Overview

1. **Overview of 2022:** Recap of the regulatory highlights of 2022 and their impact on product manufacturers.

2. **What Lies Ahead:** A look at upcoming and emerging regulatory developments and what to watch out for in 2023.

3. **How can technology help?** C2P's Product Compliance Solution and how it helps you stay on top of the regulatory developments

Compliance & Risks

Agenda - Key Themes

1. **Sustainability:** Ecodesign, batteries, packaging, textiles

2. **Safety/Liability:** Product safety, product liability, AI liability, class actions, toys

3. **Chemicals in Products:** PFAS, RoHS, REACH

4. **ESG:** Sustainability reporting, sustainability standards, due diligence

Compliance & Risks

01

Sustainability

Compliance & Risks

EU Ecodesign for Sustainable Products Regulation (ESPR)

Regulation proposed **30 March 2022**

Changes the way products are designed - establishes framework to set ecodesign requirements for specific product groups such as :

- Product durability, reparability, upgradability and reusability

- Presence of substances that inhibit circularity

- Energy and resource efficiency

- Recycled content

- Remanufacturing and recycling

- Carbon and environmental footprints

- Information requirements, including a Digital Product Passport

EU Ecodesign for Sustainable Products Regulation (ESPR)

Digital Product Passport:

- Provide information about product's environmental sustainability (previous slide)
- Help consumers & businesses make informed choices when purchasing products
- Facilitate repairs and recycling
- Improve enforcement as allow for better checks & controls by authorities

EU Ecodesign & Energy Labelling - tablets & phones

August 2022 Draft Regulation proposed on ecodesign requirements for tablets, mobile & cordless phones. Onerous requirements -

- Availability of certain spare parts (e.g. microphone, camera assembly) to professional repairers for 5 years (mobiles) 5-6 years (tablets). More limited list of spare parts for end-users
- Products are designed for disassembly & resistance to accidental drops/scratches & protection against water/dust
- Functionality & security software updates
- Information on recyclability rate/recycled content

Likely to be in force early 2023 & apply Q1 2024.


Compliance & Risks

EU Ecodesign & Energy Labelling - tablets & phones

Additionally, EU is working on energy labelling proposal for phones & tablets:

- Energy efficiency
- Material efficiency including
  - Repairability score
  - Repeated fall reliability
  - Battery endurance
  - Dust & water ingress protection

A first for an EU energy label to display such scores or info.

Compliance & Risks
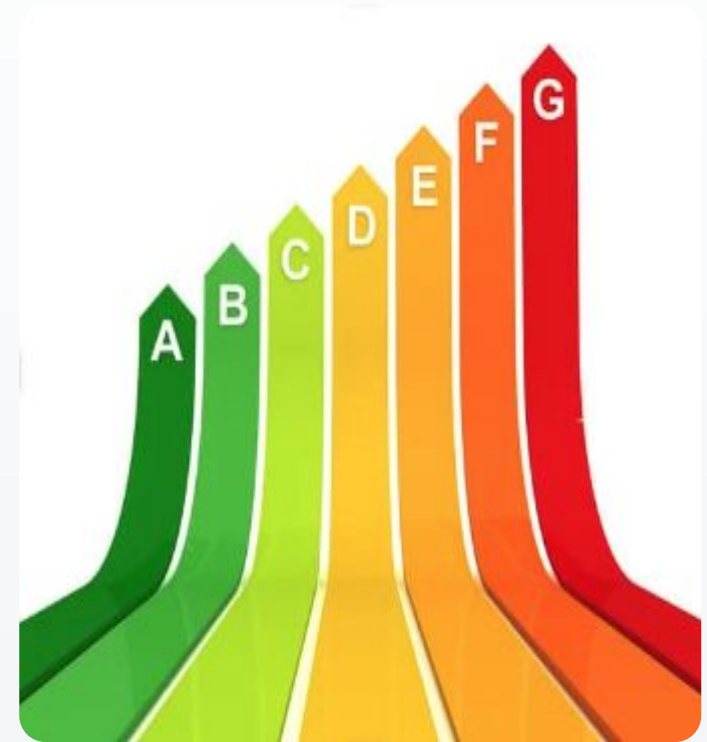
EU Draft Batteries Regulation

Proposed in **2020**. Overhaul of 2006 Directive.

Will introduce new requirements on sustainability, safety, labelling and information for **all** batteries.

