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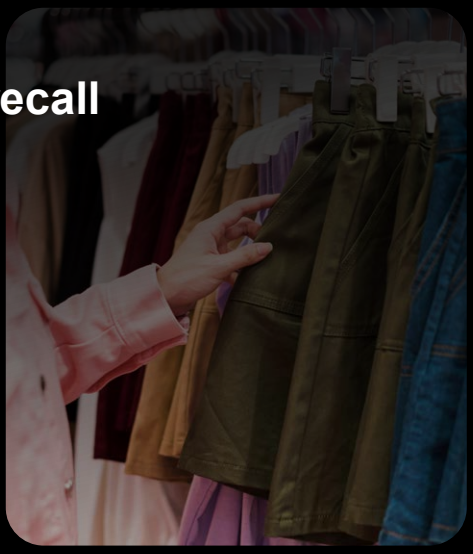
Recall Index

2026 edition 3

Product safety and recall

European edition





















DATA, TRENDS & PREDICTIONS FOR EUROPEAN INDUSTRIES

Introduction

Understanding the forces shaping product safety is fundamental to managing risk, protecting consumers and maintaining business resilience. Sedgwick's Product Safety and Recall Index provides an independent, data-led perspective on the developments reshaping the global product safety landscape, examining recall activity, emerging risk patterns and regulatory change to help business leaders understand not only where the market stands, but where it is heading.

The report draws on regulator data from the United Kingdom (UK) and the European Union (EU) across five product categories and three sub-categories: automotive, food and beverage, pharmaceutical, medical device, and consumer products, including electronics, clothing, and toys. It is designed to provide insights to help businesses protect their brands against operational risk and reputational damage.

This edition reviews recall data through the first three quarters of 2026, covering January through September. Across all the categories and sub-categories we track, EU and UK regulators recorded 10,590 recalls so far in 2026 compared with 11,474 over the same stretch of 2025, a 7.7% decrease. Even so, 2026 had the second-highest three-quarter total in the past seven years, behind only 2025 and narrowly ahead of the 10,581 recalls recorded in the first three quarters of 2024.

Consumer products accounted for most of the decline. Overall consumer product recalls fell 21.9% to 3,144, as chemical-related events dropped to less than half of last year's level. Clothing recalls fell 44.2% to 87, the lowest three-quarter total since 2020. Pharmaceutical recalls were down 25.5% to 222. Automotive recalls declined 9.7% to 623, though that is still the third-highest three-quarter figure in more than 12 years. Medical device recalls were nearly flat, slipping 1.2% to 2,557.

In contrast, three industries saw increases. Food and beverage recalls rose 4.5% to 4,044, the highest three-quarter total in the series. Consumer electronics climbed 11.3% to 865, and toys edged up 2.7% to 683. Both sub-categories posted their highest three-quarter totals in more than a decade.

Beyond the numbers, the Index looks at what is next for companies, from new compliance requirements to shifting priorities among regulators and legislators. Commentary from strategic partners at global law firms, insurers, and regulatory and safety organisations is included to help businesses protect their brands and reduce risk.

Long-standing regulatory frameworks were being revised in the third quarter. A leaked draft of the European Product Act points to the widest reset of EU product law in more than a decade, and the Council of the EU endorsed the biggest overhaul of medicines legislation in 20 years. In the UK, proposed Health Bill amendments opened the door to licensing some medical devices directly. England's food regulator backed plans to oversee the largest retailers at a national level, a big shift from the current system.

Regulators also paid close attention to what a product is and what can be said about it. Vague environmental claims now need verifiable evidence across the EU. The UK drew a line between AI scribes that simply take notes and those that shape clinical decisions, and it pressed clinics and online pharmacies to stop marketing prescription-only weight-loss treatments to the public. In addition, the UK's product safety regulator signalled that online marketplaces will carry more responsibility for what they sell.



Across these changes, the UK continued to define its post-Brexit regulatory path, sometimes in alignment with the EU and other times on its own. The sanitary and phytosanitary (SPS) agreement under negotiation would bring Great Britain back in line with EU food law, including for domestic businesses. In the automotive sector, the EU sought limits on Chinese hybrid imports, and it remains unsettled whether UK-built cars will count under "Made in Europe" proposals. The UK reviewed its electric-vehicle sales targets and consulted on safety standards self-driving cars will have to meet.

Taken together, the quarter moved several major frameworks from proposal toward law, raised the bar for the claims companies make, and left open questions about which rules UK businesses will ultimately follow. This report can help businesses assess what is next and plan even in a dynamic environment. We invite you to read the entire report cover to cover or just focus on the sections that matter most to your organisation.

One final note: This edition of the Product Safety and Recall Index focuses on recall data and regulatory developments in the European Union and UK. If your operations or supply chain extend to the U.S., we recommend that you also read our U.S. Product Safety and Recall Index.

That edition shares and analyses data and regulatory changes from the U.S. Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), the U.S. National Highway Traffic Safety Administration (NHTSA), and the U.S. Department of Agriculture (USDA). It also includes perspectives from our U.S. partners.

Our biannual Australian Product Safety and Recall Index report provides insights on regulations and recall data for that market.

Q3 2026 U.S. Recall Index: click here

H1 2026 Australian edition: click here

If you would like more information about what we have observed in recent quarters from a European perspective, you can find previous editions of the Product Safety and Recall Index below:

Q2 2026 European Recall Index: click here

Q1 2026 European Recall Index: click here

Q4 2026 European Recall Index: click here

Q3 2025 European Recall Index: click here



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Automotive

The UK continues to refine its self-driving vehicle rules. A consultation on the statement of safety principles closed in September. Automated vehicles are expected to be authorised for use on public roads in the second half of 2027.

At the same time, UK ministers opened a review of the zero-emission vehicle mandate. The 2030 end to new petrol- and diesel-only cars remains, but annual sales targets and other provisions may be changing. The government also put nearly £130 million behind zero-emission and connected-vehicle technology.

Trade policy was another key consideration in the third quarter. The EU is pressing China to limit hybrid-car exports, and Britain's place within the proposed "Made in Europe" rules remains unclear. The Society of Motor Manufacturers and Traders (SMMT) has warned that excluding UK-built vehicles would weaken both sides of a supply chain worth tens of billions of euros a year.

Automakers now have to plan against three moving parts at once: how self-driving vehicles will be authorised, how fast the shift to electric sales must occur, and whether UK-built cars will qualify as "Made in Europe" for the next round of EU industrial policies.

UK consults on safety principles for automated vehicles

In June, the UK Department for Transport opened a consultation on a draft statement of safety principles (SoSP) for self-driving vehicles in Great Britain. The SoSP is a key piece of secondary legislation under the Automated Vehicles Act 2024.



Shifting rules on automated vehicles, electrification and trade are making long-term planning increasingly complex for automotive manufacturers.



Regulators will assess automated vehicles (AVs) against the principles to determine whether they meet the “self-driving test” criteria and can be authorised for use on public roads. The standard requires AVs to achieve a level of safety equal to or higher than that of a careful and competent human driver. The SoSP will also be the benchmark for an annual report on how the self-driving fleet is performing.

Rather than being a checklist of technology features, the standard is written as a set of behavioural principles. The 10 principles in the draft SoSP include whether the AV can use the road in accordance with traffic laws and the Highway Code, maintain constant control over the vehicle, behave in a predictable manner, and adapt driving to road and weather conditions.

In addition, regulators will consider if the vehicle can predict, detect, and respond to hazards proactively, if it improves road safety in Great Britain for all, and if it interacts safely with all road users, particularly those who are most at risk. To be approved for use on public roads, the AV must also show it can interact safely with emergency services, only operate autonomously within the limits under which it is specifically designed to function, and that it is designed to take account of the specificities of the territory where it will operate.

Attorneys with Winston Taylor LLP state that the UK’s regulatory approach is designed to harmonise with international standards such as the United Nations Economic Commission for Europe’s Global Technical Regulation on Automated Driving Systems (ADS). This alignment will help establish a common safety baseline and shared assessment methods to support cross-border deployments of AVs.

The EU also supports the ADS regulation, though it is tackling AV regulations differently from the UK. It is folding automated driving into its existing vehicle-approval and General Safety Regulation framework rather than building a standalone AV statute.

The UK’s consultation closed on 9 September 2026. The legal experts with CMS state that the final SoSP will impact manufacturers, insurers, and operators seeking authorisation in Great Britain. Companies developing products for both the EU and UK markets will need to map the UK principles against that EU type-approval route as the UK regime is finalised.

UK reviews zero-emission mandate while still funding the transition

On 14 August, the UK government asked for stakeholder input on the zero-emission vehicle (ZEV) mandate. The effective date of the ban on the sale of new cars powered solely by petrol or diesel remains 2030, with hybrids allowed until 2035. Under review are the annual sales targets and whether flexibilities due to expire in 2029 should be extended.

Britain's ZEV mandate is one of the strictest programmes in Europe. Automakers that miss their targets can face fines of as much as £12,000 per car. About 28% of new cars sold in the UK in 2026 have been fully electric, according to SMMT data. That is ahead of many major EU markets, but still below the 33% goal for 2026 under the mandate. The goal for vans is to hit a 24% electric target this year.

The EU has already eased its own 2035 combustion-engine end date. In December, it proposed a 90% cut in tailpipe emissions by the middle of the next decade, with the remaining 10% offset through measures such as green steel or sustainable fuels. The U.S. has also rolled back emissions targets.

Days before the call for comments opened, the government announced nearly £130 million for zero-emission vehicle technology. About £50 million is earmarked for automakers and research partners to develop and scale the technology. A further £17 million will support nine connected and automated mobility projects, including sensors, brake-by-wire systems, and AI simulation.

Manufacturers should treat the review as a change in pace, not a change in direction. Product plans, fleet mix, and compliance credits still have to align with a 2030 end date. The economic support is a reminder that the UK wants to promote domestic design and production of the next generation of vehicles.

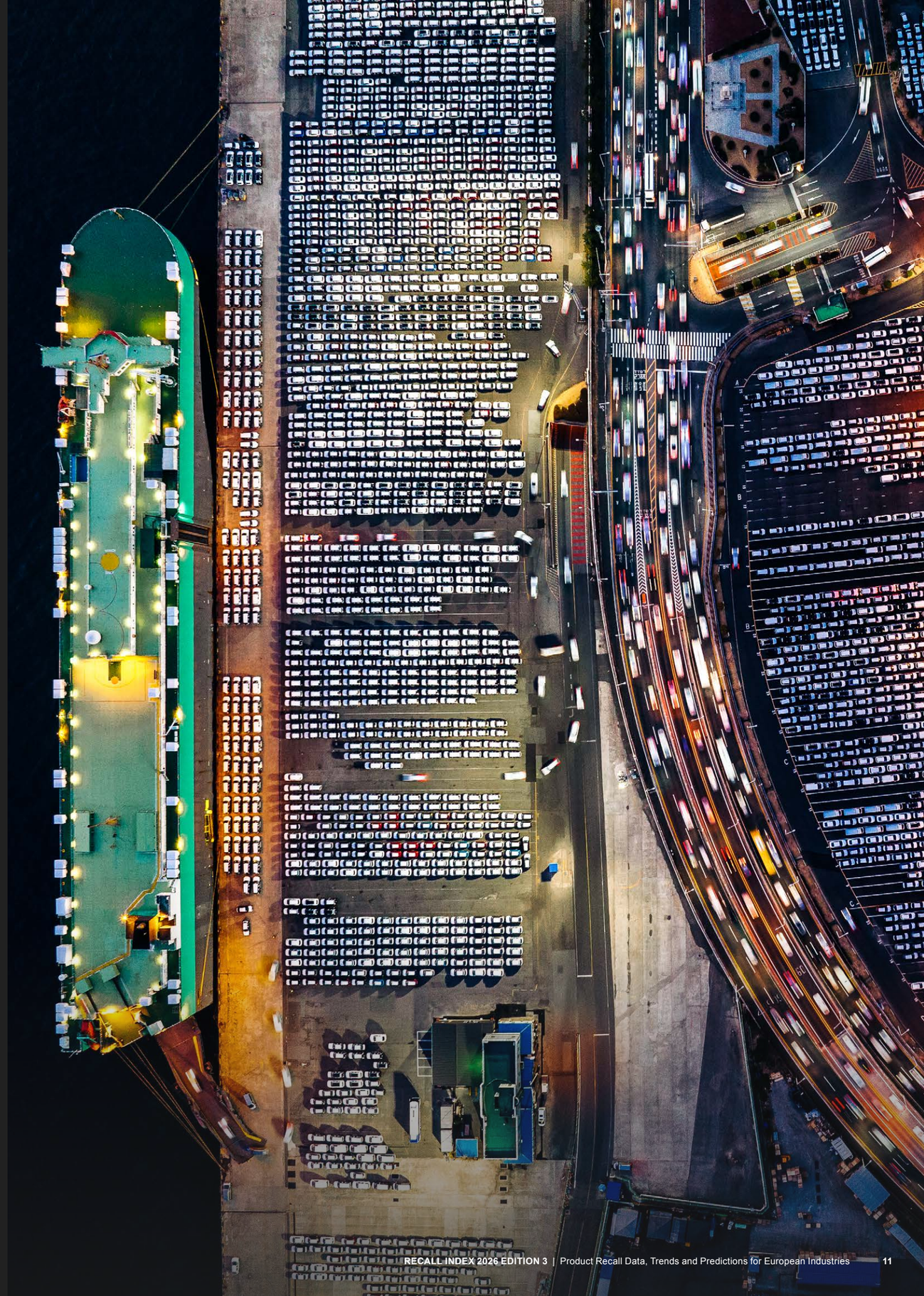
Debate over foreign imports continues

The EU spent the third quarter trying to slow a further wave of imported Chinese vehicles without opening a wider trade fight. Reuters reported that in September, European trade representatives asked China to cap hybrid-car sales at around 15% of the EU market. This measure would be on top of the additional tariffs of up to 35% on China-made electric vehicles and the standard 10% duty. European Commission President Ursula von der Leyen told the European Parliament that the EU's goods trade deficit with China—€361 billion in 2025, and wider still in the first half of 2026—had become "unsustainable."

The UK is also impacted by the negotiations. Chinese brands account for about 15% of UK new-car registrations this year, compared with about 10% across the EU/UK/EFTA region. Chinese cars entering Britain pay the standard 10% Global Tariff. According to Bloomberg News, one leading automaker is calling on the UK to raise its tariffs on imported Chinese vehicles to match the EU's duties and prevent a trade imbalance. The EU has signalled that it may restrict Britain's participation in the "Made in Europe" programme if the UK does not align its policies on Chinese-made vehicles.

The SMMT has warned that excluding UK-built vehicles from EU incentives would put British plants at a disadvantage and, because the UK is the EU's largest customer for automotive components, would also hit EU suppliers. The EU's current draft of its "Made in Europe" provisions would deny future British-built vehicles the support available to EU-built products, including measures for greener corporate fleets. UK Prime Minister Andy Burnham has said he will argue for Britain to be treated as a "trusted partner."

UK and EU manufacturers should continue to map where vehicles and components are made against both the existing China EV tariffs and the draft "Made in Europe" provisions. The third-quarter debate shows that market access, local-content rules, and China policy are now one conversation.



By the numbers

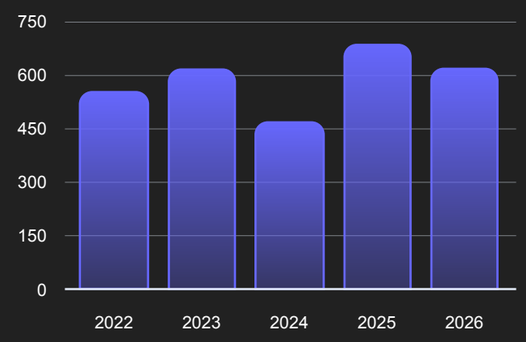
Across the first three quarters of 2026, regulators in the EU and UK reported 623 automotive recalls. That is 9.7% fewer than the 690 events recorded over the same period in 2025. However, it is worth noting that 2025 was a record-breaking year. The 2026 total remains the second-highest three-quarter figure recorded in more than 12 years.

