

CDX Newsletter

Regulatory Update Q1/2024

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Asia

China

Amendments to the Management of Ozone Depleting Substances (ODS) (in force)

On January 5, 2024, the Chinese State Council [published amendments](#) to the regulations on the management of ozone depleting substances (ODS). The amendments entered into force on March 1, 2024. The updated Regulations lay down rules on the production, import, export, placing on the market, use, recovery, recycling, reclamation, and destruction of ODS. They also cover reporting requirements related to these substances, as well as the import, export, placing on the market, and use of products and equipment containing or relying on ODS. The ecological department of the State Council has been made responsible for the supervision and management of ODSs, alongside the local government in their administrative areas.

Key Highlights:

- Ban on the use of ODSs that have been phased out in China.
- Facilities producing or using large quantities of ODSs are now required to install ODS monitoring equipment.
- Offenders face fines between 20,000 and 200,000 RMB for non-compliance. Failure to rectify issues may result in an order to suspend production or business.

The amendments aim to ensure China's implementation of the Kigali Amendment to the Montreal Protocol on Ozone Depleting Substances, as well as strengthen the overall management of ODSs in the country.

Japan

Restricting PFOA and Related Compounds (proposal)

The Japanese government has [proposed](#) new measures to restrict the manufacture, import, and use of perfluorooctanoic acid (PFOA), its salts, isomers, and related compounds. This follows the addition of PFOA to the annex of the Stockholm Convention on persistent organic pollutants.

The proposed measures, opened for public consultation until March 1, 2024, would designate PFOA and its related substances as Class 1 Specified Chemical Substances under Japan's Act on the Regulation of Chemical Substances. This would prohibit their manufacture, import, and use without prior approval. The measures also include specific restrictions on the use of PFOA-containing products like floor wax.

Non-compliance with the proposed PFOA regulations would constitute a violation of the chemical substances law.

Japan publishes Guidance on Chemical Import Clearance Procedures (information)

Japan's Ministry of Economy, Trade and Industry (METI) has released an English guidance document detailing the import clearance procedures for chemical substances under the country's Chemical Substances Control Law (CSCL). The CSCL aims

to prevent environmental pollution and protect human health through risk management of chemicals before and after they are placed on the market. The new guidance covers the import requirements for:

- Existing, publicly notified, monitoring, and priority assessment chemical substances
- Class I and Class II specified chemical substances
- New chemical substances
- Products containing Class I specified substances

The guidance includes a list of products containing Class I specified substances, such as surface treatment agents and products with PFOS or PFHxS, that are prohibited from importation. It also provides details on the required forms and documents for import clearance.

This guidance is an important resource for chemical importers to ensure compliance with Japan's CSCL regulations.

Ministry of Economy, Trade and Industry (METI), "[Guidance on Import Clearance Procedures for Chemical Substances under the Chemical Substances Control Law \(CSCL\)](#)," March 7, 2023.

Expanding PFHxS Regulations (consultation)

Japan is also proposing updates to its labeling and handling standards for firefighting products containing perfluorohexane sulfonic acid (PFHxS), its isomers, or their salts.

The [public consultation](#) on these draft proposals runs until March 11. If approved, companies would need to label PFHxS-containing products with details like the substance name, concentration, and handling precautions. Technical standards for storage, transfer, and record-keeping of these firefighting products would also be established.

This aligns with Japan's previous designation of PFHxS and related substances as Class 1 Specified Chemical Substances, banning their manufacture and import as of February 2023.

The proposed measures aim to further restrict PFOA, PFHxS, and related "forever chemicals" in line with global efforts to address the environmental and health impacts of these persistent compounds.

North America

United States

Asbestos Ban: Final Rule Published Under TSCA (final)

After 30 years, the U.S. Environmental Protection Agency (EPA) has [finalized a rule](#) to prohibit the manufacturing (including importing), processing, distribution in commerce, and commercial use of chrysotile asbestos in the United States.

Chrysotile asbestos is found in products including asbestos diaphragms, sheet gaskets, brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets.