Onerous requirements for electric vehicle, automotive and industrial batteries relating to:

- carbon footprint declaration (article 7)
- recycled content (article 8)
- supply chain due diligence (article 39)

Compliance & Risks

EU Draft Batteries Regulation

Supply chain due diligence requirements for rechargeable industrial batteries & electric vehicle batteries include:

- adopt & communicate to suppliers & public company policies for the supply chains of the likes of cobalt/nickel/lithium.
- in their supply chain policies incorporate standards consistent with standards in "model supply chain policy" in OECD's Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas Guidance

Those impacted include not only manufacturers of batteries, but also those involved in the EU-wide supply of battery powered products e.g. manufacturers and importers of laptops, phones & power tools.

Compliance & Risks

Packaging Developments

Proposed **30 November 2022**. 3 Objectives:

- Prevent generation of packaging waste - reduce it in quantity/restrict unnecessary packaging/promote reusable & refillable packaging solution
- Make all packaging on the EU Market recyclable in economically viable way by 2030 / Closed loop / impact design criteria
- Increase use of recycled plastics in packaging through mandatory targets - reduce need for primary natural resources & make plastic a valuable raw material

Aim: Not to generate packaging waste in first place ⟹ what is generated is recyclable ⟹ use recycled plastic
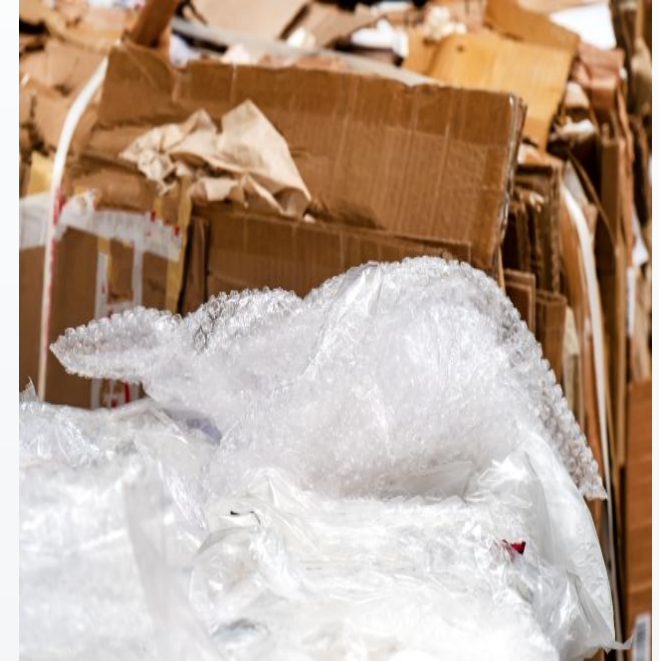
Packaging Developments

Clear up labelling confusion :

- All packaging will bear label indicating which waste stream it belongs to.
- Waste collection containers will contain the same label.
- Symbols to be used throughout EU.

Reduce packaging waste by 15% by 2040 per Member State per capita, compared to 2018.

Target = 37% reduction compared to not revising legislation.

Textiles Strategy

European Consumption of Textiles :

- Fourth highest impact on environment and climate change after food, house and mobility.
- Third sector for higher use of water and fifth for use of primary raw materials
- Estimated less than 1% of textile waste is recycled into new fibres
- A truckload of textiles is landfilled or incinerated every second around the world
- Production and consumption continues to rise - global production almost doubled in between 2000-2015 and is expected to increase to 63% by 2030

Textiles Strategy

[EU Strategy for Sustainable Textiles](#)

- Design requirements for textiles - through Ecodesign Directive

- Clearer information - mandatory digital passport

- Discourage destruction of unsold / returned textiles - ban

- Tackle greenwashing - commercial guarantee of durability

- Tackle unintentional release of microplastics

- Mandatory EPR scheme - revision of WFD in 2023

By 2030 textiles placed on the market are *long lived and recyclable* made as much as possible of recycled fibres, free of hazardous substances and produced in respect of social rights and the environment

02

Safety - Liability

Compliance & Risks

General Product Safety Regulation

Another Framework being revamped is GPSD (2001/96/EC)

Draft Regulation proposed June 2021 updating the regime as whole taking into account how products and features have developed and our way of selling has changed.

Updates current rules to ensure products sold both off and online are safe and live up to European standards; better market surveillance and enforcement; improve recall.

29 November 2022: Council & Parliament reached provisional agreement

Final adoption expected March 2023.