Injuries remained the predominant cause of automotive recalls across Europe. They were cited as a standalone hazard in 476 recalls through September, down from 525 during the same period last year. Fire ranked second with 106 recalls, down from 126 in 2025. Environmental risks and the combination of fire and injuries tied for third, with 16 recalls each, up from 13.

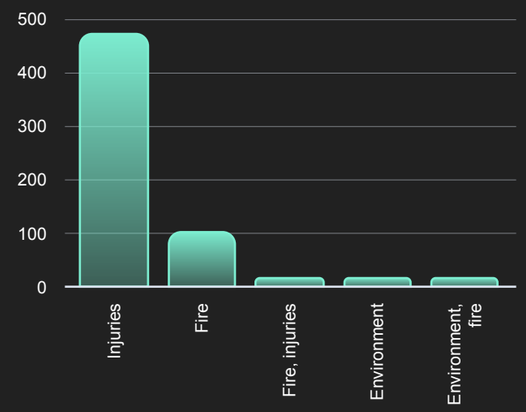
Passenger cars accounted for the largest share of activity, with 339 incidents. Passenger vans and light commercial vehicles were second with 94 recalls. Motorcycles, including electric and three-wheel vehicles, were third with 43.

The UK led the region in automotive recall alerts, issuing 305 notifications in the first three quarters of 2026. This compares with 276 in the same period in 2025. The UK recorded the highest number of alerts in both years, marking the second consecutive year it has led the region during the first three quarters. Germany was second with 154, down from 220 in 2025. France ranked third with 123, an increase from 96 alerts in 2025.

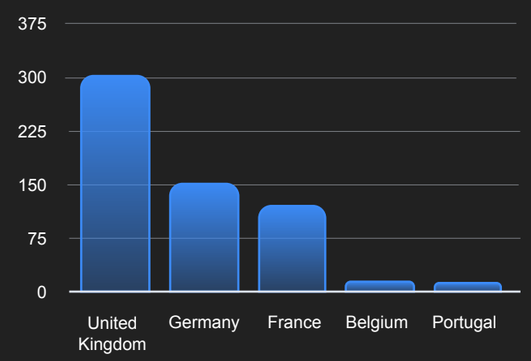
Number of recall events (Q1-Q3)



Number of recall events by risk (top 5)



Recall events by notifying country (top 5)







UK government consults on safety principles for automated vehicles

NEIL BAYLIS AND **RUTH DERRUAU,** *CMS LEGAL*

In June, the UK Government launched a consultation on its proposed Statement of Safety Principles (SoSP) for automated vehicles (AVs) under Section 2 of the Automated Vehicles Act 2024 (AVA). The SoSP is central to the AVA's regulatory framework, with the core objective of ensuring that AVs achieve safety levels equivalent to, or exceeding, those of careful and competent human drivers.

The consultation, which proposes ten draft safety principles, closed on 9 September 2026. In this article, we explore the SoSP consultation, its purpose, and the principles it sets out for AVs.

Background

The AVA was granted Royal Assent on 20 May 2024 and sets out the primary framework for AVs in Great Britain. The measure provides the legal framework for the safe deployment and authorisation of automated vehicles, with full implementation—including the authorisation regime for self-driving vehicles—expected in the second half of 2027.

However, the operational details under the AVA are being published in secondary legislation. The SoSP is one of the key pieces of this secondary legislation. Last summer, the Department for Transport (DfT) published a call for evidence on the SoSP. The UK Government has now reviewed that evidence and published a consultation on its proposed statement of safety principles for AVs.

The purpose of the SoSP

The SoSP sets out the safety levels and compliance standards for AVs and is a fundamental part of the AVA. The Centre for Connected and Autonomous Vehicles (CCAV), DfT, and UK Minister for Buses and Local Transport Simon Lightwood MP stated that "safety sits at the heart of the AV regulatory framework, ensuring that AVs are safe to use on Great Britain's roads and remain safe throughout their deployment."

Under the AVA, the SoSP serves two statutory purposes. The first is to guide the Secretary of State when determining whether a vehicle satisfies the statutory "self-driving test" and can therefore be authorised (Section 1). The second is to provide a benchmark against which the annual performance of the self-driving fleet can be assessed (Section 38).

Under Section 1 of the AVA, a vehicle satisfies the authorisation "self-driving test" if it is designed or adapted with the intention that a feature of the vehicle will allow it to travel autonomously and is capable of doing so safely and legally by means of that feature.

Under Section 38, effective and proportionate measures for safety standards must be implemented and published as an annual report by the Secretary of State, allowing the general performance of self-driving vehicles to be monitored.

The AVA requires the SoSP to ensure that authorised self-driving vehicles achieve a level of safety equivalent to, or higher than, that of careful and competent human drivers. The rule also mandates that road safety in Great Britain is improved as a result of AV deployment.

Scope of the SoSP

In shaping the draft statement and its principles, the government took account of the responses to last summer's call for evidence. It recognised that certain AV-specific attributes need to be reflected in the principles, relating to compliance with the limits of the AV's authorisation, in terms of geography and capability of the vehicle. The government also acknowledged that AVs must be designed to consider the specificities of the territory in which they operate.

Drawing on the call for evidence and public perceptions research, the government identified five broad themes of careful and competent driving: vehicle control, obeying traffic rules, interaction with other road users, adaptability to road conditions, and hazard anticipation, perception, and reaction. The SoSP therefore proposes to articulate the safety standard through a set of behavioural principles that describe how an AV should operate in real-world conditions.

The government has stated a strong preference to ensure alignment of the principles with international standards in order to lower market entry costs, enable cross-border deployments, and facilitate faster spread of safety technologies.

The draft safety principles

Among the 10 principles are that self-driving vehicles should use the road in accordance with traffic laws and the Highway Code, maintain constant control over the vehicle, adapt driving to road and weather conditions, and behave in a predictable manner.

The SoSP also requires that AVs improve road safety in Great Britain for all, interact safely with all road users—particularly those who are most at risk—and predict, detect, and respond to hazards proactively.

In addition, self-driving vehicles must interact safely with emergency services, only operate autonomously within the limits under which they are specifically designed to function, and be designed to take account of the specificities of the territory where they will operate.

Some attributes identified in the previous call for evidence—such as the ability to drive without human monitoring of the vehicle—are not drafted as standalone principles but are nonetheless captured within the 10 stated concepts.

Further views sought

The consultation seeks stakeholder views on several key questions, including whether the SoSP's purpose should be limited to guiding authorisation decisions and whether the safety standard should be set at equivalence with a careful and competent human driver.

It also explores how the concept of careful and competent driving should be defined and assessed, whether the draft principles adequately capture the expected behaviours of authorised AVs, and whether the proposed principles provide sufficient protection for all road users.

The EU's position

The European Union has adopted a technology-neutral, product safety-based approach to autonomous vehicles, integrating automated driving within its existing vehicle approval regime rather than creating a standalone regulatory framework for AVs.

The cornerstone of the EU regime is the General Safety Regulation, which establishes the legal basis for approving automated and fully automated vehicles while requiring a range of advanced safety technologies in all new vehicles.

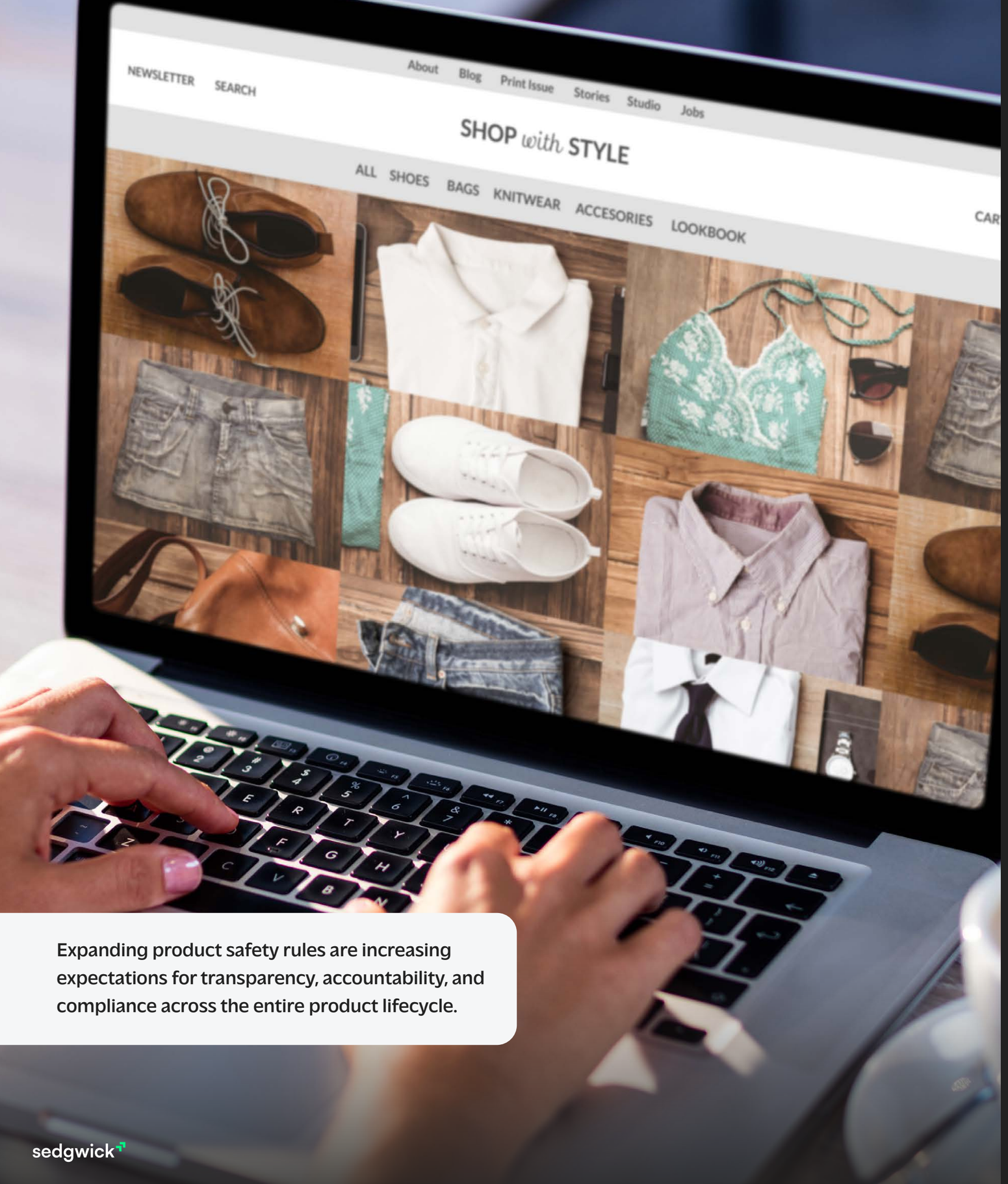
The Regulation operates alongside the EU's vehicle type-approval framework, which, like the UK, reflects United Nations Economic Commission for Europe regulations. Rather than prescribing particular technologies, the EU emphasises performance-based safety outcomes and conformity assessment, with technical requirements largely developed through implementing legislation and internationally harmonised standards.

Next steps

The finalised SoSP will have significant implications for those seeking authorisation to deploy self-driving vehicles on Great Britain's roads. The SoSP is key for stakeholders, including AV manufacturers, insurers, and operators. With the consultation closed, stakeholders should look for a report from the government on the results and the next steps in the legislative process.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.





Expanding product safety rules are increasing expectations for transparency, accountability, and compliance across the entire product lifecycle.

Consumer products

The EU is preparing its most comprehensive update to product safety regulations in more than a decade. At the same time, new rules regarding environmental claims started to apply at the end of September. In the UK, the Office for Product Safety and Standards published its latest delivery report highlighting its enforcement priorities and accomplishments.

Looking at the recall data, overall consumer product recalls across the EU and UK were down sharply for the first three quarters of the year compared to 2025, continuing a retreat from last year's peak. However, electronics and toys both recorded their highest three-quarter totals in more than a decade. Clothing remained at a multi-year low. Chemical risks were still the top risk overall. Companies selling across Europe will need to closely monitor product safety, sustainability claims, and online marketplace responsibilities.

The Packaging and Packaging Waste Regulation started to apply on 12 August, introducing new EU rules on packaging design, recycled content, and waste. In June, the European Commission also published guidelines on the Forced Labour Regulation, which will govern how companies identify and remove products made with forced labour from the EU market.

The pending European Product Act will have a major impact on compliance requirements and standardisation procedures for companies selling goods in the EU market. Businesses can expect new responsibilities—especially for online marketplaces—as well as pre-market registration requirements and heightened postmarket surveillance.

The Green Transition Directive began to apply on 27 September. Companies face stricter rules on environmental claims, including the need to provide clear evidence to support them.

The UK's Office for Product Safety and Standards (OPSS) released its 2025–2026 Delivery Report in August. The publication outlines how the regulator is using its new statutory base and highlights recent product safety consultations.

The European Product Act, the Green Transition Directive, and the UK consultations are different instruments, but they all address the same three questions—what the product is, who is responsible for it, and what can be said about it. Stakeholders across the consumer products sector should be prepared with the answers.

EU looks to overhaul product safety framework

A leaked draft of the European Product Act (EPA) circulated in September. Attorneys with Cooley LLP describe it as one of the most significant overhauls of EU product law in more than a decade—potentially broader than the General Product Safety Regulation (GPSR). The regulation would impact how products access the EU market, postmarket surveillance, and conformity assessment processes.

The EPA would replace the 2008 New Legislative Framework and the Market Surveillance Regulation with a single, directly applicable regulation. The measure would apply to most manufactured consumer products that today sit under the New Legislative Framework or the GPSR. Food, feed, and medicines would be out of scope. It is unclear whether standalone software such as apps and chatbots would have to comply.

The rules are being proposed as a regulation, which means they would apply directly in all Member States, reducing the risk of national differences. The legal experts point out that the rules would also likely take effect more quickly.

The European Commission had been expected to publish a formal proposal on 6 October. It has since postponed that date so the horizontal rules can be presented with changes to sector-specific legislation. The European Parliament's internal market committee held a public hearing on 15 October to gather input from officials, standards bodies, consumers, and businesses.

Some of the key elements of the draft include an emphasis on providing information in a digital format. This means not only digital product passports (DPPs), but also digital CE marking and a "product responsibility record" where DPPs do not apply.

The Commission also wants to require all in-scope products to be listed in a new European Product Act Registry before being placed on the EU market, with automated verification of digital product passports and product responsibility records before goods are released for free circulation.

The EPA also has provisions to restructure the accreditation process, strengthen oversight of Notified Bodies, and implement more detailed obligations for the EU-based responsible person, including a risk reporting obligation.

From a product safety standpoint, it would add stricter requirements for marketplaces to remove noncompliant products from sale, increased verification obligations on online marketplaces, and stronger market surveillance capacity, including a new market-surveillance fee applicable to products imported from third countries.

Member States would still set penalties, but the draft sketches minimum fines of between 1% and 6% of global annual turnover for a long list of infringements.

Lawyers with Cooley recommend that every business placing products on the EU market start considering how the proposals would affect the identity and accountability of its EU operator, its compliance data, and, for online marketplaces, listing and takedown processes. Businesses should also be ready to engage once the Commission issues the formal proposal.