Key Highlights:

- Bans the import of asbestos for chlor-alkali use (used in diaphragms to disinfect drinking and wastewater) immediately, while allowing a transition period of up to 12 years for facilities to convert to non-asbestos alternatives.

- Bans the use of asbestos in oilfield brake blocks, aftermarket automotive brakes and linings, other vehicle friction products, and other gaskets within 6 months of the rule's effective date.
- Phases out and bans most sheet gaskets that contain asbestos.

The first bans will take effect as early as November 25, 2024, impacting industries such as chemical manufacturing, metal product manufacturing, gasket/packing production, and automotive parts.

While asbestos use in the U.S. has declined for decades, this final rule under the Toxic Substances Control Act marks a historic milestone in protecting public health by eliminating ongoing exposures to this known carcinogen.

Initiation of Prioritization Under the Toxic Substances Control Act (TSCA) (consultation)

On December 18, 2023, the US Environmental Protection Agency [published](#) the "initiation of and soliciting public comment on the prioritization process for five chemical substances as candidates for designation as High-Priority Substances for risk evaluation under TSCA". The following substances are affected:

- Acetaldehyde (not yet regulated under REACH)
- Acrylonitrile (not yet regulated under REACH)
- Benzenamine (not yet regulated under REACH)
- Vinyl Chloride (restricted under REACH Annex XVII)
- 4,4'-Methylene bis(2-chloroaniline) (MBOCA) (SVHC list and Annex XIV under REACH)

The public commenting period ended on March 18, 2024.

Affected companies/industries:

The three substances which are currently not regulated under REACH (Acetaldehyde, Acrylonitrile and Benzenamine) are used throughout different industry sectors. Acetaldehyde is primarily used as an intermediate in the manufacture of a range of chemicals, perfumes, aniline dyes, plastics and synthetic rubber, and in some fuel compounds. Acrylonitrile is used in the manufacture of acrylic fibers, plastic surface coatings, adhesives, and synthetic rubbers, while Benzenamine is used in rubber accelerators and anti-oxidants, dyes and intermediates, in explosives as well as petroleum refining.

However, the announcement has no direct impact as the prioritization process aims at identifying substances which will undergo risk evaluation by the EPA.

This publication shows once again that compliance with the European Union's chemicals regulations (i.e. REACH) is not sufficient for companies with global supply chains. Other regions of the world may put substances in focus which are currently not regulated in the EU. For a comprehensive materials and substance management program, companies need to monitor and evaluate regulations on a global scale.

Canada

Proposed Regulatory Review of Aluminum-Containing Substances (draft)

On January 27, 2024, the Government of Canada [published a Draft Assessment for a group of Aluminum-containing Substances](#), as well as a Risk Management Scope specifically for Aluminum hydroxychloride.

Key Highlights:

- Aluminum hydroxychloride is a widely used compound, primarily in cosmetic products and water treatment applications.
- The consultation period for the draft assessment ended on March 27, 2024, allowing stakeholders to provide feedback and input.
- Currently, aluminum-containing substances, including aluminum hydroxychloride, are not regulated under the EU REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) framework.

The publication of this draft assessment represents an important step in the regulatory review process for aluminum-containing substances. As the consultation period has now closed, regulatory authorities will review the feedback received and determine the appropriate next steps, which may include the development of new regulations or the refinement of existing ones. Stakeholders in relevant industries are encouraged to stay informed about the progress of this assessment and any potential regulatory changes that may arise from it.

Assessment Published for Low Boiling Point Naphthas Group (LBPNS) (draft)

On March 16, 2024, the Government of Canada [published the Draft Assessment and Risk Management Scope for the Low Boiling Point Naphthas Group \(LBPNS\)](#). This group of 27 petroleum substances is used in a variety of consumer products such as paints, inks, automotive care products, plastics and rubber.

Key Highlights:

- 17 LBPNS substances may be harmful to human health due to skin contact and/or inhalation exposure from consumer products.
- 10 LBPNS substances with no identified uses in consumer products are not harmful to human health.
- None of the 27 LBPNS substances are harmful to the environment at current exposure levels.

