

Chemicals Quarterly

Q4 Regulatory Update 2022

18th January 2023



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Chemicals Quarterly Q4 2022

ECHA permits SCIP notifications from EEA

- In November, the European Chemicals Agency (ECHA) announced that companies supplying articles in the European Economic Area (EEA) may submit notifications to its database of substances of concern in products (SCIP)
 - Iceland
 - Liechtenstein and
 - Norway
- SCIP is the EU's public database of products with SVHCs, established under the Waste Framework Directive
- The database enables consumers to make more informed purchasing choices and helps waste operators to further develop the re-use of articles and the recycling of materials

EU limits hexachlorobenzene under the POPs Regulation

- In November 2022, the EU enacted Commission Delegated Regulation (EU) 2022/2291 to amend Regulation (EU) 2019/1021 on persistent organic pollutants, commonly known as the POPs Regulation.
- The Regulation established an unintentional trace contaminant (UTC) limit value of 10 mg/kg for HCB.
- HCB has been identified as an impurity in some substances, mixtures and articles, including pesticides, chlorinated solvents, inks, coatings, paints and toners, wood application, textile application and plastics.
- These requirements took effect 13 December 2022.

EU considers several additional POPs restrictions

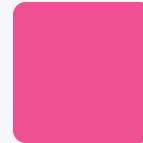
- In November, the EU announced five Draft Delegated Acts to amend Annex 1 of the EU POPs Regulation
- The proposals would:
 - Update the specific exemptions of PFOA, its salts and PFOA-related compounds, and HBCDD;
 - Reduce the Unintentional Trace Contaminant (UTC) limit for PFOS and PFOS derivatives in substances, mixtures and articles to 1 mg/kg (0.0001%); and
 - Introduce a new UTC limit of 10 mg/kg (0.001% by weight) for PCB in substances, mixtures or articles
- One of the proposals would restrict PFHxS in substances, mixtures and articles, in accordance with the Stockholm Convention Decision of June 2022

ECHA considers MCCCP & substances containing CA:C14-17

- ECHA launched a public consultation to restrict medium-chain chlorinated paraffin (MCCCP) and other substances that contain chloroalkanes with carbon chain lengths from C14 to C17 (CA:C14-17) under REACH Annex XVII
- These substances are used in flame retardants and plasticizers in PVC, adhesives and sealants, rubbers and paints and coatings, leather and waterproofing agents
- Two Restrictions have been proposed:
 - Option A: A ban on manufacturing and placing on the market substances, mixtures and articles, after a two-year transition period or
 - Option B: A ban on solely placing on the market substances, mixtures and articles, after a 2 year transition period, except for metalworking fluids, where a 7 year transition period or a derogation could be considered
- The consultation ends 22 March 2023

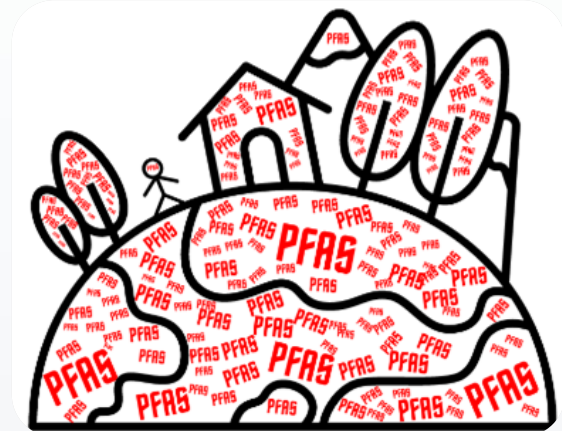
ECHA considers environmental & health risks from PVC

- ECHA is investigating whether PVC and/ or its additives cause a risk for the environment and/ or human health and whether regulatory measures at the EU level are necessary.
- Calls for evidence will compile specific information on the substances used in PVC, uses, exposures, recycling, other waste stage activities, alternatives and potential costs of alternatives and costs of potential regulatory measures.
- ECHA needs to report back to the Commission on the results of this investigation in May 2023.



