Compliance & Risks

Your Guide to Product Regulatory & Liability Developments and What to Expect in 2025

Authors:
Sarah-Jane Dobson, *Partner, Ashurst*
Louise Forrest, *Legal Consultant, Ashurst*

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01. About The Authors

Sarah-Jane Dobson, Partner, Ashurst

Sarah-Jane is the Global Head of Product Litigation and Regulatory Risk at Ashurst, where she is a Partner based in the London office. She acts on regulatory, litigious and policy matters across the full product lifecycle in respect of product safety, compliance and product liability and consumer litigation matters. Her corporate clients are from a broad range of sectors including automotive, chemicals, consumer goods, cosmetics, food (including novel foods) and beverages, industrial and life sciences products (medical devices and pharmaceuticals, and advice regarding clinical trials).

In product litigation, she has extensive experience defending corporate clients in high-stakes litigation, including notably the highest profile products-related class actions in Europe and unprecedented criminal investigations in respect of breaches of product safety regulations. She also handles product liability claims, regulatory enforcement actions, inquests, public inquiries (including acting as a Core Participant product manufacturer in the Grenfell Tower Inquiry) and judicial reviews.

In product safety and regulatory, she provides commercially-focused advice across the full product lifecycle from market entry due diligence, regulatory compliance, advertising issues to global product recalls. She has been involved in some of the largest global matters, including product launches and product recalls in respect of 193+ jurisdictions.

With a degree in Science (major in biomedical science) and with having lived and worked in 6 jurisdictions (Australia, Scotland, the Netherlands, Germany, England and the USA), Sarah-Jane is uniquely placed to advise on technical and multi-lingual and multi-jurisdictional matters.

Sarah-Jane holds prominent leadership positions – including as a Member of the Board of Directors for ICPHSO, as a Chair of International Legal Issues for DRI's Product Liability Committee and Chair (International) of IADC's Class Actions Committee.

01. About The Authors

Louise Forrest, Legal Consultant, Ashurst

Louise is a consultant in our global product litigation and product risk (safety and regulatory) practice, advising on matters across all stages of the lifecycle of the product, from product launches, product recalls and ongoing regulatory compliance. Her work crosses many sectors including consumer products, cosmetics, apparel, and chemicals.

Previously, she led a team of international product regulatory consultants for a global provider of market access and product compliance SaaS solutions to world leading brands, helping those companies ensure product compliance.

Through this work, Louise gained in-depth knowledge of the changing product regulatory landscape across a wide range of regulated areas including safety, chemicals, design, energy efficiency, batteries, packaging, labelling, waste, cybersecurity, artificial intelligence, food contact materials and ESG.

Louise is a qualified Irish barrister, receiving her barrister-in-law degree from Kings Inns, Dublin in 2002.

02. Unlocking Market Access

At Compliance & Risks, we help you keep on top of global regulatory changes and their impact worldwide. We have the right technology, regulatory content and expertise to help you unlock market access, protect revenue and elevate the role of compliance.
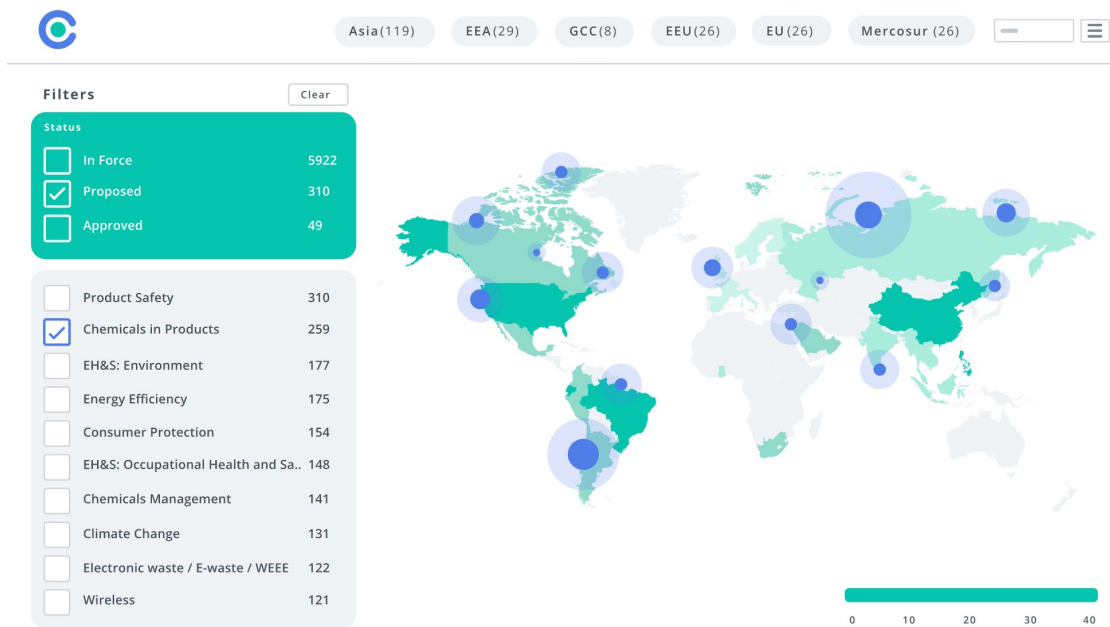
Our solution includes:

- **C2P:** The most advanced product compliance and ESG compliance software on the market, helping you streamline your compliance process and unlock market access around the world.

- **Regulatory Content:** We provide the broadest and most comprehensive product compliance regulatory content on the market, monitoring 195+ countries, 20 industry sectors, 45 topics and 100,000+ regulatory sources.

- **Ask our Experts:** Direct access to our team of experts for support

Additionally, we offer:

- **Market Access Services:** Our Market Access team helps you understand your product compliance obligations by transforming regulations into actionable knowledge with tailored advice for you and your business.

Why choose C2P?

- ✔ **Stay ahead** of regulatory changes with the world's most comprehensive regulatory database

- ✔ **Avoid delays** with alerts of changes to regulations & requirements in real time

- ✔ **Improve efficiency with powerful collaboration and workflow tools** to keep compliance evidence up-to-date & live linked back to Regulations, Standards & Requirements

Contact us to speak to one of our team today to learn how you can simplify your regulatory compliance process.

For more information, please visit
http://www.complianceandrisks.com

03. Introduction

2024 has been a year of significant change in the world of product regulation, safety and liability.

The surge in product regulations globally presents major challenges and legal risks for businesses manufacturing, importing or distributing products, with many recent measures applicable to a broad range of products and industries.

Companies must adopt a proactive and strategic approach to navigate this complex landscape, prioritize compliance, and mitigate potential risks in 2025.

To help you manage the increasing regulatory burden, this guide summarizes the key regulatory and litigation developments in 2024, and looks at what is coming down the line in 2025.

Based on our popular webinar 'Product Regulatory & Liability Developments: 2024 Roundup,' held in December 2024 in partnership with Ashurst, we highlight the top themes and trends to be aware of, as well as offering practical steps for mitigating growing legal risks.

Topics covered include:

- Product Safety;
- Product Sustainability;
- Product Liability.

This guide provides insights and guidance on:

- What's trending in product regulation;
- Recent legislative changes in the EU and UK;
- Global legislative developments;
- Current trends in legal risks;
- Predictions for 2025 and beyond;
- Mitigation strategies for minimizing legal risks;
- And more!

04. Trends in Product Regulation

What trends are we seeing in product regulation? The graph below from C2P shows year on year growth in regulations globally.

1. **Global Increase in Regulations:** A significant upward trend in product regulations is impacting businesses worldwide, with a steady increase in the volume of product regulations globally since 2017.

2. **Regional Variations:** Some regions are experiencing more growth than others. For example, South America is focusing on building their regulatory regimes, whereas in regions like the US and South Korea where there is already a lot of product regulation, it is still growing exponentially. However, some regions are seeing a reduction in regulations, such as the UK and Canada, aiming to reduce regulatory burden.

3. **Sector Focus:** Product safety, chemicals, consumer protection and sustainability are leading the surge in product regulatory developments, driven by the need to address emerging technologies and environmental concerns.

4. **Topic Trends:** There is an increased focus on Artificial Intelligence and new technologies.

Want to discover more about trends in product regulation? Watch our webinar-on-demand.