Compliance & Risks

Product Liability

Liability for Defective Products Draft Directive **- September 2022**

Reform needed to modernise framework taking account of

- emerging technologies
- circular economy
- online selling

Changes -
- Widens definitions
  - Product: includes software AI systems
  - Defect: includes cybersecurity/connectivity risks/software updates
  - Damages: data loss/psychological harm
- Extends scope of claims that can be brought
- Makes it easier to prove case
- Expands range of damages that can be recovered

Non-Contractual Civil Liability for AI (AILD)

Proposed September 2022, adapt to digital age, circular economy & global value chains.

- Harmonisation of national liability rules for AI
- Easier for victims to receive compensation
- Victims benefit from same standard of protection when harmed by AI products

Representative Actions

- Representative Actions Directive - brings about major changes to class actions in the EU

- Enables groups of EU Consumers to take class actions against traders

- Transposition deadline: 25th December 2022
  Application deadline: June 2023

Toy Safety

- Toy Safety: Replace EU Directive with Toy Safety Regulation.

- Increase protection particularly with regard to chemicals, and internet -connected and AI-enabled toys

- Possible introduction of digital product passport.

03

Chemicals in Products

Compliance & Risks

PFAS - USA

Proposed PFAS Reporting Rule June 2021: PFAS imported into US after June 2011 on their own, in mixtures or in articles or manufactured in USA will need to be reported.

On foot of industry feedback EPA has made some changes and feedback may be given until 27th December 2022.

Entry into Force: 1 January 2023

Stain- & water-resistance treatments · Nonstick cookware · Waterproof apparel · Cleaning products · Firefighting foam · Takeout containers · Carpets & textiles

Compliance & Risks

PFAS - USA

5th December EPA proposed changes to the Toxic Chemical Release Reporting Rule resulting in changes to reporting requirements for PFAS.

EPA proposed that all listed PFAS be reclassified as chemicals of *special concern* and any future PFAS listed will also be automatically considered as such. The will result in following for listed PFAS:

- Effectively eliminating the *de minimis* exemption
- Eliminate use of more streamlined Form A reporting

Deadline for comments 3 February 2023

Compliance & Risks

PFAS - Maine

- An Act to Stop PFAS Pollution enacted July 2021
- Manufacturers of products with intentionally added PFAS must report to Department of Environmental Protection by 1 January 2023.
- Sale of carpets, rugs or fabric treatment that contain intentionally added PFAS is also prohibited on the same date.
- Prohibition will be extended to all products by 2030.

RoHS

RoHS Directive been under review since 2021 with a plan to amend as required by Article 24.

Our Knowledge Partner, RIna, indicated in recent commentary published in November that the EC now plans to publish proposals no sooner than the end of 2024 partly due to resources, but also due to difficulty aligning REACH and RoHS.

MCCP, which had been proposed for restriction, is now not going to be restricted under RoHS because a REACH restriction is already at an advanced stage.

REACH

2nd November European Chemicals Agency opened a call for evidence on PVC and its additives related to use, volumes and end of life information. ECHA have been asked to investigate whether the use of PVCs and/or its additives pose risks to the environment, human health and whether they regulatory measures at European level are necessary.

Open until 6 January 2023.

EC also launched consultation on whether 9 more substances should be classified as SVHCs in September.

Compliance & Risks

04

ESG

Compliance & Risks

Corporate Sustainability Reporting - EU

- EU Corporate Sustainability Reporting Draft Directive proposed in April 2021.

- It substantially expands number of corporations subject to non-financial reporting obligations.

- Under draft an initial set of European Sustainability Reporting Standards (ESRS) should be adopted by June 2023. On 15 November agreement was reached on the first set of ESRS.

Compliance & Risks

Corporate Sustainability Reporting - EU

Reporting obligations under the CSRD to incrementally come into force between 2024 and 2028:

- From 1 January 2024 for large public-interest companies (with over 500 employees) already subject to the non-financial reporting directive, with reports due in 2025;
- From 1 January 2025 for large companies that are not presently subject to the non-financial reporting directive (with more than 250 employees and/or €40 million in turnover and/or €20 million in total assets), with reports due in 2026;
- From 1 January 2026 for listed SMEs and other undertakings, with reports due in 2027. SMEs can opt-out until 2028.

Compliance & Risks

Corporate Sustainability Reporting - USA

- US Securities and Exchange Commission's proposed rule for detailed disclosure on corporate environmental impact, with particular attention on greenhouse gas (GHG) emissions is still on the table.

- Adoption of the rules was initially scheduled for the second half of 2022, at the earliest, but recent developments may mean that the rules are now actually months away.

Compliance & Risks

Corporate Sustainability Reporting - Australia

- On 12 December Australian Government's Treasury underline announced it had begun consulting on "standardised internationally aligned requirements for disclosure of climate related financial risks and opportunities in Australia."

