.

- From July 4, 2023, the use of PFOA, its salts, and PFOA-related compounds in textiles and the production of certain high-performance materials is no longer allowed.

3. Novel Waste Concentration Limits:
- Starting from June 23, 2023, companies disposing of or recovering waste containing substances listed in Annex IV or V must comply with new waste concentration limits for additional substances like Dicofol and Pentachlorophenol, as well as stricter limits for substances already included in these Annexes.

4. Recent Amendment:
- On May 18, 2023, Commission Delegated Regulation (EU) 2023/866 will come into force, amending the PFOA entry in Annex I to review exemptions for the use of PFOA, its salts, and related compounds.

These regulations play a vital role in promoting a safer and more sustainable future. It is essential for companies to familiarize themselves with the requirements and comply with the specified deadlines to ensure their operations align with the regulations.

For more detailed information and specific requirements, we encourage you to refer to the official texts of Regulation (EU) 2019/1021 and the corresponding Commission Delegated Regulations.

Summaries of Decisions Authorizing Placing on Market and Use of Substances in REACH Annex XIV

Companies now have access to two summaries of European Commission Decisions that authorize the placing on the market and use of substances listed in Annex XIV to the REACH Regulation. One of these substances is 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO), which is used in aerospace and defense two-part polysulfide sealants.

Even if a company's products are not directly affected, it may be beneficial to review the summaries of European Commission Decisions on authorizations for placing on the market and use of substances in Annex XIV to the REACH Regulation. These decisions allow certain companies, such as Boeing Distribution Inc. and Haas Group International SP., to use 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated for specific purposes, such as formulating a hardener component in aerospace and defense two-part polysulfide sealants. It is important to note that the use or placing on the market of this substance is prohibited unless the company or its supplier holds a specific authorization.

For further details, please refer to Summary of European Commission Decisions dated on January 11th and January 12th.

Invitation for Comments on Proposed Restriction of Bisphenols

Companies are invited to provide comments on a proposed restriction for the market availability of mixtures and articles containing bisphenol A, other bisphenols, and bisphenol derivatives with endocrine-disrupting properties. The comment period is open until June 22, 2023.

The proposed restriction applies to bisphenol A, other bisphenols, and bisphenol derivatives with endocrine-disrupting properties. Interested companies can submit comments online until June 22, 2023. The restriction applies to mixtures and articles with a concentration of 10 parts per million (ppm) or higher, except for cases where the substances are covalently bound or used as intermediates in polymer manufacturing with no contact with water or a migration limit below 0.04 mg/L. Final opinions from the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) are expected by December 2022, followed by a decision from the European Commission on inclusion in Annex XVII.

For further details, please refer to ECHA website.

Stay Tuned for Upcoming Webinar Information!

If you would like to learn more or discuss how our solutions can help your business grow, please contact the CDX Team at: cdx-info@dxc.com.

Thank you for trusting in CDX!
Your CDX Team