Increased product regulations globally
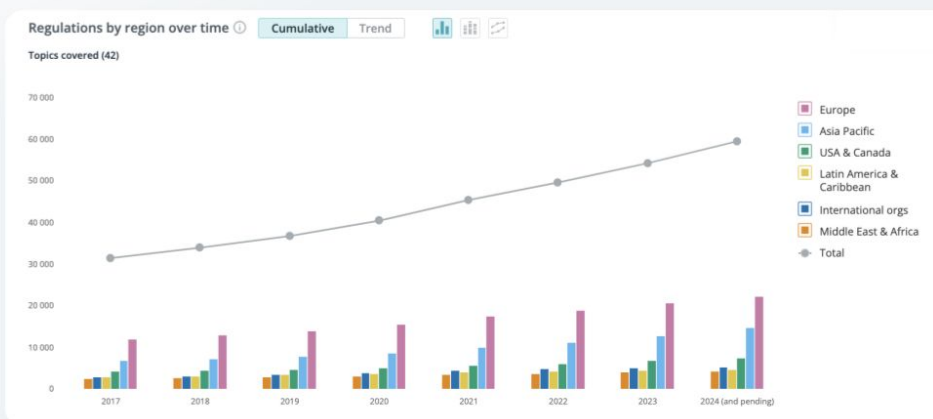
05. Jurisdiction Examples

5.1. EU Legislative Changes

2024 was a milestone year in product regulation in the EU, with increased regulation across the board and/or significant revisions.

We saw new and expanded obligations as well as greater accountability.

Many developments going through the legislative process in previous years came to fruition in 2024 and it brought significant EU legislative changes, including the Batteries Regulation, the Digital Services Act, Ecodesign for Sustainable Products Regulation, the Right to Repair Directive, the Artificial Intelligence Directive, Cyber Resilience Act, Ban on Forced Labor Regulation, the Product Liability Directive, and the General Product Safety Regulation.

Each of these measures are substantial, and they have significant consequences in terms of product compliance and product liability.

Below we look at two prominent new measures that modernize product safety and product liability in the EU, ensuring these regimes are fit for purpose and fit for the modern age.

1. **General Product Safety Regulation (GPSR):** The General Product Safety Regulation entered into force on 13 December 2024, modernizing the product safety framework for the digital age. The GPSR aims to ensure the right to a safe product, considering new technologies and changes in the way products are bought and sold. Key changes include:

   - Expanded scope to include new products, used products, repaired products, reconditioned products, online products, promotional products, as well as standalone software.

   - Stricter requirements for internal risk assessments, technical files, labeling, traceability information, and postmarket obligations such as incident reporting and product recalls.
   - New obligations for online marketplaces, requiring clear safety information and manufacturer details.

2. **Product Liability Directive (PLD):** The Product Liability Directive (PLD) entered into force on 9 December 2024, updating the existing directive to ensure rules for product liability are future-proof and applied to all types of products. The PLD makes it easier for consumers to seek compensation for harm caused by defective products. Notable changes include:

   - Extended scope to include traditional products, product-related digital services, and AI systems.
   - Liability extended to include mental and psychological harm, data loss, and cyber security-related defects as compensable damages.
   - Economic operators remain liable for their defective products for a period of 10 years from when the product was placed on the market, and this is extended to 25 years for latent claims.
   - Introduction of two rebuttable presumptions for defectiveness and causation, easing the burden of proof on consumers.
   - Claimants are entitled to damages covering death, personal injury, physical and psychological harm, and there is no value threshold for recovery.

5.2. UK Legislative Changes

In the UK, there are similar themes to what we see in the EU.

Two notable developments include:

1. **Product Security and Telecommunications Infrastructure Act 2022 (PSTI):** Focused on securing IoT products, the PSTI came into force in 2022, with associated regulations implemented in April 2024. Key provisions include:

   - Ban on default passwords for connected devices.
   - Requirements for vulnerability reporting mechanisms and information on security update availability.

2. **Product Safety and Metrology Bill (PSMB):** Introduced in September 2024, the PSMB is a new framework law expected to significantly reform the UK product safety regime. Key themes include:

   - A proposed hazard-based approach to regulation, with products categorized by their level of risk.
   - Focus on digital labeling, promoting flexibility and lowering costs.
   - Provisions for online marketplace obligations, mirroring trends in the EU.

