

CDX Newsletter

Regulatory Update Q4/2023

Agenda

Industries List updates	2
Rail Industry Substance List (RISL)	2
IEC 62474 Updates to Declarable Substances List (DSL)	2
Introducing New regulations into the CDX	2
Montreal Protocol on Substances that Deplete the Ozone Layer	2
UK REACH Candidate List	2
TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for PFAS	2
Whitepaper and Webinar	3
Regional Q4 2023 regulatory updates	3
North America	3
United States	3
One Chemical Added to California Proposition 65 Substance List	3
Navigating Changes in California Proposition 65 with CDX	4
Enhanced Reporting and Notification Requirements for PFAS	4
EPA Proposes Revisions to DecaBDE and PIP (3:1) Regulations	4
Canada	5
Canadian Department of the Environment Act: Mandate on Plastic Reporting for 2024-2026	5
Europe	5
Great Britain	5
UK Extends CE Mark Recognition Indefinitely	5
UK Implements Ban on PFHxS under POPs Regulation in Alignment with Stockholm Convention	6
European Union	6
Critical Raw Material: EU on the path to a Sustainable Future	6
REACH SVHC: Five Hazardous Chemicals Added under REACH Regulation and CDX	7
REACH Annex XVII: Amendment to REACH Regarding Synthetic Polymer Microparticles	7
Draft of Regulation on Preventing Plastic Pellet Losses to Reduce Microplastic Pollution	8
ROHS: Exemption for cadmium, lead in PVC applications	8
RoHS Refit: Report of the EU Commission on the Review of the RoHS Directive 2011/65/EU	8
EU Packaging and Packaging Waste: Upcoming regulatory changes	9

Industries List updates

Rail Industry Substance List (RISL)

On February 6, 2024 the [Rail Industry Substance List \(RISL\)](#) received its latest updates. The updated list is now available in CDX (Compliance Data eXchange), providing valuable resources for industry professionals.

The Railway Industry Substance List (RISL) presents a comprehensive and precise overview of prohibited and declarable chemicals in the railway industry. The primary objective of this list is to collect information from suppliers and sub-suppliers regarding materials and substances prohibited or regulated by European or international laws. The list defines and categorizes substances while also offering information on the scope of application where bans or restrictions need to be observed.

IEC 62474 Updates to Declarable Substances List (DSL)

The [IEC 62474 Declarable Substance List \(DSL\)](#) experienced an update on 25th January, 2024, aligning with the European Chemicals Agency's (ECHA) revision of the EU REACH Candidate List. IEC 62474, recognized as the International Standard for material declaration within the electrical and electronics industry, encompasses the DSL specific to the Electrical and Electronic Equipment (EEE) sector, along with requirements and formats for material declaration data exchange, material classifications, and exemption lists. Components of the standard subject to periodic updates, such as the lists, are accessible online through the [IEC 62474 database](#), and revisions are implemented through an expedited process.

Introducing New regulations into the CDX

Montreal Protocol on Substances that Deplete the Ozone Layer

As of January 3, 2024, CDX helps businesses comply with the requirements outlined by the Montreal Protocol on Substances that Deplete the Ozone Layer.

Originally adopted on September 16, 1987, [the Montreal Protocol](#) has become an integral component of CDX. This important international agreement watches over the making and use of about 100 man-made chemicals known as ozone-depleting substances (ODS).

The Protocol encompasses various provisions, including Control Measures (Article 2), Calculation of control levels (Article 3), Control of trade with non-Parties (Article 4), Special situation of developing countries (Article 5), Reporting of data (Article 7), Non-compliance (Article 8), Technical assistance (Article 10), and other pertinent topics. The substances regulated by the treaty are listed in Annexes A (CFCs, halons), B (other fully halogenated CFCs, carbon tetrachloride, methyl chloroform), C (HCFCs), E (methyl bromide), and F (HFCs).

