



Compliance & Risks

A 2026 Survival Guide to Sustainability & Product Compliance

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01. About The Authors



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Claire is a partner in Cooley's product compliance and liability team. She specialises in advising clients on regulatory risk, compliance and litigation issues. She helps clients who deal with products and consumers. Claire works with them to help bring both digital and physical products to market, advising on labelling, packaging, regulatory approvals and engaging with regulators and consumers. She also has significant expertise in coordinating and delivering business critical international regulatory and compliance advice and delivering complex multi-jurisdictional projects.

Claire also advises clients when things go wrong – such as dealing with regulatory and compliance issues, crisis management, handling and coordinating regulatory crises, product recalls and product compliance matters, managing customer relations and claims and investigating and defending regulatory investigations and prosecutions.

Claire is recommended within the Product Liability categories of the latest editions of the UK Legal 500 and Chambers UK.

01. About The Authors



Emma Bichet, Partner, Cooley

Emma leads Cooley's ESG (environmental, social and governance) and sustainability advisory practice in Europe. She has extensive experience counseling clients on European and UK ESG, sustainability, products and tech law. In 2025, Forward Law Review named Emma as one of the Forward 40 leaders in ESG and sustainability law.

Emma works with the world's top companies to navigate global compliance and establish ESG governance systems, with a particular focus on the European Union and UK. She advises on the full range of sustainability issues, including disclosure under the Corporate Sustainability Reporting Directive (CSRD), Sustainable Finance Disclosure Regulation (SFDR), and UK Streamlined Energy and Carbon Regime, amongst others. She also supports clients on compliance with the Corporate Sustainability Due Diligence Directive (CSDDD), supply chain diligence, forced labour and modern slavery, deforestation, and product and packaging regulation. She also supports clients with their marketing and claims.

Emma has experience making complaints to the European Commission on behalf of her clients and supporting them in litigation before the EU courts. She regularly manages multijurisdictional compliance projects for her clients.

Emma is also very active in horizon spotting, helping her clients keep abreast of new developments, providing input on the legislative process and adapting their business at a time when new rules are established.

01. About The Authors



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Jessica focuses on European law and the regulation of medicinal products and medical devices, including in vitro diagnostic medical devices. She helps guide life sciences companies through the regulatory processes and technical requirements governing the approval and marketing of their products – from classification, clinical trials and audits to promotion and marketing.

Jessica provides strategic advice from the early development stages to placing on the market and post-marketing activities. She also assists clients in their interactions with regulatory authorities, notified bodies and business partners including in contentious disputes.

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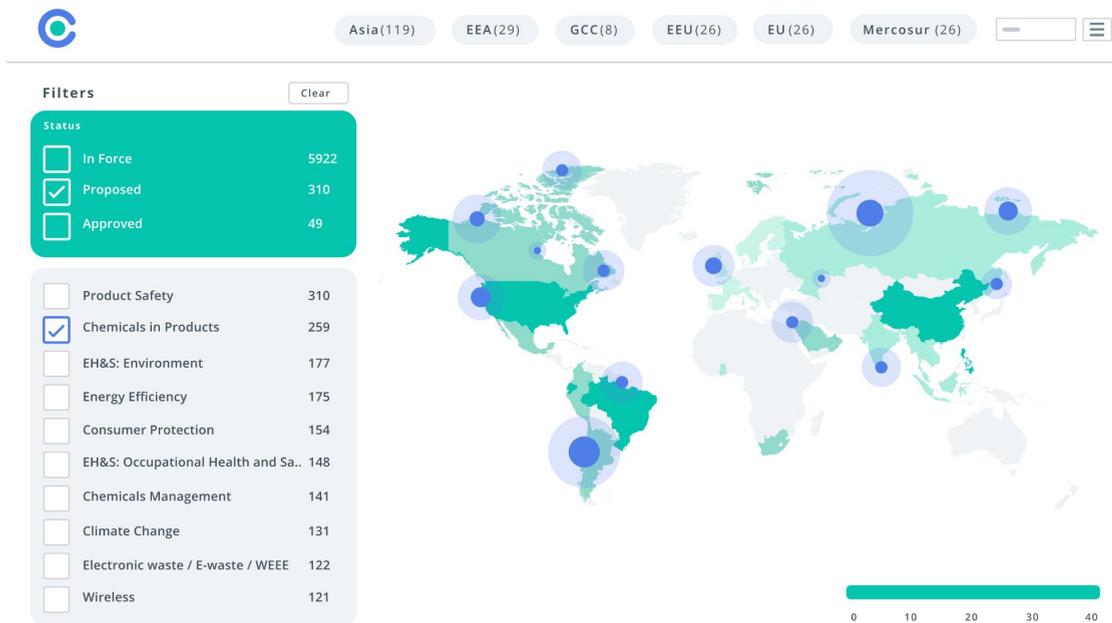
Philip Brown, Special Counsel, Cooley

Philip focuses on global product compliance and litigation. He advises innovative companies on product safety and consumer law, helping them navigate recalls, regulatory investigations, enforcement actions and complex disputes.