- Closing dates for submissions is **17 February 2023**.

Increased Due Diligence Obligations

14 September EU published draft regulation proposing a *ban on placing on the EU market any product or component made using forced labour*. National Competent Authorities (NCAs) will be responsible for enforcing the ban. Companies will be required to carry out due diligence with respect to forced labour.

February saw proposal of *Corporate Sustainability Due Diligence Draft Directive* - sets out due diligence obligations for larger companies to identify, prevent, mitigate and account for actual and potential adverse impacts on human rights, including labour rights and the environment along global supply chains.

Compliance & Risks

Poll Question

What area of product compliance regulation are you most concerned about ?

Option 1 : sustainability of products

Option 2 : safety of products

Option 3 : chemicals in products

Option 4 : liability for defective products

Option 5 : ESG / due diligence reporting

Option 6 : digitalistation e.g. cybersecurity

Option 7 : Other

Compliance & Risks

Poll Results

Option 1 : sustainability of products

Option 2 : safety of products

Option 3 : chemicals in products

Option 4 : liability for defective products

Option 5 : ESG / due diligence reporting

Option 6 : digitalistation e.g. cybersecurity
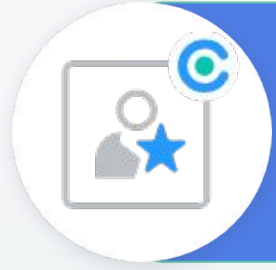
Option 7 : Other

Compliance & Risks

05

A Smarter Way to Manage Regulatory Compliance

Holistic Market Access Solutions
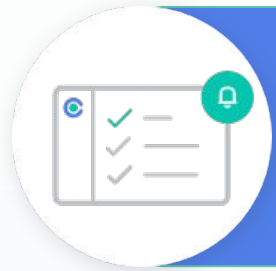
Powerful Enterprise Technology
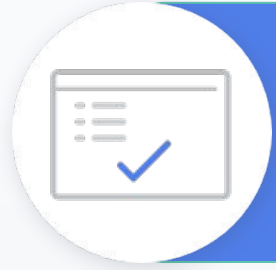
Extensive Global Regulatory Content

Team of Subject Matter Experts

Holistic Market Access Solutions...

Compliance & Risks

"Can I sell product X in market Y?"

Achieve market access

→

"Can I continue to sell product X in market Y when there is a change?"

Maintain market access

→

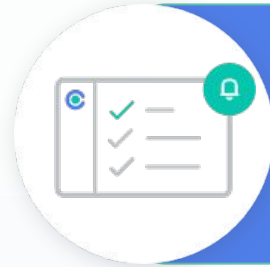"What do I need to do to sell product X into a new market?"
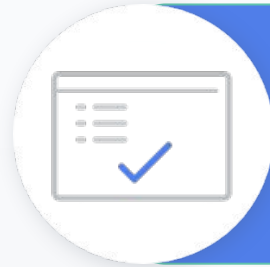
Expand market access

→

Accelerate the ability to

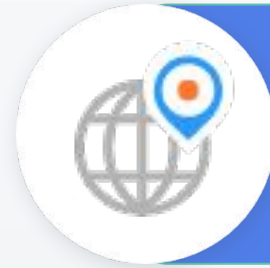Achieve, Maintain & Expand Market Access for all products in all markets

Compliance & Risks

Poll Question

When demonstrating compliance for your product, which of the following steps represents the biggest challenge for your compliance team?