Legal experts with Noerr suggest that companies review their IT infrastructure and data strategy ahead of the DPP requirements and review their supply chain contracts and allocation of responsibility, especially for imports from non-EU countries. In addition, online marketplaces will need to prepare for new liability risks.

Green Transition Directive takes effect

The EU's Empowering Consumers for the Green Transition Directive (ECGT) started to apply on 27 September 2026. It amends the Unfair Commercial Practices Directive and the Consumer Rights Directive. The aim is to stop generic or unsubstantiated environmental claims and to give consumers clearer information on durability, repair, and legal-guarantee rights.

Now any vague claims such as "green" or "eco-friendly" need reliable, verifiable evidence. Sustainability labels used in business-to-consumer communications must be run by a public authority or a certification scheme that meets the directive's tests. In addition, carbon-neutral





claims that rest only on offsetting and future climate pledges without a detailed, independently verified implementation plan are not allowed. There is no transitional relief for products already on the market.

Attorneys with Latham & Watkins LLP note that the rules capture marketing, packaging, websites, and point-of-sale information directed at EU consumers, including by companies based outside the EU. Transposition of the directive into national law has been uneven. The Commission opened infringement procedures against Member States that missed the 27 March transposition deadline.

However, the Commission's Q&A and a June common understanding from the Consumer Protection Cooperation Network allow practical fixes such as stickers, point-of-sale information, or prompt correction of online claims for products already in circulation or inventory.

The legal experts recommend that companies audit consumer-facing claims across advertising, packaging, websites, product and brand names, and stores. They should be prepared to withdraw or re-evidence generic, comparative, forward-looking, and offset-based claims and check existing labels against the new certification tests.

In addition, companies are advised to train marketing and packaging teams to ensure environmental language is signed off before launch.

OPSS publishes latest delivery report

In August, the UK's Office for Product Safety and Standards (OPSS) published its 2025–2026 Delivery Report, highlighting regulatory reform, enforcement actions, and consumer protection activities. The report covers the year in which the Product Regulation and Metrology Act 2025 received Royal Assent.

Attorneys with Squire Patton Boggs describe the document as an indication of where enforcement and reform are heading for businesses supplying products to the UK market. The report itself stresses risk-based action, online-marketplace compliance, and a dual brief to protect consumers and support economic growth.

Key themes covered in the report include product safety policy, product regulation and enforcement, weights and measures, construction products, environmental protection, and agency capability and capacity.

The agency's top product safety policy accomplishments included the passage of the Product Regulation and Metrology Act 2025, various sector-specific reforms, and a series of public consultations on the General Product Safety Regulations, enforcement and market surveillance, and furniture fire safety. Cosmetics and toys were among the priority product areas.

In terms of product regulation and enforcement, the OPSS discussed its risk-based approach grounded in structured methods to assess hazards, how harm can occur, and proportionate action needed to mitigate risks. This included corrective action around faulty heat pump tumble dryers.

The report also reinforces the agency's five objectives, including delivering protection through responsive policy and active enforcement, applying policies and practices that reflect the needs of citizens, and enabling responsible businesses to thrive. It is also focused on coordinating local and national regulation and inspiring confidence as a trusted regulator.

The legal experts note a recurring theme throughout the report: the OPSS's efforts to hold online marketplaces accountable. The OPSS emphasises its safety concerns linked to online marketplaces and states it is developing a programme to ensure that online marketplaces take more responsibility to prevent product-related harm.

The agency has increased its engagement with major online marketplaces and is promoting stronger oversight of products sold through online vendors. It has also worked with His Majesty's Revenue and Customs, Border Force, local regulators, and other enforcement partners to tackle noncompliant products entering the UK through online sales channels.

Businesses placing consumer products on the UK market should use the delivery report as a prompt to check how they would fare under the still-pending safety and enforcement frameworks: who in the supply chain holds the data, how quickly a listing can be taken down, and whether online claims would survive the same scrutiny the OPSS is already applying.

By the numbers

In the UK and EU, consumer product recalls across all product categories decreased by 21.9% between the first three quarters of 2025 and the same period in 2026, falling from 4,027 events to 3,144. Even with the lower figures, 2026 remains the second-highest three-quarter total in more than a decade, behind only 2025.

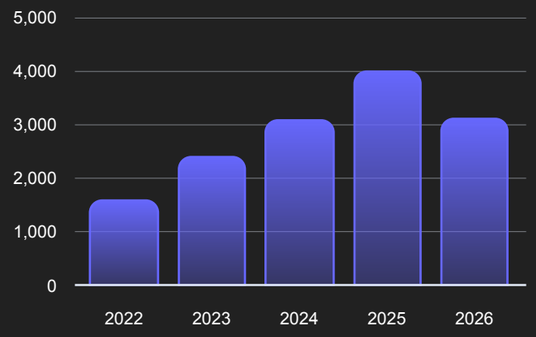
Chemicals were the most frequently cited risk through September, associated with 948 recalls as a standalone hazard. That is less than half the 2,051 chemical-related recalls in the first three quarters of 2025. Electric shock ranked second with 441 recalls. Choking was third with 336 events as the sole risk.

Gel nail polish was the most frequently recalled consumer product, involved in 167 events. Soft toys were second with 103 recalls. Lighting chains were third and were linked to 86 events.

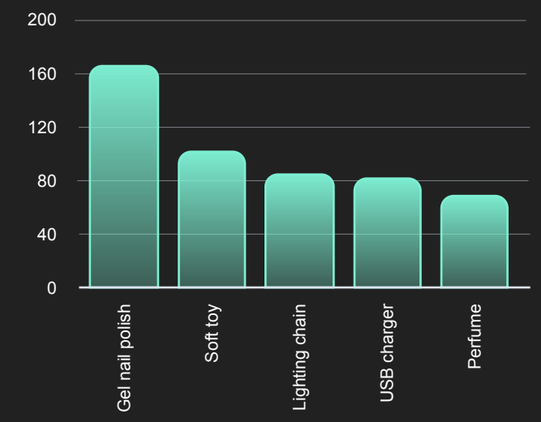
The UK was the leading notifying country, reporting 592 consumer product alerts, up from 488 in the same period last year. France placed second with 385 notifications, compared with 289 in 2025. The UK (in respect of Northern Ireland) issued 292 alerts, down from 307. Italy was next with 276, a steep drop from 1,151 a year earlier, when it led all countries.

Through the first three quarters of 2026, 41 consumer product recalls were confirmed to involve counterfeit goods. Authenticity was verified in 981 cases, while 2,120 events were classified as unknown and one was designated “not conclusive.”

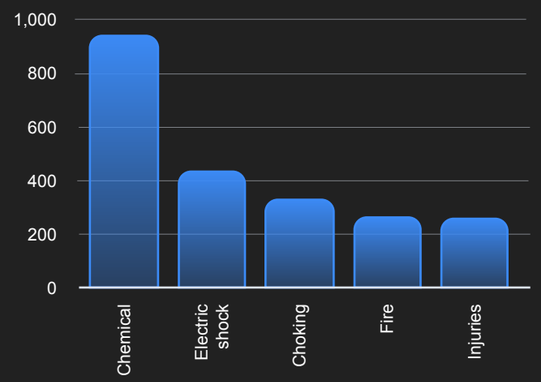
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)







A new era for product safety in the EU and UK: the reform continues

KATRIN RUHL (MUNICH) AND **ANTONIA MENKE** (MUNICH),
ASHURST PERKINS COIE UK LLP

With the European Product Act (EPA), the EU intends to undertake a further step in the fundamental modernisation of product safety law. The measure builds on existing reform at liability and regulatory levels, this time featuring digital compliance and enforcement mechanisms. Meanwhile, the UK government is also working on a significant overhaul of its product safety framework. Together, these ongoing reforms will change how consumer products are designed, documented, placed on the market, and monitored both in the UK and the EU.

The EPA: a new rulebook for products in the EU?

The European Commission postponed its legislative proposal for the EPA from 6 October 2026 to later this year. However, the draft text of the EPA was leaked in September 2026 and quickly became one of the most discussed developments in European product regulation this quarter. If the leaked text is any guide, the EPA could reshape how products are placed on, monitored in, and removed from the EU market. It is the latest step in the modernisation of EU product law.

From a patchwork to a single regulation

EU product law currently relies on several layers. The proposed EPA would consolidate three core instruments into a single legal act: the decision for a common legislative framework for marketing products; the regulation setting out the requirements for accreditation; and the regulation on market surveillance and compliance of products. In doing so, the EPA would bring conformity assessment, digital product passports, and market surveillance together in one regulation which directly applies in all Member States.

Having one single regulation will reduce differences in how Member States interpret and apply product safety rules. It would also concentrate a great deal of regulatory change in one instrument.

Online marketplaces in the spotlight

The most commercially significant proposal in the EPA concerns online marketplaces. Under the leaked draft, a marketplace that lists a product without first checking that it has a valid digital product passport or product responsibility record would take on the obligations and liabilities of an authorised representative. This would apply only where the product has no economic operator established as its responsible party in the EU. Platforms could therefore become the legally responsible party for goods sold directly to EU consumers by manufacturers based outside the EU.

This follows a pattern already visible elsewhere. The General Product Safety Regulation introduced specific duties for online marketplaces. The Toy Safety Regulation requires marketplaces to display a link to the digital product passport, safety warnings, and the CE marking. The EPA would go further and turn a failure to verify listings into direct legal responsibility for the product itself.

The Commission as an enforcer

The second key change concerns who enforces the rules. Today, market surveillance in the EU—as well as penalties and enforcement for all product-related issues—is mainly carried out by national authorities at the Member State level. The leaked EPA draft suggests the new legislation would give the European Commission its own powers to investigate and act against non-compliant products entering the EU from third countries, without going through national authorities. These powers would include ordering recalls, restricting online content, and imposing financial penalties.

This would be a marked shift towards central enforcement, comparable to the Commission's role as direct enforcer under the Digital Markets Act and the AI Act, as well as for very large online platforms under the Digital Services Act.

In the current draft, the Commission could act only if non-compliant products are likely to have been placed on the market in at least two-thirds of Member States and no national authority has opened an investigation after being notified.

Penalties linked to turnover

The third headline change proposed by the new legislation is the size of penalties. Under the draft, national penalties for infringement would range from 1% to 6% of annual worldwide turnover. The Commission could impose a separate EU-level penalty of up to 6% when it acts directly, on top of any national fines. By contrast, the current framework leaves penalties entirely to Member States. For multinational manufacturers and large platforms, this would make product compliance a board-level risk.

What businesses should do now

The text is a leaked draft and may change before the formal proposal is published and again during negotiations in the European Parliament and Council. Even so, online marketplace operators, manufacturers of regulated products, and importers should start assessing their exposure now.

Sensible first steps include reviewing how digital product passports and product responsibility records are collected and checked, mapping which products reach EU consumers without an EU-based responsible economic operator, and assessing how the proposed level of fines would affect the business.

The UK: a new framework continues to take shape

While the EU prepares the EPA, the UK is rebuilding its own product safety regime. The legal basis is the Product Regulation and Metrology Act 2025 (the PRAM Act), which received Royal Assent on 21 July 2025. The Act is mainly an enabling measure. It gives the government powers to address product safety through secondary legislation. In 2026, the shape of that legislation has started to become clear.

Reforming the core framework

On 31 March 2026, the Office for Product Safety and Standards, as the UK's national product regulator, launched two consultations. One covered a new UK product safety framework and the other covered market surveillance and enforcement. Both closed on 23 June 2026. The government committed to responding within 12 weeks, but as of 31 October 2026, its response had not yet been published. The first consultation proposes reforms to the General Product Safety Regulations 2005 that apply where no sector-specific rules exist and that forms part of assimilated law after Brexit.

The most notable proposal is a wider scope. The framework would extend beyond consumer products to all products, whether used in the home or the workplace. This would include business products such as industrial machinery, commercial equipment, and professional tools, subject to specific exceptions.

The government's stated aim is to protect all users from unsafe products. This goes further than the General Product Safety Regulations 2005 that focuses solely on consumer products. Sector-specific legislation with the same objective would continue to take precedence. Reviews of sector-specific rules are expected to follow over the next three years. The framework now being designed will therefore shape everything that follows.

Online marketplaces

Online marketplaces are a priority for the UK government, as they are for the EU. The PRAM Act expressly allows regulations to impose obligations on online marketplace operators. The framework consultation examines marketplace requirements. The government wants to create a proportionate framework requiring platforms to prevent unsafe products from being sold on their sites and to cooperate with regulators.

Alignment or divergence?

The UK government states the new framework will support trade with the EU, and it will apply across the UK in a way that takes account of the Windsor Framework. This is in line with the Product Safety and Metrology etc. (Amendment) Regulations 2024 that came into force on 1 October 2024 and extend recognition of CE marking for many products indefinitely in Great Britain.

However, several proposals take a different approach from the EU, with potential for conflict and confusion. Businesses selling in both Great Britain and Northern Ireland, or in Great Britain and the EU, may soon have to comply with two related but different rulebooks. Monitoring the government's response to the consultations will be essential.

Looking ahead: two regimes, one direction

Product safety law is continuing to develop both in the EU and the UK. The EU's General Product Safety Regulation and the UK's PRAM Act have already reshaped the field, and the next round of reform builds on them. While the details remain uncertain with the EPA existing only as a leaked draft and the UK government yet to respond to its consultations, the proposals follow a clear direction.

Regulators expect more of platforms, enforcement is becoming tougher and more centralised, and the cost of non-compliance keeps rising. Businesses selling into both markets also face a growing risk of having to comply with two related but increasingly different regimes.

Businesses should not wait for final texts before acting. Manufacturers, importers, and online marketplace operators that build on the work they did for recent reforms and review their compliance processes, supply chains, and exposure now will be better placed to adapt as the EU and UK frameworks take their final shape.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.



By the numbers

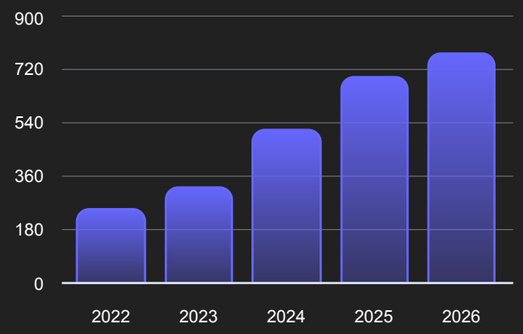
Consumer electronics recalls across the EU and UK rose by 11.3% in the first three quarters of 2026, increasing from 777 events to 865. This is the highest three-quarter total in more than a decade.

Electric shock was the most frequently cited risk, linked to 404 recalls as a standalone hazard, up from 356 in the first three quarters of 2025. Fire was the second-most common cause, cited as the sole factor in 186 events. This marks a 12-year high for fire risk and a 20.8% increase from the 154 fire-related recalls recorded during the same period last year. Environmental factors ranked third, linked to 82 recalls, down 26.1% from 111 in 2025.

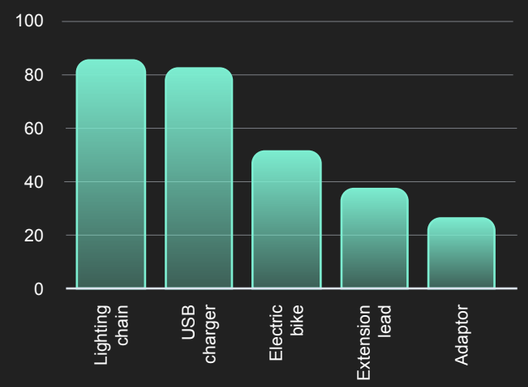
Lighting chains were the most recalled consumer electronics product, accounting for 86 events, down from 126 during the same period in 2025. USB chargers ranked second with 83 recalls. Of those, 82 were due solely to the risk of electric shock, while one involved both electric shock and fire risks. E-bikes ranked third with 52 recalls, 40 of which, or 76.9%, were linked to fire-related risks.