EU NGOs call for ban on PFAS

- A group of European NGOs urged the EU to ban per- and polyfluoroalkyl substances (PFAS) in everyday consumer products (e.g., food packaging, cosmetics, clothing) by 2025 and to achieve a complete ban of PFAS production by 2030
- Signatories include Greenpeace, Friends of the Earth Europe, ECOS and ChemTrust
- The group says this is achievable through the restriction of the whole PFAS group under REACH



EU opens a public consultation on FCMs

- In October, the European Commission (EC) opened a public consultation of the EU's rules on food contact materials (FCMs)
- The consultation asks for feedback including on the scope of products to be regulated, hazards that should be considered and tools to be used for risk management
- The consultation ended 11 January 2023
- The ECs adoption of the revised FCM regulation is scheduled for Q2 2023



Germany proposes bisphenol restrictions

- Germany proposed restrictions on bisphenols with endocrine disrupting properties for the environment:
 - Bisphenol A,
 - Bisphenol B,
 - Bisphenol S,
 - Bisphenol F,
 - Bisphenol AF and
 - Bisphenols that will in the future be:
 - Identified as substances of very high concern (SVHC), or
 - Classified as endocrine disruptors for the environment per Regulation (EC) No 1272/2008, or
 - Identified as endocrine disruptors for the environment according to the Biocidal Products Regulation or the Plant Protection Products Regulation or
 - Salts of any of the above
- The consultation ends on 22 June 2023

US EPA proposes rule on PFAS

- The US EPA is proposing to add per- and polyfluoroalkyl substances (PFAS) subject to reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA).
- The addition of these PFAS to the list of chemicals of special concern will cause them to be subject to the same reporting requirements as other chemicals of special concern.
- Removing the availability of these burden-reduction reporting options will result in a more complete picture of the releases and waste management quantities for these PFAS.
- Comments must be received on or before 3 February 2023.

US Congress urges CPSC ban on gas stoves

- US Senators and Representatives have urged the CPSC to address the high level of dangerous indoor air pollutants emitted by gas stoves.
- Reports have found that gas stoves emit dangerous air pollutants such as nitrogen dioxide (NO₂), carbon monoxide (CO) and fine particulate matter (PM_{2.5})
 - These emissions can create a cumulative burden to Black, Latino and low-income households
 - Such households are more more likely to be located near a waste incinerator or coal ash site, or living with poor ventilation, malfunctioning appliances, mold, dust mites, secondhand smoke, lead dust, pests and other maintenance deficiencies



The latest on Maine's PFAS reporting requirements

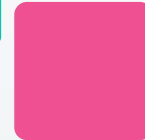
- Starting 1 January 2023, manufacturers have been required to report on intentionally-added PFAS in products distributed in Maine
 - These requirements come from Public Law c. 477 (formerly (LD 1503), An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution
- Industry associations, such as AAFA and PCPC, have been successful in petitioning the state's DEP for six-month extensions
 - As of 22 December 2022, a 44-page list of companies have received extensions
- DEP is currently considering a proposed rule detailing the notification requirements and sales prohibitions for products and product components containing intentionally-added PFAS
- DEP is holding a meeting on this draft on 19 January 2023 and will open another public comment period subsequently

The latest on New York State's ban on PFAS in apparel

- AAFA notified members that, on 31 December 2022, New York State Governor Hochul signed S. 6291 on the understanding that the bill would be amended to:
 - Ban intentionally-added PFAS for apparel except “outdoor apparel for severe wet conditions” starting 1 January 2025;
 - Direct the DEC to establish a testing threshold for “intentionally added PFAS” by 1 January 2027;
 - Ban intentionally-added PFAS for “outdoor apparel for severe wet conditions” starting 1 January 2028; and
 - Establish exemptions for used apparel and professional uniforms that are worn to protect the wearer from health or environmental hazards (including PPE)
- The association remains engaged with the DEC to ensure the testing threshold established is practical, science-based and harmonized with other jurisdictions

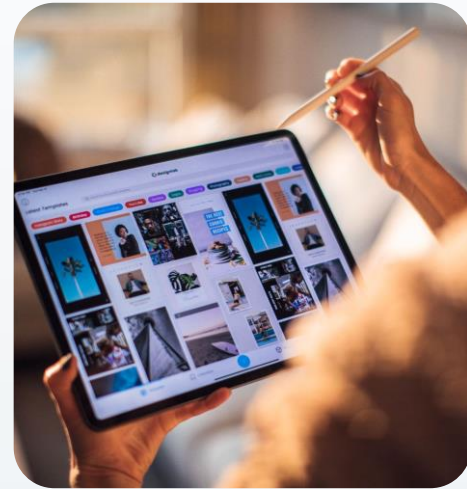
Massachusetts considers flame retardant restrictions