UK REACH Candidate List

Since October, users selling products in the UK can use CDX to take a significant step towards compliance with [the UK REACH Candidate List](#). This comprehensive list identifies substances categorized as 'Substances of Very High Concern' (SVHCs), which may be included in the [UK REACH Authorisation List \(Annex 14\)](#). Since the initiation of UK REACH on January 1, 2021, the UK Candidate List closely mirrors the EU Candidate List up until December 2020. CDX is here to assist you in understanding the obligations associated with the UK REACH Candidate List.

TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for PFAS

CDX incorporates the requirements of the [Toxic Substances Control Act \(TSCA\) Section 8\(a\)\(7\)](#), impacting entities involved in the manufacturing or import of per- and polyfluoroalkyl substances (PFAS) or PFAS containing articles since January 1, 2011. This regulation mandates electronic reporting to the EPA, covering PFAS uses, production volumes, disposal,

exposures, and hazards. Reporting deadlines differ, with the main deadline set for May 8, 2025, and an extended deadline for small article importers until November 10, 2025. The list of PFAS in scope is derived from the EPA proposed rule document.



Whitepaper and Webinar

Recently, the CDX Team, in collaboration with Will Martin, Managing Director of EPR Consulting Ltd, conducted an insightful knowledge session. The session delved deep into the discussion on per- and polyfluoroalkyl substances (PFAS), explored the implications of the new Toxic Substances Control Act (TSCA) Section 8(a)(7) Reporting and Recordkeeping Requirements, and discussed how companies can prepare for these new obligations.

For those who couldn't attend the session in person, the [recorded session](#) and [presentation slides](#) are now publicly available, offering a comprehensive overview of the topics discussed.

In addition, we are pleased to announce the release of our latest whitepaper titled "Decoding PFAS: A Comprehensive Study on TSCA Section 8(a)(7) Reporting and Recordkeeping." This whitepaper provides an in-depth examination of PFAS and the TSCA 8(a)(7) requirements. You can find the whitepaper on our website under the following [link](#).

We believe that the knowledge session, along with the webinar recording and whitepaper, will serve as valuable resources for understanding PFAS and navigating compliance with the TSCA 8(a)(7) requirements.

Regional Q4 2023 regulatory updates

North America

United States

One Chemical Added to California Proposition 65 Substance List

As of December 29, 2023, the Office of Environmental Health Hazard Assessment (OEHHA) has expanded the list of regulated substances under California's Proposition 65 by [introducing Bisphenol S \(BPS\)](#). Bisphenol S (BPS) also known as 4,4'-Sulfonyldiphenol has been identified as substance known to cause reproductive toxicity, specifically affecting the female reproductive endpoint. The warning requirement for exposures to this chemical will come into effect on December 29, 2024.

Bisphenol S (BPS) serves as a crucial component in curing fast-drying epoxy resins, commonly found in printed circuit boards (PCBs), encapsulation materials for safeguarding delicate electronic components, and adhesives. It serves as a substitute for bisphenol A (BPA), which has also been associated with health concerns.

Navigating Changes in California Proposition 65 with CDX

Did you know that the entire supply chain is responsible for implementing California Prop 65 warnings at the products? Manufacturers, distributors, and other stakeholders must ensure effective communication of warning data about Prop 65-listed substances to end customers. This obligation starts with suppliers providing information to manufacturers, who, in turn, relay it to distributors and ultimately reaching the end consumer.. Even if your products are made in the EU, it is your duty to inform the supply chain about presence of any Prop 65 chemicals.

To navigate this complex process, the Compliance Data eXchange (CDX) can be your partner. We provide support in collecting data and analyzing risks, simplifying the compliance journey for your business. If you would like to delve deeper into California Prop 65, we recommend watching our webinar '[California Proposition 65 Evolution & Updates: Whats New & Whats on the Horizon](#)' for further insights.

Enhanced Reporting and Notification Requirements for PFAS

The Environmental Protection Agency (EPA) has recently implemented modifications to the reporting requirements concerning per- and polyfluoroalkyl substances (PFAS) under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act.