Option 1 : Determining required evidence

Option 2 : Decision maker agreement

Option 3 : Evidence reporting

Option 4 : Communicating requirements

Compliance & Risks

C2P - The Key to Unlocking Market Access

- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration

Compliance & Risks
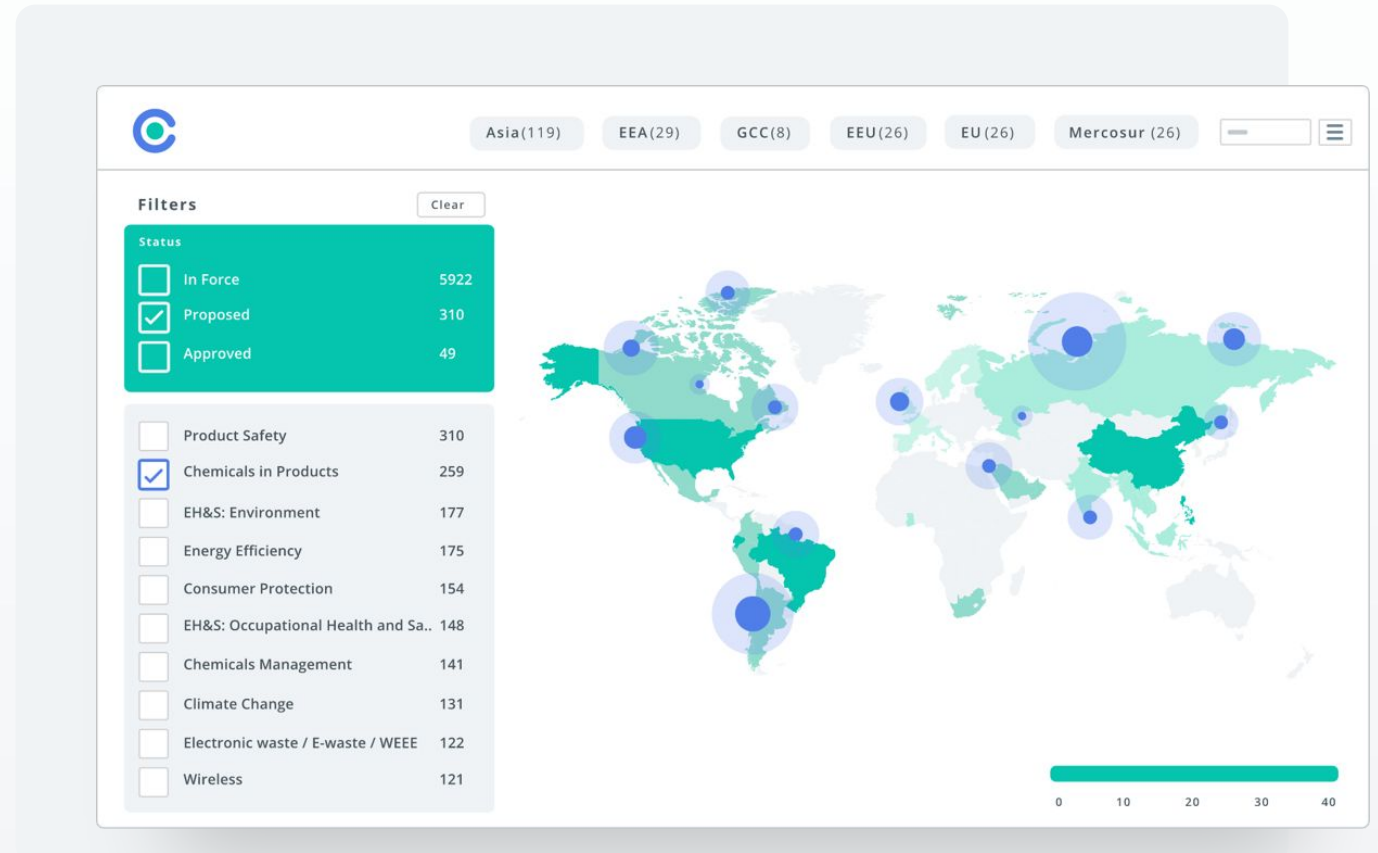
Tailored to meet your needs...
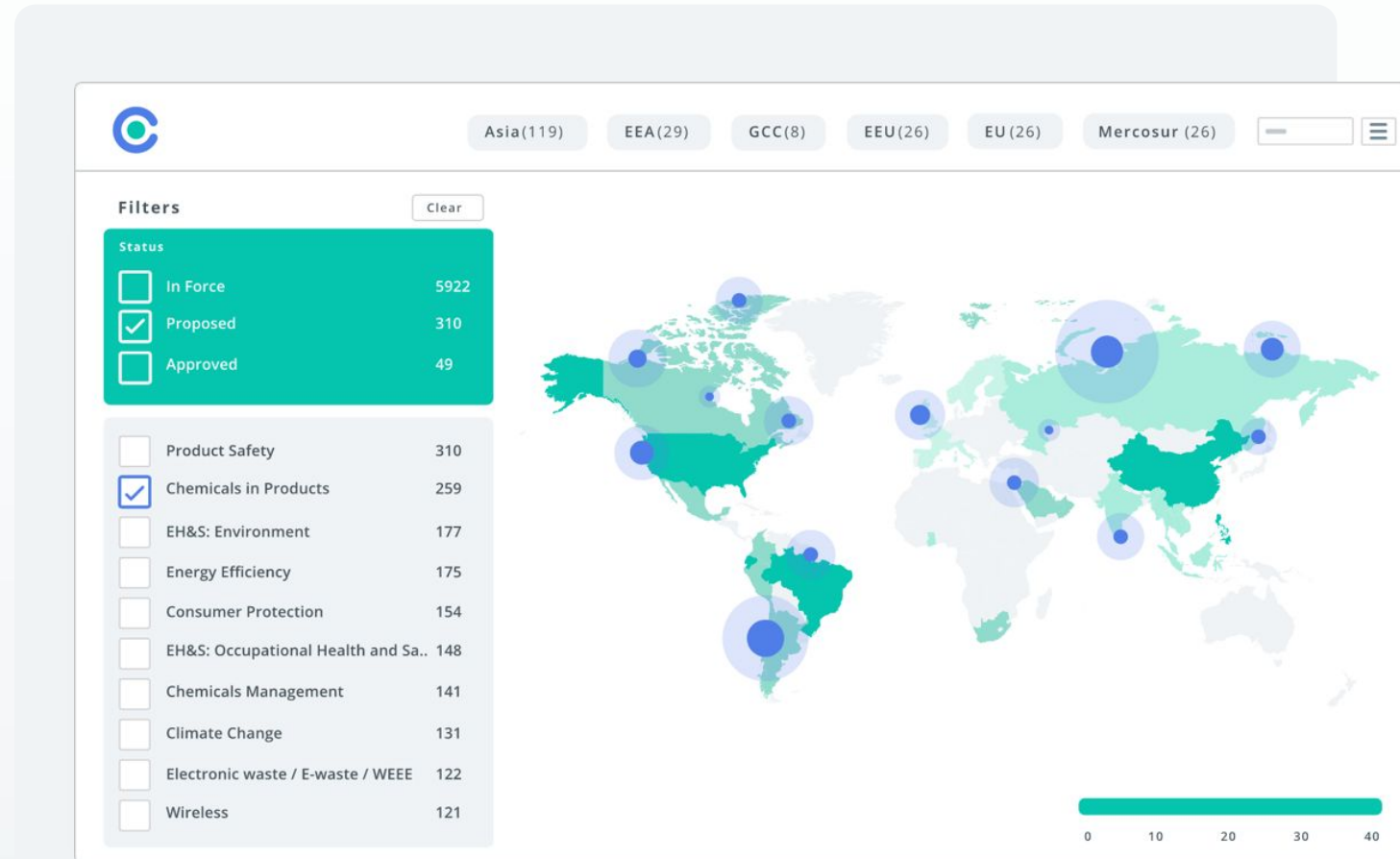
- **Comprehensive capabilities** that enable enterprise-wide management of regulations, standards, requirements and evidence

