RECALL INDEX
2023 EDITION 1

PRODUCT RECALL
EUROPEAN EDITION

DATA, TRENDS & PREDICTIONS **FOR EUROPEAN INDUSTRIES**

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The Sedgwick brand protection Recall Index is a premier resource for manufacturers, suppliers, and retailers seeking a fair, informed perspective on past and present trends and predictions for what's next in product safety and product recalls. It is a valuable tool for strategic planning and risk mitigation.

This European report reviews five product categories and three sub-categories: Automotive, Food and Beverage, Pharmaceutical, Medical Devices, and Consumer Products – including Electronics, Clothing, and Toys. It analyses data from regulators across Europe, including the UK and the European Union, to provide businesses with unique insight, and exclusive market leading commentary on matters of product safety essential to their operations.

This edition brings you updates pertaining to recall and regulatory activity from the first quarter of 2023, from January through March. It also offers analysis from a host of our strategic partners – top legal and regulatory experts who counsel international global companies on these issues every day. The purpose of the Index report is to provide business leaders a perspective on current and future risks to help protect their consumers, reputations and operations.

The overall number of recalls across all five European sectors was up 6.1% in Q1 2023 compared to the previous quarter. Recalls for automotives and clothing were on par with Q4 2022 data. Toy recalls dropped by 31.3% and pharmaceutical recalls decreased by 17.3%. As a sector, food and beverage recalls increased by 2.9%, but recalls for specific unauthorised ingredients increased more dramatically. For example, the number of recalls for products containing unauthorised cannabidiol (CBD), an active ingredient in cannabis, rose from 11 events in Q4 2022 to 24 in Q1 2023.

Environmental concerns are a major issue for regulators across all industries, whether it is ensuring that companies are not making false claims about their sustainability efforts, reducing emissions, or enforcing extended producer responsibilities for waste disposal and packaging materials.

Regulators also continue to work on ways to protect consumers when they are online, including establishing safeguards to prevent sales of counterfeit products in e-commerce marketplaces and developing regulations to make online gaming safer. In some cases, it seems that regulations are struggling to keep pace with technology.

As a reminder, this edition focuses on EU and UK recall data and regulatory developments. If your operations include the U.S., we encourage you to review our U.S. Recall Index. That edition shares and analyses data and regulatory trends 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 insights from our U.S. partners whose opinions you can only find here.

U.S. edition available here: click here

If you would like more information about what we have observed in recent quarters, you can find previous editions of the Recall Index below:

Q4 2022 European Recall Index: click here
Q3 2022 European Recall Index: click here
Q2 2022 European Recall Index: click here
Q1 2022 European Recall Index: click here

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AUTOMOTIVE

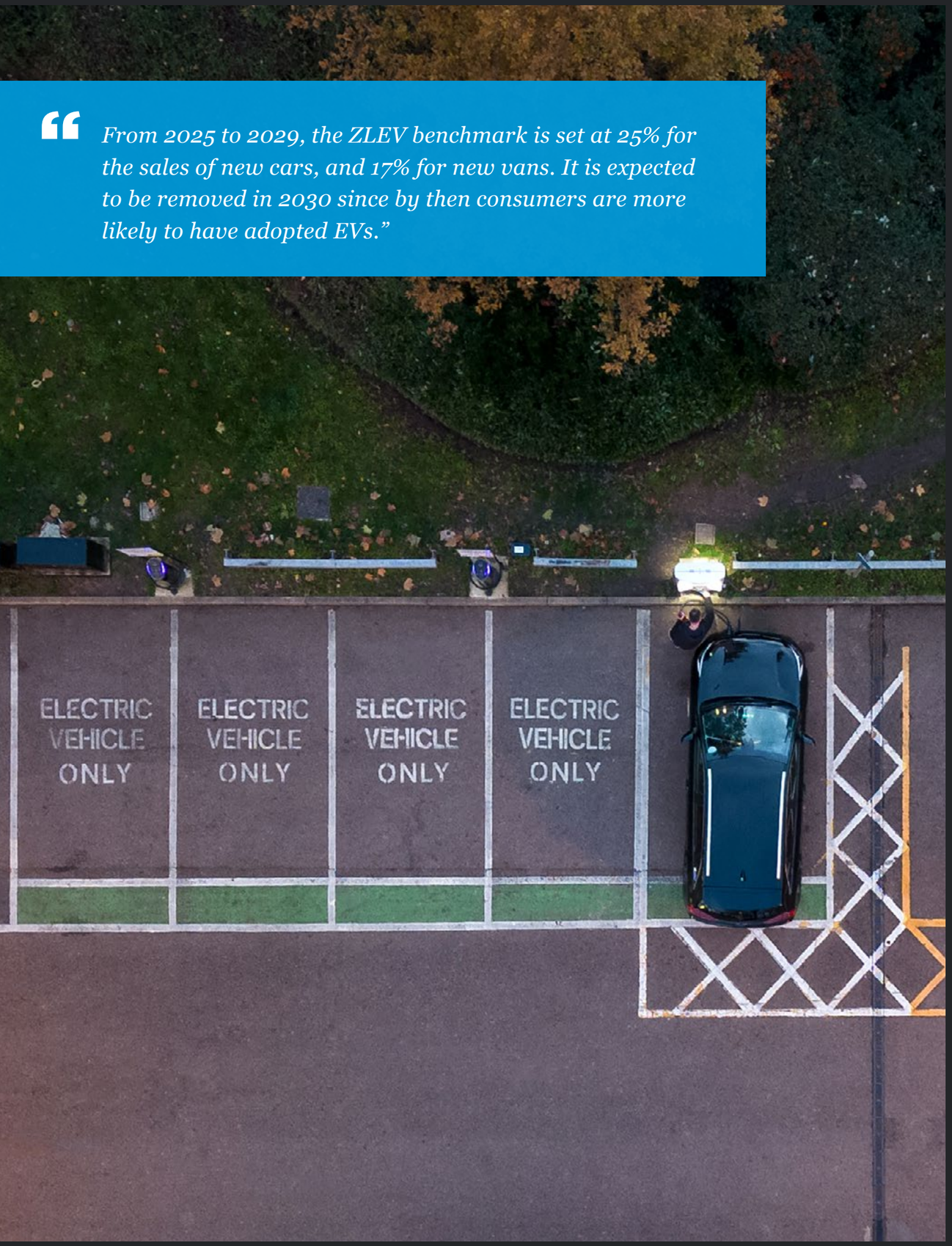
The EU's "Fit for 55" initiative is set to reduce carbon emissions by at least 55% and make the EU climate-neutral by 2050. A key part of the initiative is the EU Member States' recent approval of a new law requiring all new cars sold from 2035 to have zero CO2 emissions. The law also mandates 55% lower CO2 emissions for new cars from 2030 to 2034, compared to 2021 levels. Automakers will be under increased pressure to speed up the transition to electric vehicles to meet the standards.

In February 2023, the UK Competition Appeal Tribunal (CAT) and the High Court ruled that the Competition and Markets Authority (CMA) does not have the power to compel documents or information from a foreign-entity with no territorial connection to the UK. The matter before the CAT was the CMA's request for a German automaker to provide written information related to a competition law investigation. This was the first time the CMA's power had been tested since Brexit and businesses were watching closely to see if the CAT would allow this extraterritorial reach. Legal experts predict that the ruling will make it more difficult for the CMA to carry out cross-border competition investigations.

In other transport-related news, micromobility devices and light electric vehicles such as e-scooters are gaining popularity. However, each EU member state and the UK have their own regulations, which makes it challenging for manufacturers selling across Member States and into the UK. In a recent report, the European Transport Safety Council (ETSC) and the UK Parliamentary Advisory Council for Transport Safety (PACTS) recommend common technical standards and harmonised usage guidelines for e-scooters. E-scooter manufacturers and marketers should consider following the rules for the strictest country in which they operate to ensure compliance with regulations across multiple countries. Having consistent standards will be important for micromobility manufacturers, as different regulations could create considerable costs if models need to be adapted for each Member State.

As the EU and UK continue to make climate-friendly policies a priority, vehicle manufacturers will need to plan for new requirements that will impact production, supply chain issues, and product lifecycle management.

> *"According to ACEA, more than one in five all new cars sold in the EU in 2022 had a plug and the European market's share of battery electric car sales is expected to exceed 70% by 2030."*



> *From 2025 to 2029, the ZLEV benchmark is set at 25% for the sales of new cars, and 17% for new vans. It is expected to be removed in 2030 since by then consumers are more likely to have adopted EVs."*

EU countries approve phaseout of CO2-emitting cars

EU Member States gave final approval to a new law in late March that requires all new cars sold to have zero CO2 emissions starting in 2035. It also mandates 55% lower CO2 emissions from 2030 compared to 2021 levels. The European Commission has pledged, however, to create a legal route for sales of new cars that only run on e-fuels to continue after 2035, after Germany demanded this exemption. While this exemption offers a potential lifeline to traditional combustion vehicles, e-fuels are not yet produced at scale.

The measure is part of the EU's "Fit for 55" initiative designed to comply with the EU climate law mandate to reduce EU emissions by at least 55%. EU countries are working on legislation to not only meet this goal, but also to make the EU climate-neutral by 2050.

As part of this campaign, the European Commission is also expected to present a methodology to assess and report data on CO2 emissions throughout the full lifecycle of cars and vans sold on the EU market by 2025. More and more regulators across industry sectors are putting responsibilities on manufacturers throughout the product lifecycle.

In addition, it is anticipated that the current zero- and low- emission vehicles (ZLEV) incentive mechanism, which rewards manufacturers that sell more electric and well-performing plug-in hybrids vehicles, will be adapted to meet expected sales trends. From 2025 to 2029, the ZLEV benchmark is set at 25% for the sales of new cars, and 17% for new vans. It is expected to be removed in 2030 since by then consumers are more likely to have adopted EVs.

The European Automobile Manufacturers' Association (ACEA) said that the industry is "up to the challenge of providing zero-emission vehicles," in part due to continuous industry investments. According to the ACEA, more than one in five all new cars sold in the EU in 2022 had a plug and the European market's share of battery electric car sales is expected to exceed 70% by 2030, well ahead of the U.S.

While most automakers have been planning for the transition to electric and vehicles with zero CO2 emissions, the passage of the new law puts more pressure on automakers and clarifies some of the metrics regulators will be watching. Manufacturers can expect more guidance from authorities around implementing the e-fuel exemption and other steps moving toward the 2035 deadline. Automakers also need to be aware of the new requirements for the full lifecycle of their vehicles and be making plans on how to comply with those changes.

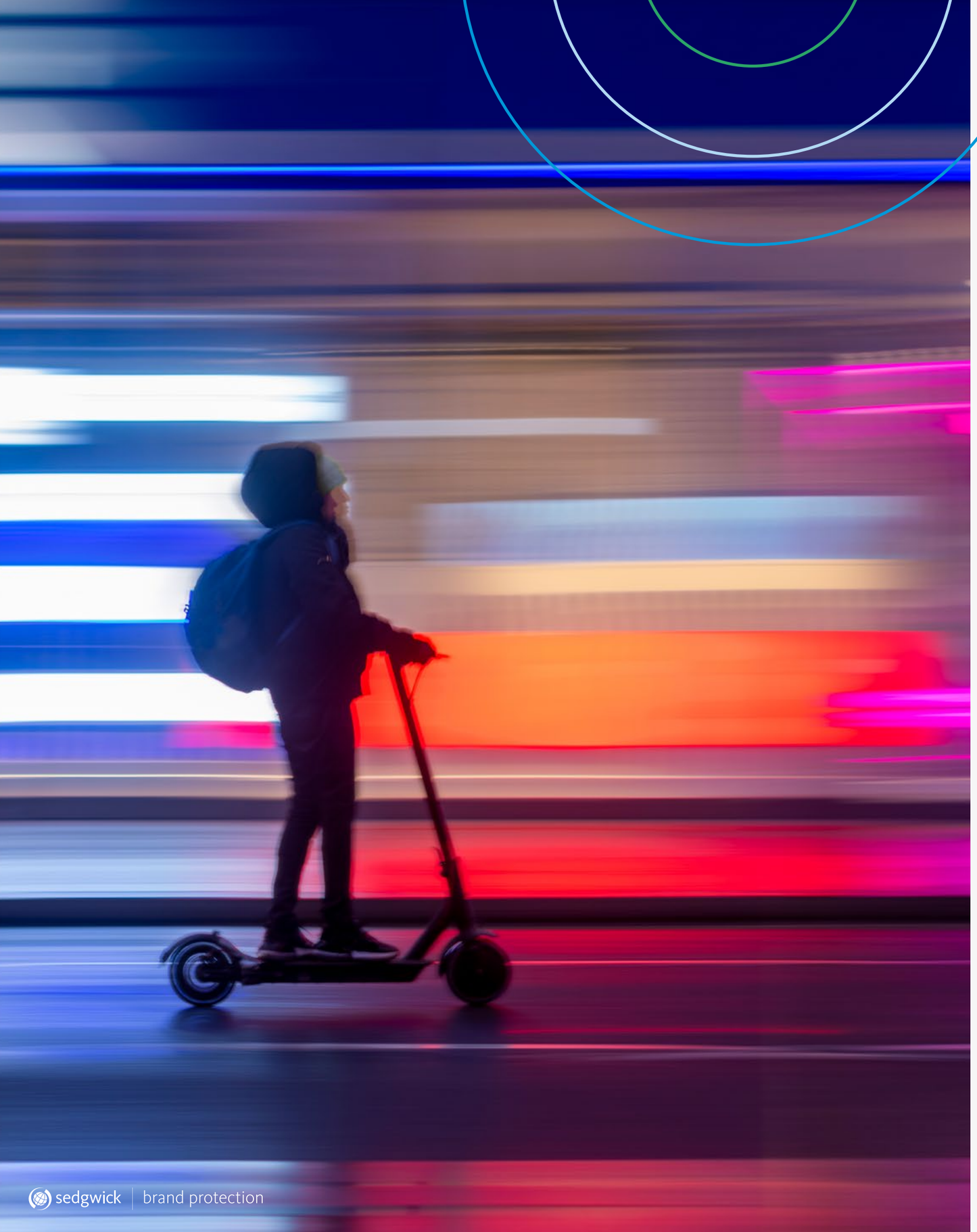
Automakers succeed in limiting regulator's extraterritorial reach

In December, the UK's Competition and Markets Authority (CMA) issued its first fine against a foreign company for non-compliance with a written information demand and its first daily penalty. Both of these actions were related to section 26 of the Competition Act 1998 (CA98). The measures were taken against a major German automaker for not complying with a written information demand tied to an investigation that the CMA and the EU launched in March 2022. The CMA's inquiry was into suspected breaches of competition law by a number of vehicle manufacturers and trade associations around take-back, dismantling, and recycling of end-of-life vehicles (ELVs).

The CMA had instructed the automaker's German parent company, its UK subsidiary, and any other legal entities forming part of the same "undertaking" to produce certain documents and information. While the UK subsidiary fully complied, the parent company pushed back, alleging that the CMA didn't have the authority to compel this information.

In a second action, another party to the investigation made similar objections in response to the section 26 notice that demanded information from its German-domiciled parent company.

In February 2023, the UK Competition Appeal Tribunal (CAT) and the High Court sided with the vehicle makers in a joint ruling that said the CMA does not have the power under CA98 to compel documents or information from a foreign-entity with no territorial connection to the UK. This was the first time that the CMA's power had been tested since Brexit. Attorneys with Skadden Arps Slate Meagher & Flom predict the ruling will make it more difficult for the CMA to carry out cross-border competition investigations.



The key points of the ruling, according to the legal experts, are that the presumption of extraterritoriality applies. This means that UK legislation does not apply to persons outside the UK. In addition, the requirement of territoriality applies to each person within the undertaking, not to the undertaking as a whole. Only persons within the undertaking with a UK connection can be compelled to produce documents and information in their direct or indirect control, including any documents held abroad.

In its ruling, the CAT said it would be open to granting the CMA permission to appeal the decision. The agency has already publicly announced that it will seek this consent. Experts speculate that the UK government may also look to address the jurisdictional reach of the CA98 in the Digital Markets, Competition and Consumer Bill expected before Parliament soon.

Status of the European regulatory framework for micromobility

As the UK and EU move towards greener transportation options and lower emissions, micromobility devices and light electric vehicles such as e-scooters are gaining popularity. However, the safety regulations are still evolving.

In February 2023, the European Transport Safety Council (ETSC) and the UK Parliamentary Advisory Council for Transport Safety (PACTS) published a report on recommended technical standards and safer usage rules for e-scooters.

The two regulators note that there has been rapid growth of e-scooter usage over the last five years, and an associated increase in deaths and serious injuries. The report analyses a wide range of data, hospital studies, vehicle safety testing, and research from across Europe.

Currently each EU Member State and the UK have their own regulatory scheme for e-scooters. There is no common standard for factors such as minimum age, maximum power and speed, and the use of helmets. In the report, the ETSC and PACTS suggest common technical standards and harmonised usage guidelines.

According to the ETSC, 16 EU Member States currently allow e-scooters, with regulations pending in two others and trials underway in another country as well as the UK. However, maximum speeds and power, helmet requirements, and other factors vary.

Among the recommendations are a ban on riding with passengers, on pavements, while using a handheld mobile phone, and under the influence of alcohol or drugs; a factory-set speed limit of 20 km/h and a 250W power limit; and independent front and rear brakes, lights, indicators, and an audible warning device.

Attorneys with Squire Patton Boggs note that having consistent standards will be important for micromobility manufacturers. If the same model of e-scooter is authorized to operate in one EU country but not in another, it could create considerable costs if models need to be adapted for each Member State. The legal experts also state that a common vehicle classification for e-scooters will be important for how matters such as vehicle registration, insurance, and license plates are handled. Currently, some countries consider light electric vehicles motorized vehicles, while others classify them as bicycles.

The report from the ETSC and PACTS were recommendations and not regulations. E-scooter manufacturers and marketers will have to wait to see if and when any harmonised standards are implemented. Until then, stakeholders should consider following the rules for the strictest country in which they operate to know that they will meet the regulations in that jurisdiction as well as the ones with less stringent laws.

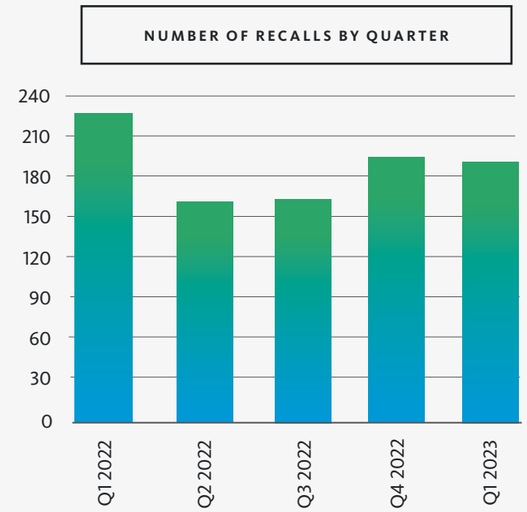
BY THE NUMBERS

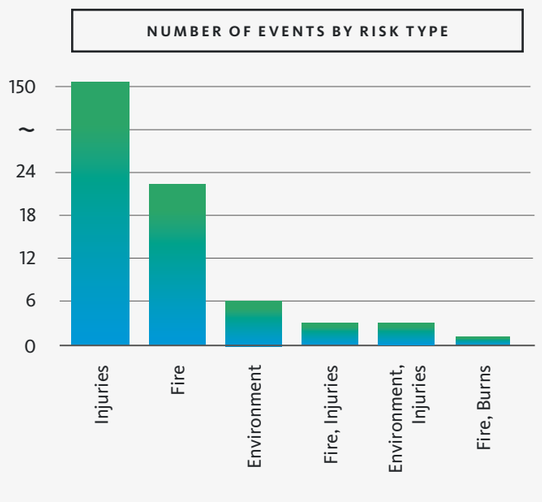
There was a 2.6% decrease in automotive recalls across Europe and the UK from Q4 2022 to Q1 2023, with the number of events falling from 195 last quarter to 190 this quarter.

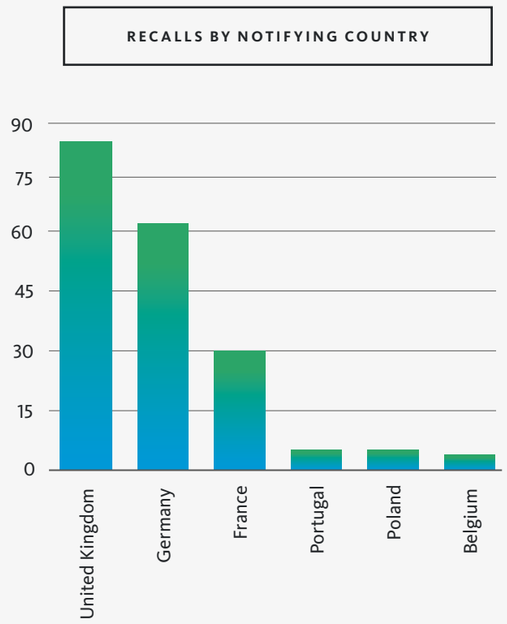
There were 152 recalls tied to injuries in the first quarter of 2023, reflecting a slight decrease from the 157 reported in the previous quarter. Fire risk was the second-most common cause for recalls, linked to 22 events.

Passenger cars were the most common product recalled in Q1 with 106 events, a 15.2% decrease from the 125 recalled in the previous quarter. Taken as a whole, passenger car recalls accounted for 55.8% of the total automotive product recalls in Q1 2023. Vans and motorcycles were the next most-recalled vehicles with 11 events each, an uplift on the nine recalls associated with vans and five recalls for motorcycles in Q4.

In Q1 2023, the UK remained the most active country with 83 alerts, a slight decrease compared to the 89 in Q4 2022. Germany issued the second highest number of alerts with 63, just shy of the previous quarter (65). France submitted 30 alerts in Q1 2023, an uplift of 130.8% compared to the previous quarter's 13 notifications.