Drawing on more than 15 years of experience – including more than a decade in federal government compliance and enforcement roles at the US Consumer Product Safety Commission and Federal Trade Commission – Philip offers clients practical strategies and steady judgment in addressing today's most complex regulatory challenges.

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01. Introduction

The global regulatory environment entering 2026 is defined by a complex "push and pull" between ambitious legislative agendas and a powerful new counter-trend toward simplification and administrative burden reduction.

As multinational organizations face this world of constant change, the core challenge remains unchanged: ensuring that internal stakeholders have the precise tools and information required to build safe, sustainable products while simultaneously protecting their global brands and driving commercial growth.

This comprehensive guide, based on our recent webinar "[A 2025-2026 Survival Guide to Sustainability & Product Compliance](#)" synthesizes high-level expert insights from the Cooley legal team and Compliance & Risks to provide a strategic roadmap for navigating the "clarity in the chaos" that defined 2025 and will shape compliance strategies throughout 2026.

This guide is designed to serve as a vital survival asset, unpacking the most significant regulatory shifts across four key pillars: EU sustainability developments, modern product safety frameworks in the EU and UK, the unique "deregulation and fragmentation" occurring in the United States, and sector-specific innovations in Life Sciences. By analyzing recent "Omnibus" simplification packages and the one-year anniversary of major regulations like the EU GPSR, this document highlights what has fundamentally changed - and, just as importantly, what remains on course with fixed deadlines for 2026.

Stakeholders will find actionable data on revised application thresholds, new mandatory reporting modules, and emerging enforcement trends that will dictate market access in the coming year.

This guide was originally published on the 19th January 2026. Further regulatory developments may have occurred after publication.

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02. The Simplification and Delay of EU Sustainability Laws

The European Union's sustainability regulatory landscape is currently defined by a strategic phase of "taking stock," which has led to significant delays and revisions intended to reduce administrative burdens on businesses.

This shift, often referred to as "simplification," is most evident in the revised timelines and application thresholds for cornerstone directives such as the Corporate Sustainability Reporting Directive (CSRD) and the Corporate Sustainability Due Diligence Directive (CSDDD).

For the CSRD, while the Wave 1 reporting requirements remain in force, a confirmed delay has pushed the application date for "Wave 2" EU companies - specifically non-listed EU subsidiaries of non-EU parents - to fiscal year 2027, with non-EU parents not required to report until fiscal year 2028.

The "Omnibus I" simplification proposal has also significantly raised the CSRD application thresholds. This move is paired with a reported 60% reduction in the European Sustainability Reporting Standards (ESRS), which now feature more generous phase-in periods to allow organizations time to mature their data collection processes.

The CSDDD has undergone even more dramatic transformations as part of the "Omnibus I" simplification proposal. These changes, which were politically agreed at the end of 2025, include raising the application thresholds, narrowing the behavioural obligations, and deleting mandatory climate plan requirements.

Similarly, the EU Deforestation Regulation (EUDR) has been further delayed, pushing its application date to December 30, 2026.

Further simplification efforts are extending into sector-specific legislation, such as the Batteries Regulation.

Under the "Omnibus IV" proposal, small mid-cap companies may be entirely exempted from certain due diligence obligations, with a confirmed delay for broader due diligence requirements moved to August 18, 2027.

Even the Carbon Border Adjustment Mechanism (CBAM), while maintaining its key provisions for January 2026, has introduced a new 50-tonne de minimis threshold to exempt smaller shipments.

Collectively, these adjustments reflect a broader EU trend of prioritizing economic competitiveness and manageable compliance over the aggressive, rapid implementation of sustainability mandates.

03. The Evolving Global Sustainability Landscape

While much of the regulatory focus has been on the delays of major EU directives, a significant portion of the global sustainability framework remains on course with unchanged and critical deadlines for 2026

Multinational organizations must recognize that "simplification" does not equal "retraction." For instance, the Ecodesign for Sustainable Products Regulation (ESPR) is pressing forward with a landmark ban on the destruction of certain unsold consumer products starting July 19, 2026.

