RECALL INDEX
2021 EDITION 3

PRODUCT RECALL
EUROPEAN EDITION

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

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The Sedgwick brand protection Recall Index is an essential reference for manufacturers and retailers seeking impartial and reliable perspectives on past, present, and future recall data and product safety trends.

This edition brings you data from the first nine months of the year, as well as expert analysis and predictions for what to expect as we head into 2022 as business leaders and regulators prepare to emerge from a global pandemic that changed the regulatory landscape, political climate, market drivers, and consumer behaviour.

As we all know, the current global pandemic will continue to impact all industries. The magnitude of that impact remains unknown, however, some industries – particularly those with global supply chains and a heavy reliance on efficient manufacturing – will feel the effects more than others.

There has never been a more important time for industries to be primed and ready for recalls, market withdrawals, and reputational attacks, and the information in this report can serve as your guide to ensure you are prepared.

We trust you will find our analysis and predictions insightful. Whether you read it cover-to-cover or focus on sections of particular importance to your company or industry, you're sure to learn a great deal about what is happening today and what is likely to happen next that will impact your business.

As a reminder, this edition of the Sedgwick brand protection Recall Index focuses on European recall data and regulatory developments. If your business also includes operations outside of Europe, we encourage you to review our U.S. edition. Like this report, our U.S. edition shares and analyses data from the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the U.S. Department of Agriculture (USDA), providing businesses with insights and guidance they cannot find elsewhere:

US edition available here: click here

In addition, if you would like more information about what we have observed in recent quarters, you can find previous editions on our website:

Q2 2021 European Recall Index: click here

Q1 2021 European Recall Index: click here

Q4 2020 European Recall Index: click here

Q3 2020 European Recall Index: click here


EXPRESS

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AUTOMOTIVE

The challenges facing the global automotive market are unprecedented. Vehicle manufacturers and Original Equipment Manufacturers (OEMs) around the world are navigating a global shift to electrified vehicles, increasing consumer demand for new technology and strict environmental standards. Yet even among these evolutions, recall activity is a reminder that long-standing recall risks are not replaced by innovations and technologies. Instead, the list is growing longer and more complex as each new feature comes to market.

> *While some EV fires have been linked directly to battery defects, others still generate questions about the role of software, EV chargers, and consumer charging practices."*

> *“From supply chain networks to production processes to the product itself – the automotive industry will have to respond to many emerging risks to make the transition to electric vehicles happen.”*

Safety and reputational risks facing the EV category

Over the course of the last year, one of the most reported challenges facing the Electric Vehicle (EV) sector is fires linked to lithium-ion batteries. While some fires have been linked directly to battery defects, others still generate questions about the role of software, EV chargers, and consumer charging practices.

But these aren't the only risks. Multiple issues continue to influence the adoption of EVs, from battery recalls and loss of power, to questions about driving range and infrastructure to support significant increases in adoption. From a consumer standpoint, the common threads running through all of these are risk and uncertainty.

"From supply chain networks to production processes to the product itself – the automotive industry will have to respond to many emerging risks to make the transition to electric vehicles happen," says Daphne Ricken, Senior Underwriter Liability at global insurance company Allianz Global Corporate & Specialty (AGCS). "The anticipated growth of electric cars brings the prospect of new defect or performance issues, more expensive repair costs, new fire and cyber threats, and even reputational issues around sustainable sourcing and disposal of critical components and raw materials for batteries."

Then there's the added pressure and scrutiny from lawmakers and regulators – particularly in response to existing and still unknown safety risk. The EV industry has a tough road ahead, and any number of safety or reputational risks can impact the entire category.

Hybrid vehicles on the way out?

EV and hybrid or fossil-fuel alternative vehicles are in high demand as the EU seeks to combat global warming. In fact, Euronews reports that "almost one in five vehicles sold in the European Union was an electric model during the third quarter." In addition, the European Automobile Manufacturers' Association (ACEA) said hybrid electric passenger cars accounted for 20 percent of third-quarter vehicle registrations, making the powertrain option the second most popular in the EU.

Still, a European Commission proposal calling for only zero-emission cars to be sold after 2035 is creating significant uncertainty to the future of hybrid vehicles despite the increasing demand. As the EU and its member states set deadlines to phase out fossil-fuel cars, automakers would be wise to continue exploring hybrid vehicles and other alternative fuel options, particularly as EVs face continued infrastructure and safety-related challenges.

Autonomous driving

Consumers want to see automakers make more advanced driver-assistance systems (ADAS) and other technological innovations available in their current and upcoming models. But this move is not without risk as ADAS receives scrutiny from regulators around the world.

In the US, the National Highway Traffic Safety Administration has launched investigations into manufacturer statements about driver assistance and self-driving technology. NHTSA's primary investigation into ADAS currently appears focused on a single automaker, but the truth is the impact may even be in the EU and UK.