Check out our webinar-on-demand for further information on these jurisdiction examples in the EU and UK.

06. Other Global Legislative Changes

As with the EU and UK, we can again see similar trends globally concerning AI, product safety and online marketplaces.

Below we list just some of the legislation making waves in product regulation and product liability.

- **USA:** Proposed Consumer Advocacy and Protection Act; Cosmetics Regulation

- **Australia:** Review of Online Safety Act, Treasury Laws Amendment Bill 2024 – Product Safety Regulation

- **Japan:** Proposal for Basic Law for the Promotion of Responsible AI

- **Switzerland:** Product Safety Act revisions

Want to find out more? Watch our webinar-on-demand.

07. Trends in Legal Risks

What does all this increased regulation actually mean in respect of legal risk for the companies that are having to navigate these regimes?

In this new age of product regulation, there's 3 types of main legal risks that we can identify.

1. **Legal Obligations Triggered:** The proliferation of regulations leads to increased legal obligations, particularly in areas of corrective action (e.g., recalls) and regulatory reporting, creating further complexities for businesses.

2. **Regulatory Investigation & Enforcement:** Heightened risk of regulatory scrutiny, investigations, and enforcement actions, including financial and criminal sanctions.

3. **Civil Litigation:** The evolving landscape is increasing the risk of civil litigation fueled by:
   - Closer convergence between litigation and regulation;
   - New causes of action / rights of recovery outside product liability regimes;
   - Reversal of onus of proof / lower proof threshold for claimants in product liability;
   - Rise of class actions with the Representative Actions Directive and Product Liability Directive increasing the potential for consumer litigation.

View our webinar-on-demand for more details on these trends in legal risks.

08. Future Predictions

So where is this all going?

Here are some predictions for 2025 and beyond:

- Increased corrective actions and regulatory reporting;

- Determination of enforcement practices for new or greatly changed regimes;

- Increased use of regulatory investigations and decisions as a basis for civil litigation;

- Increased class actions;

- Forum shopping in litigation;

- Change of global trend for leaders in litigation.

See what's coming down the line in 2025. View our webinar-on-demand.

09. Mitigation Strategies

So what can you do to protect yourself?

Here are our steps to help you minimize product regulatory and litigation risk:

1. **Review Supply Chains:** Conduct thorough due diligence on suppliers, clearly define responsibilities, and maintain strong working relationships with suppliers to manage risks and ensure compliance throughout the supply chain.

2. **Review Product Portfolio:** Analyze products for compliance with new and existing regulations, and proactively monitor and update product development processes to incorporate evolving requirements.

3. **Track Regulatory Developments & Litigation Risks:** Utilize tools like the C2P platform to monitor global regulatory changes, track emerging trends, and proactively assess potential litigation risks.

4. **Review Crisis Management Protocols:** Establish and test robust crisis management procedures to effectively handle product safety issues, recalls, and potential litigation.

5. **Consider Global Litigation Strategy:** Ensure disclosure and statements made across the jurisdictions are as streamlined as possible to normalize litigation risk strategy.

Interested in future-proofing your business? Start a conversation with our experts.

10. Webinar Q&A

During the live webinar, numerous questions were sent in by our engaged audience. Our webinar presenters from Ashurst, Sarah-Jane Dobson and Louise Forrest, have provided expert answers to the most popular queries below.

Q) Would you please share more detailed information about radio standards, and radio technology standardization process, appropriate to the selected wireless technology, or used frequency recourses (for example W-LAN technology). Also will be interested to know more details about country regulation concerning implementing modular certification recognition (radio modules, embedded to the various host equipment). Thank you.

A)   *"There are a range of mandatory legal obligations that apply to radio equipment in the EU. Generally, radio equipment placed on the EU single market must comply with the essential requirements of the Radio Equipment Directive (RED). Further information and a link to the summary list of titles and references of harmonized standards under Directive 2014/53/EU on radio equipment may be [found here](#). There will also be other product regulatory laws and standards that are likely to apply. Please let us know if you have a specific question we can assist with further."*

Q) Does GPSR compliment toy regulations?