- Add-on packages to **accelerate market access** through:
  - Use-case specific solutions
  - Global regulatory content
  - Professional services

SERVICES ACCELERATORS

CONTENT ACCELERATORS

SOLUTIONS

C2P PLATFORM

Compliance & Risks

TECHNOLOGY - C2P
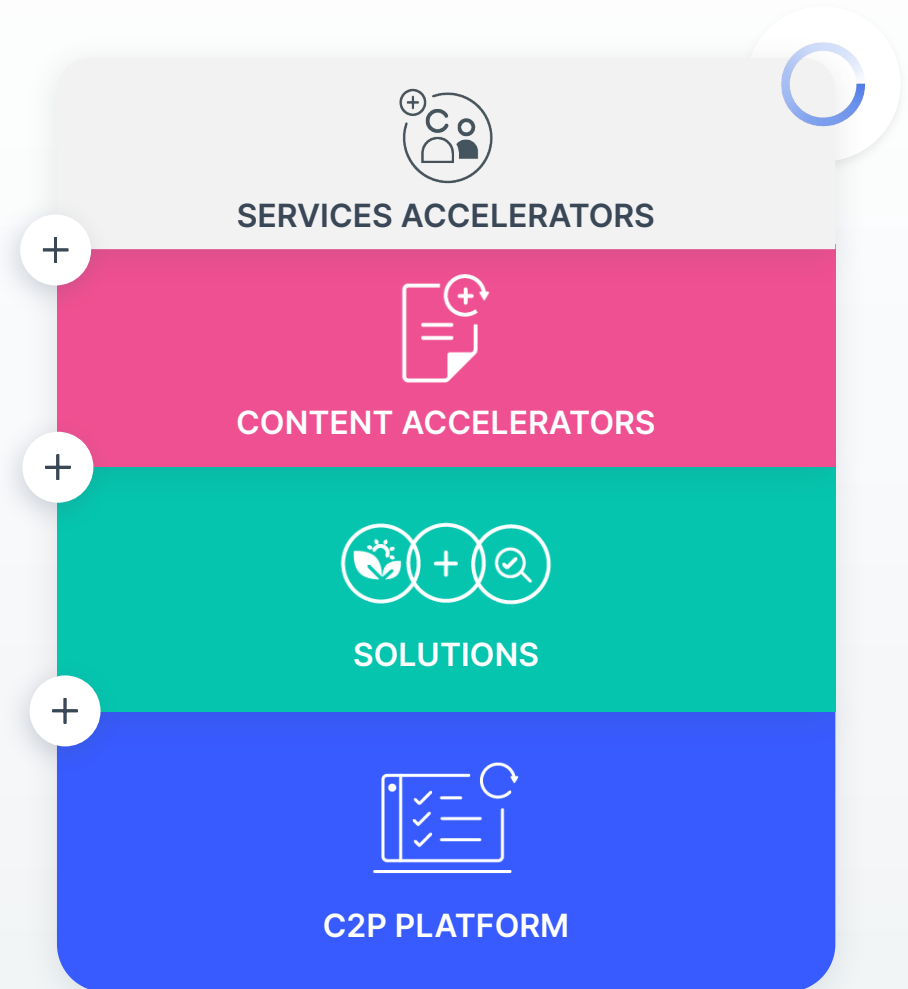
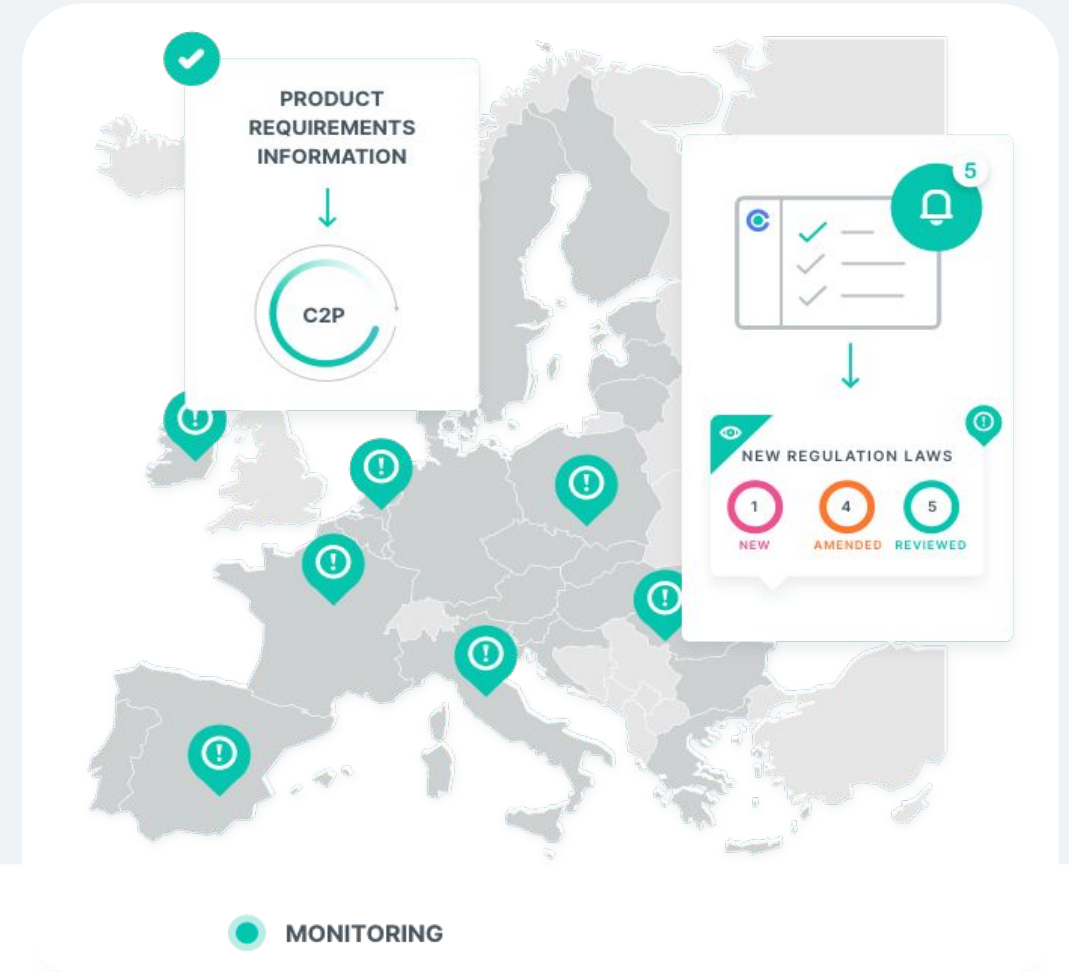# Manage everything in One Place...