Most companies will also be required to disclose the exact quantities of unsold products they discard, starting in 2026, using data collected throughout the 2025 fiscal year.

This requirement represents a shift from voluntary corporate social responsibility to mandatory public disclosure of circular economy metrics, forcing a complete overhaul of inventory and waste management data systems.

The "push for circularity" is further bolstered by a trio of major EU laws set to take effect in mid-to-late 2026. The Right to Repair Directive (July 31, 2026) and the Packaging and Packaging Waste Regulation (August 12, 2026) will fundamentally alter product design and end-of-life responsibilities.

Simultaneously, the Green Transition Directive, taking effect on September 27, 2026, will introduce strict new rules for environmental claims and sustainability labels, effectively ending the era of vague "green" marketing.

These regulations are not isolated to Europe; they create a "de facto" global standard, as any company wishing to access the EU market must align their entire supply chain with these benchmarks by the 2026 deadlines.

On the broader international stage, the landscape in 2026 is becoming increasingly fragmented as different jurisdictions move at varying speeds. In the Americas, while the U.S. SEC climate reporting rules faced federal abandonment, the California GHG emissions reporting (SB 253) continues to apply, creating a persistent reporting obligation for large entities doing business in the state.

Canada has paused its mandatory disclosure rules, yet Mexico is moving in the opposite direction, requiring listed companies to prepare ISSB-aligned reports starting in FY2025.

This divergence means global compliance officers cannot rely on a "one-size-fits-all" reporting template and must instead manage a complex patchwork of state, federal, and national requirements.

The Asia-Pacific and Middle East regions are emerging as new centers of mandatory sustainability reporting. In May 2025, the UAE began requiring disclosures of climate-related risks and GHG emissions for certain companies, while China is initiating mandatory reporting for listed companies with a planned extension to private firms by 2030.

Meanwhile, jurisdictions like Singapore have introduced nuanced delays - SGX-listed companies must continue reporting Scope 1 and 2 emissions, but non-STI constituents benefit from a 3-5 year delay for ISSB-based climate disclosures. These developments signal that as we enter 2026, the primary challenge for global brands is no longer just "what" to report, but "where" and "when," necessitating a centralized yet locally sensitive compliance strategy.

04. The New Era Of EU General Product Safety (GPSR)

The EU General Product Safety Regulation (GPSR), which became law on December 13, 2024, establishes a modernized and stringent framework for consumer protection.

By replacing the 2001 General Product Safety Directive, the GPSR seeks to address the complexities of the digital economy and emerging technologies, ensuring that only safe products reach EU consumers.

Alignment and Modernization

One of the primary changes introduced by the GPSR is the alignment of requirements for both non-harmonized and harmonized (CE-marked) products. This bridge ensures that all consumer products, including those not covered by specific sector regimes like toys or electronics, meet equivalent safety and documentation standards. Furthermore, the regulation now explicitly encompasses circular economy activities, such as refurbished, second-hand, and repaired products, as well as new technologies like AI and connected devices.

New Requirements for Online Sales

The GPSR places new obligations on the "offer" of a product sold online to consumers in the EU. For a listing to be compliant, it must clearly and visibly indicate:

- **Manufacturer details:** Name, registered trade name/mark, and postal and electronic addresses.
- **Responsible Person:** The identity and contact details of a legal person or entity established in the EU who serves as a point of contact for authorities.
- **Product Identification:** A picture of the product, its type, and any other identifier to ensure easy traceability.
- **Safety Information:** Any warnings or safety labels that are required to be affixed to the physical product or packaging.

Obligations for Online Marketplaces

Online marketplaces now face increased liability and specific statutory duties. They must establish a single point of contact for product safety and create interfaces that allow sellers to provide all mandatory GPSR information. Marketplaces are required to remove non-compliant listings within two working days of being notified of an unsafe product and must actively cooperate with authorities on product recalls.

Enhanced Consumer Empowerment and Reporting

The regulation introduces mandatory accident reporting, requiring manufacturers to notify authorities of any product-related incident that causes serious harm. It also establishes multiple channels for "interested parties" to report issues:

- Directly to manufacturers/importers through publicly available communication channels.
- To marketplace providers via their designated safety contacts.
- To the European Commission through an expanded role for the Safety Gate portal (formerly RAPEX).

05. The UK's Independent Path via the PRAM Act

While the EU implements the GPSR, the United Kingdom has established its own modern framework through the Product Regulation and Metrology (PRAM) Act, which received Royal Assent on July 21, 2025.

An Enabling Framework

The PRAM Act is an "enabling act," meaning it does not introduce substantive new safety requirements immediately but instead grants the government broad powers to reform the UK framework via secondary legislation.