The UK issued the highest number of electronics recall notifications. It had 194 alerts, up from 170 in the same period last year. Hungary was second with 159, nearly double its 84 alerts in 2025. France ranked third with 100 notifications, more than double the 41 it reported a year earlier. The UK (in respect of Northern Ireland) issued 85 alerts, down from 92.

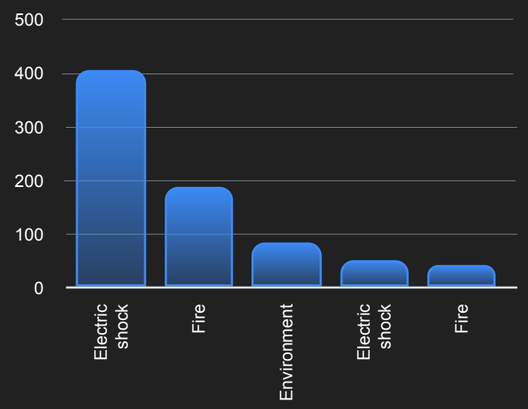
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)







Patching the problem: software updates as a corrective action in Europe's electronics industry

BY ED TURTLE, JULIA GREAVES, AND ELLEN DEELY, *COOLEY LLP*

Traditionally, recalls for consumer electronics have involved physical remedies—for example, consumers being asked to return or dispose of affected products or receiving repairs, replacements, or refunds from the manufacturer. In such recalls, it can be extremely challenging for manufacturers to remedy a significant portion of the affected products. As a result, recalled products may remain in circulation, potentially posing a risk to consumers.

We have heard much in recent years about the perceived risks of new technologies, which have prompted wide-reaching reforms in the European Union, including under the new General Product Safety Regulation, revised Product Liability Directive, and upcoming European Product Act proposal.

One point that is less often considered is the use of software updates as a corrective action tool to remedy a detected safety issue. For example, devices that are overheating could receive updates to their battery management systems, a smart home hub with an exploitable cybersecurity flaw could receive a security patch, and a faulty sensor in a wearable device could be reprogrammed. Software updates like these can be rolled out remotely, with little or no action by consumers to receive the fix. This type of correction presents an opportunity to remedy safety issues quickly and effectively, without needing to inconvenience consumers. As a result of this low-friction approach, corrective action delivered by software update can also significantly increase participation rates, which in turn increases recall effectiveness and makes products safer for consumers.

Remote fixes have been an industry standard in certain sectors for some time, including over-the-air updates in the automotive industry. Now, we are seeing that industry is increasingly recognising the benefits of these types of software fixes for consumer electronics as well. However, it is important for manufacturers to continue to be mindful of their obligations to report corrective actions to regulators and to ensure that software updates comply with relevant product compliance and recall requirements.

The benefits of software updates

The attraction of a software update as a corrective action is straightforward: it has benefits for both companies and consumers. A traditional recall requires consumers to take action, such as locating the product, identifying if it is affected by the recall, packaging it up, and returning it to a store, sending it back to the company, or scheduling a repair and waiting for a remedy. Participation rates in traditional recalls are disappointingly low, and the logistics are often complicated and expensive for the company running them, particularly for products containing a defective lithium-ion battery.

By contrast, a software update can often be delivered automatically—or with a single tap—to every affected product simultaneously. This means that the rate at which the risk is removed is typically far higher, while the burden on the consumer is minimal, or even non-existent.

Communicating a software-based fix to consumers is generally logistically more straightforward than organising a traditional recall campaign. A push notification or in-app message can explain the risk and confirm that the update has resolved it in a way that is both faster for the company to deploy and guaranteed to reach all known users of the product.

Of course, a software update will not always be a suitable substitute for a physical recall of products. However, where a safety issue can be resolved by software update, this is usually faster, cheaper, and more effective, whilst removing the risk to consumers in line with a manufacturer's legal obligation.

There can also be circumstances where a hybrid approach can be taken. For example, a software update could be used to warn consumers of the issue and reduce performance to lessen the risk, whilst allowing consumers to continue to use the product as they await a replacement.

When does a software update become a reportable corrective action?

Where a software update is rolled out to address a safety risk to consumers in the EU, it will likely be treated as a reportable corrective action by regulators. This is because EU legislation requires that where a product "presents a risk," manufacturers and importers must "immediately inform the competent national authorities of the Member State in which they made the [product] available on the market," including giving details of the corrective actions taken. For this reason, software updates that are rolled out as part of a product safety corrective action should be distinguished from routine updates which may add functionality or fix glitches or vulnerabilities that do not create a product safety risk.

Failing to report a software update that is issued as part of a corrective action to address a safety risk is an offence similar to failing to report other types of corrective action. This scenario is sometimes referred to as a "silent recall." Silent recalls can expose manufacturers to enforcement action and fines for failure to report. They can also lead to damage to the manufacturer's reputation with the regulator and the public.

Transparency requirements for software updates

When launching software updates—either in the context of a corrective action or more generally—companies should be aware that they are subject to a range of transparency requirements that mandate them to tell consumers about key attributes of software updates. For example, the Empowering Consumers for the Green Transition Directive (ECGT) makes it an unfair commercial practice to withhold from consumers the fact that a software update will negatively affect the functioning of a product with digital elements, whether the update is a security update or one that adds new functionality. This is relevant in the context of safety corrective action because often device functionality will be impacted by the software update, for example to restrict battery capacity or block certain features. Manufacturers must ensure that any potential or expected changes to functionality are made clear to consumers.

Impact of the Cyber Resilience Act (CRA)

Where a software update is being used to fix a cybersecurity vulnerability that could present a risk, manufacturers should also be aware of their obligations under the Cyber Resilience Act (CRA). Although the majority of provisions do not apply until 11 December 2027, there are vulnerability reporting obligations in Article 14 that have applied since 11 September 2026.

Under Article 14, a manufacturer that becomes aware of an actively exploited vulnerability in a product with digital elements must notify the coordinating national Computer Security Incident Response Team (CSIRT) and the European Union Agency for Cybersecurity (ENISA) with an early warning within 24 hours through a single reporting platform. A fuller notification must be submitted within 72 hours, and a final report is due once a corrective measure is available.

Manufacturers that know or have reason to believe a product no longer meets the essential cybersecurity requirements must immediately take corrective measures, including a withdrawal or recall where necessary.

Final thoughts

Looking ahead, we expect software updates to play an increasingly important role in future recalls. At the same time, software updates are subject to expanding regulation under converging EU product compliance laws. More product safety requirements, consumer information rules under the ECGT, and cybersecurity obligations under the CRA are pulling in the same direction: more transparency to consumers about what an update does and why, along with more visibility for regulators into when—and how quickly—companies respond once a risk is identified.

For electronics companies, whilst software updates present an opportunity to maximise effectiveness of a corrective action, it is important not to lose sight of regulatory obligations, both in reporting the corrective action to regulators and the requirements for the way the software update is presented to consumers.

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By the numbers

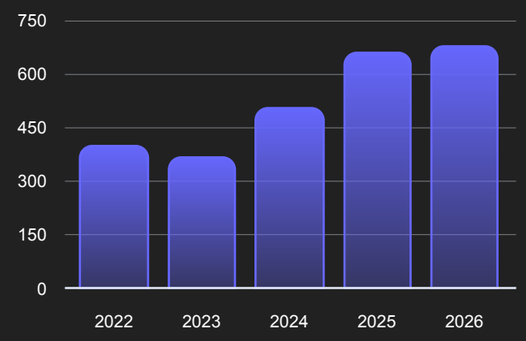
There were 683 toy recalls across the EU and UK in the first three quarters of 2026. This is a 2.7% increase from 665 events over the same period in 2025, and the highest three-quarter total in more than a decade.

Choking hazards were the most frequently cited cause of toy recalls, linked to 285 events as a standalone risk, up from 246 in the first three quarters of 2025 and marking the highest level in the past 12 years. Chemicals were the second-most reported issue, cited as a standalone concern in 128 recalls, down from 189 in 2025. Health risks ranked third with 39 events, up from two in 2025, an increase of 1,850%.

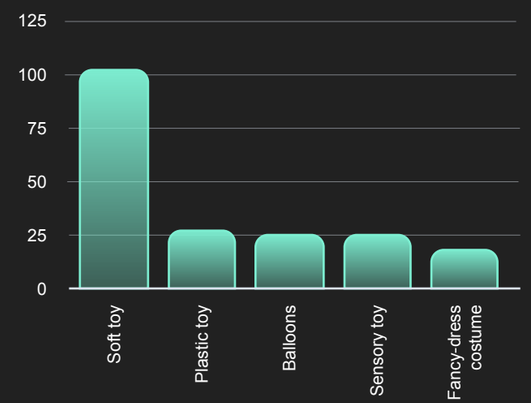
Soft toys were the most commonly recalled category, associated with 103 recalls, compared with 84 during the first three quarters of 2025. Of these, 68.0% were due to choking concerns. Plastic toys ranked second with 28 events, while sensory toys and balloons tied for third with 26 recalls each.

France submitted the highest number of toy recall alerts, with 155, up from 132 during the same period last year. Of France's recalls, 39 were for soft toys, the leading recalled product category. The UK ranked second with 121 notifications, up from 79 in 2025. Germany was third with 69 notifications, up from 45. The UK, in respect of Northern Ireland, recorded 48 alerts, down from 62.

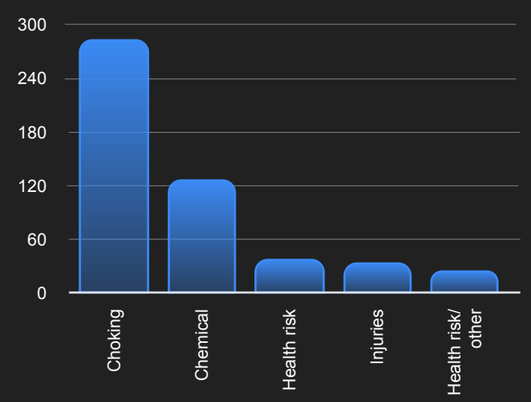
Number of recall events (Q1-Q3)



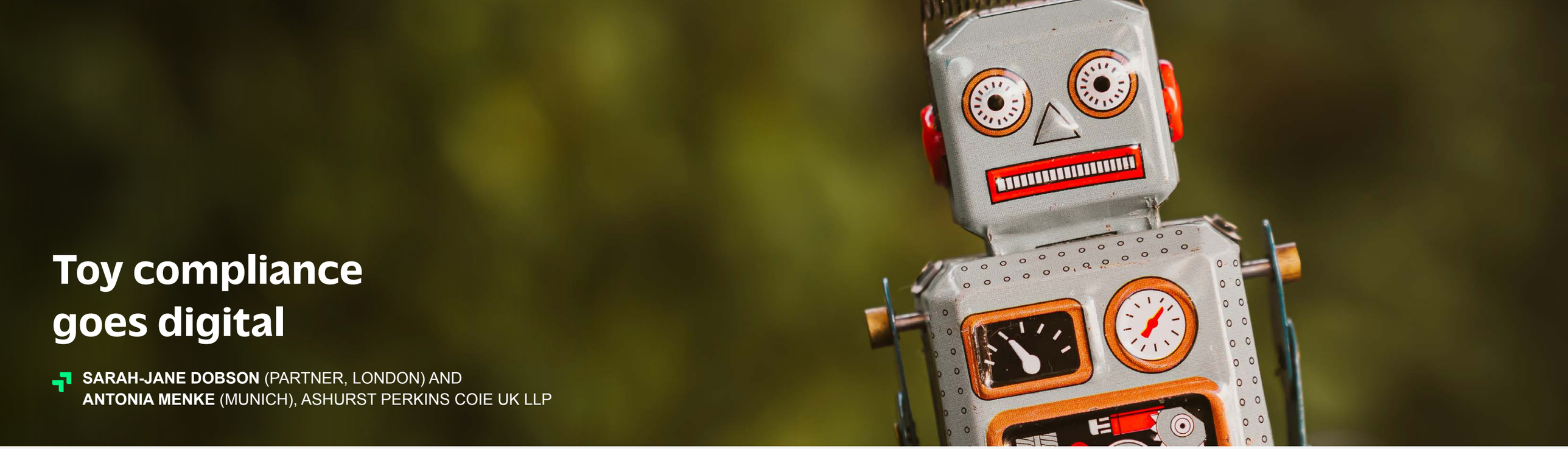
Number of recall events by category (top 5)



Number of recall events by risk (top 5)







Toy compliance goes digital

SARAH-JANE DOBSON (PARTNER, LONDON) AND
ANTONIA MENKE (MUNICH), ASHURST PERKINS COIE UK LLP

Toy safety in Europe is entering a digital era. The new Toy Safety Regulation entered into force on 1 January 2026. Its main obligations will apply from 1 August 2030, when the Toy Safety Directive is repealed. The Regulation brings in a wide range of changes, including tighter restrictions on endocrine disruptors, PFAS, and bisphenols. Compliance teams will likely see a big practical impact from the digital product passport (DPP) that each toy will need. Across the Channel, the UK is still weighing its options regarding going digital.

From paper declaration to digital record

Under the Toy Safety Regulation, the DPP must be issued before the toy is placed on the EU market and will replace the EU declaration of conformity required under the Toy Safety Directive. The passport must contain the information needed to assess whether the toy conforms with the applicable requirements, harmonised standards, and other specifications. Additional mandatory data include a unique product identifier and an identifier for the economic operator.

Users will access the information by scanning a code placed on the product itself, its label, or its packaging. The code must be accessible by market surveillance authorities and clearly visible to consumers before they buy the toy—either in person or online.

An enforcement tool first

The DPP is best understood as an enforcement tool, not a labelling formality. Importers will need to present passports when goods arrive at the EU border. Automated screening of that data will help customs decide which shipments deserve a closer look. Once goods are on the market, inspectors acting under the EU's market surveillance framework will be able to test the toys and the passport data side by side. In practice, an incomplete or inconsistent passport is likely to become the quickest route to a consignment being held at the border.

The responsibility for information is shared along the supply chain. Importers and distributors will no longer be able to rely on the existence of a signed document. They will have to confirm that a valid passport exists and that the code is correctly attached. Commercial contracts with overseas manufacturers will therefore need to address who supplies DPP data, how accurate it must be, and how quickly it is kept up to date.

From blueprint to reality: the DPP Registry opens

On 20 July 2026, the European Commission launched the EU Digital Product Passport Registry and opened a testing environment for DPPs. The Registry does not hold the full product file, which stays with the economic operator or its chosen DPP service provider. Instead, it acts as a central index of each passport's unique identifier and the registration metadata that the relevant legislation requires. Every passport must be registered before the product is placed on the EU market. Businesses can do this through a secure web interface or an Application Programming Interface and can ask for an electronic proof of registration. Toy businesses have time to use the test environment, user guides, and Commission helpdesk to practise enrolment and registration well before enforcement begins in 2030.

The UK: enabling powers and a reform programme

In Great Britain, toys remain governed for now by the Toys (Safety) Regulations 2011, legislation derived from EU law. The UK's route to modernisation is the Product Regulation and Metrology Act 2025 (the PRAM Act), which received Royal Assent on 21 July 2025. The PRAM Act does not itself impose new requirements on businesses. Instead, it gives the government broad powers to make future regulations. Those regulations will be made as secondary legislation under the affirmative procedure, so Parliament must actively approve them. The powers can be used to impose obligations on online marketplaces, as well as on manufacturers, importers, distributors, and authorised representatives.