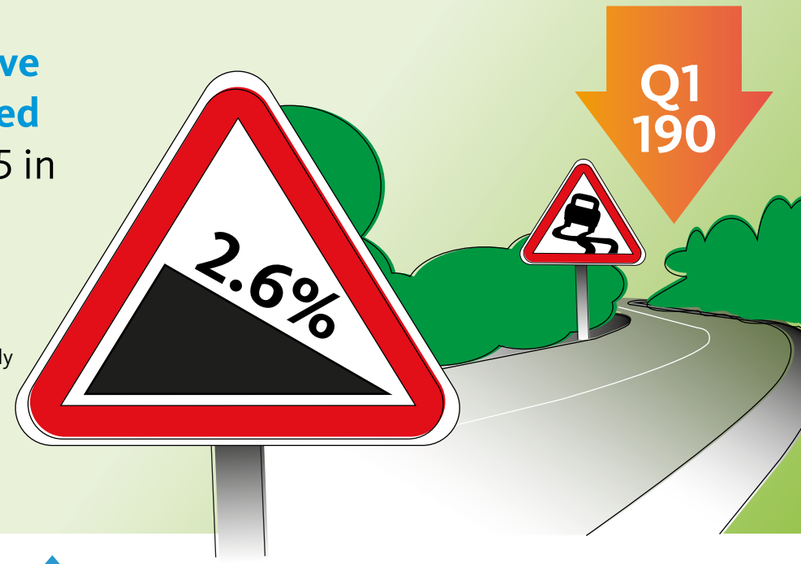






European automotive recall events dropped 2.6% in Q1 (from 195 in Q4, to 190).

Despite this slight decline, Q1's figure remains 39.7% above the 5-year quarterly average of 136 recalls.

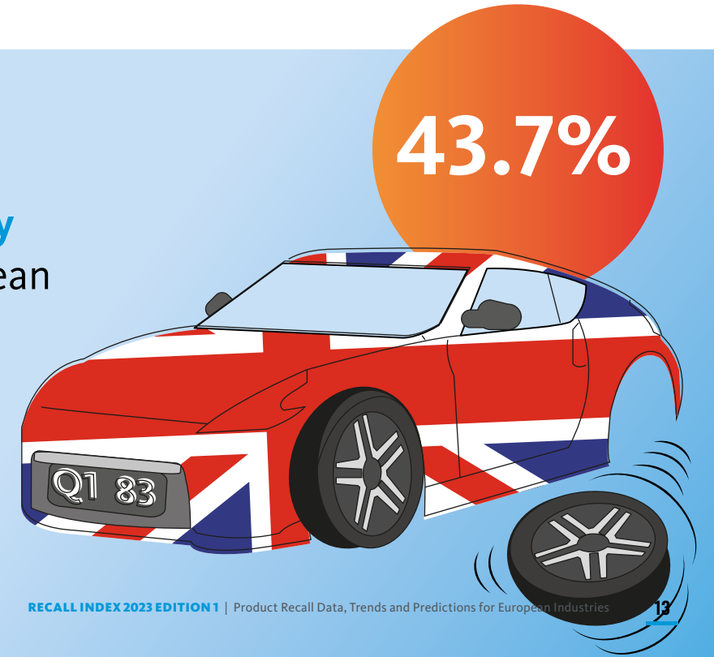


Environmental concerns increased 80.0% in the first quarter of 2023.

Q1 represents the third consecutive quarter that Environmental concerns have grown, placing them on track to reach a 5-year high.

The UK submitted nearly half (43.7%) of all European recall notifications in Q1 (with 83).

This was followed by Germany and France, with 63 (33.2%) and 30 (15.8%) notifications respectively.



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KEEPING ON TOP OF NOVEL AUTOMOTIVE RISK AND ENHANCED REGULATIONS

The automotive industry is one of the most innovative sectors in the world. Arguably it is in the most vibrant phase in its history, despite the rear-view challenges from COVID-19 and supply chain disruptions. The breadth of stakeholders and consumer desire for innovation make it more important than ever for automakers to consider novel risks and how to mitigate them. These include the threat of corrective action following the adoption of novel technology, increased focus on the environment, and more onerous regulation.

A snapshot of novel risks

There are three evolving areas that vehicle manufacturers and suppliers must be especially vigilant about: data capture; environmental, social, and governance (ESG) matters; and lithium-ion battery risks. We break down the threats in each of these categories.

Mandatory requirements for data capture

The Vehicle General Safety Regulation, in force in the EU from July 2022, exemplifies the expanded threat risk of regulatory action. It imposes compulsory minimum standards for a range of safety-related technology and autonomous vehicle features. For example, new motor vehicles must be equipped with event data recorders that capture key information before, during, and immediately after a collision. These recorders must be on a closed-loop system, incapable of deactivation, and have the capability to make the data available to national authorities. Additional data requirements are imposed in relation to autonomous vehicles, including situations where the driver is still expected or required to intervene if the vehicle is not operating in "fully automated" mode. In addition, there is a harmonised format to enable the exchange of data for multi-brand vehicle platooning.

However, there must also be protections against unauthorised data use including cyberattacks. The combined effect of being obliged to capture a significant range of data, make it accessible in multiple ways, but also protect it from unauthorised use is onerous and will require constant surveillance by data producers. In addition, insurers intending to sell truly individual risk-based motor policies may require more sophisticated means of data capture. This may assist in determining liability in the event of accidents, as well as providing a greater understanding of driver behaviour and risk when adopting new technology. Such data will also need to be protected from cyberattacks.

Breaching these minimum standards, and the range of other standards set out in the Vehicle General Safety Regulation, will lead to a swift need for risk assessment and potential corrective action.

ESG risk

Risk around environmental, social, and governance (ESG) matters will become increasingly prevalent in the automotive sector. Consumer desire to ensure that transport is environmentally friendly has fuelled demand for electric vehicles (EVs), among other technologies. Green claims in relation to the expected distance that can be travelled per charge, emissions, responsible sourcing of materials and use of labour, and the environmental impact of production and disposal of materials, all have a growing effect on consumer decisions around which brand or type of vehicle to purchase. In short, green claims are big business.

Against this is growing activism against "greenwashing" claims on products, and increasing ESG regulations that impose substantial responsibility on producers who make these claims. Automotive producers who promote responsible sourcing of materials used in production need to be very confident that they have conducted thorough due diligence on their entire supply chain.

Whilst primarily an issue for civil litigation rather than corrective action, the Dieselgate class actions around the world emphasised that the distinction between traditional health and safety risk and moral harm is increasingly blurred. Vehicle producers who find that components are not performing as expected, such that vehicle efficiency and green credentials are prejudiced, will need to carefully consider the merits of voluntary corrective action to bring performance in line with green claims made about the product. This approach will be better for companies than suffering the impact of a correction of green claims made in the public domain with potentially damaging reputational consequences.

Automotive battery risk

A third example of recall risk from novel technology is a result of the increasing adoption of EVs. Despite several incidents involving lithium-ion battery fires, more notably from products outside of the automotive sector, the regulation of vehicle batteries is inconsistent.

Producers of automotive batteries in both the UK and EU have obligations under a range of discrete regulations to register batteries before placing them on the market. They also must ensure that substances used in batteries are not subject to prohibitions or restrictions, ensure certain processes are in place for transportation and storage, and comply with obligations requiring responsible disposal and management of waste. Breaching these obligations or discovering a breach when the product is on the market could indicate a flaw in the company's processes to bring a product to market. In that case, rapid steps would be needed to ensure compliance, along with dialogue with the relevant regulator in affected countries to mitigate the risk of sanctions.

However, what is notable from this patchwork of regulations is a lack of a distinct regime relating to the safety of automotive batteries. Discovery of a risk of harm arising from a potential battery defect, or the occurrence of incidents such as a battery fire, triggers the obligations under the "umbrella" framework of the existing General Product Safety Directive, as well as relevant local regulations.

Given the complexity of battery technology, including new developments and different materials being used and combined in the cells, as well as the high potential for harm in the event of a catastrophic failure, automotive producers and others in the supply chain require a great deal of technical expertise. However, there is very little regulatory guidance around how to properly assess risk and determine corrective action in relation to this technology.

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The General Product Safety Regulation's impact on the automotive sector

At the end of March 2023, the EU Parliament endorsed the new General Product Safety Regulation (GPSR) as a vital part of the revision of the current EU product safety rules. While the Regulation still needs to be endorsed by the EU Council before it is published in the EU Official Journal and enters into force, it is unlikely the text will see major changes given the large majority in Parliament.

There are a range of parts of the GPSR highly relevant to the automotive industry and product recalls. The Regulation will apply to new technologies and lists new aspects that should be considered when assessing product safety risks. Among the new technologies that will be regulated under the GPSR are interconnected products, such as cars connected to other vehicles on the road.

The following new safety aspects will need to be reviewed: the effects that interconnected products can have on each other; the presentation of the product and the labelling including warnings and instructions for its safe use and disposal; whether a product not designed or intended for children is likely to be used by them, which is a real concern as keyless operations in vehicles become more accessible; the cybersecurity features installed to protect the product; and any evolving, learning, and predictive functionalities of a product, such as artificial intelligence systems.

The current regime focuses on protective actions and measures in case a product is found to be unsafe. Under the GPSR, the requirement for comprehensive risk assessment will increase. Manufacturers will be legally required to conduct internal risk assessments of their products.

Based on this assessment, they will need to draft internal policies and technical documentation containing the necessary information to prove the product's safety. As such, the burden shifts from reactive action to proactive documentation.

Along with conducting these assessments, companies will need to draft policies and product safety documentation before placing products on the market in the EU or European Economic Area (EEA). The GPSR also requires that products bear a type, batch, serial number, or other element allowing for their identification. The EU Commission may set up a traceability system for products, categories, or groups of products that might pose a "serious risk" to the health and safety of consumers, based on registered accidents.

In the future, the definition of manufacturer will also become wider. This means that there will be a greater range of natural or legal persons facing the responsibility for a product safety issue. Any legal or natural person other than the manufacturer that substantially modifies a product will be considered a "manufacturer" and subject to the GPSR's obligations. A change is considered "substantial" if it has an impact on the safety of the product and meets the criteria set out in the GPSR. The GPSR specifically refers to software updates and warns that these updates may substantially change the original product and impact its safety. Even software within sub-systems of vehicles may trigger the full responsibility as a manufacturer.

What's ahead?

These points illustrate just some of the sweeping changes expected. Automotive industry stakeholders should monitor and comprehensively prepare for the new regime if they are intending to sell into the EU or EEA.

> *"Under the new GPSR, the requirement for comprehensive risk assessment will increase. Manufacturers will be legally required to conduct internal risk assessments of their products."*

FOOD AND BEVERAGE

The food industry is facing increasing pressure to reduce its environmental impact, from the way food is sourced and packaged to how it is marketed and consumed. In response to growing consumer awareness of environmental issues, regulators are more intently scrutinising companies' claims about sustainability and carbon footprints.

In recent years, many companies have made commitments to reduce their carbon emissions, use more sustainable packaging materials, and source ingredients from suppliers that follow environmentally-responsible practices. However, with so many different green claims being made, it can be difficult for consumers to know which products are genuinely sustainable and which are just greenwashing.

To protect consumers, regulators are looking more closely at the statements companies make about their environmental impact. For example, in the UK, the Advertising Standards Authority (ASA) has launched a new rule that requires companies to provide "hard evidence" to back up any environmental claims they make in their advertising. This means that companies will need to be more transparent about their environmental practices and have data to back up any declarations made.

This approach aligns with the UK's Competition and Markets Authority's (CMA's) investigation into green claims. In January, the agency announced it was expanding its investigations into "fast-moving consumer goods" (FMCG) such as perishable and non-perishable food and drink, cleaning products, homecare products, and personal care items.

In addition to marketing claims, regulators are also looking at the way food is packaged. Companies have been charged with extended producer responsibilities for disposing of packaging and using recyclable and recycled materials. Single-use plastic packaging has been a particular focus. Both the UK and EU have banned single-use plastic and more restrictions are expected.

Overall, the food industry is facing more pressure to reduce its environmental impact and be transparent about its efforts to be more eco-friendly. As regulators crack down on greenwashing and consumers become more environmentally conscious, companies that can demonstrate a genuine commitment to sustainability are likely to gain a competitive advantage in the marketplace.

> *"Regulators are looking more closely at the statements companies make about their environmental impact. The EC published its Proposal for a Directive on Green Claims in March 2023. Amongst the provisions, companies would need to independently verify and prove green claims with scientific evidence."*

Regulators taking a closer look at green claims

The UK's Competition and Markets Authority (CMA) began investigating companies' "green claims" by sector last year, beginning with the fashion industry. Now "fast-moving consumer goods" (FMCG) are under the spotlight. FMCG include household essentials such as perishable and non-perishable food and beverages, cleaning products, homecare products including toilet paper, hand soap, toothpaste, shampoo, bodywash, and other personal care items.

The FMCG investigation will analyse online and in-store environmental claims, such as the use of vague and broad eco-statements that are not evidence-based, misleading claims about the recycled or natural materials content of a product, and the use of terms such as "sustainable."

The CMA noted that it would continue its wider review of potentially misleading green claims in other sectors and consider whether to open further investigations.

The Advertising Standards Authority (ASA) is also actively enforcing false environmental claims, particularly regarding meat and dairy alternative products. The ASA has also commissioned research into consumers' understanding of "carbon neutral" and "net zero" claims, among other issues.

Attorneys with Osborne Clarke predict that the CMA will issue notices to a number of companies requesting information and documentation. This material will be analysed to inform the CMA's decisions on whether or not to investigate formally.

They encourage food and beverage product companies to review their use of the term "natural" in labelling and marketing from the perspective of an environmental claim. While this has not traditionally been how this term is viewed, with the new enforcement about green claims, regulators may see it differently.

In addition, the legal experts suggest that companies review their sustainability and environmental claims wherever they are used to ensure they are complying with consumer protection legislation, such as the CMA's Green Claims Code, and recent ASA guidance.

The UK is not the only jurisdiction looking at environmental claims. The European Consumer Organisation (BEUC) has called on the European Commission to ban the use of carbon-neutral claims for all products including food and drink.

In a statement, BEUC Director General Monique Goyens said, "There is no such thing as a 'CO2 neutral' banana or plastic water bottle. Carbon neutral claims are greenwashing, pure and simple…"

Some of the objections BEUC raises against these types of claims include that the statements are scientifically inaccurate because producing food and drinks will always emit carbon; the claims mislead consumers into thinking that the products are a good choice for the climate; and that national authorities often handle complaints so slowly that the damage caused by greenwashing is already done by the time any action is taken.

In March 2023, the European Commission (EC) published its Proposal for a Directive on Green Claims, which it said will give consumers better quality information to choose eco-friendly products and services, and stronger reassurance that when products make green claims, there is evidence to support those statements.

The EC positioned the draft regulation as good for businesses, saying that companies that have worked to improve their environmental sustainability will be rewarded when well-informed consumers can trust marketing claims. The regulations will help establish a level playing field for information about the environmental performance of products, according to the EC.

Among the provisions of the proposal are the need for companies to respect minimum norms on how they substantiate and communicate their environmental claims. In addition, any green claims will need to be independently verified and proven with scientific evidence. There are also requirements for clear and harmonised rules and labels that ensure information is reliable, transparent, independently-verified, and regularly reviewed.

While the proposal does not ban carbon-neutral claims outright, it does say that if carbon-offsetting claims are made, companies must be transparent about what part of that claim concerns their own operations, and what part relies on buying offsets. There are also requirements on the integrity of the offsets themselves as well as on their correct accounting. In addition, the EC encourages companies to focus on reducing emissions in their own organisation or value chain.

It remains to be seen if the BEUC will be happy with this version or if they will continue to push for more restrictions on what marketers can say about their carbon-reducing efforts.

Energy drink sector next target of European Commission raids

On 20 March 2023, the European Commission began unannounced inspections in various Member States at the facilities of a major energy drink company. The Commission cited concerns about violations of EU antitrust rules that prohibit cartels, restrictive business practices, and abuses of a dominant position.

National competition authorities of the Member States where the inspections were carried out were also part of the actions. The Commission made it clear that the inspections themselves do not mean that the company is guilty of anticompetitive behaviour.

Inspections are often the first step in an investigation into suspected anticompetitive practices. There is no legal deadline to complete anticompetitive conduct inquiries and the timeline depends on multiple factors which are unique to each situation.

In its announcement, the Commission also referenced its leniency programme which may grant immunity from fines, or significant reductions in fines for companies that have been involved in a secret cartel if they report the conduct and cooperate with the investigation.

These actions come after the EU's Competition Commissioner, Margrethe Vestager, said in a speech in September 2022 that the Commission had already looked into possible anti-competitive market sharing practices among online ordering and food delivery companies, and opened an investigation into possible anti-competitive practices by a major biscuits, chocolate, and coffee company. Commissioner Vestager said there were more cases being worked on in the food supply chain.

The UK's Competition and Markets Authority (CMA) has also conducted an increasing number of inspections focusing on anti-competitive behaviour, both jointly with the EU and independently, across a range of industries. Companies should be aware that regulators are not only watching, but also taking action. Partnership and business relationship contracts should be carefully evaluated to ensure they cannot be viewed as violating competition rules.

> *"Companies should be aware that regulators are taking action. Partnership and business relationship contracts should be carefully evaluated to ensure they cannot be viewed as violating competition rules."*

Changes ahead for food packaging rules

Attorneys with Steptoe & Johnson LLP caution stakeholders across the food industry that food contact materials and articles are being carefully considered as part of the EU Green Deal and the Circular Economy Action Plan.

Under the Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with food, from July 2023, all plastic placed on the market for food contact must contain recycled plastic manufactured with a "suitable" recycling technology with limited exceptions. From October 2024, third-party certification will be required for quality assurance systems used to collect and pre-process plastic input.

The new regulation also has requirements for new control mechanisms to ensure plastics used as intake raw materials are sufficiently decontaminated during collection and recycling, and a new Union register of technologies, recyclers, recycling processes, recycling schemes, and decontamination installations.

While the new EU law does not apply in the UK, there are new extended producer responsibilities that went into effect there in January 2023. Certain producers in the UK are responsible for the entire cost of recycling the packaging they place on the market. That includes not only the cost of collection, but also costs tied to treatment and recycling. In some instances, businesses must also collect and report data on the packaging they handle and supply, and pay a waste management fee, among other obligations. Legal experts predict significantly higher compliance costs for some producers.

Both the EU and the UK are also looking to regulate single-use plastic materials and articles, including food items. The UK announced a ban that will take effect in October 2023 and will include all single-use plastic plates, trays, bowls, cutlery, balloon sticks, and certain types of polystyrene cups and food containers. Businesses including retailers, takeaways, food vendors, and the hospitality industry will no longer be able to sell these products to consumers.

The EU banned single-use plastic in July 2021, however new amendments to current regulations or possibly entirely new legislation, are expected later this year.

Companies should have been preparing for these changes since they have been discussed for several years. It remains to be seen how strictly the laws will be enforced or if companies will be given some grace period.

Rise in prosecutions for allergen labelling

Food and catering businesses are facing more regulatory risk for failing to warn consumers about allergens, say attorneys with Reed Smith LLP. The EU Food Information to Consumers Regulation (FIC 2011) recognises 14 allergens, including celery, milk, fish, nuts, and sesame seeds, and sets guidelines for how allergen information must be presented.

These include requirements around how and where the name of any and all allergens must appear in the ingredients list. For food that is not pre-packed, there must be other methods to highlight any allergens that may be present in the food.

The EU Food Information Regulations 2014 impose an unlimited fine for breach of allergen labelling requirements. Businesses that fail to comply can face criminal penalties.

Both restaurants and takeaways have faced lawsuits and other enforcement actions after consumers suffered from non-disclosed allergens. In the UK, Natasha's Law was implemented after the death of a young girl as a result of an allergic reaction to sesame seeds that were not identified on a pre-packaged sandwich. The law requires any Prepacked for Direct Sale (PPDS) food to clearly identify all ingredients on the product label, with an emphasis on the 14 allergenic ingredients.

The owners of a takeaway in the UK were sentenced for manslaughter in 2017 after a customer alerted the staff about a peanut allergy, but was still served food containing peanut protein. While the conviction was overturned on appeal, it shows the seriousness of these issues.

With regulators taking more notice of issues around unreported allergens, food service operators need to check their systems around labelling and cross-contamination in order to protect both their customers and their reputation.

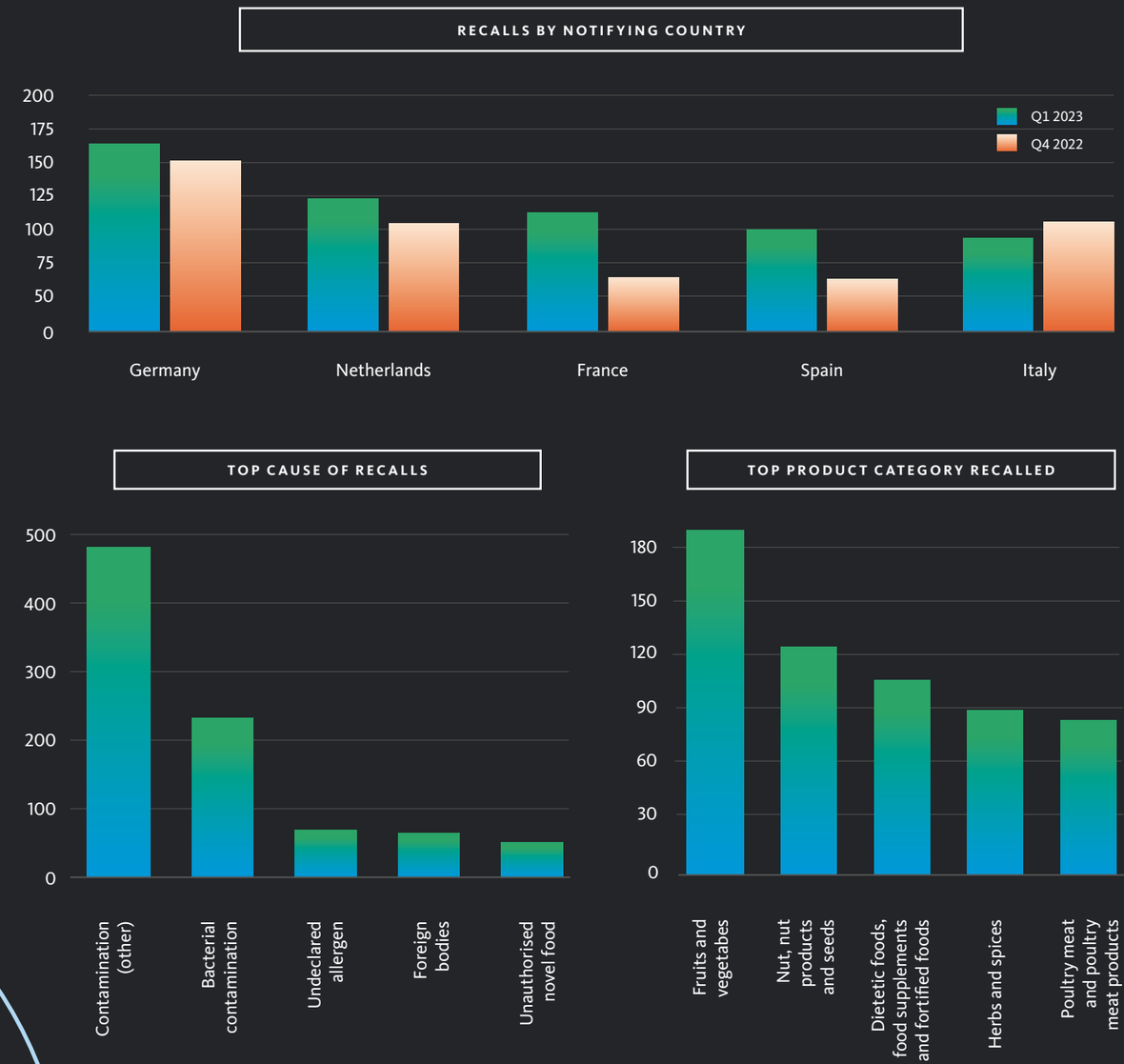
BY THE NUMBERS

Regulators in the EU and UK reported 1,154 food and beverage recalls in Q1 2023, up 2.9% compared to Q4 2022. The leading cause of food and beverage recalls this quarter was Contamination - Other with 486 events, or 42.1% of all recalls.