- Massachusetts is considering a prohibition on 11 chemical flame retardants and chemical analogues, including TDCPP, TCEP, TCPP, pentaBDE, octaBDE and TBBPA
- The draft would establish a limit of 1,000 ppm for any component part of the covered product
- Covered products are defined as bedding, carpeting, children's products, residential upholstered furniture and window treatments



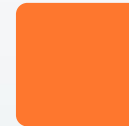
Reporting of organohalogen flame retardants in electronic displays in NYS

- C&R's Kelly Bugiera added a Regulatory Update to C2P.
- Starting 31 December 2022, manufacturers of electronic displays sold in New York State must report the presence of organohalogen flame retardants in their enclosures or stands.
- Manufacturers are encouraged to provide information to retailers regarding their compliance with this reporting requirement and whether or not they use flame retardants in the electronic displays.



Puerto Rico restricts refrigerants

- On 10 November 2022, Puerto Rico restricted the sale, use and disposal of refrigerants such as hydrochlorofluorocarbons (HCFC's), hydrofluorocarbons (HFCs) and hydrofluoroolefins (HFOs)
- These refrigerants will be subject to controls by the Department of Consumer Affairs and will be reserved to refrigeration technicians who hold a license
- Implementing regulations for the sale, use and disposal of covered refrigerants will be published by the Department
- The Act came into force immediately after its approval



EPA considers HFC restrictions

- The US EPA is proposing regulations to implement certain provisions of the American Innovation and Manufacturing Act to restrict the use of hydrofluorocarbons (HFCs) in refrigeration, air conditioning and heat pumps; foam blowing; and aerosols
- The manufacture or import of products would be prohibited by either 2025 or 2026, depending on the sector or subsector, followed a year later by a prohibition on the sale, distribution, offer for sale or distribution, export and other activities pertaining to those products.
- The proposal would also establish recordkeeping and reporting requirements
- Comments must be received 30 January 2023



Ossoff demands answers on lead in sippy cups

- Georgia Senator Jon Ossoff is demanding answers after sippy cups sold by major retailers were found to contain lead.
- FDA says no level of lead is safe or legal in children's products.
- CPSC says a part of the cup contains lead and that there have been at least seven documented cases of that lead part breaking free, which would expose children to potential lead poisoning.



Peru baby article restrictions

- In December, Peru published Resolution No. 159-2022-DIGEMID-DG-MINSA.
- Baby articles: sanitary products intended for liquid feeding, entertainment and development of the baby's teeth.
- Bisphenol A (2,2-bis(4-hydroxyphenyl) propane is prohibited.
- Baby articles made of vulcanized rubber, silicone, and thermoplastic elastomers must not exceed the following limits:
 - <0.01 mg of total N-nitrosamines released/kg
 - <0.1 mg of total N-nitrosatable substances kg
- DINP, DIDP, DNOP, DEHP, DBP, BBP: plasticizing substances mentioned may not be used as substances or constituents of preparations in concentrations greater than 0.1% by weight of the plasticized material.

Peru baby article restrictions

- Heavy metals
 - Antimony, Sb: 15 mg/kg
 - Arsenic, As 10 mg/kg
 - Barium, Ba 100 mg/kg
 - Cadmium, Cd 20 mg/kg
 - Lead, Pb 25 mg/kg
 - Chromium, Cr 10 mg/kg
 - Mercury, Hg 10 mg/kg
 - Selenium, Se 100 mg/kg



South Korea amends children's product test method

- On 14 December 2022, the South Korean Ministry of Trade, Industry and Energy (MOTIE) issued an amendment to the Notice on Common Safety Standards on Children's Products.
- Amendment primarily improves analysis methods in Annex B for hazardous element content.
- Under the previous regulations, precise (wet) analysis methods were applied to the content analysis for hazardous elements in products.
- Amendment introduces additional screening analysis methods.
- Notice will enter into force on 1 April 2023.