Under the rule, the government is authorised to regulate not only a product's physical elements, but also its intangible components such as software. Importantly, the PRAM Act provides a legal basis for future UK product regulations that may align with relevant EU law. Digital labelling is already identified as a key area for reform, meaning safety warnings and compliance data could be delivered electronically.

Under the PRAM Act's powers, the Office for Product Safety and Standards (OPSS), the UK's national product regulator, opened a call for evidence on toy rules on 6 July 2026. Responses were due by 6 October 2026. The consultation asks about the benefits and costs of following the EU's approach in the UK, whether to keep recognising EU toy requirements, including the CE marking, and how risks from chemicals, AI, and online marketplaces are changing.

OPSS is specifically reviewing digital product passports, alongside chemical safety, online marketplace obligations, and connected or AI-enabled toys. It also asks respondents directly whether they would favour continued recognition of the EU's toy requirements, and what that would mean in practice for economic operators.

On 27 July 2026, the Department for Business, Innovation, Science and Trade published a separate call for evidence on digital product record (DPR) policy. A DPR is the general term for digital product information tools, of which the EU's DPP is one example. This call for evidence is broader than the OPSS toys review.

It explores whether a UK DPR policy could simplify how businesses provide product information, while improving transparency and traceability for consumers and market surveillance authorities. It sought views on DPRs in general, on how existing DPR policy affects businesses selling into the EU and Northern Ireland, and on what the UK should consider in developing its own policy.

Northern Ireland adds a further layer. Because of the Windsor Framework, the EU Regulation, including DPP obligations, will govern toys sold in Northern Ireland once it fully applies in August 2030. If Great Britain does not adopt an equivalent regime, businesses supplying the whole UK could face two compliance-information systems.

The government's responses to both calls for evidence will therefore matter well beyond Great Britain.

Looking ahead

Although August 2030 may appear distant, the toy sector will not be among the first to implement the EU's DPP. Batteries are scheduled to lead the way, with the passport becoming mandatory for them in February 2027. Packaging, construction products, and other product categories are expected to follow before the requirement extends to toys in 2030. Toy compliance teams are therefore well placed to draw on the experience of other sectors that are already developing data models, arrangements with service providers, and registry processes.

The principal challenge is likely to be one of data management rather than legal interpretation. It will involve organising technical documentation, allocating responsibility for data across supplier networks, and putting in place systems capable of keeping passports up to date throughout a product's entire life cycle.

In the UK, the main question is no longer whether to go digital but how far to stay in line with the EU. The government has said it wants product labelling to be "digital by default." The DPR call for evidence also asks whether a future UK system should work with the EU and Northern Ireland regimes, for example through a single data carrier.

EU CE recognition by UK authorities is estimated to save businesses around £640.5 million over ten years. That figure suggests divergence would be costly. The most practical approach for businesses is to design passport data to the EU standard now so that it can be reused for whatever regime Great Britain adopts.

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By the numbers

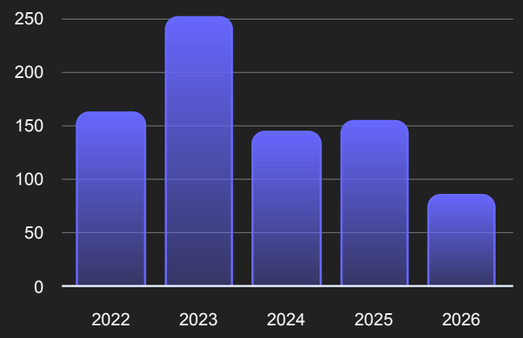
There were 87 clothing recalls across the EU and UK in the first three quarters of 2026, a 44.2% decrease from the 156 events over the same period in 2025. This is the lowest three-quarter total since 2020.

Chemicals were the most common cause of clothing recalls, cited in 39 events as a standalone hazard, slightly below the 42 in the first three quarters of 2025. The combination of chemical and environmental risks ranked second with 17 recalls, up from seven in 2025. Strangulation ranked third with 14 events, up from nine. Suffocation, which led in 2025 with 53 recalls, fell off the list of recall risks completely.

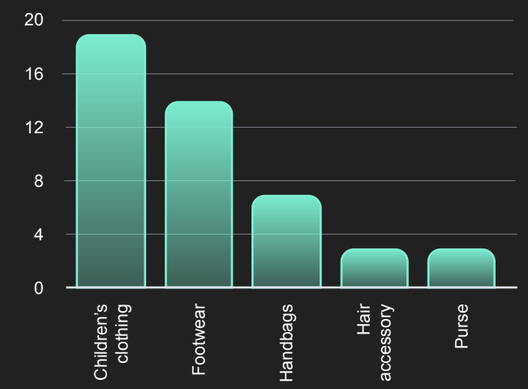
Children's clothing, including hoodies, dresses, and jackets, was the most frequently recalled item, tied to 19 events, down from 35 in the first three quarters of 2025. Footwear, including slippers, shoes, flip-flops, and children's sandals, was second with 14 recalls, compared with 26 a year earlier. Handbags were third with seven, all of which were linked to chemical risks.

France issued the most notifications with 19, up from six in the same period last year. The UK and Norway tied for second with 10 alerts each. For the UK, that is a steep drop from 43 in 2025, while Norway rose from three notifications year-over-year. Finland and Germany followed with nine alerts apiece, compared with four and seven respectively, a year earlier.

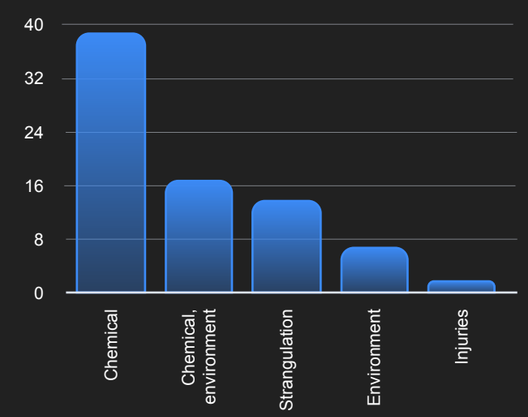
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)







Destruction banned, chemicals restricted: regulatory developments for clothing in the EU

SARAH-JANE DOBSON (PARTNER, LONDON), **ANTONIA MENKE** (MUNICH),
ASHURST PERKINS COIE UK LLP

Several long-anticipated reforms took effect in the third quarter and early fourth quarter of 2026 for economic operators placing clothing on the EU market. Since 19 July 2026, large businesses have been prohibited from destroying unsold clothing. A stringent REACH Regulation restriction on perfluorohexanoic acid (PFHxA)—a substance in the PFAS family—came into force on 10 October 2026 for textiles used in clothing.

National PFAS prohibitions in France and Denmark apply in parallel with EU law. Companies are also preparing for the first ecodesign requirements for apparel under the Ecodesign for Sustainable Products Regulation (ESPR).

The ban on destroying unsold clothing

One significant development in the third quarter of 2026 was the ESPR prohibition on the destruction of unsold apparel, clothing accessories, and footwear which has applied to large businesses across the EU since 19 July 2026. Medium-sized businesses will become subject to the prohibition in 2030, while small and micro-enterprises are currently exempt.

Textiles are the first product group to which the prohibition applies, reflecting the European Commission's concern about the amount of unsold stock that is destroyed in this industry. The European Environment Agency estimates that 4–9% of textile products placed on the European market are destroyed before use, equivalent to between 264,000 and 594,000 tonnes per year.

The relevant Delegated and Implementing Acts were adopted on 9 February 2026. The Delegated Act sets out the limited circumstances in which unsold products may still be destroyed. Among the limited derogations, destruction remains permissible where products are unsafe or damaged, are counterfeit or infringe intellectual property rights, or have been rejected by charities and donation schemes. Businesses relying on a derogation must be able to substantiate it by means of documentation, test results, or other approved methods.

They must also publish annual reports on the products they have discarded. Records must be retained for five years to enable inspection—and possible fines for non-compliance—by national authorities.

The Implementing Act introduces a standardised format for disclosing the volumes of unsold consumer products discarded. Businesses are expected to keep products in use through resale, alternative markets, donation, repair, remanufacturing, or preparation for reuse. Where destruction is permitted, it must be carried out in accordance with the waste hierarchy.

In practice, safety decisions now carry an additional legal dimension. If a business withdraws or recalls a garment and elects to destroy it rather than resell or donate it, the company must be able to justify that decision. Test reports, risk assessments, corrective-action records, and correspondence with market surveillance authorities no longer serve solely as evidence of compliance with general product safety law. They may also constitute the justification for destruction under the ESPR.

Businesses should ensure that their safety, sustainability, and logistics functions adopt a consistent approach to documenting destruction decisions. It must be clear that the claim that a product is unsafe is being made for supportable reasons and not to bypass the ban. The Commission has indicated that reporting will draw on existing customs and logistics codes in order to limit the administrative burden.

PFHxA: new EU limits for clothing from 10 October 2026

Another key date for clothing manufacturers and retailers was 10 October 2026, when the REACH restriction on PFHxA began to apply to textiles. The restriction prohibits PFHxA and its salts at concentrations of 25 parts per billion (ppb) or more, and PFHxA-related substances at 1,000 ppb or more. It covers textiles, leather, furs, and hides in clothing and related accessories for the general public.

These thresholds are sufficiently low that they may be exceeded through contamination as well as intentional use. PFHxA-related chemistry has been widely used in water- and stain-repellent finishes, and residues may enter products through finishing chemicals, surfactants, or shared production lines. Enforcement authorities and commercial customers increasingly expect to see more active supply chain controls, supplier declarations, and targeted testing.

National PFAS prohibitions alongside EU law

The REACH restriction on PFHxA is not the only new PFAS measure in force. France has prohibited PFAS in textiles

used for clothing since 1 January 2026. In Denmark, an executive order applicable from 1 July 2026 prohibits PFAS in clothing, footwear, and related waterproofing agents where the total fluorine content is 50 mg F/kg or more, subject to exemptions, including protective equipment, medical devices, and recycled items. Goods imported before 1 July 2026 may be sold until 1 January 2027.

The result is a fragmented regulatory landscape. Thresholds, measurement methods based on substance-specific analysis as opposed to total fluorine, exemptions, and timelines differ between the EU restriction and Member State national rules. A garment that complies with the PFHxA restriction may nonetheless exceed the Danish total fluorine limit.

For businesses selling across the single market, the most prudent approach is generally to design to the strictest applicable standard rather than maintaining market-specific product variants. These developments are taking place against the background of ongoing work on a broader, universal EU PFAS restriction, which would raise requirements further.

Ecodesign requirements and the Digital Product Passport

Textile-based apparel is a priority product group in the ESPR working plan for 2025–2030. The Commission's indicative timeline foresees adoption of the delegated act for textiles in late 2027, with further guidance and technical specifications to follow. The same act will set the requirements for digital product passports (DPPs) for textiles. The passports must be accessible through a data carrier such as a QR code and through online points of sale. They may contain product identification, fibre composition under the Textile Labelling Regulation, and conformity assessment information. Distributors and dealers will have to ensure that a passport is available for the products they sell.

Stakeholder positions are now emerging. In a position paper on the ESPR delegated act for textiles, published on 10 August 2026, EuroCommerce called for a stepwise and harmonised approach. It welcomed the inclusion of post-industrial and pre-consumer waste in the definition of recycled content but criticised the calculation of recycled content by reference to total product weight rather than fibre weight.

The trade organisation also highlighted difficulties in traceability of substances of concern across global supply chains, noting that certain hazard classes of the Classification, Labelling and Packaging Regulation, such as endocrine disruption, are not reflected in the UN Globally Harmonised System. This means that these categories may be absent from safety data sheets prepared outside the EU.

EuroCommerce argued that information requirements should be fulfilled digitally through the DPP, rather than by means of physical labels or hangtags. Finally, it proposed a risk-based self-assessment procedure for demonstrating compliance, comparable to the approach under REACH and the General Product Safety Regulation.

For product safety professionals, the debate on substances of concern merits particular attention. If the delegated act requires substance information to be traced and disclosed through the DPP, chemical data compiled for REACH compliance, including PFHxA test results, would form the basis of passport content. Investment now in reliable, structured supplier chemical data is therefore likely to yield benefits under both regimes.

Looking ahead

The end of destroying unsold stock is likely to push brands towards tighter demand forecasting, smaller production runs, and stronger resale, repair, and donation channels. In supply chains, PFAS-free chemistry will become the default, and suppliers that cannot provide reliable chemical data are likely to lose business.

Companies that see these obligations as a chance to rethink their sourcing, inventory management, and data infrastructure will be better placed than those that treat them as isolated compliance burdens. With the ESPR delegated act for textiles expected in late 2027, the next few months offer a valuable opportunity to engage in the consultation process and influence the final requirements.

Businesses that take part early will be better able to shape practical, proportionate obligations, rather than simply having to adapt to them.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.



Food and drink

England is considering a new model for regulating food and beverages. The Food Standards Agency (FSA) Board is drafting a national approach for the largest food businesses, starting with major retailers, as part of a wider Future of Food Regulation programme.

Alignment with EU food law is also moving back onto the UK agenda. The UK and EU are finalising a sanitary and phytosanitary (SPS) agreement that could take effect next year and change rules not only at the border but also domestically.

Meanwhile, the application window for England's latest Sustainable Farming Incentive (SFI) closed in hours, leaving thousands of farmers without a new SFI agreement. Support for farmers is becoming a major political issue.

Food businesses are being asked to plan for greater national scrutiny of large operators, a possible return to EU rules for products sold in Great Britain (GB), and a farm-support system that is falling behind. How these developments will play out for consumer prices and food safety has yet to be seen.

UK considers a new model for food regulation

In September, the FSA agreed to advance plans to overhaul the current food law framework to build a modern system with specific "growth goals" as part of its Future of Food Regulation programme. One of the biggest changes is a new national approach to regulating large food businesses in England.

Currently, the FSA's day-to-day role is largely advisory and supervisory, except for its authority over abattoirs and meat plants. It does not have the legal powers to undertake routine inspection and enforcement across shops, restaurants, and factories. Those duties are left to local authorities.

While more than 99.5% of UK food businesses are micro, small, or medium-sized companies, there are 10 national retailers providing over 97% of food sold in shops. Under the proposal, the national model would start with the FSA overseeing major retailers. A recent FSA trial found that national-level scrutiny of retailer data could identify systemic risks alongside checks on the ground. Local authorities would continue to oversee smaller businesses.



Greater demands for transparency are raising expectations around how food products are labelled, priced, advertised, and presented to consumers.



Other proposed changes in the programme include stronger tools for local authority food teams, a more consistent national approach to the very largest businesses, and better use of supply-chain data. It also lays out recommended improvements to food-business registration and making food hygiene ratings compulsory online across the UK and in shops and restaurants in England.

Legal experts with Walker Morris caution that some of these proposed changes would need primary legislation. The Food Safety Act 1990 and Food Standards Act 1999 would have to change before the FSA could become a true national inspectorate.

The lawyers also note that the SPS agreement with the EU could constrain how far England can move away from a model in which a central competent authority coordinates other enforcement bodies.

The next proposals from the FSA are expected in March 2027, followed by public consultation later that year. Large retailers and other national operators should review the current proposal to determine what might change in their safety and process plans. All companies should consider the impact of displaying food hygiene ratings online. In addition, stakeholders should look for opportunities to engage with the working groups to help shape what data, registration, and hygiene-rating duties look like.

Businesses prepare for alignment under UK–EU SPS agreement

The UK government is negotiating a sanitary and phytosanitary (SPS) agreement with the EU that would align Great Britain's food and feed rules with European law. The Department for Environment, Food and Rural Affairs (Defra) intends for the deal to take effect in mid-2027. The changes would impact GB companies whether they trade directly with the EU or not.

A July UK–EU summit was postponed, but negotiations between the two partners continued. Officials are still working through exceptions, transition periods, and how market authorisations would work, but the direction of travel is already clear for manufacturers.