The most common contaminant of concern was aflatoxins, which were linked to 89 recalls this quarter. This represents an increase of 21.9% from the 73 recalls associated with aflatoxins in Q4. The second leading contaminant was chlorpyrifos, which was cited in 62 events. Third was pesticides with 30 recalls.

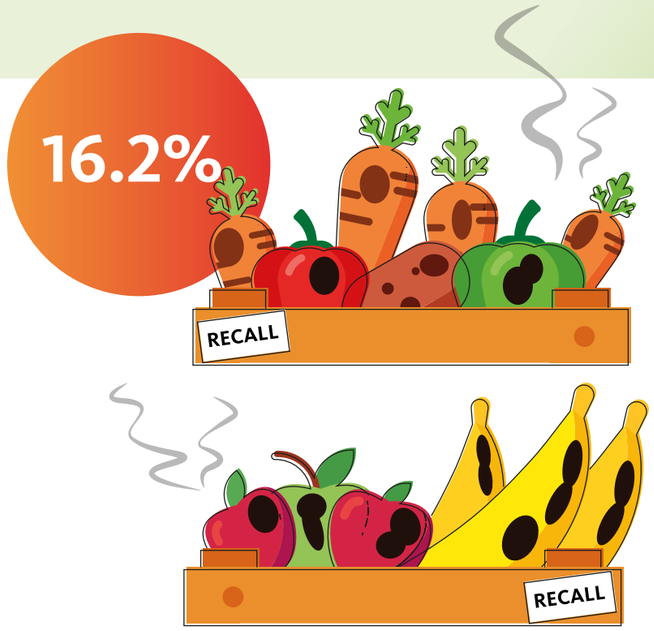
Regulators are recalling food products containing cannabidiol (CBD), an active ingredient in cannabis, though there is some inconsistency about if it is an unauthorised novel food, an unauthorised novel ingredient, an unauthorised substance, unauthorised ingredient, or an unauthorised additive. In Q3 2022, there were nine food recalls involving CBD. In Q4 2022, that number rose to 11, and this quarter there were 24, mostly classifying it as an unauthorised novel food. It is hard to determine if this increase in recalls is due to more stringent oversight or because CBD is being used in more products.

Fruits and vegetables remained the product category with the most recalls with 187 events in Q1 2023, a 12.0% rise from the previous quarter. Nuts, nut products, and seeds were the second-most impacted category with 126 recalls, slightly higher than the 116 recalls last quarter. Dietetic foods, food supplements, and fortified foods were the third-highest product category with 109 events. There were 39 recalls for bivalves, molluscs and related products, the majority of which were linked to an outbreak of norovirus contamination in oysters.



Food and drink recalls increased marginally (2.9%) in Q1, from 1,121 events in Q4, to 1,154.

With this uplift, Q1's figure remains 11.6% above the 5-year quarterly average of 1,034 recall events.

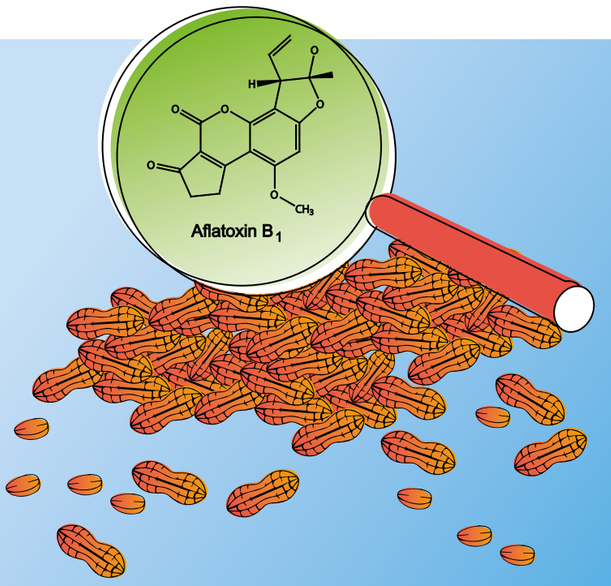


Accounting for 187 events (16.2%), **Fruit and vegetables was the most impacted category.**

This has now remained the leading category of European food recalls for 9 consecutive quarters.

Contamination (non-bacterial) was the leading cause of recalls in Q1 with 486 events.

Non-bacterial contamination recalls surged by a quarter (25.6%). Of these, aflatoxin related-events experienced the largest increase (from 73 in Q4, to 89).



NICOLA SMITH, PARTNER,
SQUIRE PATTON BOGGS

REGULATORS TARGETING HEALTH AND NUTRITION, SUSTAINABILITY, AND SUPPLY CHAIN RESPONSIBILITIES IN THE FOOD SECTOR

During the first quarter of 2023, food inflation has been a significant challenge and a source of supply chain stress for producers, retailers, and consumers. Against this backdrop, there is also the ongoing challenge of a shifting regulatory landscape. There are several changes in progress or on the horizon for the food and drink sector. Many of these amendments relate to three key areas: health and nutrition, sustainability, and supply chain responsibilities.

Other developments include the UK's Food Standards Agency (FSA) seeking views on "may contain" allergen labelling. Currently this type of precautionary labelling is not mandated by law. However, it is important to ensure food is safe for consumers with allergies.

The FSA also plans to launch a consultation on developing its food hygiene delivery model, which includes a proposal to adapt the frequency of inspections based on risk and inclusion of remote assessments.

Amongst all the fluctuation, companies received some small reprieve towards the end of last year; the measures aimed at restricting the promotion of high fat, salt, and sugar (HFSS) foods in the UK were postponed in consideration of the ongoing cost-of-living crisis, but are still currently due to come into force in October 2023.

Supply chain challenges and responsibilities

Supply chains continue to present significant challenges in the food sector. Product availability is an issue, as seen with the limited access to salad items as a result of unseasonal weather. However, businesses are also combatting substantial inflation. In April, general inflation fell less than expected and the price of food and non-alcoholic drinks has accelerated by 19.1% from January to March, according to reports. If businesses have limited ability to pass on these rising costs to their end customers, operating profits may be significantly squeezed, resulting in cash-flow challenges.

Supply chain stresses can also have food safety implications. For example, food business operators may need to ensure that new or alternative suppliers or ingredients have undergone proper auditing and quality control checks in a short timeframe; that substituted ingredients are properly reflected on ingredients and allergen lists; and that workforces apply food safety systems and precautions in a consistent way, even when that workforce includes agency and temporary workers.

In addition, import controls can impact the supply chain. The UK's FSA announced in April that it welcomes proposals for new import controls to be phased in from October 2023. The agency also published its draft Border Target Operating Model on 5 April. The initial focus will be on health certification for higher-risk foods and feed imported from the EU. Border checks will be risk-based.

Supply chain transparency also continues to be important. There is a growing focus on requirements for food business operators to conduct human rights and environmental due diligence across the supply chain, particularly for big businesses in certain sectors of the food industry.

The German legislation requiring mandatory supply chain due diligence for human rights violations and environmental breaches came into effect on 1 January 2023. The regulations require companies that meet certain criteria to implement specific risk management practices to detect and combat child labour, forced labour, poor environmental practices, and other problematic issues. To the extent that a German retailer or catering business is in scope, this is likely to result in additional demands on food and drink suppliers to that business.

In addition, the EU has approved the Deforestation-Free Regulation, which is intended to ensure that certain products that European consumers buy and consume do not contribute to deforestation and forest degradation. The legislation will also takes steps to reduce carbon emissions and address deforestation driven by agricultural expansion. It will require supply chain due diligence linked to the production of palm oil, cattle, soy, coffee, cocoa, timber, and rubber. The legislation will be directly applicable in all EU Member States, although local regulators will be responsible for enforcement.

There is a separate European Commission proposal for a Sustainable Corporate Due Diligence Directive, which was adopted in February 2022. The rule aims to "foster sustainable and responsible corporate behaviour and to anchor human rights and environmental considerations in companies' operations and corporate governance."

Health and nutrition – regulatory changes for food and drink products

The UK government delayed the measures originally set to come into force in October 2022 that restrict volume price promotions of HFSS foods. Regulators cited pressures on the sector and on consumers due to the cost-of-living crisis for the delay. However, the restrictions which prohibit multi-buy deals, such as "buy one, get one free" promotions for HFSS products and free in-store refills of non-pre-packed sugar-sweetened drinks, were postponed, not cancelled. They are now due to come into force in October 2023.

In addition to the postponement of volume price promotion restrictions, on 9 December 2022, the UK government announced a further delay to the 9 p.m. watershed restriction on TV and online adverts for HFSS products. Those restrictions include a watershed for advertisements of HFSS foods for television and UK on-demand programmes, and an outright ban on paid-for online advertisements for HFSS products. These measures are now expected to be introduced in October 2025. Nevertheless, in parallel to the announcement on the delay, the government launched a consultation on proposed draft secondary legislation to give effect to the restrictions, which is expected to define the products in scope of the restriction, small and medium-sized enterprises (SMEs) for the purposes of the SME exemptions, and the services connected to regulated radio services and relevant radio exemptions.

HFSS foods are not the only category seeing new regulations. From 8 December 2023, new requirements for ingredients and nutrition information for wine and aromatised wine products in the EU will come into force via amendments to the common agricultural policy. The changes will require wine to be labelled with the energy value (kilojoules/kilocalories) on the package/bottle or on a label attached to the package/bottle. However, producers have the option to provide the remainder of the nutrition declaration and the ingredient list electronically through a QR Code. If the nutrition declaration and the ingredients list are provided through electronic means, companies are not permitted to also display "other information intended for sales or marketing purposes."

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CONTINUED FROM PREVIOUS PAGE

The long-running discussion in the EU on the application of nutrition labelling requirements to other types of alcoholic drink also seems to be gathering pace. In April, the European Commission confirmed that the revision is designed to have a positive impact on public health. The Commission also stated that a common approach can be built at the EU-level, which is beneficial for European citizens and acceptable for food businesses. It also verified that an impact assessment is currently in preparation and will involve a wide-ranging evidence and data gathering exercise.

Sustainability and the environment

There are a number of ongoing initiatives and reforms in relation to sustainability and the environment in food production, manufacturing, and retail.

Some key developments include the following:

- **ECHA published a proposed restriction on PFAS "forever chemicals."** Perfluoroalkyl and polyfluoroalkyl substances, or PFAS, are a group of waterproof, greaseproof, and non-stick chemicals that are found in a broad range of consumer products, including some food packaging. The chemicals have been reported to persist for decades in the environment and in humans who are exposed to them. The proposed restrictions are extremely broad and focus on the whole group of PFAS. The aim is to reduce their emissions into the environment and make products and processes safer for consumers. The first restriction is on the manufacture, use, and placement on the market of PFAS as substances on their own. The second restriction addresses concentration limits for PFAS as a constituent in another substance or contained in mixtures or articles. A public consultation on the proposal runs through 22 September 2023. The European Chemicals Agency's (ECHA's) scientific committees will then consider the input and publish their opinions on the proposed restriction in 2024.

- **DEFRA published a UK government response to the consultation on a proposed ban for single-use plastics, including food containers.** The consultation from the Department for Environment, Food and Rural Affairs (DEFRA) ran from November 2021 to February 2022. Responses from members of the public and non-governmental organisations demonstrated support for the proposals, but responses from businesses were more varied. Legislation will be introduced to ban the supply of the following single-use plastics in the UK from October 2023. It will apply to plates, trays, bowls, cutlery, balloon sticks, and certain types of polystyrene food and drinks containers, including cups.

- **UK Competition and Markets Authority (CMA) announced a crackdown on greenwashing in the fast-moving goods (FMCG) sector.** The CMA announced plans on 26 January 2023 to examine the accuracy of green claims made in the FMCG sector. This analysis will cover essential items that people use on a daily basis and buy frequently, including food and drink products, as well as cleaning products, toiletries, and personal care items. The CMA will analyse environmental claims made both online and in stores, targeting "vague and broad eco-statements for example packaging or marketing a product as 'sustainable' or 'better for the environment' with no evidence."

- **The EU published a Draft Green Claims Directive.** The EU has published its draft Green Claims Directive, which regulates the substantiation and communication of explicit environmental claims. Once finalised, the directive will set general principles which must be implemented by the national laws of all EU Member States. The recitals to the draft legislation note that climate-related claims are particularly prone to being unclear, ambiguous, and to misleading consumers. These include claims such as "climate neutral," "carbon neutral," or "net-zero" in relation to carbon off-setting. It seems likely that such claims will come under particular scrutiny.

- **Implementation date for Scotland's Deposit Return Scheme was delayed.** The planned 16 August 2023 effective date has now been pushed back to 1 March 2024. It remains to be seen whether it will need to be pushed back further given that the schemes in England, Wales, and Northern Ireland are not expected to start until October 2025. There has been some speculation as to whether the Scottish scheme, which has differences from the proposed English scheme, would be "excluded" from the principle of non-discrimination under the Internal Market Act 2020. This principle is intended to prevent differential treatment of goods in one part of the UK from another. The scheme was already facing scrutiny, both in the courts by way of judicial review from small businesses, and from Scottish ministers voicing concerns about potential repercussions on trade.

The food and drink sector is facing considerable challenges with increased regulations combined with supply chain and economic issues. Stakeholders should be taking a thorough look at their current practices and processes related to health and nutrition, sustainability, and supply chain responsibilities to determine if any of the legislative updates will require changes to their own policies.

PHARMACEUTICAL

There were several key issues impacting the pharmaceutical industry in the EU and UK in the first quarter of 2023. Controversy arose after a draft of the Pharmaceutical Strategy for Europe was leaked in February 2023. The draft document proposes several changes to the industry, including a reduction in incentives for developing unmet medical need (UMN) products and a decrease in market exclusivity time for drugs. Industry trade groups have expressed concern about the proposal, stating that it could be harmful to the industry's competitiveness in Europe.

A new initiative is due to launch in May 2023 to help tackle the online sales of counterfeit drugs. Major e-commerce platforms, credit card companies, and Interpol have already signed on to join the Pharmaceutical Security Institute (PSI)'s E-commerce Alliance for a Responsible Ecosystem (ECARE).

Another policy that will impact pharmaceutical companies is the UK's decision to recognise foreign regulatory approvals for medicines and to simplify the approval process for medicines and technologies approved by regulators in other countries. The change aims to incentivise companies to develop medicines in the UK by streamlining the regulatory approval process and reducing associated costs.

The UK's Prescription Medicines Code of Practice Authority (PMCPA) published its long-awaited social media guidance for pharmaceutical companies in January 2023. The guidance covers both companies' use of corporate social media channels and employees' personal use of those channels. It also provides clarity and direction to help compliance teams align with the Association of the British Pharmaceutical Industry (ABPI) standards.

"Industry trade groups have expressed concern about the Pharmaceutical Strategy for Europe proposal, stating that it could be harmful to the industry's competitiveness in Europe."

Industry pushes back on draft Pharmaceutical Strategy for Europe

The European Commission (the Commission) adopted its Pharmaceutical Strategy for Europe in November 2020 but did not share the document with the public. It promised to share a revision of the basic pharmaceutical acts in late 2022, but missed the December 2022 and March 2023 deadlines to publish the document. Controversy arose after the news outlet POLITICO leaked a draft of the plan in February 2023.

The Commission had announced the strategy would consist of four pillars: ensuring access to affordable medicines and addressing unmet medical need (UMN) products; supporting competitiveness, innovation, and sustainability across the industry while developing high quality, safe, effective, and greener medicines; improving the sector's crisis preparedness and response mechanisms by ensuring supply chains are diversified and secure and medicine shortages are addressed; and promoting a high level of quality, efficacy, and safety standards to guarantee that the EU pharmaceutical sector has a strong voice in the world.

Legal experts with Sidley Austin reviewed the media report and identified several unexpected provisions in the proposal. They note that the strategy lacks analysis of how some of the proposed changes will affect manufacturers' decisions on whether to develop or launch new products in the EU. They highlight the narrow definition and support for UMN products and the reduction in incentives for developing these products as being among the issues that will be of concern to the industry.

The draft review also shortens both the Regulatory Data Protection (RDP) period for all product categories and reduces the market exclusivity time for all categories of orphan medicinal products. Orphan drugs are those used to treat rare conditions that affect fewer than five in 10,000 people across the EU. Traditionally there have been incentives such as protection from competition for drugs meeting this designation once they are on the market.

As reported by POLITICO, the plan would let unbranded drug companies enter the market earlier, driving down prices for consumers but eliminating some of the benefits which serve as incentives.

Companies could maintain their exclusivity for an additional year if their product is launched in all EU Member States, though the plan does not assess all of the challenges of market access due to very different medical systems and infrastructures across Member States.

This attempt to improve the inequalities in access to medicines is being welcomed by consumer groups and civil society organisations, according to POLITICO. However, industry trade groups such as the European Federation of Pharmaceutical Industries and Associations (EFPIA) have said that the proposal would be harmful to the EU's pharmaceutical industry and that CEOs of some of Europe's leading drug companies are considering moving the focus of their research and development to the U.S. and Asia because it is too difficult to be innovative in Europe.

The Commission's plan has raised other concerns as well. The attorneys also state that for some of the proposals, there have been no assessments or consultations. For others, the financial calculations do not fully match the plans that are put forward, losses are presented as gains, and the right baseline was not used for the calculation. This issue was also raised by the EFPIA, who asked the Commission to deliver a full assessment of the impact of the proposed pharmaceutical legislation on European competitiveness.

Given the reaction from the industry to the leaked drafts, it will be interesting to see what changes, if any, the Commission makes once the proposal is finally published. Pharmaceutical manufacturers should review the initial draft and consider what changes might need to be made not only in product development planning, but also in financial planning if the incentives do change.

> *"As reported by POLITICO, the Pharmaceutical Strategy for Europe would let unbranded drug companies enter the market earlier, driving down prices for consumers but eliminating some of the benefits which serve as incentives."*

> *It is unclear how the EU DMA and DSA will apply to counterfeit drugs. They both increase the accountability and responsibility of major e-commerce sites, so those platforms should ensure the safety and quality of products listed on their marketplaces."*

Leading online marketplaces join effort to tackle sales of counterfeit drugs

The Pharmaceutical Security Institute (PSI), a non-profit trade association comprised of the security directors from thirty-seven international pharmaceutical manufacturers, reported a 38% increase in incidents of pharmaceutical crimes between 2020 and 2021. These crimes include counterfeiting, illegal diversion, and theft.

The organisation is planning to launch a new initiative in May 2023 to combat online sales of counterfeit and unapproved pharmaceuticals. The E-commerce Alliance for a Responsible Ecosystem (ECARE) programme follows work that the PSI has done over the last few years to identify counterfeit drugs being sold on social media platforms and take down illegal products.

As of January 2023, 12 organisations had committed to participate in the programme including Interpol, major credit cards companies, and some of the largest e-commerce platforms.

Todd Ratcliffe, President and Chief Executive Officer of the PSI, said at the end of 2022 that there has been "an increase in the number of seizures of counterfeit pharmaceutical products, the result of bad actors taking advantage of easing pandemic restrictions and new opportunities."

It is unclear how the EU Digital Markets Act (DMA) and the Digital Services Act (DSA), which both went into effect in November 2022, will apply to counterfeit drugs. They both increase the accountability and responsibility of major e-commerce sites, so those platforms should be even more eager to ensure the safety and quality of products listed on their marketplaces.

UK to recognise foreign regulatory approvals for medicines

In the third quarter of 2022, the European Commission Decision Reliance Procedure (ECDRP) was extended until 31 December, 2023. This programme speeds up UK marketing approval for medical products that have already been approved by the European Medicines Agency (EMA).

In the UK's Spring Budget which was published in March 2023, pharmaceutical companies looking to market in the UK received more good news. The Chancellor of the Exchequer (Jeremy Hunt) included plans to simplify medicines and technology approvals.

According to lawyers with Covington & Burling, there were two key changes in the Budget related to medicines and technology. First, the UK Medicines and Healthcare products Regulatory Agency (MHRA) will allow "rapid, often near automatic sign-off" for medicines and technologies approved by other trusted regulators, such as the U.S., Europe, and Japan.

This change will allow pharmaceutical companies to prioritise their regulatory approvals in other countries rather than also being concerned about UK-specific regulatory requirements and associated costs. Similar processes already exist for medicines authorised by the European Commission. The new policy will expand this flexibility to other foreign regulators for both pharmaceutical products and "technologies."

To incentivise companies to develop medicines in the UK, the new Budget also promises a swift approval process from the MHRA for the most impactful new medicines and technologies, including cancer vaccines and AI therapeutics for mental health.

The legal experts note that high-quality marketing authorization applications can already request a 150-day assessment route from the MHRA with an option for the application to be fast-tracked under certain conditions.

As part of the Budget, the MHRA will also receive £10 million in extra funding over the next two years to implement these new initiatives. It remains to be seen how pharmaceutical companies will respond to these new policies – and if they will choose to gain regulatory approvals in other markets first and leverage the streamlined process in the UK, or embrace the expedited policies in the UK and focus research and development there.

New social media guidance for pharmaceutical companies

On 26 January 2023, the UK's Prescription Medicines Code of Practice Authority (PMCPA) published new social media guidance aimed at pharmaceutical companies and their online communications.

The PMCPA is the self-regulatory body that administers and enforces the Association of the British Pharmaceutical Industry (ABPI) Code of Practice, the voluntary advertising code followed by many pharmaceutical companies in the UK.