Draft Saudi packaging technical regulation

- TR will apply to all types of packaging products made of paper, cardboard, plastic, glass, wood, metal or textiles that are used for the packaging, protection, handling and display of products.
- TR will not apply to the packaging of food contact materials and medical products.
- Total concentration levels of lead, cadmium, mercury and hexavalent chromium in the product or its parts shall not exceed 100 parts by weight.
- Excludes:
 - products made entirely of lead crystal glass
 - recycled products
- Suppliers will be given one year to comply with provisions.

Canada updates on labeling of toxic substances

- In October published Notice of intent on the labelling of toxic substances certain products, such as cosmetics, cleaning products and flame retardants in upholstered furniture.
- Government of Canada is currently consulting interested parties.
- Intend to consider the applicability of consumer-facing digital mechanisms for providing information on certain toxic substances in products, in addition to traditional physical labels.
- Considering most appropriate information to require on a label, for example either information on the presence of a substance, its concentration or its quantity.
- Government intends to publish and consult on a product labelling strategy in 2023.

Canada amends pest control product requirements

- Regulations Amending the Pest Control Products Regulations (Applications and Imports): SOR/2022-241.
- Treated articles are now explicitly define and prescribe a “treated article” as a pest control product.
- Treated article: means an inanimate product or substance, but does not include a food as defined in section 2 of the Food and Drugs Act,
 - that, during the manufacturing process, is treated with a pest control product either by intentionally:
 - incorporating the product into the article; or
 - applying it to the article, and
 - whose primary purpose, prior to that treatment, is not, directly or indirectly, to control, destroy, attract or repel a pest or to mitigate or prevent the injurious, noxious or troublesome effects of a pest.

Canada amends pest control product requirements

- Articles treated with antimicrobial material preservatives will be authorized under the Regulations (meaning they will not have to be registered) if they meet the following conditions:
 - Antimicrobial preservative used to treat the article is registered or otherwise authorized under either paragraph 21(5)(a) of the PCPA or paragraph 4(1)(b) of the PCPR;
 - Use is limited to preventing degradation or damage to the product from micro-organisms; and
 - Article is treated in accordance with the approved range of application rates, the approved method of application, and the approved uses of the registered or authorized antimicrobial preservative. The approved range of application rates is set out in the approved end-use product labels associated with the active ingredient.
- PCPR amended to exempt antimicrobials used for preservation from the application of the PCPA, if they are used in treated articles regulated under the Feeds Act, the Fertilizers Act or the Food and Drugs Act (including drugs, cosmetics, and Class II, III or IV medical device).

Canada proposes amendments for products containing mercury

- Required to fully align with the Minamata Convention.
- Amendments would lower the mercury content limit currently allowed for straight fluorescent lamps for general lighting purposes, cold cathode fluorescent lamps, and external electrode fluorescent lamps.
 - For example, the mercury content limit for cold cathode fluorescent lamps that are 1.5 m or less in length would be lowered from 10 mg per lamp to 3.5 mg per lamp.
- Adding an exemption end date of January 1, 2028 for catalysts used in the manufacturing of polyurethane.
- End the exemption for most mercury-containing lamps under the Regulations
 - Most lamps for general lighting purposes would be prohibited by January 1, 2024.
 - High-pressure sodium vapour lamps for general lighting purposes would be prohibited by January 1, 2029.

Vietnam amends chemical requirements

- Decree 82/2022/ND-CP amending Decree 113/2017/ND-CP implementing Law on Chemical.
- Amends document requirements for license application.
- Amends Article 23 on GHS hazard classifications.
- Substances added to the List of chemicals subject to conditional production and trading in the industrial sector in Appendix I including: ammonia; acetylene; chlorine; fluorine; and nitric acid.
- Decree No. 82/2022/ND-CP took effect from December 22, 2022.



Vietnam report on amending Chemicals Law No. 06/2007/QH12

- Proposed revision aims to address some practical problems arising from the current Chemicals Law.
- Vietnam joined international conventions and agreements which determine additional regulations that must be codified in the current Law.
- Amend the definition of "chemicals" as it is currently too broad.
- Regulations on management of hazardous chemicals in products: limit the content of hazardous chemicals in products, chemicals not used in products, risk assessment for products containing chemicals.
- Regulations requiring the provision of information on chemical safety for products containing chemicals to consumers.