The legislation encompasses a range of topics, including general food law, consumer information and labelling, organics, nutrition and health claims, and additives. Also covered are novel foods, hygiene, contaminants, marketing and compositional standards, food contact materials, and official controls.

The Food and Drink Federation notes that this is broader than a border-facilitation deal. Alignment would change the rules for food and drink sold on the GB market, including for businesses that do not export to the EU. Any future EU amendments to the laws would also apply in GB, as well as the EU rules in force today.

In many cases, EU rules would replace current GB requirements rather than sit alongside them. Once the agreement enters into force, existing GB market authorisations for regulated products would cease, subject to any limited exceptions still being negotiated. Products already authorised in the EU—and the conditions attached to those authorisations—would take effect in GB.

Lawyers with Walker Morris LLP describe the shift as dynamic alignment. The new regulation is expected to make EU food law directly effective in GB, prioritise EU rules over conflicting domestic GB rules, and allow the GB framework to update without a fresh UK amendment each time. Northern Ireland is already aligned with EU food law through the Windsor Framework.

The FSA is also asking whether Great Britain should allow earlier access to EU market authorisations as part of implementation, so companies are not left waiting until the treaty is fully in force. Detailed guidance for businesses is expected later in 2026, with the agreement's effective date still aimed at mid-2027, subject to negotiations.

Food and drink manufacturers, importers, and retailers should not treat this as a matter only relevant to exporters. If the final deal reflects the current draft, the compliance baseline for products sold in Great Britain will move.

The legal experts recommend that food businesses take stock of the rules that apply to them now and identify where GB and EU requirements have diverged since Brexit. Recipes, processes, wrapping, and packaging may all need to change. The sooner that mapping begins, they argue, the easier the transition is likely to be.

Sustainable Farming Incentive faces criticism

England's 2026 Sustainable Farming Incentive (SFI) scheme opened for applications on 22 September and was fully allocated within six hours. The scheme pays farmers for delivering environmental benefits related to nature, soil, and other public goods. It is the main successor in England to support that used to flow through the EU's Common Agricultural Policy. For many farmers, this was the first chance to apply since the scheme was closed with little notice in March 2025. The next window is not expected until 2027.

The government said small farms and new applicants had an earlier exclusive window in the summer, and that extra money—including £50 million announced by the prime minister in August and a further £20 million as demand surged—took the 2026 allocation to £310 million for the year. Farming and nature groups said the "first-come, first-served" approach used in the September funding round was a failure of budget management. According to Farmers Guardian, MPs and industry bodies have described the scheme as "not fit for purpose" and a risk to food security and environmental targets.

Food safety and security are key political issues. Farmers Guardian reports that the Liberal Democrats adopted a "Good Food" policy at their autumn conference. The initiative calls for a permanently reopened SFI, a statutory food-security audit, and a larger farming budget, though it is unclear if the government will adopt any of these proposals as policy priorities.

Without the government support, it is harder for suppliers to plan environmental measures, manage drought and input-cost shocks, and keep domestic production steady. Companies that rely on UK-grown ingredients should monitor how Defra designs the next funding round expected in 2027, including whether applications will again be time-limited.



By the numbers

Regulators across the EU and UK reported 4,044 food and beverage recalls in the first three quarters of 2026. That is a 4.5% increase from 3,870 events over the same period in 2025, and the highest three-quarter total in more than six years.

Non-bacterial contamination remained the leading cause, accounting for 1,593 events, down slightly from the 1,615 recorded over the same period in 2025. Aflatoxins featured prominently, cited in 194 recalls, with nuts particularly affected. Ground nuts, pistachios, and peanuts from a range of countries were among the products most frequently involved.

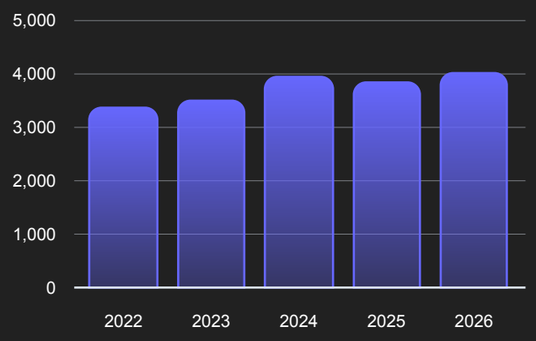
Bacterial contamination was second with 949 recalls. Salmonella was the primary bacterial agent, linked to 678 of those events, while listeria accounted for 145 recalls and E. coli for 70.

Excessive substance levels ranked third overall with 242 recalls, broadly in line with the 248 recorded in 2025. This was followed closely by foreign bodies with 223 recalls and undeclared allergens with 209.

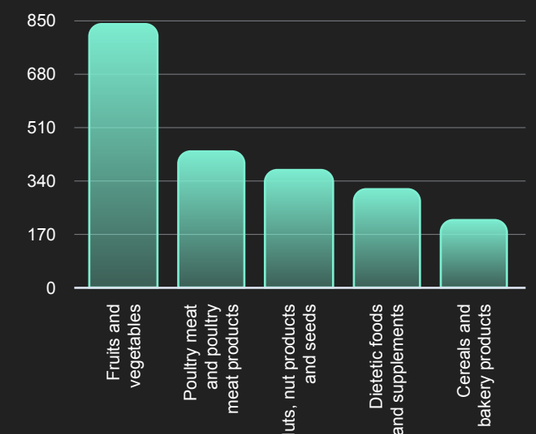
Fruits and vegetables had the most recalls by product category, with 843 events. Poultry meat and poultry meat products were second with 439. Nuts, nut products, and seeds were third with 380.

The Netherlands led the region in recall alerts, issuing 543 notifications through September 2026, down from 608 in the first three quarters of 2025. Nearly a quarter (23.6%) of recalls in the Netherlands involved nuts and nut products. Germany was second with 460, down from 528 for the same time last year. Italy ranked third with 372 alerts, up from 329 over the same period in 2025. The UK issued 89 food and beverage alerts in the first three quarters of the year compared with 100 in 2025.

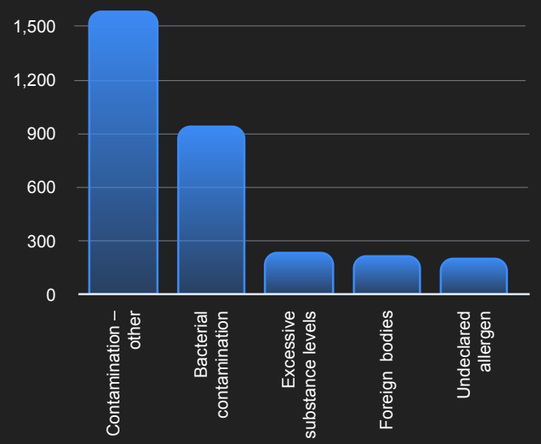
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)







Food for thought: recalls, records and liability in the European food and beverage sector

WILLIAM TRUEICK, *SIMMONS & SIMMONS*

Food businesses have long been judged on how quickly and effectively they remove unsafe products from the market. As a new product liability regime arrives in the EU, businesses will increasingly be judged on another factor: the record they leave behind.

In the first half of 2026, the food and beverage sector had more recalls than any other industry as tracked by Sedgwick's Product Safety and Recall Index. It was also one of the few sectors to record an increase against the same period in 2025. The prominence of product safety events in this sector makes it particularly important to consider the effect of changes in the regulatory and liability landscape.

When a recall becomes evidence

Food businesses have little discretion when they have reason to believe that food is unsafe. Under Article 19 of the General Food Law Regulation, a food business operator that considers or has reason to believe that food it has imported, produced, processed, manufactured, or distributed is not in compliance with food safety requirements must immediately initiate procedures to withdraw it from the market and inform the competent authorities.

Where the product may have reached consumers, the operator must effectively and accurately inform them of the reason for the withdrawal and, if necessary, recall products already supplied where other measures are not sufficient to achieve a high level of health protection. Article 19 also separately requires immediate notification to authorities where an operator considers or has reason to believe that food it has placed on the market may be injurious to human health.

The legal context in which those decisions may later be examined is changing under the new Product Liability Directive (the PLD). The PLD applies to food and beverage products, whether finished products or ingredients, placed on the market or put into service from 9 December 2026. That is the date that all Member States need to have transposed the rule into national law.

The PLD imposes strict civil liability on manufacturers and others in the supply chain for harm—including personal injury and death—caused by defective products. When assessing whether a product is defective, all circumstances are to be taken into account. This includes any recall of the product or any other relevant intervention relating to product safety by a competent authority or by an economic operator.

While a recall is a relevant factor to defect, recital 34 of the PLD makes clear that it should not in itself create a presumption of defectiveness. This reinforces the importance of recording what was known, what remained uncertain, and why the business acted as it did, if the business wishes to defend its civil liability position under the PLD.

Food law's limits and the PLD's presumptions

Article 10 of the PLD requires that the claimant prove defectiveness, damage, and causation, but provides a rebuttable presumption of defect and causation in certain circumstances. One of these is where the claimant demonstrates that the product does not comply with mandatory product safety requirements laid down in European Union or Member State national law that are intended to protect against the risk of the damage suffered.

Food law contains a number of quantitative limits. Maximum residue levels (MRLs), for example, set the highest level of pesticide residue legally tolerated in or on food or feed. A laboratory result showing an exceedance may therefore be important evidence against a food business. However, exceedance is not the same as proof of the whole liability claim. The requirement must be intended to protect against the risk of the damage suffered. Article 10(3) provides a separate causation presumption where defectiveness is established and the damage is consistent with that defect. Businesses should consider whether their testing data, sampling methodology, and records would withstand scrutiny in litigation, not only in an audit.

The PLD's disclosure provisions add a further dimension. Under Article 9, a defendant can be required to disclose relevant evidence at its disposal at the request of a claimant who has presented facts and evidence sufficient to support the plausibility of the claim—subject to necessity, proportionality, and the protection of confidential information and trade secrets.

Failure to comply with the disclosure obligation gives rise to a rebuttable presumption of defectiveness. Internal testing records, supplier audits, and recall correspondence are examples of material that may be the subject of such requests. Businesses should make sure these documents are readily available in order to comply promptly with PLD disclosure obligations.

Lessons from the cereulide recalls

The infant formula recalls that began in December 2025 offer a useful case study. Routine checks following the installation of new equipment on a production line at a factory in the Netherlands detected very low levels of cereulide, a toxin produced by some strains of Bacillus cereus.

Further testing traced the contamination to an oil blend containing arachidonic acid (ARA) oil sourced from a global industry supplier, and the wider industry was alerted through trade associations. The European Food Safety Authority (EFSA) has stated that the ARA oil found in the infant formula was supplied by a producer in China. In a report published on 13 March 2026, the World Health Organization (WHO) stated that cereulide was detected in batches of multiple internationally distributed brands and that, as of 25 February 2026, affected products had been distributed to 99 countries and territories.

Several points stand out as food for thought. First is that the source was upstream. The investigation traced the contamination to an ingredient sourced from a global industry supplier. WHO likewise identified ARA oil as the source, while noting in its March report that full root-cause analysis and complete traceability remained under investigation.

Another key point is the limits of routine testing. The account of the incident describes detection through routine product checks. Separately, WHO highlighted diagnostic and surveillance difficulties, while the joint EFSA–European Centre for Disease Prevention and Control assessment noted that testing for cereulide in clinical samples is not routinely available in many settings. Clinical diagnosis and manufacturing controls are different issues, but both illustrate the importance of detection capability. Businesses should consider how their testing programmes identify, and plan for, less familiar hazards.

Finally, the issue highlights the shared supplier problem. Given that the issue affected multiple brands, questions of contractual recourse, recall cost allocation, and insurance response may arise across several businesses at once. Businesses should consider reviewing—and where appropriate strengthening—their supply-chain contracts, including provisions dealing with indemnities, limits of liability, and dispute-resolution mechanisms.

Simplification and liability: two parallel developments

On 30 September 2026, the Council of the European Union agreed on its negotiating position on the remaining part of the “Omnibus X” package, which aims to cut unnecessary administrative costs and burdens for the agrifood sector while maintaining food and feed safety standards. That negotiating position is not final legislation.

Alongside this action, the PLD strengthens claimants’ access to evidence and introduces the presumptions described above. Administrative simplification should therefore not be mistaken for a reduced need to maintain evidence capable of supporting the business’s position in a future claim.

The UK and Ireland: Close neighbours with different rules

Ireland, as an EU Member State, must transpose the PLD into national law. The UK is also required to implement it in respect of Northern Ireland under the Windsor Framework. In Great Britain, the statutory product liability regime remains governed by Part 1 of the Consumer Protection Act 1987.

In England and Wales, that regime is under review by the Law Commission, whose Product liability consultation paper published on 8 October 2026 includes a proposed mechanism for cases in which claimants face exceptional difficulty obtaining evidence to prove that a product was defective. The consultation closes on 14 January 2027, and a final report is expected late in 2027. It will then be for the Government of the day to decide whether to take the recommendations forward.

At the same time, the UK and the EU are negotiating a Sanitary and Phytosanitary (SPS) Agreement, which the UK Government intends to take effect in mid-2027. The Government has said the changes for food, feed, and drink businesses will include hygiene rules, food law, additives, pesticide MRLs, marketing standards, labelling, and food contact materials. It has urged businesses to prepare, including those that do not currently trade with the EU.

The UK Food Standards Agency has described the expected direction of travel as being towards dynamic alignment. One consequence worth considering is that, if the agreement is concluded, food businesses in Great Britain could see their regulatory obligations move closer to those in the EU while their product liability framework continues to differ, at least unless and until reform follows the Law Commission’s review.

Takeaway points

Rather than a checklist, food and beverage businesses may find it useful to ask the following questions internally. First, if a court ordered disclosure of the records behind the business’s most recent recall, would those records clearly show what was known, when it was known, and why the business acted as it did?

Second, do supplier controls reflect the consequences if an ingredient failed, rather than simply its volume or the spend on it? Another key consideration is if contamination originated with an upstream supplier shared with other businesses, how would existing contracts allocate recall costs and recourse, and would the business’s insurance respond?

Businesses should also ask themselves if they have mapped how their liability exposure differs across the EU Member States they sell into, Northern Ireland, and Great Britain.

Including these questions as part of their preparation for the new PLD rules will help ensure that companies are ready to face the new liability risks.

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Greater transparency and traceability are becoming central to medical device regulation, while new pathways aim to improve market access for innovative products.



Medical device

In the third quarter, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) worked to clarify when AI scribes are medical devices and when they are not. New guidance on ambient voice technology says transcription, summaries, draft letters, and suggested clinical codes for a clinician to review do not, by themselves, make a product a device. Claims or features that guide diagnosis or treatment still do.

In September, the UK government proposed amendments to the Health Bill that would affect future medical-device licensing, information sharing on medicines and medical devices, and the Secretary of State's power to make consequential amendments to medical device regulations. The amendments are still at an early stage.

In the EU, the overhaul of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) entered the parliamentary stage. A July draft report from the Committee on Public Health (SANT) sets out more than 130 amendments and will shape how far simplification goes and where patient-safety requirements remain.

In August, the European Commission abandoned a "Have Your Say" initiative that would have revised the MDR to reclassify certain well-established medical devices, so the rules better reflect the products' nature and the limited risks associated with them. The feedback may already be reflected in the MDR and IVDR changes now before SANT.

AI scribe developers should assess their products' features against intended purpose, so they know which rules apply. Stakeholders across the medical device sector should weigh the draft Health Bill amendments and the proposed MDR/IVDR changes against their own processes. Both are still under discussion, and preparing now will help stakeholders adapt to future changes.