With these changes, PFAS will be added to the list of "Chemicals of Special Concern" with a reduced reporting threshold of 100 pounds. This means they will now follow the same reporting rules as other chemicals in this category. This involves removing certain reporting exemptions and limiting range reporting, which improves the overall coverage of information about PFAS releases and waste management practices.

At the same time, the EPA removed the de minimis exemption for Supplier Notification Requirements that applies to all chemicals categorized as chemicals of special concern. This guarantees that buyers receive information about the existence of these chemicals in products. The main goal of these changes is to collect more extensive data on PFAS, providing benefits to the public, especially focusing on communities with environmental justice concerns and public water utilities. The collected data will shape upcoming EPA initiatives within different environmental regulations.

The main objective is to enhance the gathering of data, covering not just PFAS but also other chemicals classified as chemicals of special concern. This provides the EPA and the public with more information on the waste management practices related to these substances. These modifications apply to the reporting year starting on January 1, 2024, and it's crucial to emphasize that no penalties are specified in connection with these updates.

For further details, please refer to the comprehensive information available in [the Federal Register](#).

EPA Proposes Revisions to DecaBDE and PIP (3:1) Regulations

On November 16, 2023, [the EPA proposed revisions](#) to the regulations for decaBDE and PIP (3:1) in response to comments received after the 2021 PBT final rules. The aim is to address implementation issues and minimize human and environmental exposures. Comments on the proposals were accepted until January 8, 2024.

1. DecaBDE:
 - Proposed changes include prohibiting releases to water during manufacturing, processing, and distribution of decaBDE and related products.
 - Labeling is required on plastic shipping pallets containing decaBDE.
 - Compliance for decaBDE-containing wire and cable insulation for nuclear power generation facilities is extended until the end of the component's service life.
 - Export notices are required for decaBDE-containing wire and cable for nuclear power generation facilities.
 - Recordkeeping requirements are increased to five years, and the 30-day timeframe to make records available is removed.

2. PIP (3:1):

- Proposed changes involve narrowing exclusions for PIP (3:1) in lubricants and greases, applying a 5-year phased-in prohibition for non-aerospace uses, and repealing the exclusion for new and replacement parts for motor and aerospace vehicles.
- For motor vehicles, a 15-year prohibition on the use of PIP (3:1) and PIP (3:1)-containing products in new and replacement parts will be implemented.
- Distribution of PIP (3:1) and related products for use in replacement parts for motor vehicles is allowed for an additional 15 years.
- The exclusion for new and replacement parts for aerospace vehicles is replaced with a 30-year phased-in prohibition for new parts and service life duration for replacement parts.

The proposed rules impact those involved in the manufacture, processing, distribution, or use of decaBDE or PIP (3:1) and PIP (3:1)-containing products or articles. Industries potentially affected include Aircraft Manufacturing, Automobile Manufacturing, Motor Vehicle Parts Manufacturing, Construction Machinery Manufacturing, Electronic Computer Manufacturing, and Communications Equipment Manufacturing.

Canada

Canadian Department of the Environment Act: Mandate on Plastic Reporting for 2024-2026

The Canadian Department of the Environment issued a significant notice, titled "[Notice of Intent to Issue a Notice under Section 46 of the Environmental Protection Act](#)," regarding the reporting of specific plastic products for the years 2024, 2025, and 2026. Published on December 30, 2023, this notice proposes mandatory reporting obligations for producers within the outlined timelines.

Obligated producers will be required to report detailed information on various plastic resins (PET, LDPE, HDPE, PVC, PP, PS) and/or plastic products to the authority. The information includes identity, source of the resin, and quantity. Affected product categories encompass Packaging, Electrical and Electronic Equipment (EEE), Tires, Construction, and Automobiles, among others. It is essential for obligated producers to maintain records of the submitted data for a period of 3 years. The reporting deadline for the previous year is set for September 29, with the initial reporting due on September 29, 2025, for the year 2024. This initiative aims to collect crucial data to effectively manage plastic pollution and formulate sustainable policies for the responsible use and management of plastics.