This structure allows for significant reforms - such as rules for online marketplaces and emerging risks - to be implemented in short time frames without the lengthy scrutiny required for primary legislation.

Strategic Priorities

The UK government intends to use these powers to address gaps in the digital economy and regulate high-risk products. Key priorities include:

- **Online Marketplaces:**
Enhancing oversight to ensure a "level playing field" between the high street and digital platforms.
- **New Technologies:**
Creating guardrails for e-mobility (like e-bikes and e-scooters) and the intangible components of products, such as software.
- **Lifecycle Approach:**
Extending regulatory obligations beyond the point of sale to cover product updates and integrations throughout their use.

Consultation and Alignment

Following a late amendment, the government is now required to consult with stakeholders before enacting new secondary legislation.

While the UK has indicated it may align core marketplace obligations with the EU GPSR to facilitate trade, it retains the flexibility to diverge where beneficial for the UK market.



06. US Regulatory Trends: Deregulation and State Fragmentation

The United States presents a contrasting landscape where a trend toward federal deregulation is being countered by an aggressive patchwork of state-level mandates.

The Federal Retreat and State Vacuum

As federal agencies pull back in certain areas, individual states are filling the "regulatory void" with their own rules. This is particularly evident in the absence of a comprehensive federal privacy law, which has led nearly **20 states** to enact their own privacy statutes.

This state-led movement has also resulted in over **1,000 AI-related bills** being introduced in 2025 alone, with states like California and Colorado continuing to lead in implementing comprehensive frameworks.

Active Federal Enforcement

Bucking the trend of deregulation, the Consumer Product Safety Commission (CPSC) remains highly active. The agency is intensifying its enforcement actions by:

- **Increasing Penalties:** Continuing to seek penalties for late reporting Section 15(b) of the Consumer Product Safety Act (CPSA).
- **Port Surveillance:** Implementing new eFiling requirements for certificates of compliance for imported products, effective in July 2026, to better focus resources on non-compliant shipments.
- **DOJ Coordination:** Referring matters to the Department of Justice to pursue both civil and criminal safety-related cases.



07. Life Sciences: Pharma and Medical Device Innovations

The life sciences industry is navigating a critical transition period as the EU works towards overhauling its medical device and pharmaceutical legislation to balance innovation with patient safety.

Medical Devices and EUDAMED

A major milestone for the MedTech sector is the mandatory rollout of the European Database on Medical Devices (EUDAMED). Following a functionality notice on November 26, 2025, a six-month transition period began, making the first four modules mandatory on May 28, 2026:

1. Actor registration (manufacturers, importers, etc.).
2. UDI/Device registration.
3. Notified Bodies & Certificates.
4. Market Surveillance.

Additionally, new information obligations entered into application on January 10, 2025, requiring operators to inform the supply chain six months in advance of any anticipated interruption that could lead to serious harm to patients.



The EU Pharma Package

In December 2025, the EU reached a landmark trilogue agreement to modernize its pharmaceutical laws. Key outcomes of this reform include:

- **Regulatory and market exclusivity:**
A baseline of eight years of regulatory data protection, but a reduced market protection of one year, with potential extensions up to 11 years.
- **Orphan and 'breakthrough' medicinal products:**
Reshaped incentives for orphan medicinal products with a reduced baseline market exclusivity to nine years but an extension to 11 years for "breakthrough" orphan medicinal products.
- **Incentives for Innovation:**
The introduction of a transferable exclusivity voucher to encourage the development of priority antibiotics, though restricted by a "blockbuster clause" for products with high annual sales.
- **Efficiency:**
Streamlining procedures to cut EMA evaluation times from 210 days to 180 days.
- **Bolar Exemption:**
Clarifying and expanding the exemption to allow generic manufacturers to prepare for market entry - including HTA and pricing approvals - while patent protection still applies.

08. Webinar Q&A

During the live webinar, numerous questions were sent in by our live audience. Our webinar presenters, [Claire Temple](#), [Emma Bichet](#), [Jessica Koffel](#) and [Philip Brown](#) provided expert answers to the most popular queries below.

Q1. Under the GPSR, if I am acting as the importer, am I required to hold copies of the technical documentation for 10 years, or is it sufficient that the manufacturer retains the documentation but can provide it to me (or the authorities) within 24 hours upon request?

The legislation and the guidance taken together suggest that you should have your own copies of the documentation in your control. The GPSR says you should have the technical documentation "at the disposal of the market surveillance authorities for a period of 10 years".

We might say that "at the disposal" provides some room for argument, but the guidance says that you must "keep this technical documentation for 10 years".