China revision of precautionary label for chemicals

- Ministry of Industry and Information Technology published a notice seeking comments on revision of mandatory standards.
- Revision of GB 15258-2009 General Rules for Preparation of Precautionary Label for Chemicals.
- Possibly implemented in 2024.
- QR Code could be included.

China consultation on HCFCs in disposable medical devices

- On 12 December 2022, the Ministry of Ecology and Environment commenced a public consultation on proposed measures to implement the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol.
- Prohibition on disposable medical devices that use HCFCs as a silicone thinner or cleaning agent.
- Applicable disposable medical device products: "14.01.02 Sterile Syringe", "14.01.03 Needle-free syringes", "14.01.06 Injection Needles", "14.01.08 Puncture Instruments", "14.01.09 Biopsy Needles", "14.02.06 Intravenous Infusion Needles", "14.02.07 Intravascular Indwelling Needles" and other products.
- Prohibition would enter into effect on 1 July 2023.

Türkiye RoHS regulation

- On 26 December 2022, the Turkish Ministry of Environment, Urbanization and Climate Change published a Regulation on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("EEE").
- Modeled on the RoHS II Directives (2011/65/EU and 2017/2102/EU).
- EEE placed on the market, including cables and spare parts, cannot have restricted substances in concentrations exceeding the maximum values defined in Annex 2.
- Lead, Mercury, Hexavalent chromium, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), Diisobutyl phthalate (DIBP): 0.1%.
- Cadmium: 0.01%

Türkiye RoHS regulation

- Manufacturer contact information must to be provided in Turkish.
- Regulation will enter into force on 1 February 2023.
- Date of application of restrictions with regard to medical devices, in vitro diagnostics medical devices, monitoring and control instruments (including industrial) and all other EEE not included in the 2012 Regulation but covered by the this Regulation is 1 January 2024.
- Provisions on EU Declaration of Conformity and "CE" marking will apply from 1 January 2024.

Australia proposed regulatory scheduling decisions

- Minister for the Environment is considering a proposed regulatory scheduling decision for:
 - polychlorinated naphthalenes (PCN), including dichlorinated naphthalenes, trichlorinated naphthalenes, tetrachlorinated naphthalenes, pentachlorinated naphthalenes, hexachlorinated naphthalenes, heptachlorinated naphthalenes and octachlorinated naphthalenes, including any mixture of these chemicals
 - 1,3-Butadiene, 1,1,2,3,4,4-hexachloro- (HCBD)
 - hexabromobiphenyl (HBB), defined as chemical compounds based on the biphenyl structural element, where six hydrogen atoms have been replaced by bromine atoms
- Prohibit the import, manufacture and end use of the chemical, whether on its own, in mixtures or in articles.
- Would enter into force on 1 July 2023.

Australia plan to phase out PFAS in fibre-based food contact packaging

- Australian Packaging Covenant Organisation (APCO) issued an Action Plan to Phase Out PFAS in Fibre-Based Food Contact Packaging.
- Designed to support businesses to voluntarily phase out intentionally added PFAS in fibre-based food contact packaging by 31 December 2023.
- Includes:
 - A guide on how to test for total organic fluorine (TOF) which is indicative of PFAS;
 - How to report on the PFAS present in fibre-based food contact packaging; and
 - Considerations for selecting alternatives

Mercosur amends cellulose food contact resolution

- On 17 November 2022, Mercosur published Resolution GMC No. 26/2022 to amend Resolution No. 40/15 on Cellulose Materials, Packaging and Equipment in Contact with Food.
- This Resolution replaces item 2.15.1, in Part I of the Annex to Resolution GMC No. 40/15, with the following:
"2.15.1 Pigments and dyes shall not migrate as per the procedure described in BS EN 646 - Paper and board intended to come into contact with foodstuffs - Determination of colour fastness of dyed paper and board, and shall comply with grade 5 of the grayscale as defined in the mentioned standard."
- Resolution shall be incorporated into the legal system of the States Parties before 16 May 2023.

Israel updates toy standard

- Israel notified the revision of the Mandatory Standard SI 562 part 3 - Safety of toys: Migration of certain chemical elements.
- Entered into force immediately, allowing for a transition period until 16 April 2023.
- During this time, products may be tested according to the old or the new standard editions.