Europe

Great Britain

UK Extends CE Mark Recognition Indefinitely

The United Kingdom (UK) has recently revised its [guidance on the UK Conformity Assessment \(UKCA\)](#) marking. Currently, products meeting the European Union's (EU) requirements, including those with the CE (European Conformity) marking, can be introduced into the Great Britain (GB) market until December 31, 2024. However, the UK is working on new legislation to extend this recognition indefinitely. The proposed extension aims to ensure the ongoing availability of certain EU-compliant products in the GB market beyond December 31, 2024, without a specified end date. These changes specifically impact the eighteen regulations under the Department for Business and Trade (DBT), affecting various Aerospace and Defense (A&D) relevant products. These products include, but are not limited to:

- 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
- Aerosol dispensers
- Low voltage electrical equipment

Furthermore, specific regulations apply to construction products, civil explosives, marine equipment, cableways, eco-design, transportable pressure equipment, and hazardous substances (RoHS). Depending on the risk profile of products, manufacturers may employ either self-declaration of conformity or third-party conformity assessment procedures. Updates to technical documentation, record-keeping, and the UK Declaration of Conformity were implemented on 3 October 2023, with no associated penalties.

UK Implements Ban on PFHxS under POPs Regulation in Alignment with Stockholm Convention

The UK has put a [new rule](#) in place to stop the use of a chemical called perfluorohexane sulfonic acid (PFHxS) under its Persistent Organic Pollutants (POPs) law. This decision follows an international agreement known as the Stockholm Convention. Starting from November 16 2023, people in the UK can't use, make, or sell PFHxS in Great Britain. It's important to know that this rule doesn't apply to Northern Ireland. This ban is part of a worldwide agreement made by many countries through the Stockholm Convention.

European Union

Critical Raw Material: EU on the path to a Sustainable Future

On December 12th, 2023, the EU Parliament approved a "[Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials.](#)" This proposal aims to boost the EU's competitiveness by reducing reliance on third countries for critical raw materials. Its primary objectives include supporting the development of alternative materials and fostering environmentally-friendly mining and production methods.

This regulation sets targets for 2030:

- The Union extraction capacity must be capable of extracting a minimum of 10% of the Union's annual consumption of strategic raw materials.
- The Union processing capacity should produce at least 40% of the Union's annual consumption of strategic raw materials.
- The Union recycling capacity must generate a minimum of 25% of the Union's annual consumption of strategic raw materials, with the ability to recycle increasing amounts of each strategic raw material in waste.
- No third country should supply more than 65% of the Union's annual consumption.

The current list of strategic raw materials comprises 17 materials, including Lithium and Manganese (battery grade), Nickel, and Tungsten. The regulation also addresses the recyclability of permanent magnets. To facilitate recycling, marketers of various products, such as magnetic resonance imaging devices, wind energy generators, and electric motors, must label their products, specifying whether they incorporate permanent magnets and, if so, whether the magnets contain specific materials.

Furthermore, the recycled content of the materials listed above, obtained from post-consumer waste and present in permanent magnets of the specified products, must be disclosed on a public website. The law also mandates declaring the environmental footprint of certain critical raw materials. Within 18 months of the regulation coming into force, the Commission will provide a report prioritizing critical raw materials for assessing the necessity and proportionality of declaring their environmental footprint. This comprehensive regulatory framework will likely impact the manufacturing industry and final producers, driving increased demand for locally sourced and recycled materials. Consequently, industries may need to adapt their supply chains and sourcing strategies, potentially influencing the pricing of raw materials and products. Additional rules will be developed accordingly.

REACH SVHC: Five Hazardous Chemicals Added under REACH Regulation and CDX

On 23 January 2024, the European Chemicals Agency (ECHA) has made a [significant update to the EU Candidate List of substances under the REACH Regulation](#). This update highlights the inclusion of five hazardous chemicals, now classified as substances of very high concern (SVHCs).