New oversight for AI scribes

On 29 July, the MHRA published guidance on ambient voice technology (AVT) products—also called AI scribes—used in health and care settings in Great Britain. The agency developed the guidance with NHS England to provide clarity to manufacturers. NHS England had treated the summarisation of clinical conversations as enough to qualify the products as medical devices, and some developers went through the conformity assessment process for Class I devices.

Attorneys with Covington & Burling LLP say the MHRA has now put the focus back on intended purpose in determining device classification. Products intended solely to transcribe or summarise a consultation, draft a letter, structure notes, or suggest clinical codes for a clinician to review and confirm are not regulated as medical devices.

An AVT product is a regulated device if it is intended to guide diagnosis or treatment, offers “generated insights” such as suggested diagnoses or follow-up, or acts without a clinician in the loop—for example by placing orders from a transcript.

The guidance explains how regulators will apply the UK Medical Devices Regulations 2002, and the obligations that follow, to products marketed in Great Britain. Northern Ireland remains under the EU MDR. Lawyers with Bristows note that this GB-only framing leaves open how the EU will treat the same tools.

NHS England has updated its own materials to refer to the MHRA’s definition and removed earlier statements that classified tools summarising patient information as medical devices. Legal experts with Covington & Burling LLP caution that NHS England has not said whether it will still require a CE or UKCA mark on ambient scribes as part of its procurement process.

Developers and suppliers should review the latest MHRA update to determine where their products fit in the regulatory scheme. They also need to watch how those products evolve to ensure that a change in function does not move a product from outside the rules into a category that requires a conformity assessment before it can be placed on the market.

The Australian Therapeutic Goods Administration has also been increasing its oversight of digital scribes, drawing the same line between transcription and therapeutic functionality. Manufacturers and distributors who also sell to that market should take note.

UK Health Bill could bring big changes

In September, the government proposed amendments to the Health Bill that would reshape how medicines and medical-device law can be updated. The three focus areas are wider information-sharing powers for the MHRA, a faster route to amend regulations, and expanded powers for a future medical-device licensing regime.

The licensing changes may have the biggest impact. Under the draft provisions being considered, some devices placed on the Great Britain market through a domestic route could in future need a licence from the MHRA rather than relying only on third-party approved bodies. The government says any future system would be risk-proportionate and built through further policy work, consultation, impact assessment, and parliamentary scrutiny. The bill itself does not create a licence, set fees, or tell manufacturers what to file.

The proposal would also allow automatic updates to medicines and medical device legislation to reflect changes such as revised technical standards or international guidelines. The government states that it wants a more proportionate approach to consultation, with public input on major policy reforms and more targeted engagement for small revisions. The goal is to streamline technical, administrative, and minor regulatory changes so the UK’s regulatory system remains aligned with new technologies and discoveries.





Information sharing is another part of the draft amendments. The revision would provide the MHRA with clearer powers to share information about medicines and medical devices with the UK government and international regulatory partners where doing so would benefit public health, patient safety, and effective regulation. Any existing safeguards—including those covering commercially sensitive or patient information—would remain in place.

Attorneys with Burges Salmon LLP emphasise that the amendments do not require manufacturers to take immediate action and do not change the existing framework. If they become law, the next step would be secondary legislation and public consultation.

Manufacturers, UK responsible persons, and healthcare providers should track the bill through Parliament and be ready to comment when the licensing model is consulted on. They should also consider what they might need to change in their own systems if the measures are passed.

European Parliament moves forward on MDR/IVDR reform

The European Commission's proposal to simplify the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) moved into Parliament in the third quarter. On 1 July, the rapporteur for the Committee on Public Health (SANT) published a draft report with more than 130 suggested amendments to the Commission's December 2025 text.

The Commission wants to maintain a high level of patient protection while reducing the burdens that manufacturers, Notified Bodies, and health systems have faced since the MDR and IVDR began to apply, especially for lower-risk and orphan devices. The SANT draft is the first detailed signal of how far Parliament is willing to go and where it wants obligations restored.

Attorneys with Arnold & Porter Kaye Scholer LLP note that the committee is broadly supportive of a more proportionate framework. The proposed amendments would simplify some areas and restore manufacturer duties in others.

Among the changes flagged by the legal experts is a new "niche" device category, which would complement the breakthrough and orphan device categories in the Commission's proposal. Niche devices would be products made in limited volumes for a specific clinical use or patient subgroup, where no suitable alternative is available. They would follow an adapted conformity assessment route and could benefit from longer transition periods.

The draft would also require authorities seeking to reopen the regulatory status of a CE-marked product already on the market to provide more information, including "substantiated evidence," before the process could begin. SANT also suggests giving the Commission power to settle status and classification questions EU-wide through implementing acts.

Other proposed changes include restoring express liability and financial-coverage language that the Commission had proposed deleting and allowing manufacturers to decide whether a device is single-use. The report also suggests allowing English-only product information for devices intended solely for professional use.

The SANT committee discussed the draft on 14 July. There was support for many of the changes, along with recommendations for further streamlining and for certain patient-safety measures to be restored. The next steps are technical meetings, expected in the autumn, and a plenary vote in late 2026 or early 2027.

Device manufacturers—as well as Notified Bodies and health systems—should review the latest draft on the understanding that nothing is final. Planning now for major revisions, such as new product classifications or changes to conformity assessment, will leave stakeholders better prepared if the proposal is approved. Companies should also bear in mind that some SANT committee members want more obligations reinserted in the legislation.

By the numbers

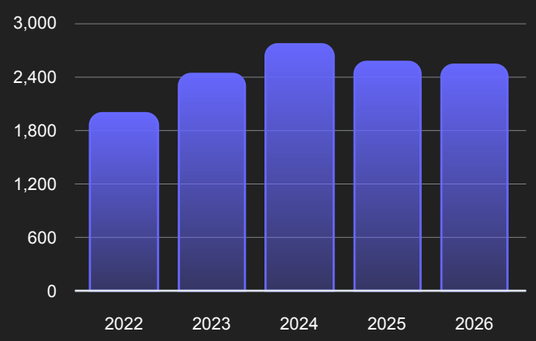
Regulators across the EU and UK recorded 2,557 medical device recalls in the first three quarters of 2026. This was 1.2% lower than the 2,589 events recorded over the same period in 2025 and represented the lowest number of medical device recalls for the first three quarters of the year in the last three years.

Manufacturing defects were the leading cause of medical device recalls, cited in 496 events through September 2026. This marked the first time in more than eight years that manufacturing defects were the leading cause of recalls during the first three quarters of the year. The number of recalls attributed to manufacturing defects increased 69.3% from 293 events in 2025 to 496 in 2026.

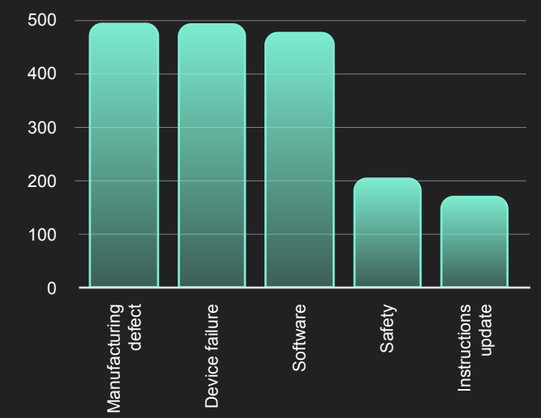
Device failure was a close second, accounting for 495 recalls, up from 413 over the same period in 2025. Software-related issues ranked third with 479 recalls, compared with 438 a year earlier. The three leading causes remained closely grouped through the first three quarters of 2026, continuing the pattern recorded during the first half of the year.

Germany recorded the most medical device recall notifications, with 597 alerts through September 2026, broadly in line with the 600 issued over the same period in 2025. France ranked second with 563 notifications, down from 622, while Italy followed with 376, compared with 407 in 2025. Ireland recorded 339 alerts, up from 239 a year earlier, while the UK issued 308 notifications, down from 326 over the same period in 2025.

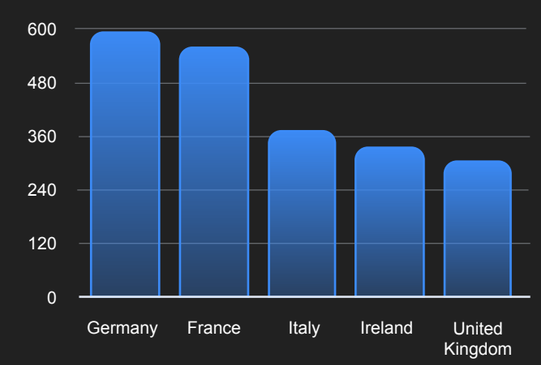
Number of recall events (Q1-Q3)



Number of recall events by risk (top 5)



Recall events by notifying country (top 5)







MDR/IVDR 2.0: safety, access, and innovation—can the EU have it all?

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The European Commission's proposed reform of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) is a substantial attempt to recalibrate the EU's medical device framework after several years of difficult implementation. The reform responds to a growing tension. In some cases—and alongside other markets, economic, and supply-chain factors—rules intended to strengthen patient safety have also contributed to high compliance costs, lengthy certification timelines, and reduced device availability.

The Commission's targeted evaluation found that the MDR and IVDR have strengthened device safety, performance, and transparency. However, regulatory complexity, capacity constraints, divergent interpretations, and uneven evidence requirements have undermined predictability and contributed to reduced availability, particularly for innovative and niche devices.

The proposal seeks to make the system more proportionate, risk-based, and predictable, while retaining the basic MDR/IVDR architecture. The reforms are broad. They extend well beyond notified body certification to address clinical evidence, post-market surveillance, innovation pathways, software, clinical studies, governance, and international cooperation—among others. However, the final outcome remains uncertain as Parliament and the Council consider how far the proposed changes should go.

A more proportionate conformity-assessment system

One of the most significant changes would be to move some fixed and repetitive conformity assessment activities towards a more risk-based approach. The Commission proposes replacing the current five-year certificate validity limit and recertification cycle with periodic reviews proportionate to risk. It would also reduce routine technical-documentation sampling for certain devices, allow surveillance audits to move to a two-year cycle if no concerns have been identified, and make unannounced audits more targeted. Predetermined change-control plans would allow manufacturers and notified bodies to agree in advance how specified future changes will be handled.

Predictability is also being tackled. The proposal would establish pre- and post-submission structured dialogue between manufacturers and notified bodies, allowing the parties to discuss documentation and conformity assessment expectations before problems arise.

Separate EU measures also introduced maximum timeframes for defined notified body activities. The remaining issue is whether these measures will produce genuinely predictable end-to-end certification.

A broader evidence framework

Clinical evidence is another major focus. The proposal would broaden the range of data that can contribute to a clinical evaluation, including information from equivalent or similar devices, literature, real-world evidence, and evidence validated through simulations (in silico) or other new methodologies.

It would also remove the current default expectation of a clinical investigation for Class IIa implantable devices where existing evidence is sufficient. The aim is to align evidentiary requirements more closely with the risk and maturity of the technology, rather than require new studies where existing evidence is sufficient.

That shift could reduce costs and development time—particularly for established technologies, modifications, and devices intended for small patient populations, where generating new clinical data can be disproportionately difficult and costly. However, the approach also creates a key point for the legislative negotiations: how far should manufacturers be allowed to rely on evidence from other products without weakening product-specific evidence for higher-risk devices?

Parliament's June 2026 draft report takes a more cautious approach to equivalence, excluding Class III implantable devices from the proposed expanded equivalence route and retaining additional safeguards for reliance on equivalent devices.

Adaptive pathways for innovation

The proposal would introduce specific regulatory pathways for breakthrough and orphan devices, recognizing that the current system offers limited flexibility for technologies which address serious unmet needs or rare conditions.

These new routes would provide earlier expert panel input, prioritized conformity assessment, and rolling review, where appropriate. Parliament's amendments would also extend the framework to a third category of "niche devices," broadening the accelerated pathway beyond breakthrough and orphan devices. The reform would further expand expert panel advice on issues including classification, regulatory status, and clinical or performance development strategies.

The reform is also designed to reduce fragmentation during development. A proposed coordinated pathway for combined studies involving medicinal products and medical devices or IVDs would allow a single coordinated assessment rather than parallel procedures under the MDR/IVDR and Clinical Trials Regulation. The Commission identifies duplicated submissions, divergent Member State views, and misaligned timelines as key problems with the current framework.

Software is another area of change. The proposal would revise MDR Rule 11 to align software classification with international approaches and better distinguish between software that provides information and software that drives or informs clinical management. One consideration would be the seriousness or criticality of the condition involved.

The proposal is also more broadly intended to modernize the existing framework. Other proposed measures address Summary of Safety and Clinical Performance (SSCP) and Summary of Safety and Performance (SSP) requirements, Periodic Safety Update Reports (PSURs), performance studies, and in-house devices. Additional topics include digitalisation, classification and regulatory status procedures, notified body oversight, and international reliance.

Where the debate is likely to be

A central question is how far simplification can go without weakening the safety architecture of the MDR and IVDR.

Industry broadly supports a more proportionate and predictable framework, particularly where it reduces duplication and makes conformity assessment more efficient. Notified bodies also support a more risk-based model but have highlighted an important practical dependency: risk-based oversight requires reliable information about devices, incidents, clinical performance, and market experience.

Team-NB, the European Association of medical devices notified bodies, has argued that assessors need broader access to information from the European Database on Medical Devices (EUDAMED) to make meaningful risk-adaptive surveillance decisions. Without sufficient data, reducing routine oversight may simply shift uncertainty rather than resolve it.

Positions also diverge on specific issues, including reprocessing—the system of cleaning, disinfecting, sterilising, and inspecting used medical devices so they can be safely reused. The Commission wants to require that manufacturers justify single-use designation and facilitate reprocessing of devices not designated as single-use. Parliament's draft would retain the manufacturer's responsibility and add safeguards, including justification and traceability. Equivalence and clinical evidence are another fault line, with Parliament taking a more cautious approach to reliance on other devices.

The eventual compromise will mandate changes to the Commission's current proposal.

The balancing act ahead

The MDR and IVDR retain a decentralized model in which Member States remain responsible for competent authorities and notified bodies, while the Medical Device Coordination Group (MDCG) remains the main EU governance body. The proposal strengthens coordination and expands EU-level scientific expertise but does not create a single EU medical device regulator.

That may improve consistency, but it does not entirely remove the underlying risk of divergent national or notified body interpretations. The Commission's evaluation itself found persistent concerns about unclear requirements and inconsistent implementation despite the extensive body of MDCG guidance.

A more risk-based system will also only work if notified bodies have the information needed to identify where additional scrutiny is warranted. This makes effective use of EUDAMED and access to relevant safety and performance data increasingly important.