- Design, build, and collaborate on new products with confidence

- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements

- Continually monitor regulatory changes & keep ahead of proposed changes before they happen

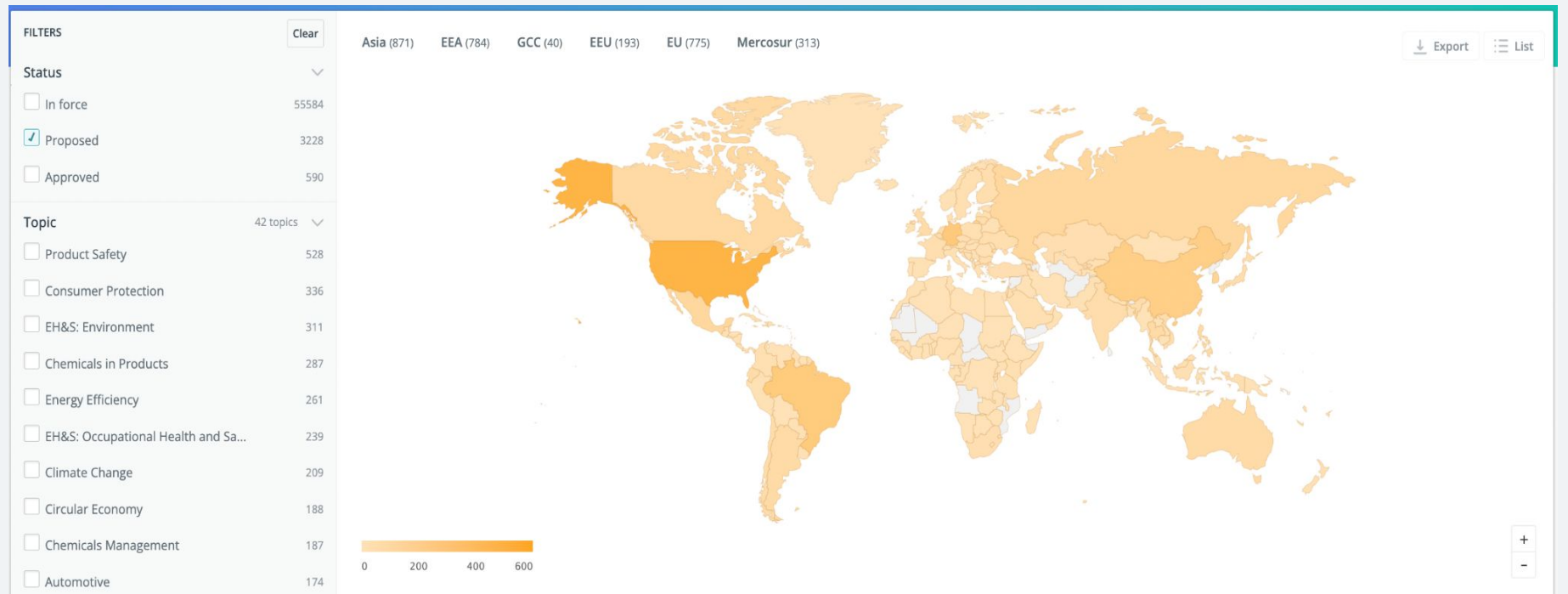- Integrate with other systems to enable streamlined business processes

Compliance & Risks

Asia(119)   EEA(29)   GCC(8)   EEU(26)   EU(26)   Mercosur (26)

Filters   Clear

Status

☐ In Force   5922
☑ Proposed   310
☐ Approved   49

☐ Product Safety   310
☑ Chemicals in Products   259
☐ EH&S: Environment   177
☐ Energy Efficiency   175
☐ Consumer Protection   154
☐ EH&S: Occupational Health and Sa.. 148
☐ Chemicals Management   141
☐ Climate Change   131
☐ Electronic waste / E-waste / WEEE 122
☐ Wireless   121

0   10   20   30   40

Why Invest in a Technology Platform?

- **Accelerate** time-to-market
- **Reduce** non compliance risks
- **Enable** business continuity
- **Improve** efficiency
- **Save** time

Compliance & Risks

See what the
future holds...

Compliance & Risks

Thank You!

Compliance & Risks

Q&A

Compliance & Risks