The PMCPA consulted with the Medicines and Healthcare Products Regulatory Agency (MHRA), the ABPI, and pharmaceutical companies to develop the guidance, which covers companies' use of corporate social media channels and employees' personal use of those channels. It also directs companies to the applicable laws and ABPI Code provisions that apply in different cases, and how they may be relevant across social media platforms.

According to attorneys with Covington & Burling, a significant number of PMCPA complaints, investigations, and adjudications relate to corporate or employee social media posts. Having a clear and codified guidance should provide some clarity and help compliance teams align with the ABPI standards.

They also note that the PMCPA's guidance is broadly similar to the Joint Note for Guidance on social media and digital channels that the European Federation of Pharmaceutical Industries and Associations (EFPIA) and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) published in September 2022.

Legal experts with Freshfields Bruckhaus Deringer shared the top ten social media best practices for pharmaceutical companies according to the PMCPA. These include using links with discretion, only using hashtags that are appropriate and relevant to the post and do not contain product claims, ensuring posts designed to educate the public on a disease and its management are non-promotional in nature, and being transparent about any relationships with social media influencers.

In addition to the new PMCPA rules, pharmaceutical companies and marketers also need to be mindful of restrictions for social media content set forth in the Medical Devices Regulations 2002, relevant consumer protection legislation, and the Advertising Standards Authority (ASA) Codes. Companies may want to consider consulting with outside experts for help in updating their compliance policies to ensure all of these different regulations are considered.

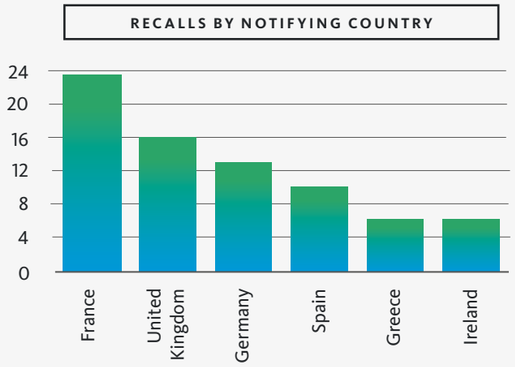
BY THE NUMBERS

Pharmaceutical recalls across the EU and UK declined 17.3% in Q1 2023 compared to Q4 2022. There were 86 events this quarter compared to 104 the previous quarter. It is worth noting that Q4 was a very active quarter with a much higher number of recalls than the rest of the year. There was an average of 69 events in each of the other three quarters last year.

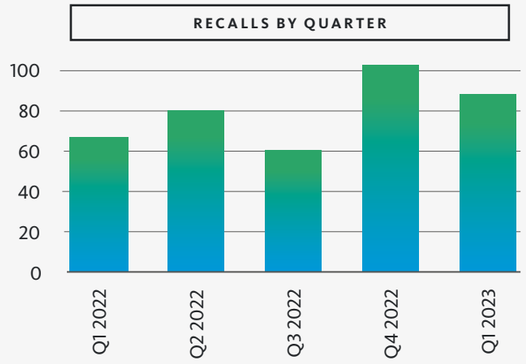
Safety risks were the leading cause of pharmaceutical recalls and were linked to 31 events this quarter. The second-most common concern was foreign materials / contamination with 12 events, up from 5 events in Q4 last year. In third was mislabelling with 11 recall events. The number of recalls tied to failed specifications dropped from 18 last quarter to 10 in Q1 2023.

Once again France issued the most notifications, with 23 (or 26.7% of the total figure) in Q1 2023. The UK followed with 16 notifications, up from 13 in Q4 2022. Germany had 13 notifications (down from 17 in Q4), which put it in third place. Portugal saw the greatest decline in pharmaceutical notifications with two this quarter compared seven in Q4 2022.

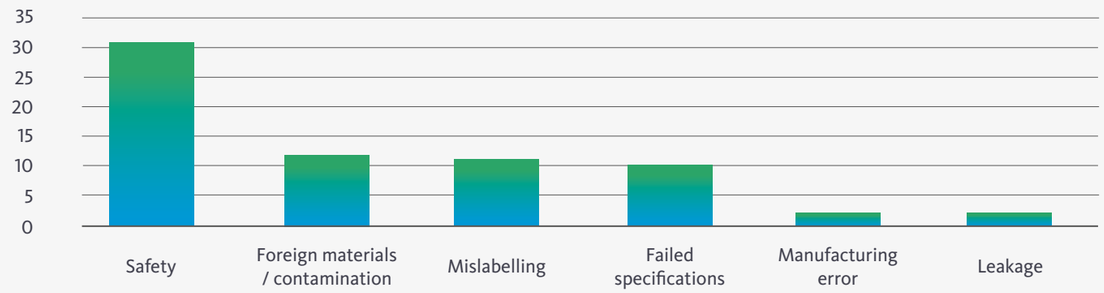
RECALLS BY NOTIFYING COUNTRY



RECALLS BY QUARTER

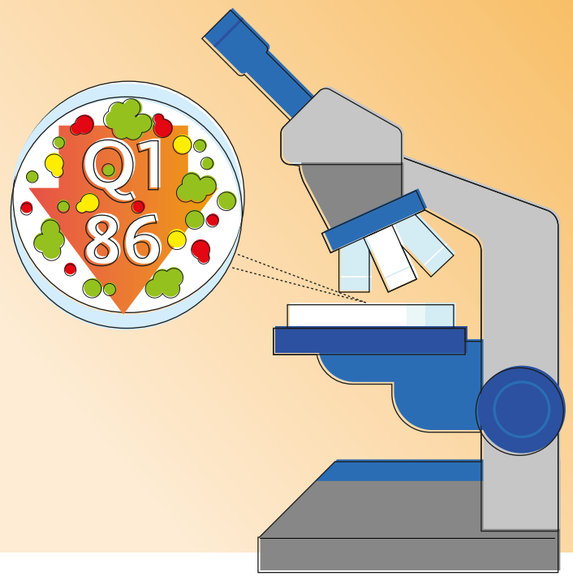


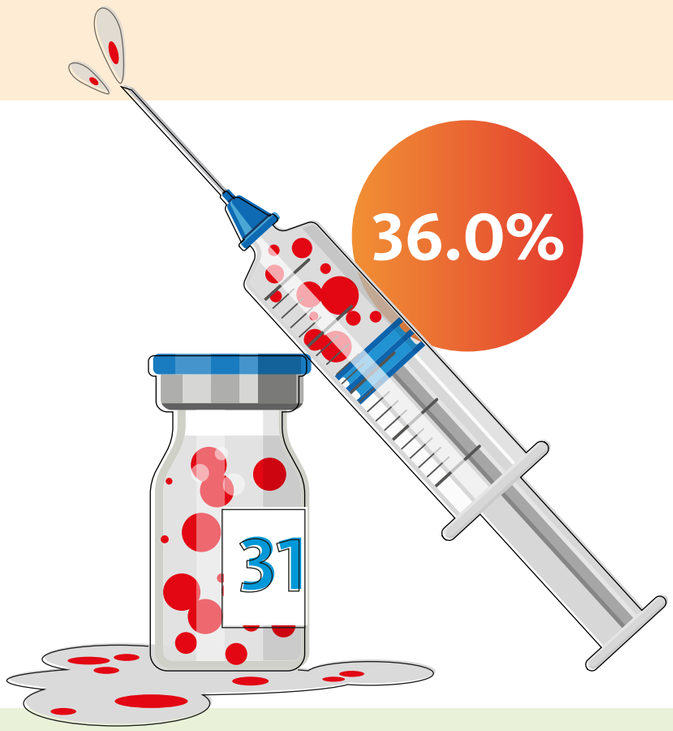
TOP CAUSE OF RECALLS



Pharmaceutical recalls fell 17.3% in Q1, from 104 events in Q4, to 86.

Despite this decline, Q1's figure remains 10.3% above the quarterly average of the last 3 years (78).



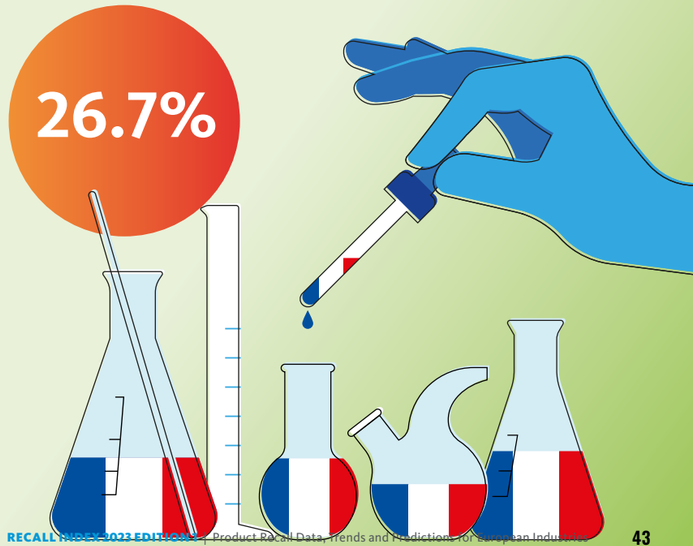


Accounting for 31 events (36.0%), Safety concerns were the leading cause of recall in Q1.

The only cause to experience an uplift in recall events in Q1 was Foreign materials/ contamination, which surged 140.0%.

At 23 events (26.7%), France submitted the greatest proportion of recall notifications in Q1.

This marks the eighth consecutive quarter that France has been the leading notifier.



ALISON NEWSTEAD, PARTNER,
SHOOK HARDY & BACON INTERNATIONAL LLP

HARNESSING TECHNOLOGY AND MANAGING RISK IN THE PHARMACEUTICAL INDUSTRY

In 2023, the pharmaceutical industry will continue to accelerate its use of technology in a variety of applications. These range from creating virtual clinical trial platforms to developing new treatments and alleviating supply chain pressures.

The scope and complexity of technological applications will continue to grow, as the industry strives to remain agile in the ever-changing global environment.

The industry will harness technology to navigate the continued effects of the pandemic, particularly in relation to clinical trials. Technology will also be leveraged to reduce supply chain pressures caused by the Ukrainian conflict and tensions between China and Taiwan. In addition, the legislative landscape will continue to evolve as regulation tries to keep pace with new technologies and their many applications.

How does this evolving landscape and the continued development of new, cutting edge-technology translate into potential liability and risk?

Patient data and "wearables"

The value of patient data has long been recognised in enhancing drug and medical device development, as well as improving patient diagnosis, treatment plans, and outcomes. The UK Government acknowledged the value of health data in its 2022 strategy, "Data saves lives: reshaping health and social care with data." In that publication, the government recognised that if it could "unlock the incredible power that data possesses, we can bring the future forward, and make us all healthier and safer."

The ability to gather patient data – and the variety of data that can be collected – has been significantly improved by the rapid development and widespread availability of wearable technology. With the advent of such new technologies, greater insight can be gained into a patient's daily activities, behaviour, and health status. This data can be used in many ways: not only to improve an individual's diagnosis and treatment, but also by playing an important role in research and development when employed in areas such as clinical trials and regulatory approval processes.

As a result, the accuracy and reliability of health data is imperative. Errors in the collection, storage, transmission, or interpretation of data from wearables could raise issues of liability, particularly in relation to those who may have suffered injury or other losses as a result. For example, if wearables are used to detect certain health conditions or trigger an alert if certain symptoms arise, then failure to do so could have significant legal consequences – both in terms of regulatory obligations and responding to civil claims.

Given the complexity of many wearables, in particular the interaction between software, hardware, and digital services, determining who may be liable in any particular scenario may be complex. Absent clarity in liability legislation, litigation between those involved in producing and supplying new technologies may become as frequent as litigation between producer and end-user. Furthermore, as the number and nature of wearable technologies increases, the level of litigation surrounding these technologies is highly likely to escalate.

In addition to ensuring the robustness of the data that is collected, stored, and transmitted by wearables, the personal nature of data captured also gives rise to related liability concerns. The very nature of the data collected is sensitive and care needs to be taken when processing data to comply with the relevant rules surrounding security and privacy. The EU continues to see a steady stream of fines and penalties imposed by data protection authorities across the Member States for breaches of the General Data Protection Regulation. Scrutiny of how personal data is handled is likely to continue.

Cybersecurity and cyber resilience are issues high on the agenda for EU legislators and regulators, with recalls being seen in relation to products that are not cyber secure. An upward trend in recalls relating to cybersecurity shortcomings in wearable devices can certainly be expected.

The expanding use of AI

Every week, we are presented with new, innovative artificial intelligence (AI) applications. There are enormous benefits to be gained across the pharmaceutical industry from the expanded use of AI and machine learning. Potential applications include uses in drug development, diagnosis, and clinical decision-making. However, the development and use of AI within the pharmaceutical and clinical arena also carries inevitable liability risks.

Any shortcomings in AI applications which ultimately lead to patient injury or other losses could potentially form the basis of a civil claim. AI is nevertheless complex in nature and legislators across Europe have already recognised the technical challenges that may be faced by individuals advancing claims which involve an AI element. Recent proposed changes to the EU Product Liability Directive to incorporate AI and the proposed introduction of a completely new EU Artificial Intelligence Liability Directive demonstrate recognition at an EU-level that AI may call for specific, targeted legislation to ensure that those adversely affected by the technology have an adequate means of redress.

As can be expected, regulators are keen to have any potential issues that arise because of the use of AI brought to their attention quickly. In the UK, for example, in January 2023 the Medicines and Healthcare products Regulatory Agency (MHRA) indicated that software, apps, and AI intended to be used for a medical purpose are likely to be considered medical devices, and any adverse incidents involving the devices should be reported on the MHRA's Yellow Card scheme. This position is a direct indication that AI is firmly on the regulator's radar and that it is ready to take any action necessary to monitor and address any potential safety issues which may arise from employing AI.

Looking ahead

The benefits that technology brings to the pharmaceutical industry – as well as patients and care providers – cannot be overstated. More efficient drug development, better diagnosis and treatment, and improved overall patient outcomes are all benefits of the tremendous advances that we are currently witnessing in this sector. However, risk and liability will need to be managed alongside these technological developments, with regulation and litigation being carefully balanced with innovation.

> *“The EMA has launched a pilot programme offering scientific advice for manufacturers of high-risk medical devices. The goal is to foster innovation and promote faster patient access to safer, more effective devices.”*

MEDICAL DEVICE

The UK government is advancing reforms to medical device regulations post-Brexit to encourage international investment, promote innovation, and improve safety in the UK medical devices market. The Department of Health and Social Care recently published a response to recommendations for reforms to rules in this sector made by the Regulatory Horizons Council, an independent expert committee.

In the EU, the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) entered into force on 20 March 2023. The regulations include extensions on the transition periods for devices certified under the previous rules, Medical Devices Directive 93/42/EEC (MDD) and Active Implantable Medical Devices Directive 90/385/EEC (AIMDD).

Due to concerns from medical device manufacturers and bottlenecks with notified bodies for the new MDR and IVDR, there are also extensions for the validity of MDD and AIMDD certificates and the transitional period for devices that will require a conformity assessment under the new regulations. In addition, the “sell-off” periods have been removed, which means that devices lawfully placed on the market under the applicable transitional provisions will not have to be taken off the market once the new regulations are enforced.

Another change that will benefit device makers is that a complete re-assessment will only become mandatory five years after the notification by a notified body, and then every five years after that. The original draft of the regulations required more frequent assessments.

Meanwhile, the European Medicines Agency has launched a pilot programme offering scientific advice for manufacturers of high-risk medical devices. The goal is to foster innovation and promote faster patient access to safer, more effective devices. The programme is designed to provide expert consultation and regulatory input in the strategy and investigational phases of new product development.

Both the EU and UK are clarifying and refining their clinical trials regulations. Some of the changes appear to be adopting modifications that were made during the COVID-19 pandemic, such as decentralised clinical trials. These adaptations could have benefits for both trial participants and sponsors.

> *“EMA’s scientific advice pilot programme will run until the end of Q1 2024 in twophases of selection. Medical device manufacturers can submit a letter of interest until the end of August 2023.”*

UK moves forward with reforms to medical device regulations

Post-Brexit, the changes being made to medical device regulations in the EU will not impact device makers, distributors, and marketers in the UK. Instead, the UK government is moving forward with its own plans to reform medical device regulation. In January 2023, the Department of Health and Social Care published a response to recommendations made by the Regulatory Horizons Council on ways to encourage international investment, promote innovation, and improve safety for the UK medical device market.

The Regulatory Horizons Council (RHC) positions itself as an independent expert committee that identifies the implications of technological innovation and provides the government with impartial, expert advice on the regulatory reform required to support rapid and safe introduction of these innovations. The RHC’s report to the UK government listed 11 recommendations, all of which were accepted in some part by the regulators.

According to attorneys with Burges Salmon LLP, the response reinforces the UK’s desire to be a premier destination for innovative life sciences companies. It also aligns with reforms that were proposed in response to the Medicines and Healthcare products Regulatory Agency’s (MHRA’s) consultation on the future of medical device regulation.

The RHC’S suggestions covered four primary areas: patient outcomes and safety, international leadership and engagement, investment in regulatory capacity, and unlocking innovation and emerging technology.

Some of the key recommendations include the need for medical device regulations to address the needs and desired outcomes of patients; to provide a way to address bottlenecks in the approval of medical devices, specifically for conformity assessments; and to build international partnerships which may improve efficiencies.

Other suggestions make it clear that regulators are working to implement lessons learned from the COVID-19 pandemic, such as including a fast-track evaluation of new In Vitro Diagnostics and recognising the need for transparency and standardisation around the reporting of diagnostic tests.

There is no clear timeline for next steps on new medical device regulations but given that the RHC proposal and the earlier MHRA response are well-aligned, stakeholders across the medical device sector can anticipate the direction the government is likely to take.

EU launches pilot programme for high-risk medical devices

In February 2023, the European Medicines Agency (EMA) launched a pilot programme that will offer scientific advice for manufacturers of certain high-risk medical devices. The EMA will provide input from medical device expert panels on the intended clinical development strategy and proposals for clinical investigation for up to 10 selected applicants.

The agency said that scientific advice is a key tool to foster innovation and promote faster patient access to safer and more effective devices. The test programme is designed to help establish an efficient procedure to make this type of counsel available.

For the pilot programme, the EMA placed the greatest emphasis on those devices intended for paediatric use or treating rare conditions; those that address medical conditions that are life-threatening or cause permanent impairment but lack current safe medical alternatives; or novel devices that may have a major clinical or health impact.

The initiative will run until the end of Q1 2024 in two phases of selection. The first five participants will be selected in April 2023 and the second group will be decided in September 2023. Medical device manufacturers can submit a letter of interest until the end of August 2023.

The opportunity to have an expert consultation and regulatory input in the strategy and investigational phases of new product development could prove to be immensely valuable and potentially save device manufacturers considerable time and money.

> *Regulators in the EU and UK are working to make clinical trials more accessible, equitable, and representative of the population. How this will ultimately impact device manufacturers remains to be seen."*

Changes for both EU and UK clinical trials

The European Commission (the Commission) introduced a new Clinical Trial Regulation (CTR) for medicinal products that went into effect in January 2022. One of the goals was to harmonise the rules for conducting clinical trials in the EU and European Economic Area (EEA).

In February 2023, the Commission published an updated set of Questions & Answers (Q&As) to provide additional clarity to trial sponsors. Attorneys with Cooley report that the most significant change to the new version is the addition of Annex III. This amendment includes links to websites with information regarding national requirements of individual EEA countries. It also provides the email addresses of the national competent authorities of EEA countries in the event that sponsors have questions.

Bringing all the information together is much more efficient for trial sponsors. The CTR allows one online application via a single platform to gain approval to run a clinical trial in several European countries. However, trial sponsors still need to comply with country-specific, patient-level requirements. These requirements may vary from one EEA country to another. While the Commission has developed standardised templates, certain EEA countries have also developed national templates that are specific to their jurisdiction. The new information will help applicants find the information relevant to their trials.

More clinical trial guidance came from the Commission, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) which published a Recommendation Paper to simplify the use of decentralised clinical trials (DCTs).

DCTs use digital tools, telemedicine, and mobile and local healthcare resources to allow clinical trials to be conducted away from a specific trial site. According to legal experts with Baker McKenzie, other tools such as remote monitoring and diagnostics, home health visits, electronic informed consent, and direct-to-patient shipment of study drugs also help ensure the necessary data are collected.

Among the key takeaways in the recommendations are clarification around the roles and responsibilities of the sponsor, investigator, and service providers; recommendations on managing incoming data, especially if it is coming in as a constant flow from various inputs; and the need for at-home procedures to not cause additional risk to the trial participant or to the reliability of the data.

The UK government is also assessing its clinical trial regulations. In March 2023, it released its long-awaited response to a consultation conducted in Q1 2022 that proposed ways to update, improve, and strengthen UK clinical trials regulations.

The report outlined several goals for the new regulatory framework including the need to ensure patients and their safety are at the centre of all clinical trials; that everyone has access to the benefits of clinical trials; that the regulatory environment is proportionate and flexible; and that the UK will be viewed as a destination for international clinical trials.

Some of the proposed changes to streamline the regulatory process include setting a maximum of 30 days to complete an application, a standard of 10 days for the regulator to make a decision once all the information has been received, and an integration of the regulatory and ethics reviews for applications.

While the report states that regulators will begin drafting legislation, there is no clear timeline for when the draft rules will be available. It is expected that there will be opportunities for public comment as the plans move forward.

Regulators in the EU and UK are working to make clinical trials more accessible, equitable, and representative of the population. How this will ultimately impact device manufacturers remains to be seen.

BY THE NUMBERS

Across the UK and EU, there were a total of 790 medical device recalls in Q1 2023. This represents a 6.8% uplift from the 740 events recorded in Q4 2022.

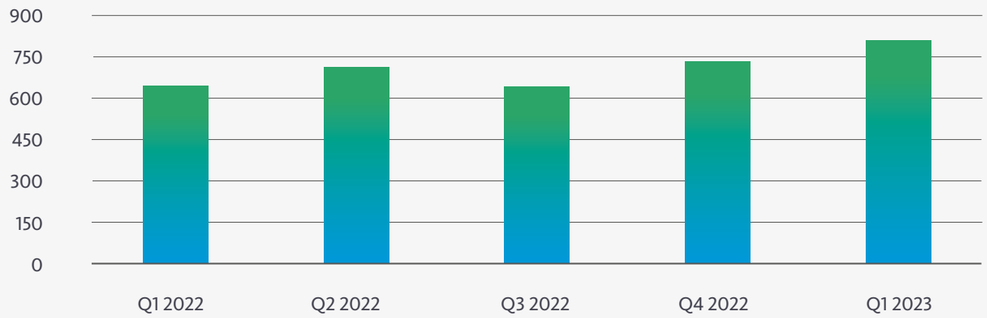
Continuing the trend of the previous six quarters, software issues were the most common reason for recall in Q1, with 115 events. This reflects an 18.6% increase from the 97 events recorded in Q4.