Brazil chemical inventory bill approved

- In November, the Commission for Economic Development, Industry, Commerce and Services of the Chamber of Deputies approved Bill PL 6120/2019 which would establish a National Inventory of Industrial Chemical Substances.
- Require that producers or importers of industrial chemical substances in Brazil, including substances in mixtures, in an amount equal to or greater than 1 ton per year submit the specified information.
- Article 6 provides a list of chemical substances exempted from registration, including: pharmaceuticals, agrochemicals, cosmetics and personal hygiene products, food and food additives.
- Anyone who fails to register in the National Inventory of Chemical Substances may be warned, suspended or fined.

Ukraine chemical law adopted

- On 1st December 2022, the Ukrainian Parliament adopted Law No. 2804-IX, 2022 on Chemical Safety and Management of Chemical Products.
- Creates a regulatory framework for the management of chemicals.
- Implements the Globally Harmonized System of Hazard Classification and Labeling of Chemical Products (GHS) into national law and transpose the requirements of international Conventions.
- Exceptions include: medicines, pesticides and agrochemicals, biocides, disinfectants, and final cosmetic products.

Ukraine chemical law adopted

- Business entities obligations include:
 - carry out environmental impact assessments;
 - assess the safety of a chemical substance in accordance with Article 25;
 - use, if possible, alternative chemicals before the start of production;
 - provide information on hazardous chemicals, chemical incidents and other events resulting in environmental pollution;
 - conduct hazard classification of chemical products and identification of chemicals;
 - comply with the requirements for state registration of chemicals and safe management of chemical products;
- Law came into force on 29 December 2022 and implementation will take place from 29 June 2024

Eighteenth meeting of the POPs Review Committee

- Outcomes eighteenth meeting of the POPs Review Committee of the Stockholm Convention include:
 - Adopted the risk management evaluation for Dechlorane Plus
 - Adopted the risk management evaluation for UV-328
 - Adopted the risk profile for chlorinated paraffins with carbon chain lengths in the range C14-17 and chlorination levels at or exceeding 45% chlorine by weight
 - Adopted the risk profile for long-chain perfluorocarboxylic acids (PFCAs), their salts and related compounds
- Stockholm Convention COP-11 in May 2023 will consider the recommendations by the POPs Review Committee.

Trying to keep on top of **it all...**



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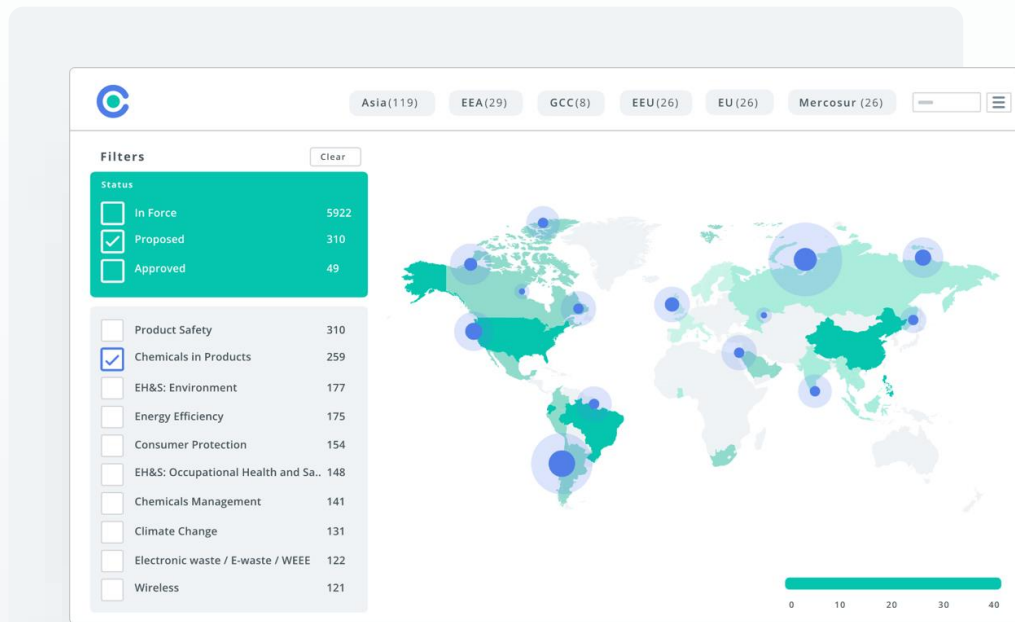
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TECHNOLOGY - C2P