We anticipate a regulator would expect you to have it readily to hand, but the reality is that they might understand if there is a short delay in your seeing their email and responding.

Q2. For footwear, what minimum data set is expected first (materials, origin, repairability)? Any guidance on data carriers (QR vs. NFC) and interoperability?"

Footwear has been dropped from the ESPR working plan, meaning we are not expecting DPPs covering footwear in the first wave (only textiles).



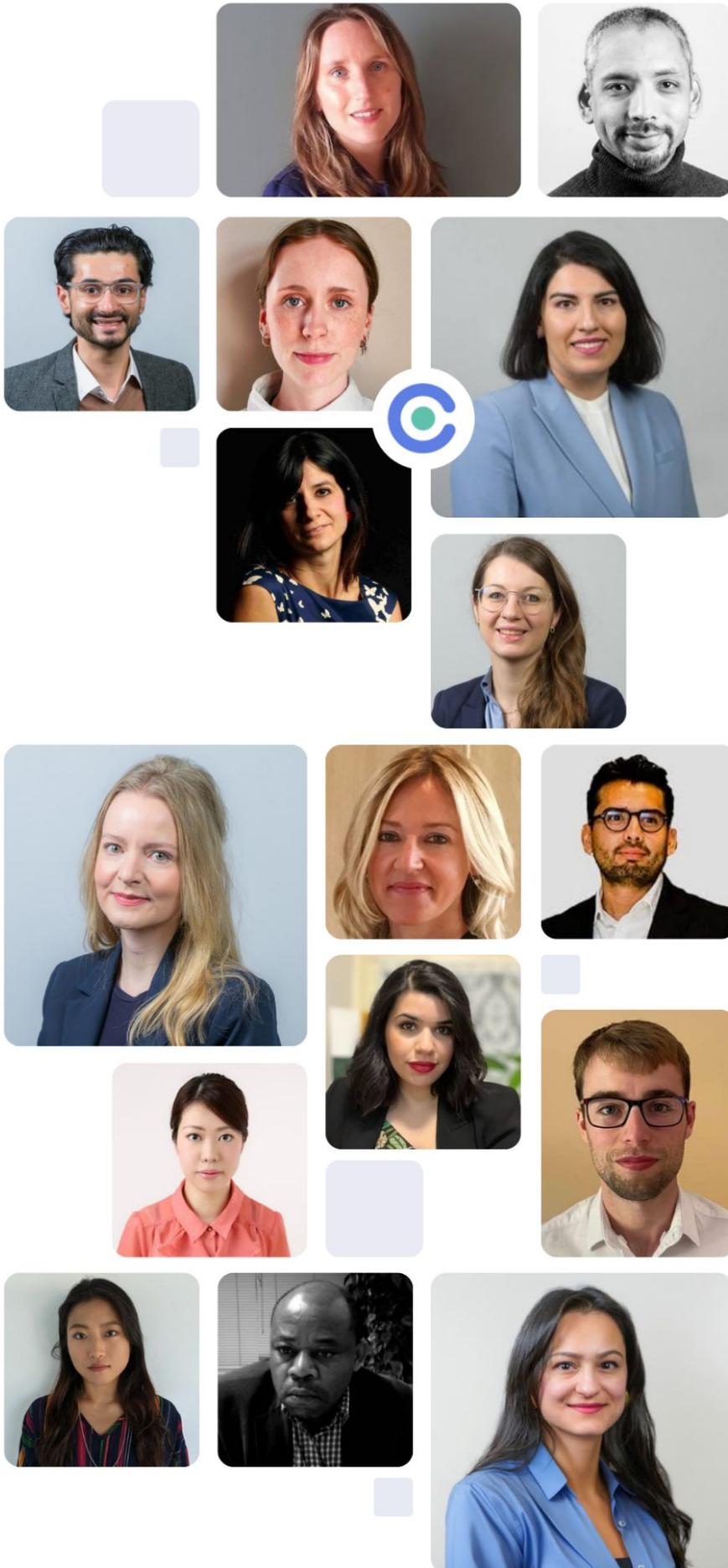
09. Conclusion

The regulatory environment of 2026 is one of strategic transition.

While "simplification" has delayed some major EU sustainability mandates, circular economy laws like the ESPR and new safety frameworks like the GPSR are already in full effect.

The divergence between the UK's PRAM Act and the EU's direct regulations, alongside the fragmented state-level rules in the US, necessitates a localized yet centralized compliance strategy.

By leveraging the "reprieve" provided by certain delays to mature their data systems, organizations can build the resilience needed to protect their brands in this "world full of change".



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