The Risk Management Scope outlines potential regulatory and non-regulatory measures to reduce dermal and inhalation exposures for the 17 LBPNS substances identified as harmful to human health. These may include restrictions, labeling requirements, or other risk mitigation actions.

The final assessment and proposed risk management approach is anticipated to be published in March 2025. If the proposed conclusions are confirmed, the 17 harmful LBPNS substances may be added to Schedule 1 of the Canadian Environmental Protection Act, subjecting them to pollution prevention and notification/consent requirements.

It's important to note that **LBPNS are currently not restricted under the EU REACH regulation**, but are subject to the Classification, Labeling and Packaging (CLP) Regulation and may be restricted under other EU product-specific regulations like the Cosmetics Products Regulation.

Stakeholders are invited to provide comments on the Draft Assessment and Risk Management Scope during the public consultation period, which is open until May 15, 2024.

Implementation Framework for a Right to a Healthy Environment in the CEPA (consultation)

In June 2023 the Canadian government adopted Bill S-5, the Strengthening Environmental Protection for a Healthier Canada Act, which amends the Canadian Environmental Protection Act, 1999 (CEPA) to include a right to a healthy environment. The

government has [now published a discussion document](#) outlining an implementation framework for this new right. The Document was open for a public comment period ending on April 8, 2024

Key Highlights:

- The government is developing an implementation framework to set out how the right to a healthy environment will be considered in the administration of CEPA.
- The existing chemical management regime under CEPA will be updated, including changes to risk assessment, public accountability, and the management of toxic and new substances.
- A Plan of Chemicals Management Priorities (PCMP) will be developed by June 2025, considering stakeholder input, public comments, and the toxicity of substances.
- The amendments emphasize the importance of considering vulnerable populations and cumulative effects in risk assessments.
- The classification and management of high-risk toxic substances will be modified, with the potential for prohibition of the most hazardous substances.
- The finalization of the implementation framework is planned for mid-2025.

Implications for Industry:

- The changes will affect not only the chemical industry, but also any companies and industries that process, use, or trade chemical substances.
- Classification, labeling, and other obligations related to toxic and hazardous substances are likely to be updated, requiring companies to adapt to the new rules.

Companies should closely monitor the development of the implementation framework and be prepared to update their processes and procedures to ensure compliance with the new requirements under the amended CEPA.

Europe

Great Britain

UK Initiates Call for Evidence on PFAS in Firefighting Foams (consultation)

The Health and Safety Executive (HSE) has launched a call for evidence on per- and polyfluoroalkyl substances (PFAS) in firefighting foams. This is part of the preparation of a restriction dossier that the UK REACH authority expects to finalize within a year. The [consultation, announced on April 4th](#), comes as the HSE concludes its 2023-24 work program, which included the commitment to prepare the restriction dossier. Stakeholders have until June 3rd to submit their comments.

The HSE has invited stakeholders to provide information on the use, manufacture, import, and distribution of firefighting foams containing PFAS, as well as the transition away from these foams and the suitability of alternatives. After receiving the stakeholder input, the HSE plans to engage in follow-up discussions, and any proposed restrictions will undergo further review and commentary.

UK HSE Adding Diisohexyl Phthalate to REACH Authorization List (recommendation)

The UK Health and Safety Executive (HSE) has finalized its [recommendation to add the substance of very high concern](#) (SVHC) diisohexyl phthalate to the authorization list under UK REACH. This is the third substance the agency has designated for Annex 14 of the UK's chemical regulations since Brexit.

The final recommendation follows the HSE's draft opinion in September 2023 and a three-month public consultation period that ended in December. Appropriate authorities, including the Secretary of State for the Department for Environment, Food and Rural Affairs (Defra) and the Scottish and Welsh ministers, will now make the final decision on including diisohexyl phthalate in the authorization list.

Diisohexyl phthalate is identified as an SVHC under Article 57(c) of UK REACH due to its classification on the GB Mandatory Classification and Labelling (MCL) list as toxic for reproduction, category 1B. The substance was also included in the EU candidate list in 2020.