These latest events impacted a myriad of devices, from proton therapy systems and ventilators to implantable neurotransmitters, defibrillators, and dialysis equipment.

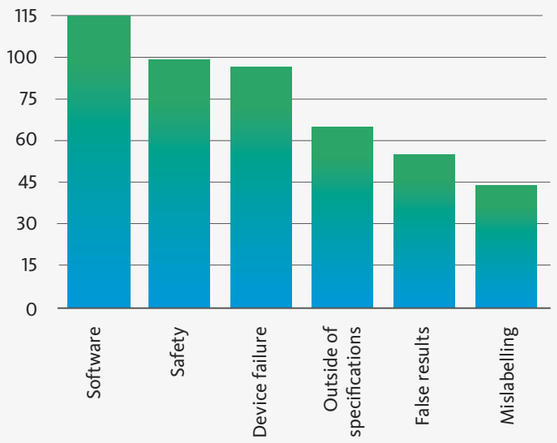
Safety concerns were the second most cited issue, accounting for 97 recalls, a 70.2% increase from last quarter. That was followed by device failure (with 89), and outside of specifications (with 65).

In Q1 2023, France issued the most recall notifications for medical devices with 205, a 15.8% increase from the previous quarter. Germany was the second top issuer with 187 notifications, down 12.6% from the previous quarter. The UK had four notifications, up from zero in Q4 2022.

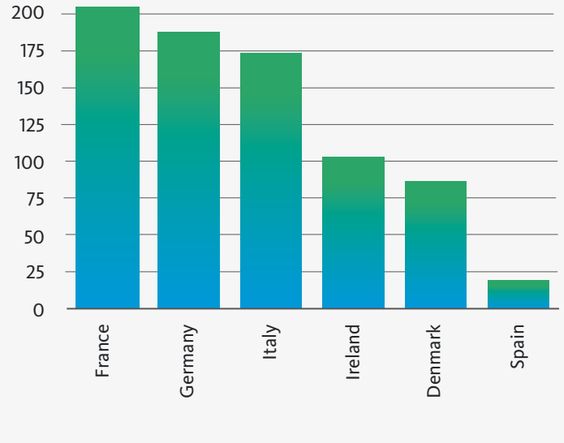
MEDICAL DEVICE RECALL EVENTS BY QUARTER



TOP REASONS FOR RECALL EVENT

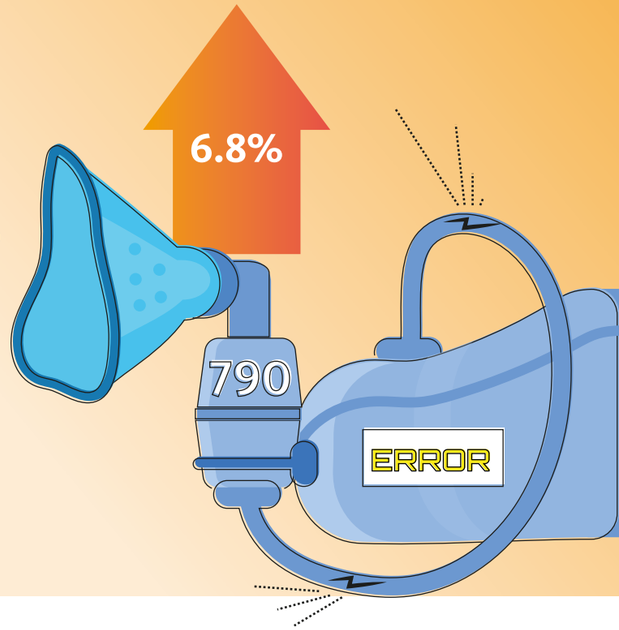


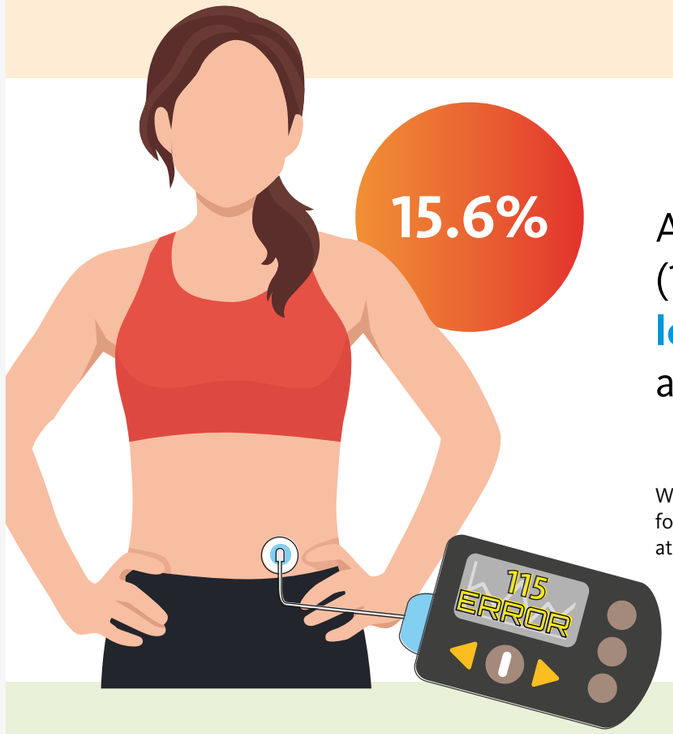
RECALLS BY NOTIFYING COUNTRY



At 790 events, **medical device recalls increased 6.8%** in Q1 (from 740 in Q4).

With this increase, Q1's figure remains 23.1% above the quarterly average of the last 3 years (642).



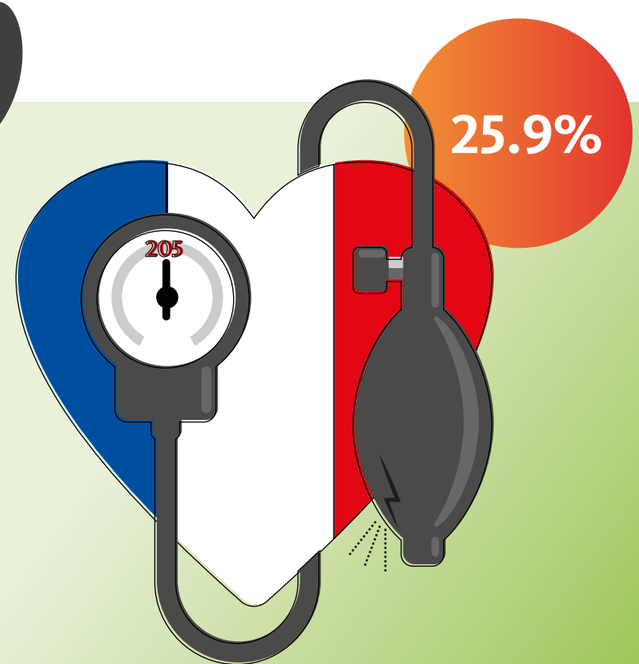


Accounting for 115 events (15.6%), **Software was the leading cause of recall** activity in Q1.

While Software has been the leading cause of device recalls for seven consecutive quarters (since Q3 2021), Q1's figure is at its highest level for over 3 years.

At 205 events (25.9%), **France was the leading recall notifier** in Q1.

This replaced Germany, which experienced a 12.6% decrease from 214 events in Q4, to 187.



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SOFTWARE AND AI IN MEDICAL DEVICES

In recent years, the use of software and artificial intelligence (AI) incorporated as part of a medical device (and as a medical device in its own right) has been a controversial subject covering patient safety, data privacy, ethics, market access, and practical applications. However, the many opportunities offered by AI to improve patient outcomes are expected to be one of the key drivers for innovation in the medical technology sector, with AI's use likely to increase exponentially.

The European Commission anticipates that "by 2025, North America is projected to hold the largest market share [of Software as a Medical Device (SaMD) and AI as a Medical Device (AIaMD)] followed by Europe, which is expanding dynamically." As SaMD and AIaMD become more prevalent, regulators will be working to update their rules to account for new risks posed by these products.

What is SaMD and AIaMD?

Due to the significant innovation in digital data and software technologies in recent years, many medical device manufacturers are actively developing new products that apply AI and software. These developments include products such as medical condition monitoring apps, medical imaging devices, robotic surgery systems, and smart Internet of Things (IoT) wearable devices that all provide more practical medical treatments to patients.

Globally, SaMD and AIaMD are generally regulated through existing regimes, many of which were drafted and came into force before AI was used by the medical device industry. Regulators are increasingly realising that the existing regimes are not fit for purpose as the use and uptake of AI enabled devices has expanded rapidly, and society has become increasingly aware of the opportunities and risks posed by the technology.

Conventionally, medical device regulations centre around manufacturers performing conformity assessments before placing products on the market. When a product or its software is modified, further review and approval is commonly required. One of the challenges presented by AI is how this existing system of approval fits with adaptive AI and machine learning technologies that are in essence continually adapting and modifying as they process new data.

The EU perspective

Medical devices are regulated at the Member State level, but the European Medicines Agency (EMA) is the principal governing body that regulates medical devices through a centralised procedure at the EU-level. Recently, the EU has been transitioning its medical device regulatory framework by entering into Regulation (EU) 2017/745 for medical devices (EU MDR) and Regulation (EU) 2017/746 for in vitro diagnostic medical devices (EU IVDR).

EU MDR and IVDR apply to what would be considered "traditional" medical devices as well as AI-based medical devices and accessories. The extent to which these regimes are considered fit for purpose is another matter, and an area of considerable debate, which is discussed further below.

Of note, EU MDR and IVDR already set requirements regarding the testing of AI used in medical devices during development and its ongoing evaluation through an appropriate risk management system covering the full product lifecycle. The purpose of these requirements is to ensure safety, quality, and performance of devices.

On 21 April 2021, the European Commission issued a 'Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending certain union legislative acts' (AI Act) which is soon expected to be adopted by the European Parliament and Council. The AI Act proposal aims to implement a harmonised EU framework that ensures more robust regulation of AI and its distinct challenges to ensure safety without disrupting the functioning of the internal market. This will include distinct obligations for AI with respect to development and post-market surveillance systems.

However, the AI Act will be the first law of its kind applying across a broad spectrum of industries and sectors with limited exceptions. With regards to medical devices, there is still uncertainty in the proposed text on how it will apply to the industry, particularly how it will interplay with EU MDR and IVDR.

The medical device industry has already raised concerns about how the likely classification of all medical device products as high-risk under the AI Act, and the corresponding additional regulatory burden, might disincentivise investment and innovation. There would appear to be conceivable scenarios where a product is categorised under a lower risk for MDR/IVDR purposes but the highest category under the AI Act. There is also further potential risk for conflict between the regulations on certification requirements, responsible competent authorities, post-market surveillance systems, and the definition of "provider" or "importer."

It is important that there is as much harmonisation as possible where these distinct regimes overlap to avoid disruption in the medical device industry, as well as the ultimate risk of stemming innovation and investment in the sector.

The medical device industry will have to pay close attention to how, and to what extent, these contradictions are addressed as the AI Act advances through the legislative process.

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The UK perspective

The UK was closely involved in the development of EU MDR and IVDR whilst still part of the EU. However, following Brexit the government announced its intention not to proceed with implementing these substantial regulations but rather start from scratch with its own regulatory regime outside of the EU. On 26 June 2022, the UK Medicines & Healthcare products Regulatory Agency (MHRA) published the UK government's response to a consultation on the future regulation of medical devices. This specifically highlights that the current UK medical devices regulations lack clarity on issues including requirements of SaMD and AIaMD.

The outcome of the consultation recognised the necessity of a reform of the current UK medical devices regulations, including clearly defining the scope of device classification and addressing cybersecurity, pre-market and post-market requirements, and distance sales of SaMD and AIaMD.

The UK MHRA announced the 'Software and AI as a Medical Device Change Programme Roadmap' (Medical Device Change Programme Roadmap) on 17 October 2022. This Roadmap establishes 11 work packages to deliver a regulatory framework that will ensure comprehensive guidance to medical device businesses on regulatory requirements for these products.

On 6 April 2023, the UK MHRA further published guidance on software and AI by reiterating MHRA's Medical Device Change Programme Roadmap and introducing the MHRA's Software Group. This group is responsible for developing regulatory frameworks for SaMD and AIaMD, as well as conducting technical reviews and post-market surveillance activities.

It is clear the UK is still in the early stages of shaping what SaMD and AIaMD regulations will look like within a wider medical device framework. However, key themes have already started emerging. These include a patient-centred approach with safety at its heart, inclusivity of design to serve the needs of a diverse population, harmonisation and convergence with international standards where possible, and privacy and data protection.

Together with broadening the scope of SaMD and AIaMD regulation and seeking to strengthen MHRA powers to act in respect of regulatory breaches, there are also multiple references to ensuring the UK remains a strong place to develop and introduce innovative medical devices, as well as ensuring the sector has time to adapt to changes.

Given the UK's significant influence in shaping the EU MDR and IVDR before Brexit, it will be interesting to see how the UK legislature's approach to regulating this space diverges from the EU now that it has given itself a blank page following Brexit.

Given the global nature of modern supply chains, any significant divergence from international (particularly EU) regulation will have cost implications for medical device manufacturers, who will want as smooth a path as possible to market for their products.

The U.S. perspective

On 27 October 2021, the UK MHRA, U.S. Food and Drug Administration (FDA), and Health Canada jointly published guiding principles of 'Good Machine Learning Practice for Medical Device Development.' These were:

- Multi-Disciplinary Expertise Leveraged Throughout the Total Product Life Cycle
- Good Software Engineering and Security Practices Are Implemented
- Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population
- Training Data Sets Are Independent of Test Sets
- Selected Reference Datasets Are Based Upon Best Available Methods
- Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
- Focus Is Placed on the Performance of the Human-AI Team
- Testing Demonstrates Device Performance during Clinically Relevant Conditions
- Users Are Provided Clear, Essential Information
- Deployed Models Are Monitored for Performance and Re-training Risks Are Managed

Manufacturers and economic operators of medical devices that are placed on the US market must comply with Title 21, Chapter I, Subchapter H of the U.S. Code of Federal Regulation (CFR) that sets out regulatory requirements on registration, labelling, reporting, pre-market notification, classification, clinical studies, and quality systems. Whilst software is covered within this framework, there are currently no specific references to AI and the nuances this presents from a regulatory perspective.

The FDA has acknowledged that the traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies. In order to further complement and keep up with the increased use of AI and software in medical devices, the FDA issued the "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan" (Action Plan) in January 2021.

The Action Plan is considering a total product lifecycle-based regulatory framework to address risks presented in SaMD and AIaMD and strengthen the premarket submissions, evaluation, testing, and ongoing monitoring of AI and machine learning algorithms used in medical devices. No specific proposal for a new framework has yet emerged but it is an area to watch closely.

Outlook

It is clear that software and AI are transforming product development within the medical technology industry. A significant number of medical device manufacturers are competing to develop and commercialise SaMD and AIaMD. The FDA's own publicly available list of AI-enabled medical devices currently marketed in the U.S. totals 521. The current regulatory frameworks in prime medical device markets such as the U.S., UK, and EU are seeking to strengthen the regulation of software and AI in medical devices.

It is crucial for medical device and technology businesses to closely monitor how regulatory frameworks develop to better respond to the challenges and opportunities of SaMD and AIaMD.

CONSUMER PRODUCTS

Consumer products manufacturers and marketers producing or selling goods in the UK and EU have a number of regulatory changes ahead that could add to their legal risk. The European Commission (EC) has published the full text of its new European General Product Safety Regulation (GPSR).

Once passed, the GPSR will repeal and replace the General Product Safety Directive 2001/95 (GPSD) and provide the basic rules for product safety that products must follow to be permitted on the EU market.

According to attorneys with Cooley, the GPSR is a substantial update from the rules in the GPSD. Some of the biggest changes noted by the legal experts include a new EU-wide obligation to report incidents "without delay" in which a product causes death or serious health effects. In addition, online marketplaces will be obligated to report any product-related accidents that result in "serious risk to, or actual damage of, the health or safety of a consumer." This goes beyond the current reporting obligation on manufacturers and may create new challenges.

The new regulation also implements requirements around product recalls, documentation and labeling requirements for products that do not have the CE-mark, as well as new requirements for online offers and premarket risk assessments. This includes factors such as connectivity or interconnection with other products, cybersecurity, and AI features such as evolving, learning, and predictive functionalities of a product. Breaches of the GPSR could result in class action lawsuits.

In the final draft, the transition period was extended from six to 18 months. It is expected that the legislation could be in effect in Q2 2023 and enforceable by Q4 2024. Because of the extensive revisions compared to the GPSD, companies should evaluate their current processes against the draft rule and start planning for any organisational changes, even though the GPSR is not likely to be enforced for more than a year.

According to an analysis by attorneys with Covington & Burling LLP, another development that could add to companies' legal risk is the EU Representative Actions Directive (Directive 2020/1828). The rule, which harmonises class action regimes across the 27 EU Member States, goes into force in June 2023. Because each Member State has the option to introduce its own mechanisms (while also meeting common minimum standards), combined with the fact that the use of class actions is more developed in some jurisdictions than others, the impact of the Directive will vary by country.

The UK is also seeing more use of class actions, especially with the Competition Appeal Tribunal (CAT), which certified its first class in 2021. While claims before the CAT must be competition law claims, the legal experts note that the tribunal has been "permissive and claimant-friendly." As of January 2023, 11 proposed class actions had been certified by the CAT.

To-date, many of the class action suits in the UK and EU have dealt with competition law, data protection, and consumer protection. However, the attorneys predict that there will be more environmental, social and governance (ESG), and AI-related product liability claims, especially with the proposed AI Liability Directive. With the help of regulators' guidelines to avoid greenwashing, some of the risk associated with ESG-focused class action claims may be mitigated.

Regulators continue to work to protect consumers from hazardous products and practices. Companies should be vigilant to not only review their own processes, but also the actions of their supply chain partners.

> *"The new GPSR implements requirements around product recalls, documentation and labeling requirements, as well as requirements for premarket risk assessments. Breaches of the GPSR could result in class action lawsuits."*

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REGULATORS PUSH MANUFACTURERS TO MAKE SUSTAINABLE CHOICES

The desire for sustainable products continues apace with consumers' increasing preference to make more socially conscious choices. Companies are seeking to adapt to this growing demand through positive change within both the product lifecycle and their own corporate governance. This is having a profound impact on the way consumer products are designed, manufactured, and used. In turn, the green credentials of these products and the companies that produce them are subject to a tightening regulatory framework to encourage more sustainable manufacturing processes, restrict erroneous environmental claims, and extend the life of products including through repair, reuse, and recycling.

Promoting the repair of goods

A more circular economy with improved repairability of consumer products is one of the central tenets of the European Commission's (EC's) Green Deal, New Consumer Agenda, and the New Circular Economy Action Plan. Historically, when faced with a defective product we have seen replacement prioritised over repair. There has been little incentive for consumers to repair items when their legal guarantees expire. In particular, the EC has noted that recent studies show "up to 80% of EU consumers claim to have difficulty in finding information on how easy it is to repair a product."

There are several key statutes that will form the basis of the new regulatory framework to promote the repair of goods. Repairing, not discarding, defective goods when possible helps reduce waste, greenhouse gas emissions, and the unnecessary use of resources. These statutes will sit alongside other relevant regulations and reforms that deal more broadly with environmental issues at the core of the repair laws. Some of these regulations include the proposed Ecodesign for Sustainable Products Directive, the proposed Directive on Empowering Consumers for the Green Transition, and the proposed common rules promoting the repair of goods, also known as the "Right to Repair Proposal."

The proposal for a New Ecodesign for Sustainable Products Directive

One of the expected impacts of the new Ecodesign for Sustainable Products Directive, which was announced on 30 March 2022, is "increased economic value of the recycling, repair, and re-use sectors." Several information obligations will be implemented under the new rule. These include a requirement for products to be accompanied with information on how to install, use, maintain, and repair them, and the use of a "Digital Product Passport" which will allow repairers or recyclers to access the relevant information about a product across the full value chain.

The proposal for a Directive on Empowering Consumers for the Green Transition

This proposal was also announced on 30 March 2022. Its goal is to enable consumers to make informed purchasing decisions by amending consumer rights in two existing directives: the Unfair Commercial Practices Directive 2005/29/EC and the Consumer Rights Directive 2011/83/EU. The proposal also aims to provide information on the repairability of all types of goods through a repairability score or other relevant repair information.

The Right to Repair Proposal

The EC adopted the Right to Repair Proposal on 22 March 2023. The draft legislation extends the lifecycle of goods through the implementation of several provisions such as requiring sellers to offer to repair a product that is inside the legal guarantee unless the repair is more expensive than replacement.

There are also new rights available to consumers to make repairs a more attainable option including: a requirement for producers that have an obligation to repair to inform consumers and offer information about their repair services; the implementation of an online repair platform to connect consumers with repairers of refurbished goods in their local area; the implementation of a European Repair Information Forum in which consumers can request key information on the conditions and price of the repair service from any repairer; and the creation of an European Quality Standard for repair services to assist consumers in identifying repairers who commit to a higher quality. The EU will develop minimum quality standards that repairers must meet to be granted the designation.

In addition, the obligation to repair goods to which reparability requirements under EU legal acts apply will be expanded to include more products. Currently product groups such as household washing machines, dishwashers, refrigerating appliances, and vacuum cleaners must meet this obligation. More products will be added in the coming years, starting with smartphones and tablets.

Green Claims regulations

On 22 March 2023, the EC published its Green Claims Directive Proposal which regulates the substantiation and communication of explicit environmental claims. The proposal seeks to prevent false environmental claims and improve information to consumers on the sustainability, durability, and carbon footprint of products to allow better-informed choices based on transparent and reliable information.

There are four key aspects for companies to consider. First, the substantiation of explicit environmental claims must be based on an assessment that meets the selected minimum criteria to prevent claims from being misleading. These include relying on recognised scientific evidence and state-

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CONTINUED FROM PREVIOUS PAGE

of-the-art technical knowledge when providing information on whether the product performs significantly better environmentally than what is common practice.

Second, the directive sets requirements, including the creation of a certification scheme, for environmental labelling. It will prohibit the use of sustainability labels that fall outside an established certification scheme. Third, under the proposed rule, the use of certain environmental claims and labels will have to be third-party verified and certified by an officially accredited body.

Finally, there are criteria and requirements for comparative claims that state or imply that a product or trader has less or more environmental impacts than other products or traders.