Substance Name	EC Number	CAS Number	Reason for Inclusion
2,4,6-tri-tert-butylphenol	211-989-5	732-26-3	Toxic for reproduction (Article 57c) Persistent, bioaccumulative and toxic (PBT) (Article 57d)
2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol	221-573-5	3147-75-9	Very persistent and very bioaccumulative (vPvB)
2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	438-340-0	119344-86-4	Toxic for reproduction (Article 57c)
Bumetrizole	223-445-4	3896-11-5	vPvB (Article 57e)
Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	700-960-7	-	vPvB (Article 57e)

Key points to note:

- **Legal Obligations:** Companies must adhere to legal obligations when their substance is included in the Candidate List, whether on its own, in mixtures, or in articles.
- **Information Disclosure:** Suppliers must inform customers and consumers if an article contains a Candidate List substance above a concentration of 0.1% (w/w), providing guidance on safe usage.
- **Notification Requirements:** Importers and producers of articles must notify ECHA if their article contains a Candidate List substance within six months from the inclusion date (23 January 2024).
- **Safety Data Sheet Updates:** EU and EEA suppliers of substances on the Candidate List in mixtures must update safety data sheets provided to customers.
- **Waste Framework Directive:** Companies must notify ECHA if articles contain substances of very high concern above 0.1% (w/w) under the Waste Framework Directive.

The CDX has already been updated to incorporate this substance within the REACH SVHC Candidate List.

REACH Annex XVII: Amendment to REACH Regarding Synthetic Polymer Microparticles

[Commission Regulation \(EU\) 2023/2055](#), adopted on September 29, 2023, introduces amendments to Annex XVII of REACH, focusing on synthetic polymer microparticles. This regulatory change, effective from October 17, 2023, imposes restrictions on the intentional addition of synthetic polymer microparticles to products under the EU chemicals legislation REACH. Notably, it prohibits the sale of microplastics and products intentionally containing microplastics that release these

particles during use. The ban encompasses all insoluble synthetic polymer particles with a size less than 5mm, resistant to degradation, and will have widespread implications, particularly affecting medical devices.

Suppliers now have an obligation to annually report their estimated microplastic emissions. Additionally, they must provide clear instructions on product usage and disposal methods to prevent the escape of microplastics into the environment.

This Regulation introduces a new layer of mandatory material and product data requirements, specifically focusing on microplastics, including the size of synthetic polymer particles. The impact of these rules is substantial, particularly affecting industries such as cosmetics, medical devices, and toys. Companies within these sectors will need to adapt to the new reporting and compliance measures to align with the amended regulations.

Draft of Regulation on Preventing Plastic Pellet Losses to Reduce Microplastic Pollution

As of October 16, 2023, the European Commission has put forth [a proposed regulation](#) to prevent plastic pellet losses and reduce microplastic pollution. A feedback period has been opened until January 4, 2024, and it is continually extended until the adopted proposal is available in all European Union (EU) languages. This regulatory initiative stems from the Microplastics Pollution Initiative, initially addressing synthetic textiles, tires, and plastic pellets. The current proposal now focuses solely on plastic pellets, as it was deemed that plastic pellet losses from textiles and tires could be more effectively managed through alternative measures. Notably, the proposal aims to complement the above mentioned Annex XVII REACH restriction on intentionally added microplastics.

The proposed regulation applies to economic operators handling plastic pellets in the EU, exceeding five tonnes in the previous calendar year, along with EU and non-EU carriers transporting plastic pellets within the EU. The objective is to build upon existing voluntary approaches initiated by the industry through Operation Clean Sweep, where companies acknowledge the importance of eliminating pellet losses and commit to adopting best practices.

The proposed regulation is set to become effective 18 months after its entry into force, with the obligation to avoid losses and take immediate cleanup measures applicable from the date of entry into force. Penalties for non-compliance will be determined by Member States and may include fines proportionate to the turnover or income of the infringing party, as per Article 15.