The HSE noted that there are currently no registrations for diisohexyl phthalate under either EU or UK REACH. However, it is considered a potential replacement for other phthalates already recommended for or included in Annex 14, such as for use as a plasticizer in polymers. The agency is recommending its addition to the authorization list to avoid regrettable substitution. During the public consultation, the HSE received only one comment, which supported the inclusion of diisohexyl phthalate in the authorization list.

European Union

On January 20, 2024, the European Union published two important new regulations aimed at protecting the environment - Regulation (EU) 2024/590 on ozone-depleting substances (ODS) and Regulation (EU) 2024/573 on fluorinated greenhouse gases (F-gases).

Regulation (EU) 2024/573 on Fluorinated Greenhouse Gases (in force)

The European Union has adopted a new regulation, [Regulation \(EU\) 2024/573](#), which will replace the previous Regulation 517/2014.

Key Highlights:

- The regulation limits the amount of greenhouse gases that can be sold in the EU.
- The regulation bans the use of these greenhouse gases in several product categories, including refrigerators, chillers, air conditioners, foams and others
- The list of affected products and equipment has been greatly expanded and is detailed in Annex IV of the regulation.

Phase-Out of Hydrofluorocarbons (HFCs)

The European Parliament and EU Council of Ministers have formally adopted this revised EU F-gas regulation, which will provide for a complete phase-out of hydrofluorocarbon (HFC) consumption by 2050.

The regulation includes specific phase-out dates for the use of F-gases in certain products, such as:

- Heat pumps and air conditioning units by 2035
- Medium and high voltage switchgear by 2030 and 2032

The European Commission is required to review the effects of the regulation, including an assessment of the existence of alternatives to replace F-gases, by 2030.

This new regulation marks a significant step forward in the EU's efforts to reduce greenhouse gas emissions and combat climate change. By phasing out the use of harmful fluorinated gases, the EU is paving the way for more sustainable and environmentally-friendly technologies.

Regulation (EU) 2024/590 on Ozone-Depleting Substances (in force)

The [new ODS regulation](#) replaces the previous Regulation (EC) No 1005/2009. It establishes stricter rules for the production, import, export, use, recovery, recycling, and destruction of ODS. The regulation also encourages the use of ODS alternatives and improves the efficiency of control measures to prevent illegal activities.

The regulation applies to ODS listed in Annexes I and II, as well as products and equipment containing or relying on these substances.

Key Highlights:

- Expanded requirements to recover ODS for destruction, recycling or reclamation in sectors like building materials, refrigeration, air conditioning, and fire protection systems.
- New reporting requirements for manufacturers, importers, exporters, and operators of ODS-containing products.

Directive on the Protection of the Environment through Criminal Law (proposal)

The European Commission [has proposed a new Directive](#) to strengthen the protection of the environment through criminal law.

Key Highlights:

- Violations of restrictions or prohibitions under REACH, Biocides, CLP, and POP regulations would constitute criminal offences if they cause or are likely to cause death, serious injury, or substantial environmental damage.
- Member States will be required to impose imprisonment (up to 10 years) and fines (either 3-5% of yearly worldwide turnover or fixed amounts of 24-40 million euros) for natural and legal persons.
- Additional measures may include compensation for environmental damage, withdrawal of licenses, and exclusion from public funding.
- The Directive will enter into force 20 days after publication in the EU Official Journal.
- Member States will have 2 years to transpose the rules into their national legislation.

This proposal aims to harmonize and strengthen the criminal law approach to environmental protection across the European Union, ensuring consistent and effective enforcement against the most serious environmental crimes.

Substances Proposed for Inclusion in the Authorization List (consultation)

ECHA is proposing to include the following [five substances](#) in the Authorization List (REACH Annex XIV):

- S-(tricyclo[5.2.1.0-(2,6)]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate (EC No. 401-850-9; CAS No. 255881-94-8)
- Melamine (EC No. 203-615-4; CAS No. 108-78-1)
- Siphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC No. 278-355-8; CAS No. 75980-60-8)
- Bis(2-ethylhexyl) tetrabromophthalate (EC No. 247-426-5; CAS No. 26040-51-7)
- Barium diboron tetraoxide (EC No. 237-222-4; CAS No. 13701-59-2)

The public consultation on these proposed inclusions is open until May 7, 2024.