The new EU General Product Safety Regulation

On 30 March 2022, the European Parliament voted in favour of a resolution to formally adopt the new General Product Safety Regulation (GPSR). While the regulation has a broader remit than solely environmental issues, the impact of the EU Green Deal is clear.

The new GPSR toughens the obligations on companies with respect to corrective actions generally, but also includes specific reference to Market Surveillance Authorities (MSAs) and economic operators choosing the corrective action that is the most sustainable action and that will result in the lowest environmental impact. Often this is a repair instead of a replacement or refund where the consumer would dispose of the product. The rule also seeks to address product safety challenges of emerging technologies, including the use of artificial intelligence (AI) and connected devices, and to establish clear obligations for online marketplaces.

Some of the key changes proposed in the new GPSR include extending the definition of product, and the resulting increased regulatory burden, to "any item, interconnected or not to other items." This would include cybersecurity and evolving, learning, and predictive functionalities such as AI.

In addition, online marketplaces will be subject to the new GPSR and, together with the Digital Services Act, they will be required to establish a single point of contact for MSAs and apply voluntary measures based on the notifications in Safety Gate. MSAs could order an online marketplace to remove listings for, disable access to, or display an explicit warning for dangerous products without further delay or within two working days. Providers of online marketplaces will also have to make reasonable efforts to check randomly for dangerous products.

Another requirement under the GPSR is the need for every product, including non-harmonised products, that is placed on the internal market to have a manufacturer, importer, authorised representative, or fulfilment service provider established in the EU.

In addition, economic operators face new product recall rules. They will be required to inform all consumers who can be identified about a recall. The proposal includes more prescriptive and detailed rules on how a recall notice should look and requires avoiding expressions that could decrease consumers' perception of risk.

Another key provision is that in the event of a recall, consumers will be entitled to at least two of the following possible remedies: repair, replacement, or an adequate refund. As noted above, preference should be given to the most sustainable action resulting in the lowest environmental impact.

Manufacturers, importers, distributors, and online marketplaces operating in the EU need to be prepared for adapting to the new GPSR as it introduces a relatively short transition period of 18 months.

Following the European Council's approval on 25 April 2023, the new GPSR has now been formally adopted.

Energy labelling requirements

The EU Energy Labelling Regulation 2017, which came into force on 1 August 2017, sets out requirements for energy-related products that encourage consumers to purchase products that are more energy efficient. This will ultimately limit energy consumption, reduce energy bills, and promote investment into energy efficient products.

In March 2022, the EC offered more energy-conscious guidance to consumers and businesses in light of the current political attention on energy prices. The Ecodesign and Energy Labelling Working Plan 2022 – 2024 focuses on the circularity aspects of ecodesign and energy labelling requirements for energy-related products. A key focus of the plan is modernising and rescaling energy labels to better assist consumers in choosing among new generations of products available on the market.

Outlook

The growing focus on sustainability and the environment within the UK and EU, both by consumers and regulators alike, continues apace. Companies that prioritise product safety together with improving environmental manufacturing standards, including in relation to repairability, reuse, and recyclability, stand to gain a competitive advantage in what is a fast-growing market. Companies must be aware of the risks and fast-changing regulatory requirements regarding claims about their products' green credentials. Notwithstanding the risk of regulatory breach, ensuring such claims are accurate will build trust with consumers and avoid the pitfalls of many companies in recent years who have been accused of greenwashing.

CONSUMER PRODUCTS

ELECTRONICS

The electronics sector is facing new regulations in the EU and UK aimed at protecting consumers and the environment. These regulations cover a range of issues such as the protection of online video game players, the design and production of batteries, and the security of connected consumer products.

One change that will impact many online games is regulations around how virtual items are sold within games. These purchases can have negative psychological and financial consequences for players. The European Parliament has called for a harmonisation of rules to address these and other problematic practices, as well as to better protect children and other vulnerable groups.

Meanwhile, the EU Batteries Regulation aims to make batteries greener, increase the lifespan of consumer electronics, and ensure that supply chains adhere to social and environmental standards. It imposes several new requirements on manufacturers.

The UK's Product Security and Telecommunications Infrastructure Act (PSTI Act) introduces mandatory security requirements for consumer products that connect to the Internet. While the precise nature of these requirements is still being determined, businesses should be aware of their potential impact and start planning for any necessary changes.

Overall, these new regulations signal a growing concern for the safety of consumers and the environment in the electronics and computer industries, and businesses should be proactive in adapting to these changes.

> *“Video game creators should appreciate that their value and contributions are recognised, but they should also be aware that the impact and safety of online games will continue to be monitored by regulators.”*

EU strengthens enforcement of consumer protections for video games

On 18 January 2023, the European Parliament adopted a report calling for harmonised EU rules to protect online video game players. The document also acknowledged the sector’s value in innovation, growth, and job creation and proposed measures to support the industry.

Among the ways the regulators want to make players safer are to address problematic purchase practices such as “loot boxes” where players spend real money to buy bundles of virtual items that offer in-game advantages.

There are concerns that these purchases can have negative psychological and financial consequences. The report calls on the European Commission to examine how these loot boxes are sold and develop a common European approach to protect consumers.

The report also calls for ending the practice of “gold farming,“ which allows players to gain currency or other items in the game, including whole user accounts, and exchange, sell, or bet on them for real money outside the video environment. This contradicts the terms and conditions applied by video game publishers and more importantly, regulators have found that gold farming has been exploited in connection with money laundering, forced labour, and child exploitation in developing countries.

Other changes that were put forth in the document include making cancellation of game subscriptions easier and better protection for children and other vulnerable groups against targeted advertising and possible harms of online games such as isolation, cyberbullying, and uninformed purchasing decisions. It also suggests that online games should meet the requirements of the General Data Protection Regulation.

The report was not all bad news for the industry. It noted that online video games can be useful educational tools and help with mental exercises. The Parliament asked the Commission to develop a European Video Game Strategy to support job creation in Europe as well as to establish an annual EU online video game award and provide funding for the EU Kids Online research project and similar initiatives.

Video game creators should appreciate that their value and contributions are recognised, but they should also be aware that the impact and safety of online games will continue to be monitored by regulators.

New rules on battery design and production

In January 2023, the European Commission, Parliament, and Council published the approved text of the EU Batteries Regulation. The proposed rule, which will replace the current Batteries Directive 2006/66/EC, includes provisions to make batteries more environmentally-friendly and increase the life of consumer electronic devices.

Attorneys with Cooley highlight some of the major revisions in the new law, including stricter removability and replaceability requirements with very limited exceptions, and a ban on certain substances including a restriction on lead that goes beyond the provisions under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation and the End-of-Life Vehicles Directive.

The regulation also introduces new marking, labelling, and information requirements including traceability information and requirements for CE marking, as well as the mandate that all batteries undergo a conformity assessment. Since the EU is already backlogged for conformity assessments for medical devices, it will be interesting to see how it handles another strain on resources.

Another new obligation for manufacturers and suppliers is the need to develop and implement a supply chain due diligence policy to address the social and environmental risks linked to sourcing, processing, and trading raw materials and secondary raw materials. The policy should include suppliers as well as their subsidiaries or subcontractors.

Once the regulation is formally approved, there are different transition periods for different provisions in the rule. However, manufacturers and supply chain partners should review the approved proposal and start planning for any production, compliance, or reporting changes they will need to make.

New rules for IoT products

When the UK's Product Security and Telecommunications Infrastructure Act (PSTI Act) became law in December 2022, it created a new regulatory regime to make consumer products that connect to the Internet more secure, among other provisions. It also brought new obligations that apply to entities across the supply chain including manufacturers, importers, and distributors.

UK regulators had introduced a voluntary Code of Practice for Consumer Internet of Things Security (the Code) in 2018 for manufacturers, with guidance for consumers on smart devices at home. The document included 13 outcome-focused guidelines for best practices in Internet of Things (IoT) security. But with the proliferation of connected device usage (including smart TVs and home assistants), there was a sense that mandatory regulations were needed.

Under the PSTI Act, the Secretary of State has the power to specify security requirements relating to "relevant connectable products." However, the precise nature of the security requirements for connectable products has not been finalised. They will be set out in secondary legislation.

Legal experts with Taylor Wessing anticipate that the initial requirements will be in sync with some of the standards in the current Code, including banning universal default passwords, requiring a way to manage reports about vulnerabilities, and a need for manufacturers to be transparent about the how long they would provide security updates to a product.

To help businesses prepare, the attorneys recommend that companies determine if the products they sell in the UK will be considered consumer IoT products, and if so, if their organisation will be viewed as a manufacturer, importer, or distributor and thus subject to the legislation.

In addition, companies need to follow any updates on the specific security requirements since those are still being finalised. The Code is a good reference point, but the final requirements may be different.

The EU's Cyber Resilience Act is also designed to improve the security of consumer IoT products, so businesses in the IoT supply chain should be following and planning for those regulations as well if they are selling into the EU.

> *"Attorneys recommend that companies determine if the products they sell in the UK will be considered consumer IoT products, and if so, if their organisation will be viewed as a manufacturer, importer, or distributor and thus subject to the PSTI legislation."*

BY THE NUMBERS

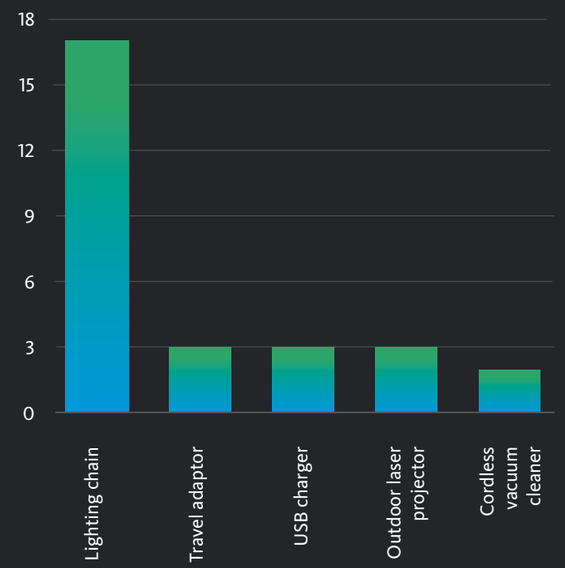
Electronics recalls across Europe and the UK increased 11.5% between Q4 2022 and Q1 2023, with 87 events this quarter. Compared to the same time last year, this is considerably fewer than the 141 recalls in Q1 2022.

The most common risk was electric shock, which was linked to 41 recalls as a standalone cause, and a total of 61 recalls when combined with other factors such as burns, fire and microbiological. The combination of electric shock and fire together were cited in 10 recalls in Q1 2023 making them the second most common reason for consumer electronic product recalls.

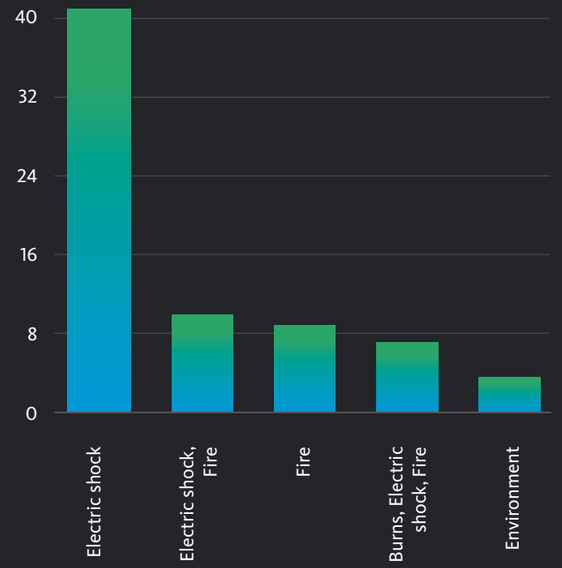
Lighting chains were the most-recalled electronics product, cited in 17 events in Q1 2023, a dramatic increase from five recalls in Q4 2022. There were an additional four separate events involving home lighting products recorded in Q1. The opening quarter of the year also saw two recalls for electric vehicle (EV) charging cables, one for risk of fire and the other for risk of shock. There were also two lithium-ion battery recalls, both due to fire concerns.

The UK issued the most notifications with 23, an increase of 130.0% compared to Q4 2022. Germany had the second-most with 10, up from only two notifications last quarter. Hungary, which issued 18 notifications in Q4 2022 only had seven in Q1 2023.

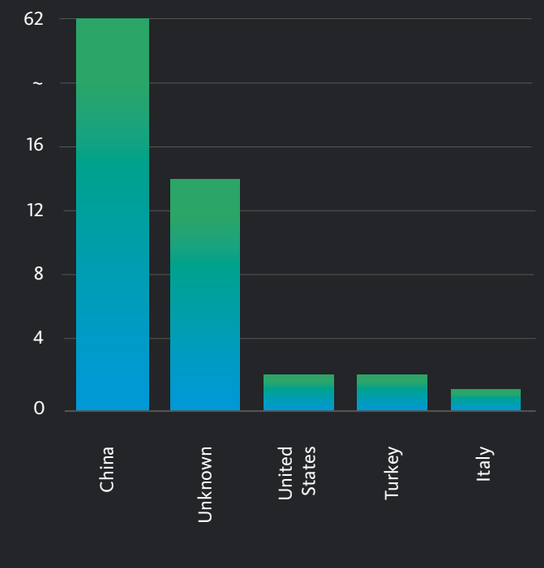
TOP ELECTRONIC PRODUCTS RECALLED



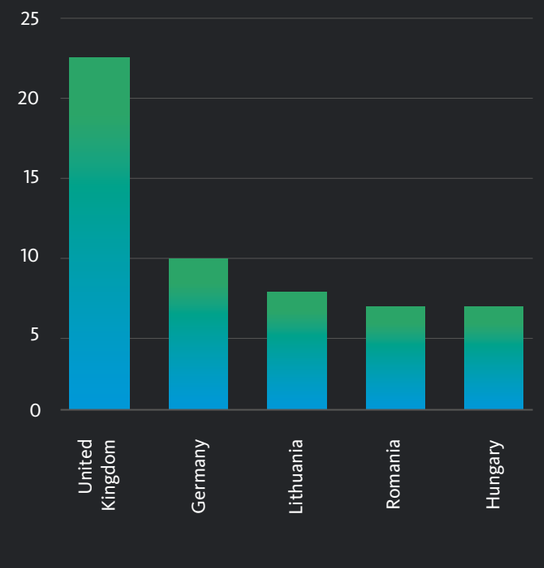
TOP CAUSE OF RECALLS



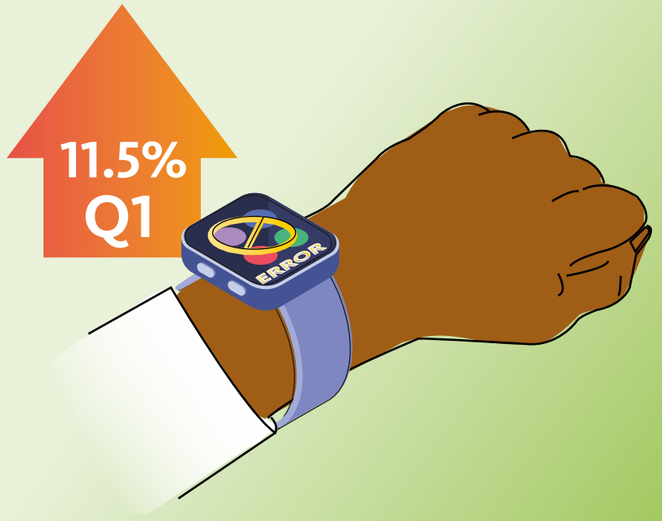
RECALLS BY COUNTRY OF ORIGIN



RECALLS BY NOTIFYING COUNTRY



European consumer **electronic recalls increased 11.5%** in Q1 (from 78 in Q4, to 87).

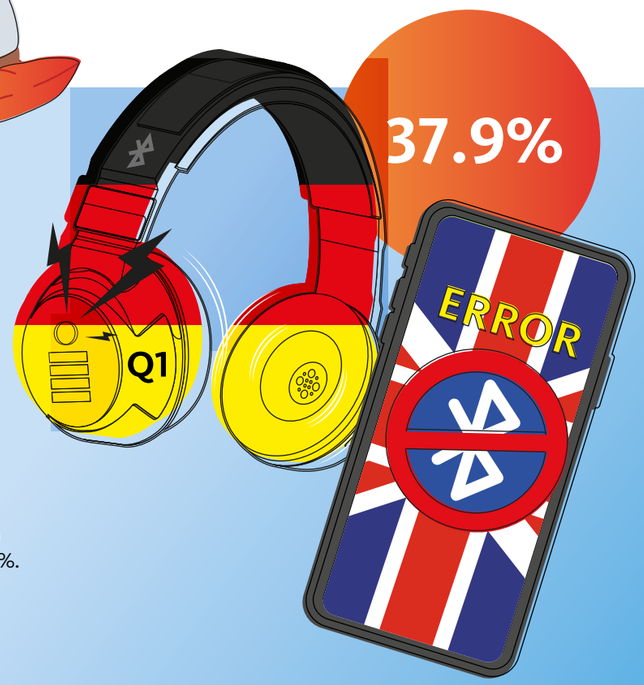


Q1's figure is only a single recall shy of hitting the 3-year quarterly average for electronic recalls.

Accounting for 17 events, **Lighting chains were the most recalled product** in Q1.

Travel adaptors, USB chargers, and Outside laser projectors followed with 3 recalls each.

The UK and Germany submitted over a third (37.9%) of all recall notifications.



With 23 and 10 recalls respectively, the UK saw an increase of 130.0% from Q4, and Germany 400.0%.

IBRAHIM JILANI, GLOBAL DIRECTOR, CONSUMER TECHNOLOGY,
UL SOLUTIONS

CONSUMER SAFETY IN EUROPE AND THE USE OF LITHIUM BATTERY-OPERATED PRODUCTS

Lithium batteries power many of the products we use every day, including cellphones, tablets, power tools, power banks, hoverboards, and e-bikes, to name just a few. The safety risks posed by lithium cells and batteries are generally a function of type, size, and chemistry. Lithium cells and batteries can present chemical hazards such as corrosive or flammable electrolytes. They can also pose electrical and fire related hazards.

The number of incidents involving lithium battery-operated products is rapidly increasing. In the UK, London alone had more than 100 fires in 2022 just from e-bikes and e-scooters, according to the London Fire Brigade. Unlike standard alkaline batteries, most lithium batteries manufactured today contain a flammable electrolyte and have a relatively high energy density. They can overheat and ignite under certain conditions, such as a short circuit or improper design or assembly.

Risk mitigation efforts in the European Single Market

The European Single Market leverages a risk-based approach to determine when independent third-party conformity assessments for higher-risk categories are mandatory. In some cases, the use of Supplier's Declaration of Conformity (SDoCs) is allowed.

In the European Union (EU), the rapid product incident alert system used across Member States, Safety Gate, ranks electrical products among the five most frequent product categories in terms of alerts. Fire and electrical shock comprise 18% of the risks identified and are considered two of the most frequent types of safety risks.

The EU Machinery Directive (2006/42/EC) regulates personal mobility devices, which in the EU include e-bikes. The regulation sets out the applicable requirements with the detailed technical specifications defined in the EU harmonised standards. However, under the rule, lithium battery-operated personal mobility devices do not require mandatory third-party product safety certification. The overall safety of the market relies heavily on post-market surveillance authorities.

In December 2017, the European Commission (EC) published legislative proposals to improve the cooperation of market surveillance authorities. The EC simultaneously issued a press release stating that there were still too many unsafe and non-compliant products sold on the EU market. As many as 32% of toys, 58% of electronics, 47% of construction products, and 40% of personal protective equipment inspected do not meet the safety requirements or include consumer information foreseen in EU legislation such as labels and safety instructions in official languages. In the same year, the Netherlands Court of Auditors reported its concerns about manufacturers' ability to rely on self-assessment and issue a SDoC when using European harmonised standards.

Thermal runaway events and consumer safety issues

Consumers may face safety risks when using lithium battery-operated products, even though these are considered to belong to the lower-risk profile goods. In 2019, the EC conducted a conformity assessment of personal e-transporters and batteries as part of its Coordinated Activities on the Safety of Products (CASP) program. The study found more than 80% of personal e-transporters, which include e-bikes, e-scooters, hoverboards, and uni-wheels, and more than 10% of lithium batteries, such as power banks, 18650 cells, and smartphone battery replacements, to be noncompliant. These high noncompliance rates create unsafe conditions for consumers in Europe. The 2022 CASP study included goods and products sold at street markets, some of which include lithium battery-operated products. It will be important to review the results of that study, which are scheduled for release later this year.

In 2022, TIC Council, which is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry, decided to repeat previous studies conducted between 2012 and 2017. The aim was to check to see if the consumer safety situation in the EU had improved in the past 10 years. The results, published in March 2023, show that the situation has deteriorated further. The key takeaway was that "of the 120 products tested, 85 were not in compliance with the standards, and 28 presented dangerous nonconformities (meaning defects that can cause hospitalisation, permanent bodily damage to the consumer, potential loss of property, or fires)." It is alarming that more than 70% of the products failed to meet safety standards, and more than one in five were considered dangerous nonconformities.

By comparison, a study by TIC Council found less than 1% dangerous faults for products that were third-party certified, compared to 17% dangerous faults in those without independent verification. Research published in the International Review of Administrative Sciences found that products within a system requiring third-party certification were between 10 and 20 times less likely to be recalled for safety violations.

For lithium batteries, the danger is from an event known as thermal runaway, which is defined as "a phenomenon in which the lithium-ion cell enters an uncontrollable, self-heating state." Thermal runaway can be caused by multiple means, including manufacturing defects, physical abuse, unsafe charging and discharging, and environmental stressors. Thermal runaway can result in an explosion, fire, and venting of toxic gases.

Any lithium battery-operated product has a risk of experiencing this type of event. Because thermal runaway can propagate from cell-to-cell, there is increasing risk as the number of battery cells increases. Noncompliant lithium battery-operated products significantly increase risk. Lack of coordination and evaluation of the entire lithium battery system – including chargers, batteries, and products – also significantly increase risk. To reduce this danger, these types of products should require mandatory conformity assessment using an independent third-party certification body.

There is also a growing concern for products adapted once in market, driven both by consumer demand as well as efforts to promote sustainability through circular battery regulations. Similar to what has taken place regarding the United States' expanding right-to-repair laws, there is a significant gap in the safety requirements presented in the EU. Consumers may unknowingly put their safety at risk when adapting or repairing products. For example, unregulated e-bike conversion kits can be used by anyone to modify a regular bike into an e-bike without a proper system to verify compliance with applicable EU legislation and related standards.