In 2022, the European Commission is expected to consider changes to regulatory frameworks to incorporate safety risks associated with advanced driver-assistance systems and autonomous driving capabilities.

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Greenwashing allegations

A company's sustainability and eco-friendliness plays an increasingly influential role in consumer decision-making. In response, the UK Competition and Markets Authority (CMA) published a new Green Claims Code in September 2021 that focuses on the entire product or service lifecycle. With that in place, the CMA disclosed that a "full review" of misleading sustainability and environmental claims will commence in 2022.

But don't expect the CMA to sit and wait. There is already precedent that corporate greenwashing will result in enforcement action. White & Case notes that "the European Commission has a number of ongoing initiatives to tackle greenwashing, including the European Green Deal, the 2020 Circular Economy action plan, a legislative proposal to empower consumers for the green transition, and a legislative proposal on the substantiation of green claims." Within the context of these initiatives, the Directorate-General for Competition has fined companies for such activities in trucks and car emissions cases.

Businesses would be wise to use the coming months to check their own environmental and sustainability claims for compliance.

Environmental standards leading to recalls

Beyond greenwashing allegations, the European Commission's commitment to enforcing automotive emissions standards is progressing and will ultimately take the form of more recalls. Expect an increase in the coming months in response to the Commission's recently expanded authority to recall vehicles across the entire 27-country bloc if they breach EU emissions limits. But the recall risk isn't the only threat.

The new rules allow the Commission to revoke a vehicle's certification for roadworthiness for breach of EU emissions limits. There are also the financial implications and legal risks that follow. Not just in terms of fines for non-compliance. But if the Commission would take the drastic steps of revoking a vehicle's certification, it opens the door to compensation claims from owners of impacted vehicles.

In fact, while these rules officially came into effect in late August, we may already be seeing the impact as recalls for environmental reasons increased in the third quarter.

Innovation in repair and recall management

Automotive repairs, remediations, and recalls can impact the entire supply chain – from component manufacturers all the way to the consumer. The implications range from loss of reputation to significant, and potentially company-ending, financial loss. Some of those losses have to do with the challenge associated with completing the repair.

That's where connected vehicles are driving innovation far beyond in-vehicle features. Consider vehicles that need a software upgrade or fix. These days the update can often be pushed out to the consumer without the need to visit a dealer or independent mechanic. This type of repair can result in high completion rates in a short amount of time. While not every repair can be conducted as easily, the process has the potential to inspire repair and recall management enhancements and innovations for the better.

For vehicle owners who live far from the nearest dealer location, taking their vehicle in for a repair can be an inconvenience and easily put off, or worse, disregarded completely. Making repairs more convenient helps raise completion rates while also supporting dealers by managing capacity challenges.

> *"Beyond greenwashing allegations, the European Commission's commitment to enforcing automotive emissions standards is progressing and will ultimately take the form of more recalls."*

THIRD QUARTER OVERVIEW

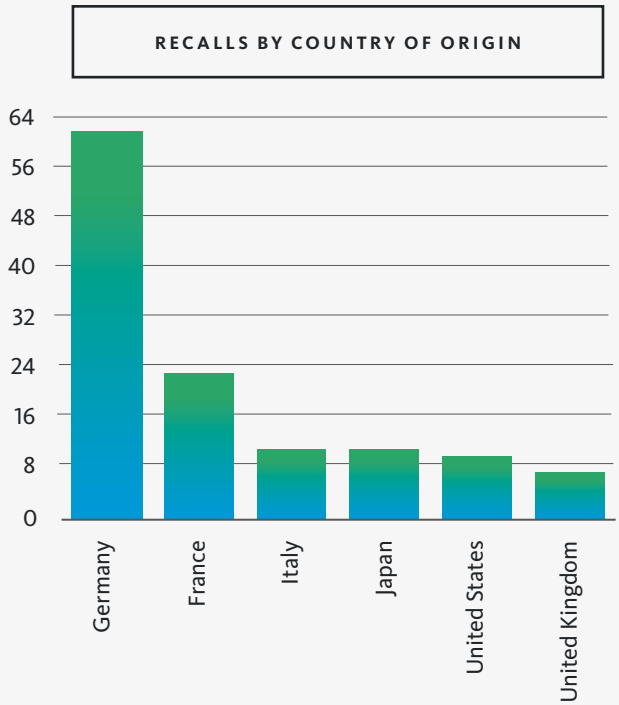
Automotive recalls returned to first quarter activity with 152 recalls in the third quarter. While this activity represents a 14 percent decrease quarter-over-quarter, 2021 quarterly recall volumes remain higher than the last pre-pandemic quarter (Q1 2020) which saw 133 recall events. This signals that recall events remain high despite decreased demand and ongoing supply chain, policy, and pandemic-related challenges.