Additionally, ECHA is seeking feedback on a draft recommendation to [amend the entry for dibutyl phthalate](#) (DBP; EC No. 201-557-4; CAS No. 84-74-2) in Annex XIV. The proposed amendment would introduce a temporary derogation to extend the latest application date and sunset date for food contact materials and medical devices. The consultation for this proposal is also open until May 7, 2024.

Finally, ECHA has opened a call for evidence to gather more information on aromatic brominated flame retardants to help decide if a restriction dossier needs to be prepared. The consultation aims to collect information on the sectors where these substances are used, materials, concentrations, end-uses, volumes, information on releases, and end-of-life information per use. The [call for evidence](#) was opened until April 5, 2024.

Updates to the Authorization List (consultation)

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 (in force)

[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.

ECHA Consults on SVHC Identification for Triphenyl Phosphate and Bis(α,α -dimethylbenzyl) Peroxide (consultation)

The European Chemicals Agency (ECHA) has announced that France and Norway have proposed to [identify two chemicals as Substances of Very High Concern \(SVHCs\)](#) under the REACH regulation. The substances are triphenyl phosphate and bis(α,α -dimethylbenzyl) peroxide. Interested parties are invited to submit any relevant information on the identity or hazard properties of these substances during this consultation period by 15 April.

The SVHC identification process aims to make interested parties aware of substances that may be of high concern, in order to prepare for potential future regulatory actions. Once a substance is identified as an SVHC, suppliers must provide safety data sheets and information to customers on the safe use of products containing the substance above 0.1% by weight.

The SVHC identification is an important step in the EU's chemicals management framework under REACH, as it can lead to further regulatory measures such as authorization or restriction of the use of these substances. Companies using these chemicals should closely monitor the SVHC identification process and prepare for potential future obligations.

The Next Generation of ECHA's Chemicals Database (information)

On January 30, 2024, the European Chemicals Agency (ECHA) launched a new chemicals database called ECHA CHEM. ECHA CHEM enables ECHA to share with the public the growing amount of information hosted by ECHA on chemical substances, and to enable wider awareness and education regarding the information generated by the European Union's (EU's) regulatory framework.

Initially, ECHA CHEM will host information on over 100,000 REACH registrations that companies have submitted to ECHA, and it will continue to be expanded with a redesigned Classification and Labeling Inventory, as well as the first set of regulatory lists. Figure 1 represents the proposed timeline for the release of new features and functionality on ECHA CHEM.

This new database is part of ECHA's efforts to improve the protection of human health and the environment from the risks that can be posed by chemicals, as mandated by the REACH regulation. By making this information publicly available, ECHA aims to increase transparency and enable wider awareness and education on chemical substances and their regulation.