ROHS: Exemption for cadmium, lead in PVC applications

[The European Commission has granted an exemption](#) allowing the use of lead and cadmium in electrical and electronic windows and doors containing recovered polyvinyl chloride (PVC). The amendment to the EU Directive on the restriction of hazardous substances (RoHS) in electrical and electronic equipment, officially published on January 10 in the EUs Official Journal, permits this specific use until May 28, 2028.

This provision comes into effect on January 30 and applies uniformly across all EU member states from August 1. According to RoHS regulations, lead is restricted to a maximum concentration of 0.1%, and cadmium has a maximum concentration of 0.01% by weight in homogeneous materials.

Lead and cadmium are utilized in recovered PVC frame material for window and door sets to enhance the polymer stabilization of the profiles. A technical and scientific assessment study, conducted to evaluate the requested exemption, revealed that although lead- and cadmium-free virgin PVC is available, the use of recovered PVC requires lower amounts of energy and natural resources than virgin PVC.

RoHS Refit: Report of the EU Commission on the Review of the RoHS Directive 2011/65/EU

The [EU Commission has released a report](#) assessing the potential revision of the EU RoHS Directive 2011/65/EU. This report reflects the outcomes of a comprehensive review of the Directive, evaluating its relevance, effectiveness, efficiency, coherence, and EU added value. The Commission's overall assessment indicates that the RoHS Directive is functioning

effectively, maintaining control over hazardous substances in electrical and electronic equipment (EEE) and ensuring a level playing field for EEE producers.

EU Commission believe that there are areas for improvement have been identified, particularly concerning the transparency and efficiency of the exemption process, as well as the updating of substance restrictions under the Directive. Instead of a complete recast, the Commission suggests a targeted improvement approach. One key proposal is to transfer the responsibility for the technical assessment of time-limited exemptions and the review process of the restricted substances list to the European Chemicals Agency (ECHA), a shift from the current Commission-led process with external consultants. This change aims to enhance transparency and address potential interactions with other chemicals legislation, such as REACH.

EU Packaging and Packaging Waste: Upcoming regulatory changes

The European Parliament took a pivotal step towards sustainability on November 22, 2023, by adopting its position on the ["Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste."](#) This proposal, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, while repealing Directive 94/62/EC, signifies a shift from the current EU Directive's end-of-life focus towards a more holistic approach that considers the entire life cycle of packaging.

The Council reached a consensus on the proposal on December 18, 2023. The envisaged rules introduce obligations aimed at enhancing the sustainability of packaging, emphasizing recyclability, minimizing the presence of substances of concern, and improving consumer awareness through labeling.

Key Provisions Include:

1. **Substances in Packaging:** The proposal mandates minimizing the presence and concentration of substances of concern. By December 31, 2026, a joint report by the Commission and the European Chemicals Agency will assess the negative impact of such substances on material re-use and recycling, potentially leading to further restrictions.
2. **Recyclability Requirement:** All packaging placed on the market must be recyclable. Implementing acts will define the conditions for packaging to meet the recyclability criteria.
3. **Recycled Material Content:** Starting in 2023, 35% of any plastic part of packaging must be from recycled material obtained from post-consumer plastic waste. This percentage increases to 65% by December 2026. The Commission will establish the methodology for calculating and verifying the recycled content percentage.
4. **Mandatory Labelling:** Packaging must be labeled with its material composition, and a mark indicating the share of recycled content will become mandatory. The Commission will adopt implementing acts to standardize labeling requirements and formats.

This regulation affecting all industries involved in packaging, including packaging manufacturers and manufacturers/sellers of products in packaging. The regulatory changes underscore a collective commitment to fostering sustainability and environmental responsibility across the packaging supply chain.

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@dxs.com.

Thank you for trusting in CDX!
Your CDX Team

Newsletter has been obtained in collaboration with