C2P

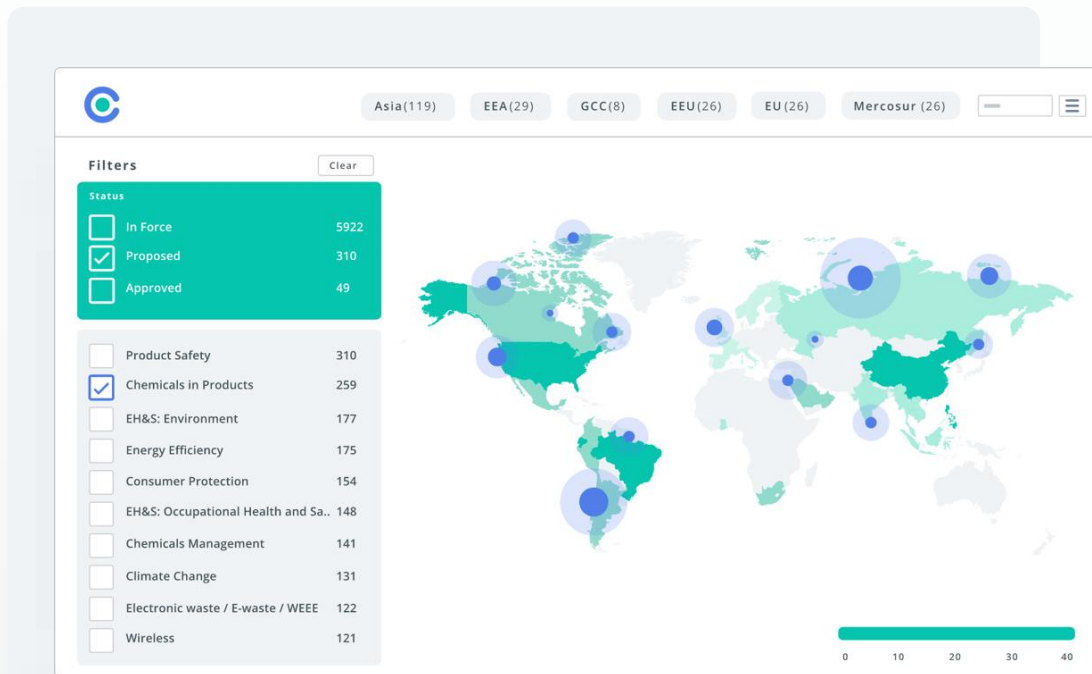
The Key to Unlocking Market Access

- Enterprise grade technology
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- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration



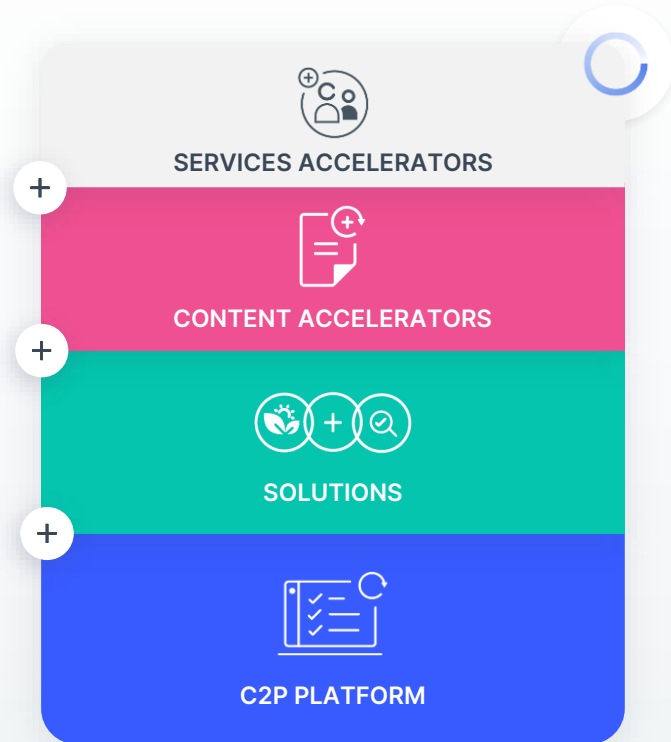
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Q&A

Thank you!



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