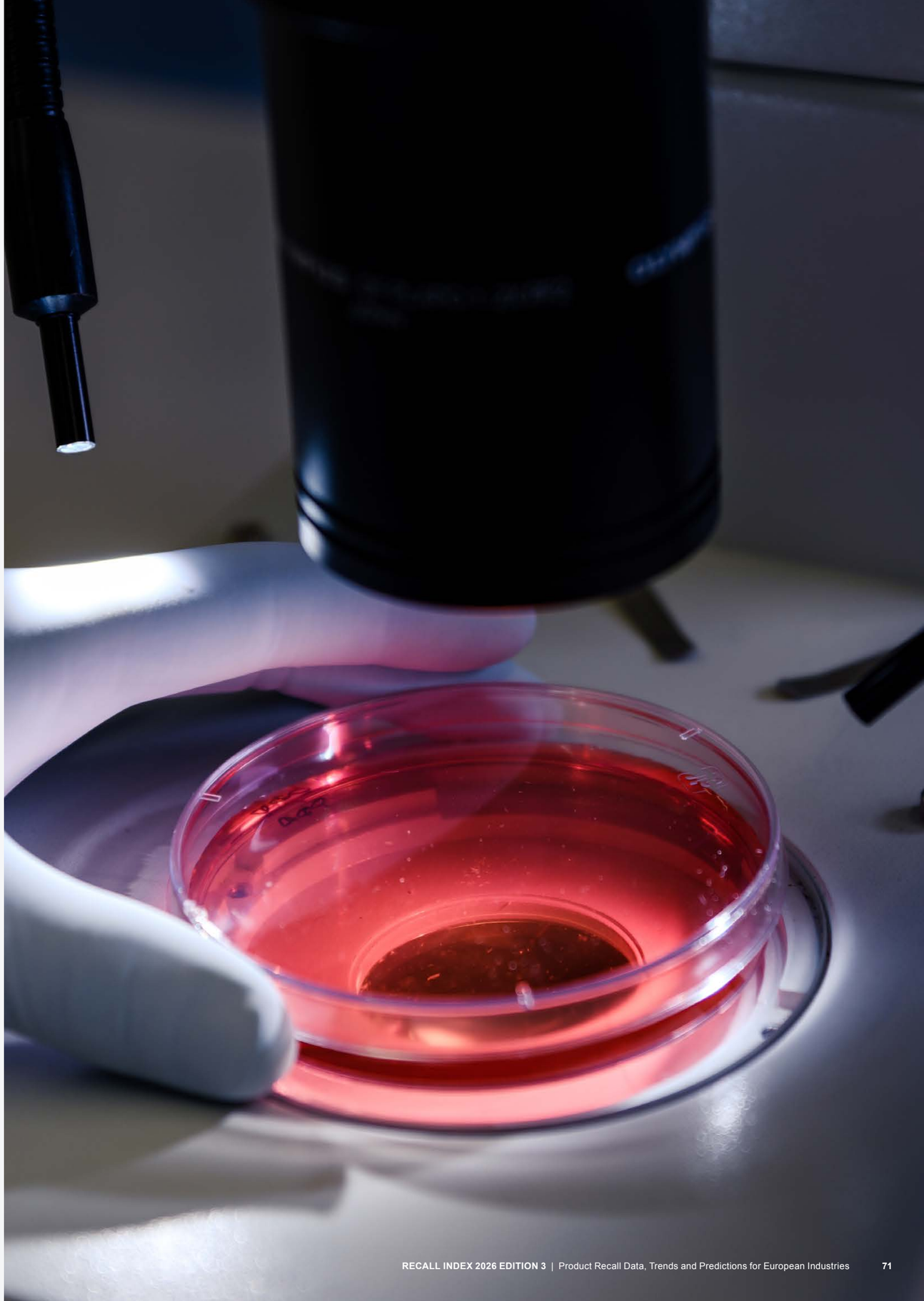
The evidence framework will also need further clarification, particularly around equivalence, real-world evidence, and new methodologies. In addition, the proposal addresses the interface with the EU AI Act, seeking to reduce overlap between the two regimes through changes to the AI Act's treatment of MDR/IVDR requirements. However, how that interface will work in practice will depend heavily on the final text and its implementation.

The final legislation may therefore differ from the Commission's opening proposal, particularly on the extent of the proposed simplifications. But the direction of travel is clear: away from fixed and repetitive processes and towards a more proportionate, risk-based, and predictable system.

That shift could benefit both industry and patients. A regulatory system that is unnecessarily burdensome can itself create a patient access problem when manufacturers delay launches or discontinue low-volume products. Equally, simplification without adequate data, expertise, and safeguards could undermine the protections that the MDR and IVDR were introduced to strengthen.

The challenge for the EU is therefore not simply to reduce regulation, but to make it work better. Lawmakers must focus resources where they deliver the greatest safety benefit while making it easier for safe and innovative technologies to reach European patients.

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Pharmaceutical

The EU's major revisions to its regulatory framework for pharmaceuticals took a further step in September, when the Council of the EU adopted its first-reading position on the Pharma Package. The reforms would reset regulatory data and market protection, speed up some European Medicines Agency (EMA) reviews, and add new rules to ensure adequate supplies of key medicines, among other changes.

The industry is also reassessing how it communicates with patients. The European Federation of Pharmaceutical Industries and Associations published a practical guide on health literacy and plain language, with a reminder that clearer materials still have to stay non-promotional.

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) stepped up enforcement against advertising of weight-loss medicines, including GLP-1 products which are promoted to the public without a marketing authorisation.

Stakeholders need to be planning for a series of changes: new protection periods and supply obligations under the EU Pharma Package, new guidance on how to speak to patients, and stricter oversight of consumer-facing promotion of prescription-only weight-loss treatments.

EU Pharma Package advances

On 28 September, the Council of the EU adopted the Pharma Package at first reading. It is the most comprehensive update to EU medicine regulations in more than 20 years.

The core protection model provides eight years of regulatory data protection—which ensures exclusive rights to data from pre-clinical tests and clinical trials. The current plan also provides companies with one year of market protection, granting them exclusive rights to sell a new medicine without immediate competition from generic medicines or biosimilars.



Efforts to streamline drug development are increasing the importance of robust data, risk management, and patient safety throughout the clinical trial process.



An additional year of market protection is available for innovative medicines that meet two of three conditions: comparative clinical trials, early EU filing, and clinical trials in more than one Member State. A second extra year is available for medicines that address an unmet medical need. Total protection is capped at 11 years—or 12 if a transferable antimicrobial voucher is used.

Orphan products would follow a separate exclusivity track. The package also widens the Bolar exemption, which shields generic and biosimilar developers from patent infringement claims while they carry out the studies and trials needed to launch when protection expires. The exemption will now also cover applications for procurement tenders.

Additional changes include shortening the standard EMA scientific assessment timeframe from 210 days to 180 and authorising Member States to require companies whose drugs have market protection to supply adequate quantities to meet patient needs.

Attorneys with CMS caution that companies can use the latest draft to refine implementation plans but should not treat the rules as final law. The texts still need to be adopted by the European Parliament and published in the Official Journal before they enter into force. A plenary vote has been signalled for November 2026, though no date has been confirmed. Once in force, Member States would generally have two years to transpose the directive.

Companies should use this time to determine whether they need to adjust their development and marketing schedules, supply chain processes, or other operations in response to the latest revisions.

Pharmaceutical companies look to improve patient communications

In July, the European Federation of Pharmaceutical Industries and Associations (EFPIA) published a guide to help pharmaceutical companies create materials that are easy for patients to understand and empower them to take a more active role in their care. However, the trade group cautioned companies that they still needed to ensure these communications are not promotional.

The guidance is aimed at regulatory, medical affairs, pharmacovigilance, patient-engagement, communications, legal, and compliance teams—not only consumer-marketing functions. It is built around four key pillars. The first is to start with health literacy and plain language. Materials should be accurate, accessible, inclusive, and actionable. Information should be written from the reader's point of view, without unnecessary jargon, and be consistent across a product's documents.

The second pillar is to establish core principles of patient-centred communication. EFPIA lays out eight working principles, which cover purpose, language, structure, numbers, visual aids, digital formats, accessibility, and consistency. The other two central concepts are identifying strategies to embed these principles across the industry and a call to action for all stakeholders.

The guide also includes an overview of legal considerations around the use of materials written in plain language. Attorneys with Osborne Clarke LLP highlight three main risks. First, the materials could be seen as promotional or potentially coercive. Promotional content could also breach EU rules against direct-to-consumer advertising for prescription medicines.

Second, content must stay consistent with the summary of product characteristics and other public sources. Third, patients must not be given the impression that a leaflet can replace advice from a healthcare professional.

To address these concerns, EFPIA recommends that companies use a neutral tone, provide clear disclaimers, and include an explicit statement that the information is not a substitute for clinical advice. If generative AI is used to simplify drafting the content, human medical and plain-language specialists still need to check the output.

The legal experts recommend that companies operating in the EU review patient-facing communications for transparency and clarity. They should also consider creating internal plain-language policies, updating templates and approval processes, and involving patients in the design and review of materials.

MHRA tightens enforcement of weight-loss drug advertising

In the third quarter of 2026, the MHRA published investigations into how a clinic and an online pharmacy offered a waitlist for GLP-1 products that had not been authorised in the UK. Some of the phrases the agency cautioned against included “early access” and “coming soon.”

Under UK law, medicines cannot be advertised to the public without a marketing authorisation. In addition, prescription-only medicines (POMs) cannot be promoted to consumers. The MHRA said that creating consumer demand—by naming a product, referring to “weight-loss pills” or “oral weight-loss treatment,” or inviting people to join a waitlist—meets the definition of a promotion. The MHRA, Advertising Standards Authority, and General Pharmaceutical Council also warned businesses against promoting newly licensed prescription-only weight-loss medicines, such as oral GLP-1s, and products still awaiting authorisation.

In addition, the MHRA listed several treatment-service providers that amended their websites, emails, or text messages to comply with regulations against promoting POMs for weight loss to the public. Providers may advertise a consultation or service but may not make indirect references to weight-loss injections or GLP-1 medication that would lead a member of the public to request one of these drugs. Providers are also prohibited from sending proactive emails or texts that identify a medicine, even to patients who have previously used the treatment.

Attorneys with CMS cautioned that the promotion of prescription weight-loss drugs through online providers and social media remains an enforcement priority. The lawyers note that prescription-only injectable weight-loss medicines cannot be advertised to the public even if the ad does not name a specific product. They also warn that influencers and landing pages that direct a consumer from a general weight-loss service toward a request for a prescription medicine can bring a campaign inside the prohibition.

The legal experts expect regulators to keep a firm approach while demand for these medicines remains high and advertising continues to evolve rapidly online. Sponsors, clinics, pharmacies, and digital health providers should review websites, emails, social posts, and waitlist campaigns against the MHRA Blue Guide and Appendix 6 for treatment-service advertising. Enforcement actions in the third quarter show that “coming soon,” “pre-order,” and “early access” language does not provide a safe workaround.

The UK’s actions mirror similar steps taken in the U.S. to curb unsupported claims about GLP-1 products. Companies that sell in both markets should be aware of increased oversight on both sides of the Atlantic.



By the numbers

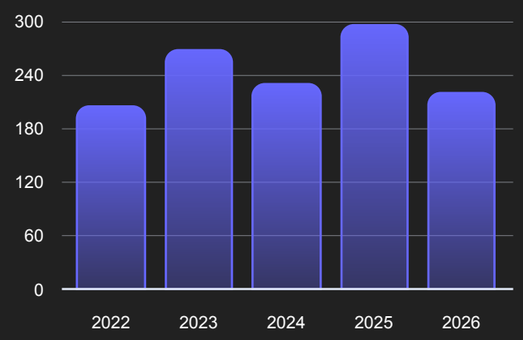
Regulatory authorities across the UK and EU reported 222 pharmaceutical recalls in the first three quarters of 2026. This was 25.5% lower than the 298 events recorded over the same period in 2025, representing a decrease of 76 recalls year-over-year.

Safety was the leading cause, accounting for 53 events. This is on par with the 54 recalls in the first three quarters of 2025. Manufacturing errors were second with 39 recalls, nearly triple the 14 recorded in the same period last year. The combination of foreign materials and contamination ranked third with 30 events, in line with the 34 recalls during the same time period in 2025.

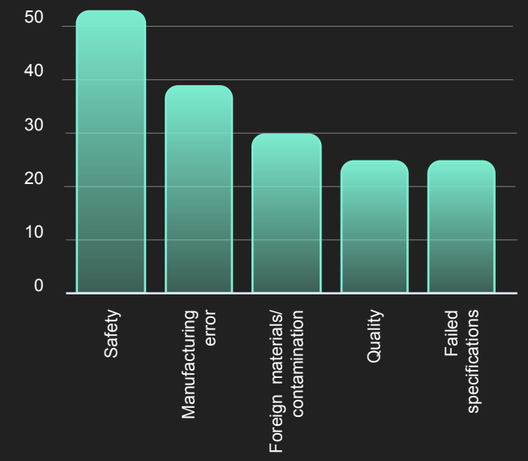
France issued the highest number of pharmaceutical recall notifications through September, with 59 alerts, up from 48 in the first three quarters of 2025. Safety concerns were the most frequently cited cause among notifications issued by France, accounting for 13 recalls. This was followed closely by manufacturing errors with 12 recalls and foreign materials and contamination with 11.

The UK recorded the second-highest number of notifications, with 40 alerts through September 2026, three fewer than the 43 recorded over the same period in 2025. Germany ranked third with 34 notifications, up from 29 during the first three quarters of 2025.

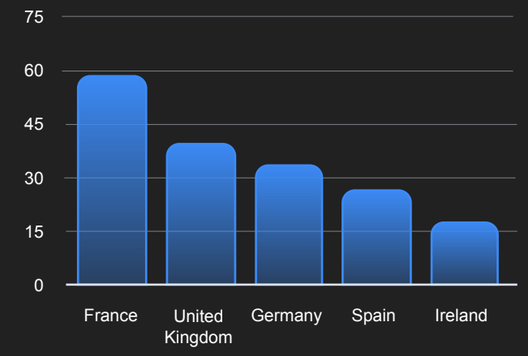
Number of recall events (Q1-Q3)



Number of recall events by risk (top 5)



Recall events by notifying country (top 5)





Conclusion

In the coming months, many of the proposals introduced this year will move closer to becoming law. While few rules were finalised in the third quarter, companies have more clarity around what to expect and can begin to prepare.

Consumer product companies are facing expanding obligations under the European Product Act. Among the considerations are what product data businesses maintain and in what format, and, for online marketplaces, how quickly a noncompliant listing can be taken down.

Pharmaceutical companies can use the time before the European Pharma Package is final to test launch timing and supply plans against the new protection periods and supply obligations. Patient materials and any consumer-facing promotion of prescription weight-loss treatments also deserve a fresh review, with regulators on both sides of the Atlantic watching closely.

With software among the top three causes of medical device recalls this year, developers of AI and digital tools should keep evaluating their product's usage against stated intended purposes so currently unregulated products do not shift into a regulated category unnoticed.

Food and drink businesses selling in Great Britain should analyse where national rules have diverged from EU law since Brexit, ahead of detailed guidance on the SPS agreement and an implementation date targeted for mid-2027. Large retailers should also be ready for the Food Standards Agency's next proposals, due in March 2027. With food recalls at their highest three-quarter level in the series, supplier oversight and traceability remain essential.

Automakers will need to plan for self-driving authorisations in the UK from the second half of 2027 and trade rules that could treat UK-built vehicles and components differently from those made in the EU. Knowing where every vehicle and part is made is no longer just a supply chain exercise; it may determine market access and eligibility for incentives.

Across all industries, the common thread is preparing for rules that are not yet final. Companies that assess their exposure now—and engage while consultations are still open—will be in a stronger position when today's drafts become tomorrow's requirements.

Product safety is an increasingly complex business challenge, shaped by evolving regulatory expectations, global supply chain dependencies, technological change and shifting consumer demands. For organisations, the consequences of a product safety issue can extend well beyond a recall, disrupting operations, exposing financial vulnerabilities and undermining customer and stakeholder confidence.

Effective risk management demands more than contingency planning. It requires the foresight, resources and specialist capabilities to anticipate emerging threats, make informed decisions and maintain control when incidents occur. Whether strengthening preparedness or managing an active event, an experienced external partner can provide the expertise and operational capacity to navigate regulatory and litigation challenges, minimise disruption and protect long-term business value.





Sedgwick Recall

A product recall is a defining moment for any organisation.

Beyond the immediate safety concerns, it places significant demands on decision-making, operational resources and stakeholder relationships, often across multiple markets and regulatory environments. How effectively an organisation responds can have lasting implications for its customers, reputation and commercial performance.

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