A)   *"There are a range of mandatory legal obligations that may apply to toys in the EU contained within a range of product safety regulation. Primarily, in the EU toys are regulated under Union harmonization legislation, specifically the Toy Safety Directive 2009/48/EC (TSD). This sector-specific piece of legislation is thought to most comprehensively address the inherent risks of the toy product safety category uniquely.*

Note, a legislative proposal was published in July 2023 to replace the TSD and is currently working its way through the EU legislatve process.

However, the GPSR provides a general, broad-based legislative framework of a horizontal nature and therefore may be complementary to harmonized legislation such as the TSD where gaps exist within the more specific legislation. For example, this is where certain types of risks are not covered, such as cyber threats for example, or where there is otherwise a legislative gap. For example, there may be additional obligations contained within the GPSR not covered in sector-specific legislation such as the TSD, in respect of online marketplaces, in respect of product-related accidents, in respect of the right to information and to a remedy for consumers as well as the product safety recalls."

Q) Do electronics products like home speakers which operate in AC voltage, come under GPSR? Does it qualify under toy products?

Q) Do electronics products come under GPSR or toy products standard? For example, a speaker which operates at AC 230V. Thanks.

A)   *"Electronic products in the EU are subject to a range of mandatory legal obligations contained within various product regulations. The electrical safety of home speakers over 50 volts AC would likely be governed in large part by the Low Voltage Directive as the most response legislative regime specific to inherent risks of the product. Nonetheless, the GPSR may have effect in certain circumstances in respect of these*

products, an example is where the product has a voltage lower than 50V AC or potentially when it comes to the physical and/or mechanical safety of the product. By way of context, the GPSR, as a general overarching product safety regime, applies to products not already subject to harmonized legislation. Further, for products subject to harmonized legislation (i.e. CE marked products) it will only apply if there are gaps in the product safety regulation.

To fall under the toy safety regime in the EU, the Toy Safety Directive (TSD), a product would need to meet the definition of a toy i.e. products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys). Annex I of the TSD contains a list of products that are not considered toys including electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, keyboards, joy sticks or steering wheels. Note there was a legislative proposal published in July 2023 to replace the TSD. This proposal is currently working its way through the EU legislative process."

Q) Despite all the advantages to digital labeling, are there any concerns?

A) "The benefits of e-labeling are well publicized. In short, it is thought that e-labeling has the potential to reduce waste and thereby promote sustainability. Further, e-labels can be thought to be easily updated to avoid time and cost associated with errors or updates needed for labeling. Although they are not as widely discussed, some potential disadvantages to digital labeling may include additional costs linked

to the putting in place the necessary technology and infrastructure to create the e-labels initially. Further, labels in a digital format may be less secure and more prone to interference from third parties, including being subject to cyber security issues. Furthermore, there is a possibility errors or dysfunction impact e-labels more than traditional labels. Furthermore, consumers may have more arguments to allege they weren't able to or did not view the e-labels in a way that might expose companies to greater risks regarding failure to warn."

Q) What are the differences between the Swiss and EU product safety?

A) "As Switzerland is not part of the EU (and is part of the EEA), it does not adopt EU product safety laws. However, Swiss product safety laws are nonetheless largely aligned with those of the EU. As one example, Switzerland has attempted to implement the EU's Product Safety Directive through its Product Safety Act and Product Safety Ordinance in order to harmonize with EU legislation and reduce technical barriers to trade.

Recently, the Swiss State Secretariat for Economic Affairs, the responsible Swiss authority for product safety, is currently analyzing the GPSR and will partially revise the Swiss Product Safety Act and Ordinance in order to ensure alignment."

11. Conclusion

The rise in product regulations globally presents significant challenges and legal risks for businesses. Staying on top of regulatory developments and maintaining compliance is crucial.

In order to mitigate legal risks and navigate the complexities of the regulatory landscape, companies should consider leveraging technology in order to future-proof business operations and prioritize compliance in an evolving environment.

Empower your business today - begin your journey and speak to a regulatory expert.

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OUR NUMBERS

300+
CUSTOMERS WORLDWIDE

195
COUNTRIES COVERED

100,000+
REGULATIONS