Enhancing safety compliance management

A higher degree of trust in the safety of the products that consumers use, driven by mandatory conformance to applicable safety requirements and transparency, is critical for the public, regulators, retailers, employers, and other stakeholders. While meeting market entrance requirements is one important aspect, supplementing that with independent and impartial third-party certification of lithium battery-operated products, especially those which have demonstrated a pattern of nonconformance and safety incidents, can significantly increase consumer trust and reduce risk.

CONSUMER PRODUCTS

TOYS

Both the UK and the EU have proposed changes to packaging regulations that will impact many industries, including the toy sector. There also continues to be a push to increase consumer protection when shopping online or being influenced by social media. While these will not only affect toy companies and suppliers, this industry will be closely watched to help keep children safe.

The UK's Office for Product Safety and Standards (OPSS) launched a product safety campaign in March 2023 urging consumers to be cautious when buying products from online platforms. As consumers become more aware of risks, smarter buying practices, and product recalls, toy manufacturers, retailers, and e-commerce sites should be sure their product safety and recall plans will stand up to scrutiny.

The proposed revision of the Packaging and Packaging Waste Directive (2022/0396) will impact toy manufacturers given the fact that most toys have considerable packaging materials. The regulation could pose challenges for businesses, particularly for online distributors, whose transport packaging is specifically regulated. There are concerns that implementing the current draft is not feasible given the limitations of Member States' recycling programmes.

In another step to protect consumers, the UK's Competition & Markets Authority (CMA) has released guidelines for social media platforms around unlawful practices and hidden advertising. The guidance recommends platforms make it easier for content creators to label messages as advertising when appropriate, but also encourages them to enforce their policies if illegal content is posted.

Toy manufacturers need to stay up-to-date with these developments to ensure compliance and avoid reputational damage. Safety, sustainability, and transparency should be at the forefront of every toy manufacturer's priorities to ensure the well-being of children and the longevity of the business.

> *"As consumers become more aware of risks, smarter buying practices, and product recalls, toy manufacturers, retailers, and e-commerce sites should be sure their product safety and recall plans will stand up to scrutiny."*

UK urges consumers to shop smart and stay safe

The UK's Office for Product Safety and Standards (OPSS) launched a product safety campaign in March 2023 with Netmums and the Child Accident Prevention Trust (CAPT) to urge consumers to be wary when buying products from online platforms.

The social media campaign focuses on three main messages: 1) be aware that products advertised on an online platform might not be sold by that platform; 2) search "product recalls" on GOV.UK to see if a product has been recalled before purchasing it; and 3) report any unsafe products to the relevant authority.

Some of the posts being deployed across Facebook, Twitter, and Instagram state that 91 types of toys and 40 types of electrical products were recalled in 2022. Other product categories highlighted in the campaign include hot hairbrushes, power adaptors, and electric bikes and scooters.

Manufacturers, retailers, and ecommerce sites should be aware that consumers will be more knowledgeable about smarter buying practices and more aware of product recalls, which could be harmful to a company's reputation if they do not act swiftly and are not transparent with the public. Product safety and a robust product recall plan will be even more important.

Changes to packaging regulations

In addition to the European Commission Regulation (EU) 2022/1616 which impacts recycled plastic materials and articles intended to come into contact with food, manufacturers and retailers (including toy companies), should be preparing for another EU proposal, the Revision of the Packaging and Packaging Waste Directive (2022/0396) (RPPWD).

A review of the proposal by attorneys with DWF LLP raises questions about how likely it will be that businesses can comply with the requirements, since many EU Member States are already struggling to meet current recycling targets.

Some of the changes included in the RPPWD include EU-wide deposit returns schemes (DRS) and labelling, mandatory recyclability, and minimisation requirements. Even tea and coffee bags or other single-serve units that are disposed of with the product would be regulated as packaging under the proposal.

The rule states that "all packaging shall be recyclable." It sets five criteria that must be met for packaging material to be considered "recyclable." Some of the provisions include the need for materials to be "designed for recycling," that materials are sorted into defined waste streams but do not affect the recyclability of other waste streams, and they can be recycled at scale.

The legal experts note that online distributors may face some of the biggest challenges because transport packaging used to deliver products sold online or by other distance means, also known as "e-commerce packaging," is specifically regulated in the proposal.

While businesses may do their best to design packaging to meet these standards, in most cases they will be reliant on the recycling capabilities and systems in the Member State in which they are operating or marketing. Businesses should follow this legislation as it moves through the approval system to see if changes are made to reflect the fact that parts of any recycling plan are out of the control of businesses and solely up to national and local entities.

Since each Member State will also have its own interpretation of the rules, companies need to review the laws in each jurisdiction in which they market to ensure they are complying with the patchwork of regulations and capabilities.

> *"The Revision of the Packaging and Packaging Waste Directive states that "all packaging shall be recyclable." It sets five criteria that must be met for packaging material to be considered "recyclable"."*

New guidance for social media platforms and content creators

In an effort to keep pace with how businesses are using social media, the UK's Competition & Markets Authority (CMA) is one of the latest regulators to release guidelines for social media platforms to protect consumers from unlawful practices. The guidance was published at the end of 2022 and provides companies with best practices to combat hidden ads and comply with consumer protection laws.

The six principles were developed after a review of social media platforms and a consumer enforcement investigation around suspected use of hidden online advertising by social media content creators.

Some of the actions the CMA recommends for social media platforms are to inform users that incentivised endorsements must be clearly labeled as advertising; provide content creators with tools to easily and effectively label advertising content; be appropriate, proportionate, proactive about preventing the use of hidden advertising on the site; and enforce its terms and conditions if content creators are violating the rules.

The CMA offers the caveat that these new principles outline what platforms should be doing now, but that technology develops quickly, and each platform is different. Platforms need to review their compliance regularly to stay up-to-date.

This is not the only guidance the CMA has offered. It also co-published a guide on how to label ads correctly with the Committee of Advertising Practice (CAP). The document explains how to comply with consumer protection law and the Advertising Codes enforced by the Advertising Standards Authority (ASA). In addition, it has provided recommendations for content creators in its guide for influencers on social media endorsements.

Both social media platforms and companies that use social media for advertising should review their practices against the new guidance. It remains to be seen how aggressively the CMA will enforce the existing consumer laws against unlawful practices and hidden advertising, but they are clearly on the regulator's radar and companies should be on notice.

BY THE NUMBERS

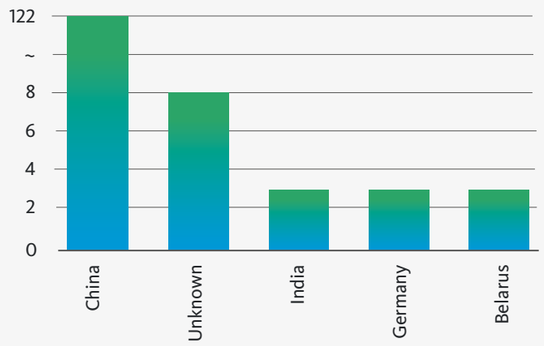
There were 149 toy recalls across the UK and EU in Q1 2023, a 31.3% drop from the previous quarter. This also reflects a 17.7% decrease compared to Q1 2022.

Chemical risk was the most common reason for toy recalls in Q1 2023 with 60 events, down 7.7% from the previous quarter. The second most-cited risk for Q1 2023 was choking, with 49 recalls.

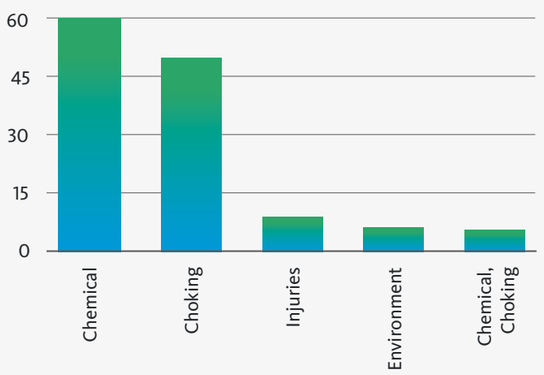
There were 18 recalls for plastic dolls this quarter, making it the most common type of toy recalled. As a whole, recalled toys made of plastic were involved in 34 recalls, accounting for 22.8% of all events. In second place was toy slime with 17 events, an increase of 88.9% compared to Q4 2022. Soft toys were the third-most recalled category with 15 events.

Poland submitted the most toy recall alerts with 39 counts in Q1 2023, up 39.3% from Q4 2022. France was second with 17. The UK had the third-highest number of notifications with 16, a dramatic drop (of 78.1%) from its 73 notifications last quarter.

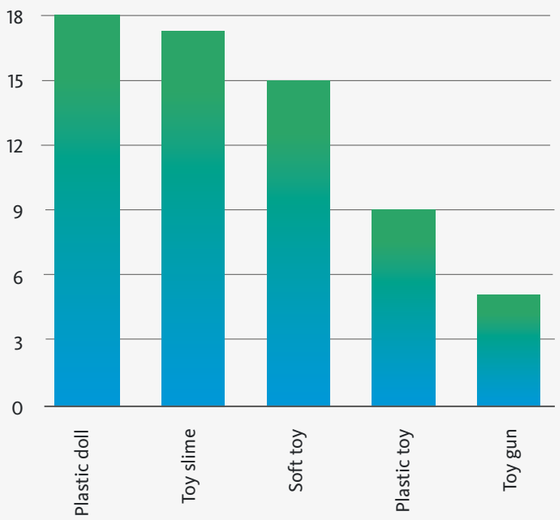
RECALLS BY COUNTRY OF ORIGIN



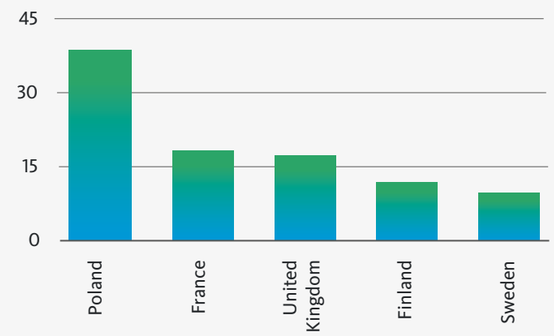
TOP CAUSE OF RECALL BY RISK TYPE



TOP RECALLS BY PRODUCT

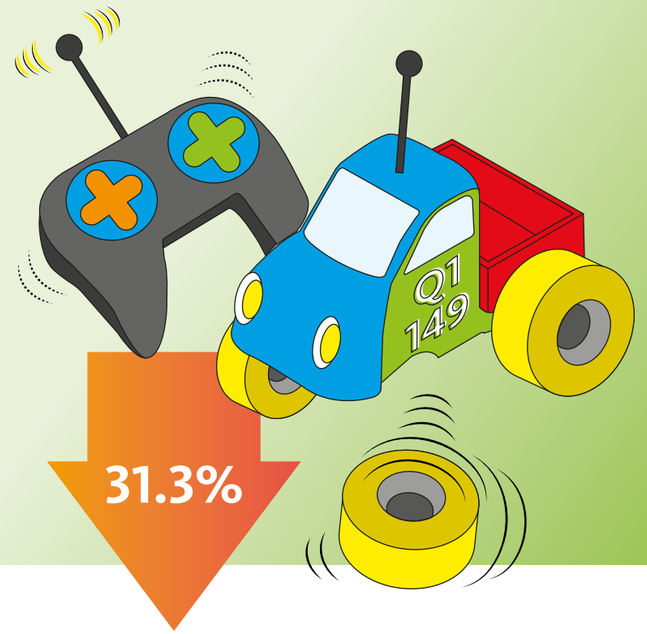


RECALLS BY NOTIFYING COUNTRY



European Toy recalls plummeted by a third (31.3%), from 217 events in Q4, to 149 in Q1.

Despite this decline, Q1's figure remains 10.4% above the sector's 3-year quarterly average of 135 recalls.

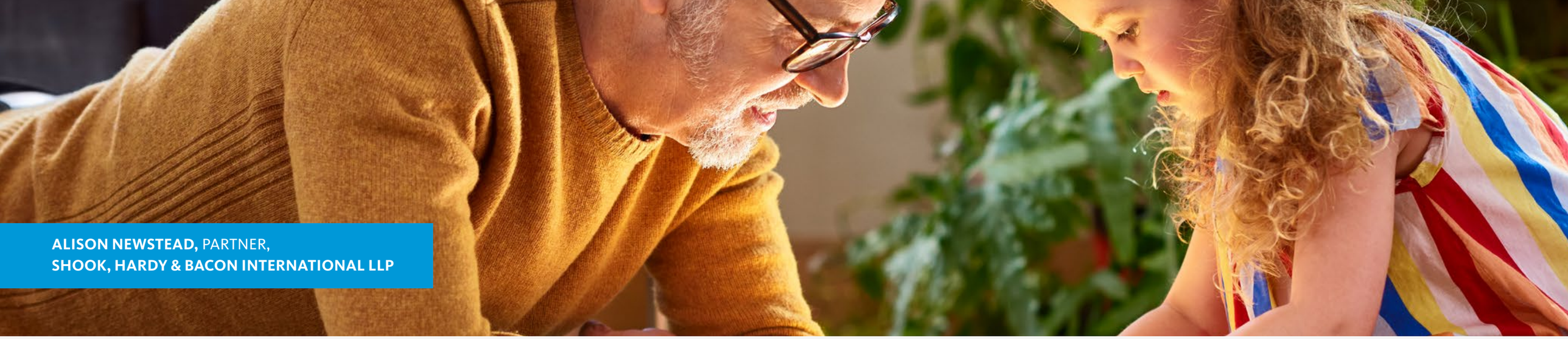


Accounting for 18 events, Plastic dolls have remained the most recalled toy for 3 consecutive quarters.

Toy slime and Soft toys followed with 17 and 15 events respectively, increasing 88.9% and 25.0% quarter-over-quarter.

Chemical and Choking risks dominated Q1 recalls, accounting for 60 and 49 events respectively.

Environmental concerns experienced the greatest increase of all risks recorded (climbing 250.0%).



ALISON NEWSTEAD, PARTNER,
SHOOK, HARDY & BACON INTERNATIONAL LLP

REGULATORY AUTHORITIES FOCUS ON MODERNISING THE TOY REGULATORY FRAMEWORK IN 2023

Toys top EU Safety Gate alerts

The European Commission's annual *Safety Gate* report presents data collated from product safety notifications made to the European Commission in relation to products sold in EU Member States, Iceland, Norway and Liechtenstein and provides an interesting insight into consumer product safety trends in Europe.

Over the past decade, toys have consistently maintained a high profile in the *Safety Gate* statistics. In the recently published 2022 *Safety Gate* report, toys were once again the subject of a substantial number of product safety alerts, representing 23% of all alerts made. Since children are one of the most vulnerable sectors of consumers, potential toy safety issues are often quickly picked up and acted upon by consumers and national authorities alike. For example, 84% of product notifications made by Malta to the EU in 2022 were related to toys, with Poland not far behind with 60% of notifications concerning toys.

The country of origin of a product is an important factor when it comes to assessing safety. Country of origin often piques the interest of national authorities, particularly when assessing products at border entry. In 2022, half of all EU product safety alerts (not just those relating to toys) concerned products of Chinese origin. The European Commission has long acknowledged that collaboration with China on safety issues is key to improving the safety of toys entering the EU market. To this end, the EU will undoubtedly continue to work directly with Chinese product safety authorities and promote the dedicated training programme that is in place in the EU which raises awareness of EU product safety requirements among Chinese producers.

With increasingly stringent requirements being introduced in respect of toy safety and national authorities stepping up their market surveillance activities, it is likely that toys will remain a focus of product safety alerts for some years to come.

Revision of the EU Toy Safety Directive – Focus on chemicals and connectivity

The proposal for a revised EU Toy Safety Directive is still eagerly anticipated. Adoption of the proposal was expected by the end of 2022, but publication is still awaited from the European Commission.

The proposal can be expected in the coming months and revisions will likely reflect those put forward by the European Parliament in 2022. In line with the European Commission's *Chemicals Strategy for Sustainability Towards a Toxic Free Environment*, the European Parliament placed a heavy emphasis on chemicals in toys in its proposed revisions. Going forward, toy manufacturers will likely be required to give additional consideration to the use of carcinogenic, mutagenic, and reprotoxic (CMR) chemicals; to stop the use of endocrine disrupters; and to comply with a potential extension to the lower limit values for chemicals in toys for children under 36 months.

The revised Toy Safety Directive is also likely to tackle the potential risks posed by connected toys and the use of artificial intelligence (AI). Risks posed by connectivity and AI are an issue that has been debated widely in the sphere of product safety and liability and features in proposed revisions to the EU Product Liability Directive and a new proposed AI Liability Directive. It is certainly an area in which toy manufacturers will see increased regulation and product liability exposure. With the ever-growing market for connected and AI toys, manufacturers can certainly anticipate an increase in recalls and other corrective actions.

If the forthcoming proposal for a revised Toy Safety Directive is adopted, then – following any period of transition – an uptick in the number of non-compliant toys on the EU market can be expected, with a parallel increase in the number of product safety notifications made to the EU.

New toys, new guidance

In February 2023, the European Commission published new Guidance on the classification of toys, which will hopefully ease confusion, differences in opinion, and the risk of regulatory action for toy manufacturers.

The 2023 *Guidance on Toys Intended for children under 36 months of age or of 36 months and over* replaces the European Commission's 2009 *Guidance document on the classification of toys intended for children under 3 years of age*. The 2009 Guidance had fallen behind advancements in the toy market, and differences in opinion as to the correct classification had become increasingly common between manufacturers, national authorities, and EU Member States.

The 2009 Guidance is limited to puzzles, dolls, and soft and stuffed toys, so an enormous section of the toy market remained outside of its scope. The 2023 Guidance covers a significantly wider range of toys – with 12 additional categories including fidget toys, slime, play sets and board games, push and pull along toys, and audio and visual equipment.

The introduction of the Guidance should make marketing toys across the EU simpler from a regulatory perspective, reducing the risk of inconsistent categorisation, potential regulatory action, and recalls.

What's ahead?

Looking forward, the toy sector can expect to see the regulatory landscape evolve as we move through 2023. Safety regulations will become more stringent and national authorities will continue to use more sophisticated tools (such as the e-surveillance web crawler) to remove non-compliant products from the market. International cooperation between enforcing authorities will increase, and targeted testing and investigations will continue to be undertaken with the aim of ensuring that only safe products reach the hands of children.

> *"The European Commission's proposed Green Claims Directive signals a growing awareness and commitment towards sustainable practices in the fashion industry. Companies will need to adapt to these changes in order to remain competitive and meet regulatory requirements."*

CONSUMER PRODUCTS

CLOTHING

The fashion industry has long been under scrutiny for its impact on the environment due to its heavy use of water and land, primary raw materials, and greenhouse gas emissions. The European Commission's proposed Green Claims Directive, which requires environmental claims made by companies to meet minimum substantiation requirements, will impact fashion companies that are trying to highlight their eco-friendly practices.

Additionally, sustainability agreements may provide a way for fashion and textile producers to have a more positive environmental impact, and the UK's Competition and Markets Authority (CMA) has published draft guidance to help businesses interpret how competition rules apply to these agreements. The push to curb fast fashion has also gained momentum, with the European Commission launching a new campaign to encourage Europeans to support sustainable fashion and the EU Strategy for Sustainable and Circular Textiles.

In another development, the European Chemicals Agency has proposed a ban on approximately 10,000 perfluoroalkyl and polyfluoroalkyl substances, or PFAS, which are commonly used in the fashion sector to provide functionality such as stain resistance and waterproofing. This ban, if implemented, would have a significant impact on companies manufacturing textiles and clothing, as well as many other product categories. It is important for fashion and textile companies to evaluate their risk if these chemicals are banned and consider alternative solutions.

Overall, these developments signal a growing awareness and commitment towards sustainable practices in the fashion industry, and companies will need to adapt to these changes in order to remain competitive and meet regulatory requirements.

> *"According to the European Commission, the fashion and textile industry has the third-highest use of water and land, and the fifth-highest use of primary raw materials and greenhouse gas emissions."*

Impact of the Green Claims Directive on the fashion industry

The fashion industry has been heavily criticised for its outsized environmental footprint. It was the first sector reviewed by the CMA to see if companies' environmental claims complied with the Green Claims Code.

According to the European Commission, the fashion and textile industry has the third-highest use of water and land, and the fifth-highest use of primary raw materials and greenhouse gas emissions. That led to the development of the EU Strategy for Sustainable and Circular Textiles, which aims to create a greener, more competitive, and more modern textile sector that is more resistant to global shocks.

This focus on making the fashion sector more environmentally friendly, as well as the fact that the industry has been called out for its processes, makes the European Commission's proposed Green Claims Directive (the Directive) particularly relevant to these companies.

Under the new regulation, claims including, but not limited to, "sustainable," "eco-friendly," "packaging made of 100% recycled plastic," and "climate neutral" would need to meet minimum "substantiation requirements."

Another way that fashion and textile producers can aim for a more positive environmental impact is through the use of sustainability agreements. The CMA published a draft guidance to help businesses interpret how competition rules apply to agreements that are focused on environmental and sustainability goals. If agreements are specifically designed to mitigate climate change, entities have more flexibility in their agreements.

The European Commission is also looking at how to allow exclusion from some EU competition rules for joint sustainability initiatives. While the initial proposal is focused on the agricultural sector, it is possible that it could be expanded into other industries once it is tested.

In addition, the Netherlands Authority for Consumers and Markets (ACM) has drafted its own guidance and other national competition authorities (NCAs) within the EU are considering their own approaches as well.

An assessment by attorneys with Osborne Clarke discovered that the proposals published by the CMA, the Commission, and the ACM show several types of agreements that have a low risk of infringing competition rules. Some of the areas identified by the legal experts include the internal corporate affairs of businesses such as using less heat or air-conditioning in the company's facilities, as well as industry-wide initiatives to raise awareness for environmental issues.

The CMA, European Commission, and ACM have all invited companies to speak with them about possible sustainability agreements. This will be important input so that organisations can understand how the regulators interpret the rules and where there is flexibility.

Companies across the textile and fashion supply chain should consider if there are any sustainability objectives they could achieve by partnering with other companies. They will need to balance promoting those objectives with an effort to avoid any claims of greenwashing, or risk investigations by regulators and possible distrust from consumers.

The push to curb fast fashion

The European Commission started 2023 with a new multilingual campaign to encourage Europeans to not support fast fashion and to raise awareness for the EU Strategy for Sustainable and Circular Textiles.

The ReSet The Trend initiative uses the phrase #ReFashionNow to make the public more aware of the environmental, social, economic, and health-related benefits of transforming the textiles sector. It also highlights the value of sustainable fashion for businesses and consumers. The campaign encourages young Europeans to become role models and "make fast fashion out of fashion."