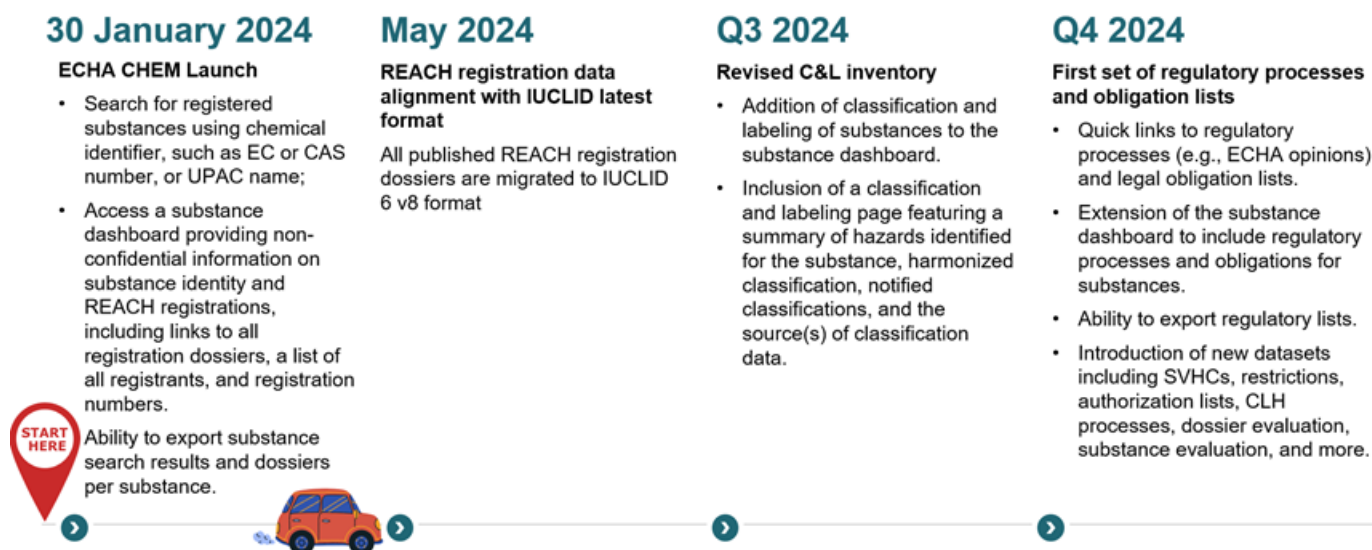


Figure 1. Proposed 2024 timeline for the release of new features and functionality on ECHA CHEM

Ecodesign for Sustainable Products Regulation (agreement)

The European Parliament and the Council have reached a provisional agreement on the [Ecodesign for Sustainable Products Regulation \(ESPR\)](#), a landmark legislation aimed at making sustainable products the norm in the European Union (EU).

Key Highlights:

- **Expanded Scope:** The ESPR will go beyond energy-related products and cover a wide range of consumer and industrial goods, including textiles, furniture, and electronics.
- **Mandatory Sustainability Requirements:** The regulation will set mandatory sustainability requirements for products sold in the EU, ensuring they are designed to be more durable, repairable, recyclable, and energy-efficient.
- **Digital Product Passports:** The ESPR will introduce digital product passports, providing consumers and businesses with detailed information about a product's environmental footprint, materials, and repairability.
- **Ecodesign and Labeling:** The regulation will establish ecodesign requirements and mandatory labeling schemes to help consumers make informed choices and drive the transition towards a more sustainable economy.
- **Enforcement and Penalties:** The ESPR will be accompanied by robust enforcement mechanisms, including the ability to impose penalties on non-compliant manufacturers and importers.

Implications for Businesses

The ESPR will have significant implications for businesses operating in the EU market. Companies will need to adapt their product design, manufacturing, and supply chain practices to meet the new sustainability requirements. Proactive engagement with the regulatory changes and early adoption of sustainable practices will be crucial for maintaining competitiveness and compliance.

Next Steps

The provisional agreement on the ESPR is a significant milestone, but the legislation still needs to be formally adopted by the European Parliament and the Council. Once approved, businesses will have a transition period to prepare for the implementation of the new rules. We encourage you to stay informed about the ESPR's development and its potential impact on your operations.

Corporate Sustainability Due Diligence Directive approved with compromise (agreement)

In a significant development, the European Commission (EC) gave its approval to the [Corporate Sustainability Due Diligence Directive \(CSDDD\)](#) on March 15, 2024. This came after the EU Council and Parliament reached a provisional deal on the directive in December 2023.

The final, negotiated version applies the directive to companies with at least 1,000 employees and EUR 450 million turnover, down from the initially proposed thresholds. The idea of lower thresholds for companies in 'high risk' sectors was also scrapped. Additionally, the timetable for the phased roll-out of the regime has been extended, with full implementation now at least seven years away.

The directive establishes a corporate due diligence duty, requiring companies to identify, address, prevent, mitigate and account for negative human rights and environmental impacts in their own operations, subsidiaries, and value chains. Large companies must also have a plan to ensure their business strategy is compatible with limiting global warming.

The obligations will be enforced by regulatory bodies in EU member states, as well as through private lawsuits. Non-compliance can result in fines of up to 2% of global revenue. The directive also includes provisions for civil liability and limits on disclosure of evidence for claimants.

The provisional agreement reached between the EU Council and Parliament now needs to be formally adopted by both institutions. Member states will then have two years to transpose the directive into national law.

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.

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