Virginijus Sinkevicius, EU Commissioner for the Environment, Oceans and Fisheries said in a statement, "The world is changing. Producing, using, and then throwing things away is old-fashioned. In our world, it no longer makes economic sense… That's why Europe has a new strategy for textiles. We want to be part of the solution…"

The programme was launched in Antwerp in January 2023 with an event that included designers, industry representatives, fashion sustainability experts, policy makers, young professionals from the textiles sector, and students from around the EU who shared best practices in sustainable fashion and discussed other topics, such as how to avoid greenwashing and the role of circular business models.

The campaign website offers more resources including social media filters, stories of change, and profiles of the youth ambassadors working to bring about change in the fashion industry and consumer buying habits.

PFAS ban expected for clothing sector

On 7 February 2023, the European Chemicals Agency (ECHA) published a proposal from authorities in Denmark, Germany, the Netherlands, Norway, and Sweden that would ban the manufacture, use, and marketing in the EU of approximately 10,000 perfluoroalkyl and polyfluoroalkyl substances, or PFAS. This class of thousands of different synthetic chemicals is found in a wide range of consumer, commercial, and industrial products. The new rule would apply to both the specific PFAS as standalone chemicals as well as their use in products.

The draft document states that all types of PFAS listed in the proposal are very persistent in the environment and if their emissions are not reduced, people, plants, and animals will have increased exposure to these chemicals. This exposure would have negative effects on public health and the environment. The authorities estimate that unless action is taken, over the next 30 years approximately 4.4 million tonnes of PFAS will end up in the environment.

Legal experts with Cooley describe this action as "the biggest proposed chemical restriction in EU history" and predict it will have a major impact on companies manufacturing everything from electronics, textiles and clothing, and cosmetics to food contact materials, packaging, medical devices, and other products. Currently, only PFAS used as active substances in pesticides, biocides, and human and veterinary medicinal products are excluded from the proposal.

In the lawyers' estimation, the ban would force companies to redesign products sold on the EU market. They also suggest that once the EU's restrictions take effect, other countries may adopt a similar approach.

They note that some types of PFAS including PFOA, PFOS and PFHxS are already regulated under the Stockholm Convention on Persistent Organic Pollutants. In addition, certain PFAS have already been restricted or are being restricted in the EU, and have been identified as substances of very high concern (SVHCs) under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. Sector-specific EU legislation regulating industrial emissions, water, and drinking water also address the release of PFAS into the environment.

Experts suggest there is a high likelihood that the proposal will move forward. Certain types of PFAS are used extensively in the fashion sector to gain functionality such as stain resistance and waterproofing. Textile and clothing companies should determine if these substances exist in their products, and if so, evaluate their risk if the chemicals are banned and investigate what alternatives they have.

BY THE NUMBERS

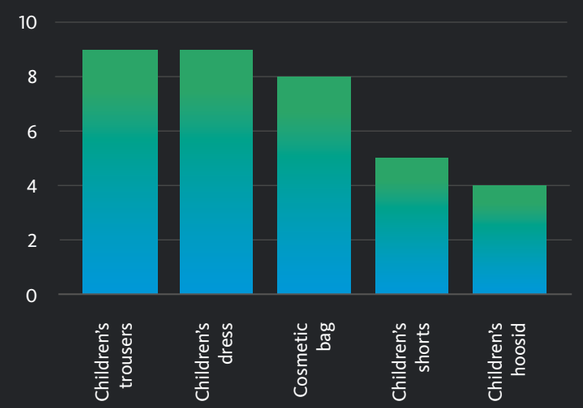
There were 77 clothing recalls in Q1 2023 in the UK and EU. This represents a 2.7% increase on the 75 recall events recorded in both Q4 and Q1 of 2022.

Children's and baby's apparel, including trousers, dresses, shorts, hoodies, jackets and sweatshirts were responsible for 54 of all clothing recalls in Q1 2023, or 70.1%. This is on par with the 58 recalls in Q4 2022.

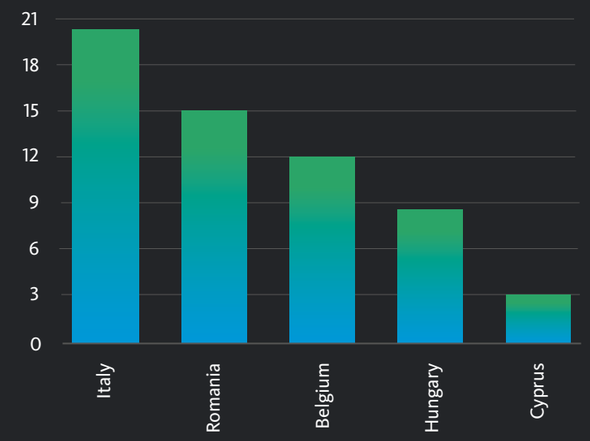
Injuries were the most common reason for clothing recalls, cited in 25 events alone and 41 when combined with other causes such as strangulation or cuts. Chemical risk was linked to 17 recalls, however when combined with environment risk, this figure increased to 19 events.

In terms of notifications, Italy issued the most with 20, up from the 11 issued last quarter. Romania had the second-most notifications with 15, which was far fewer than the 29 in Q4 2022. The UK had two notifications in Q1 2023, down from five in the previous quarter.

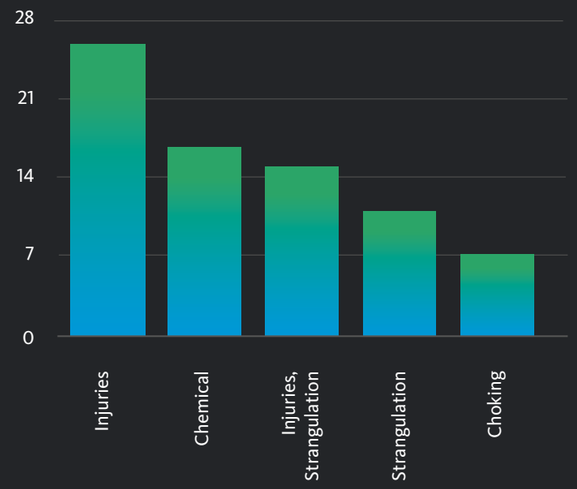
TOP CLOTHING PRODUCTS RECALLED



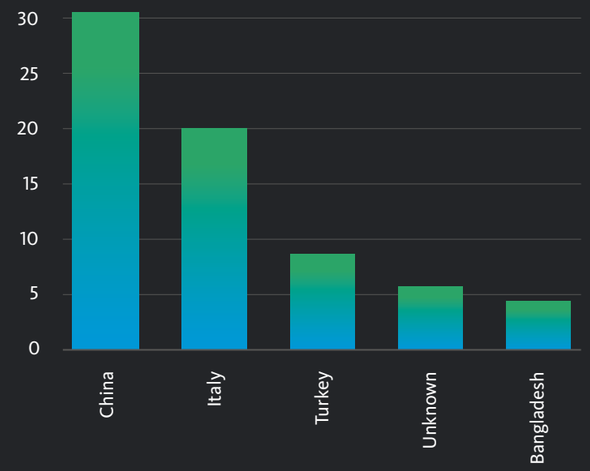
RECALLS BY NOTIFYING COUNTRY



TOP CAUSE OF RECALL BY RISK TYPE

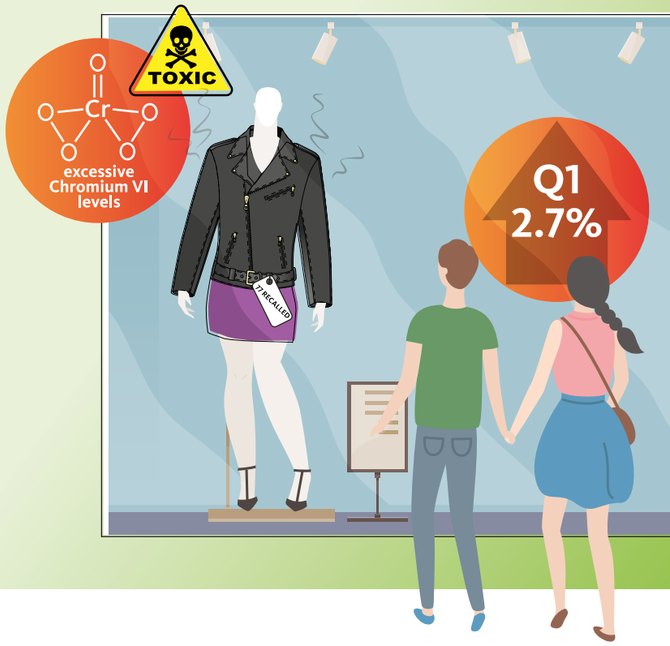


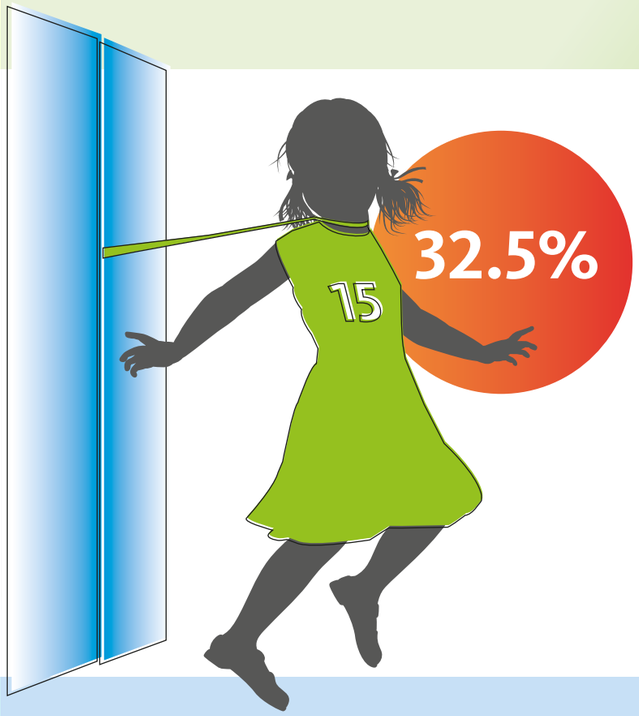
RECALLS BY COUNTRY OF ORIGIN



European clothing recalls remained steady, increasing 2.7% in Q1 (from 75 in Q4, to 77).

With this, quarterly events now sit 44.2% above their 5-year quarterly average of 43 events.



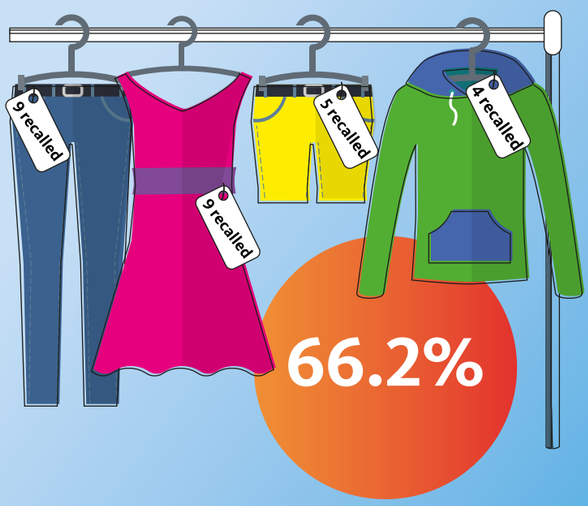


Injuries were the leading cause of clothing recalls in Q1 with 25 events (32.5%).

Chemical concerns was the second most prevalent risk type with 17 events, followed by the combined risk of Injuries and Strangulation with 15.

With 51 events (66.2%), **Children's apparel dominated clothing recalls** in Q1.

Of these, children's trousers (9 events), dresses (9), shorts (5), and hoodies (4) were the leading items.



SARAH-JANE DOBSON, PARTNER; **THOMAS PANTER,** SENIOR ASSOCIATE; **MYUNGHOON PAIK,** ASSOCIATE; **MIRAN BAHRA,** ASSOCIATE; **AND TEGAN JOHNSON,** SOLICITOR APPRENTICE, **KENNEDYS LAW**

ENVIRONMENTAL SUSTAINABILITY AND PRODUCT SAFETY KEY ISSUES FOR THE CLOTHING INDUSTRY IN 2023

In the European Union (EU), consumption of textiles (which are mostly imported) now accounts on average for the fourth-highest negative impact on the environment and on climate change – with 5.8 million tonnes of textiles being discarded each year in the EU. With this statistic in mind, on 30 March 2022 the European Commission published its EU Strategy for Sustainable and Circular Textiles, which aims to create a framework for the transition of the textiles sector to a more sustainable model. As part of this, the Commission has set out its vision for the future of the sector, which says that "by 2030 textile products placed on the EU market should be more sustainable, ethical and also free of hazardous substances."

Given this regulatory drive within Europe, together with growing consumer awareness and demand, two of the key areas of focus for the clothing industry over the next decade will be environmental sustainability and product safety – for consumers, the supply-chain, and the wider environment.

Eco-labelling

The Commission in January 2023 announced its intention to review Regulation (EU) No 1007/2011 on textile fibre names, as well as related labelling and marking of the fibre composition of textile products (the "Textile Labelling Regulation"), as part of the EU Strategy for Sustainable and Circular Textiles.

A key thrust of the Commission's review of the Textile Labelling Regulation is to establish a sustainable, eco-friendly textile economy. Early proposals include introducing digital labels and mandatory disclosure of types of information such as sustainability and circularity parameters, products' size, and, where applicable, the country where manufacturing processes take place ('made in').

The review of the Textile Labelling Regulation is still at an early stage and requires further impact assessments and the Commission's review. However, certain Member States have made their intentions clear in this space already – giving an idea of where EU-wide regulation may develop.

For example, France, through Decree 2022-748 AGEC on Anti-Waste for a Circular Economy Law (the "French Decree"), has made verified environmental labelling a requirement for large clothing companies. This applies to producers, importers, and retailers, including online marketplaces with a turnover of more than €50 million selling products from January 2023. The labelling requirements will apply gradually to more companies based on level of turnover up to January 2025, at which point all companies with an annual turnover of more than €10 million will be required to comply.

As part of the French Decree, consumers in France are required to be supplied at the point of purchase of certain products, including clothing and footwear, with information on its environmental qualities via a product sheet, containing:

- The amount of recycled material incorporated;
- Recyclability;
- The presence of hazardous substances;
- Geographical traceability of the three major manufacturing steps (weaving, dyeing, and assembly/finishing); and
- The presence of plastic microfibers when the proportion by mass of synthetic fibres is greater than 50%.

The format of the product sheet can be by electronic means and/or labelling display at point of purchase.

Consumer demand and regulatory changes initiated by the French Decree and EU-wide initiatives, such as the review of the Textile Labelling Regulation, have seen many companies adopt a proactive approach to get ahead of the curve. This includes steps such as implementing improvements to enhance transparency within their supply chain and/or the adoption of QR and NFC tags within their labelling. The intention is to provide consumers access to a wealth of additional information on product sustainability, which is a positive development for the clothing industry.

However, the speed of change will pose significant challenges to companies who do not place supply chain due-diligence, transparency, and sustainability at the core of their product design. There is also a risk over the medium-term of diverging labelling and sustainability requirements being implemented across Europe. This poses further challenges from a compliance perspective for multi-national clothing companies seeking to place individual products across multiple markets.

The chemicals in our clothing

Chemicals are commonly used in the production of clothing, from dyes and bleaches to finishing agents and flame retardants. The safety of these chemicals has been a growing concern for many consumers following increased publicity of the health risks associated with exposure to certain chemicals.

On 30 March 2022, the Commission noted that in respect of "the presence of hazardous substances used in textile products placed on the EU market – around 60% are considered as carcinogenic, mutagenic or toxic to reproduction."

Restriction of per- and polyfluoroalkyl substances under REACH

In recent years, there has been a growing focus on the risk posed by per- and polyfluoroalkyl (PFAS) substances, often referred to in the general press as "forever chemicals" because of their extreme persistence in the environment. PFAS comprise a group of more than 4,700 industrial chemicals widely used in everyday products, including clothing. The full impact of these chemicals on health and the environment is not fully understood. However, a number are known to be toxic and, together with their extreme persistence, are of considerable concern to consumers and regulators.

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The European Chemicals Agency (ECHA) indicated PFAS can be released from professional and industrial facilities and during use of consumer products including cosmetics, food contact materials, and clothing. They can pollute ground and drinking water and cause toxic effects to humans, animals, and plants.

PFAS substances have been found in a variety of clothing products including rain jackets, hiking pants, shirts, yoga pants, sports bras, and underwear, as well as in many clothing products marketed as non-stick, water or stain resistant.

As it stands, a considerable number of PFAS chemicals still do not carry any restriction. However, certain substrates are already banned by international convention, under the EU's Persistent Organic Pollutants (POPs) Regulation, and/or restricted or listed on the EU REACH substances of very high concern (SVC), and within other relevant regulations.

The number of PFAS subject to restrictions looks set to increase considerably with the Commission adding Perfluoroheptanoic acid (PFHpA) and its salts to the candidate list of REACH SVCs in January 2023. Additionally, that same month, Germany, the Netherlands, Denmark, Norway, and Sweden submitted a proposal to ECHA to extend the restriction of additional substrates of PFAS under EU REACH. A six-month consultation on the proposal runs from 22 March 2023 to 25 September 2023, inviting interested parties to send in scientific and technical information on the manufacture, placing on the market, and use of PFAS.

In March 2023, the UK Health and Safety Executive also published an "Analysis of the most appropriate regulatory management options" on PFAS, which is a non-binding technical document examining the nature of the risks posed by PFAS and options for the management of these risks. The analysis proposes potential restrictions on one or more PFAS and includes requiring authorisation under UK REACH and for using PFAS as a processing aid in the manufacture of fluorinated polymers.

The growing speed by which PFAS chemicals are being subjected to restrictions within the UK, and in particular the EU, means that manufacturers must ensure their supply chains are sufficiently agile and transparent to respond to the risk of regulatory requirements. In the U.S., PFAS-related civil litigation has resulted from the contamination of water supplies during the manufacture of PFAS, as well as damages being sought against companies that produce products containing PFAS, including clothing items that are marketed as sustainable and non-toxic but in fact contain PFAS. We are now seeing these product litigation trends grow within Europe.

Those companies who are able to proactively develop and/or source alternative chemicals or processes to replace PFAS within their supply chain are likely to be at a competitive advantage as regulations continue to tighten and consumer scrutiny increases.

Child safety

We've also seen an increase in the number of product safety alerts issued by the EU Safety Gate (formerly known as RAPEX) and the UK Office for Product Safety and Standards on children's clothing that have led to recalls, replacement, withdrawals, and bans on the sale of certain products. A number of these incidents have led to high-profile adverse publicity reporting on the risk to children of strangulation, drowning, entrapment, choking, and inflammability.

The current UK General Product Safety Regulation and the EU General Product Safety Directive require, as part of assessing the safety of a product, that a 'safe product' should take into account the risk posed to children when using the product.

The proposed EU General Product Safety Regulation (EU GPSR)

On 30 March 2023, the European Parliament voted in favour of a resolution to formally adopt the new EU GPSR. As part of its press release, the European Parliament reiterated the express requirement for the new EU GPSR to take into account the risks for vulnerable consumers, such as children, during safety assessments.

Indeed, the adopted wording of the new EU GPSR confirms that the safety of products, including clothing, should be assessed considering their characteristics and presentations, as well as specific risks for categories of consumers who are likely to use the products, such as children. Notably, this extends to assessing the safety of products that may not ordinarily be designed for or marketed to children but may have certain qualities within its design, packaging and/or characteristics that would appeal to them.

Looking ahead

The European Council moved to adopt the EU GPSR on 25 April 2023, putting into motion the 18-month transition period for businesses and regulatory authorities to comply with the new rules. With the EU GPSR adopted and other new regulations, including the potential to ban the destruction of unsold apparel, impacting the clothing sector expected soon, 2023 is shaping up to be a busy – and challenging – year for business.

CONCLUSION

Despite having different regulatory regimes, regulators in both the EU and the UK are addressing similar issues including clinical trial and medical device reforms, and aligning good environmental practices with consumer protection and business innovation.

A proposed restriction on perfluoroalkyl and polyfluoroalkyl substances (PFAS) in the EU has the potential to significantly impact companies across multiple industries from performance clothing and baby products to kitchen goods and furniture. It could also result in more class action lawsuits, which are already on the rise in the UK and EU.

With all the unknowns, companies will need to plan for risks across a variety of areas, including the following:

- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades, and warranty work
- Product recalls and market withdrawals
- Data privacy and cybersecurity issues
- Innovation and advancements in technology
- Dynamic consumer demand
- Customer and partner apprehension

No business likes to admit that they will eventually face a recall. But many regulatory agencies recommend, even mandate, that companies have recall, remediation, and/or risk management plans in place as part of their standard business processes. Thus, when the inevitable does occur, you can better protect your consumers, brand, and bottom-line.

Working with an expert partner to leverage their experience and insights can save millions of dollars in regulatory and litigation costs, as well as time and stress on other internal resources. In addition, their expertise will help you honour your commitments to customers, supply chain partners, industry groups, and regulators, while protecting your reputation among the stakeholders that matter most.

ABOUT SEDGWICK BRAND PROTECTION

At Sedgwick brand protection we are in-market risk experts. We are problem solvers. We protect businesses, their customers and our environment through best practice recall, remediation and retention solutions.

Trusted by the world's leading brands and businesses, we work in partnership to manage the risks and minimize the impacts of in-market business and product crises.

When your reputation is on the line, we put our 25+ years of global experience on 5,000+ recalls affecting 500MM+ units to work for YOU. No one knows more about the recall and regulatory process than we do.

Through that lens, we've seen industries evolve based on changing legislation, advancements in technology, shifts in consumer preferences and behaviors and the growing complexities brought about by the transformation of supply chains.

We haven't just watched this evolution. We've been part of it. We've helped companies around the world prepare for and adapt during some of the most challenging events in their history.

While this index gives a roadmap for expected changes ahead, our experience means that there is nothing we haven't seen or dealt with before. In fact, it's often that these events, even those that feel devastating to companies experiencing them, that offer opportunities to demonstrate trustworthiness and to build greater customer loyalty when done well.

Sedgwick's extensive brand protection resources, combined with our unmatched experience handling thousands of recall events, give us a unique perspective on the risks, challenges and often overlooked opportunities associated with the reputational threats you face every day.

In an increasingly complex and regulated world, being prepared for risks is essential. Having the capabilities to act quickly and effectively is critical. Let us leverage our capabilities for you.

To find out more about our product recall capabilities, contact us today.

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