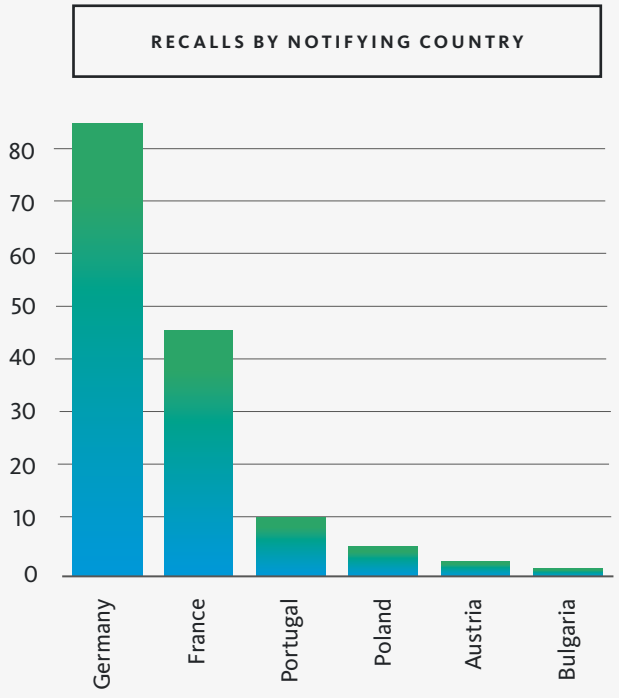
Germany continued to lead in terms of notifications, submitting 84 recall alerts or 55.3 percent of all recalls. France was responsible for the second most notifications (46), followed by Portugal (10), and Poland (5).

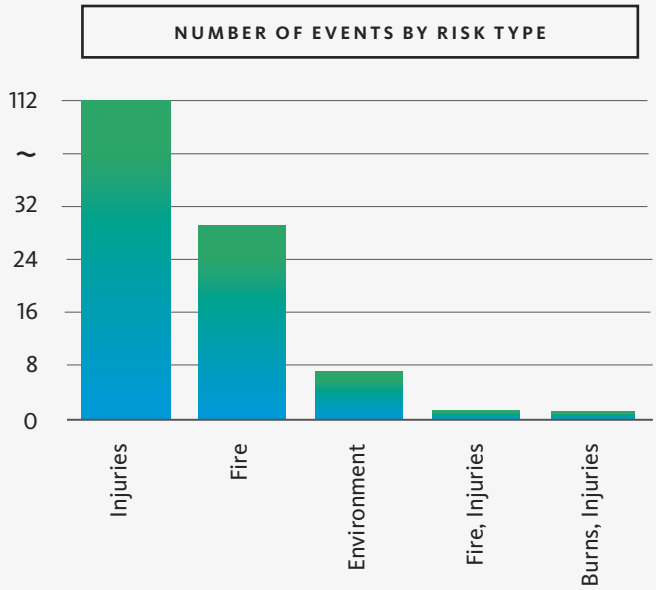
Germany was also the leading country of origin for second quarter recalls with 61 recalls or 40.1 percent of events. France was the second most frequent country of origin at 23 recalls, followed by Italy (10), and Japan (10).

Consistent with previous quarters, injuries remained the leading risk associated with automotive recalls, accounting for 112 recalls or 73.7 percent of notifications. The next most common risk types were fire and environment-related issues, cited in 29 and 7 recalls respectively.

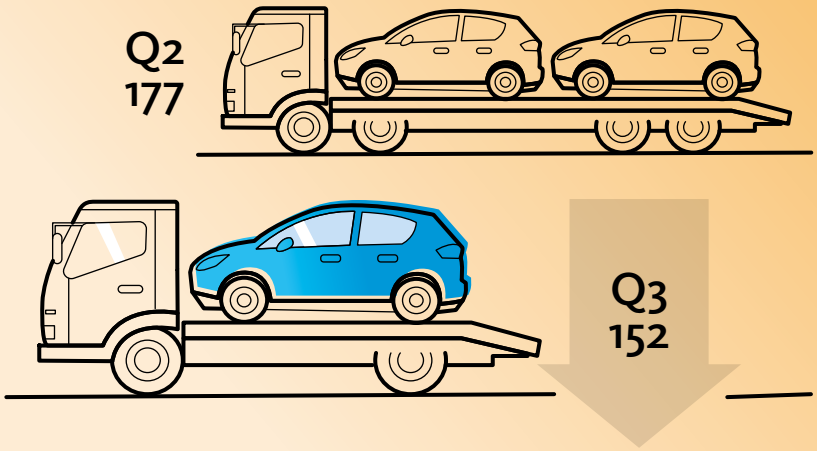
Of all third-quarter recalls, 69.1 percent (105 recalls) impacted passenger cars. Passenger vans and light commercial vehicles were the second most-impacted category with 13 recalls, followed by motorcycles with 8 recalls.



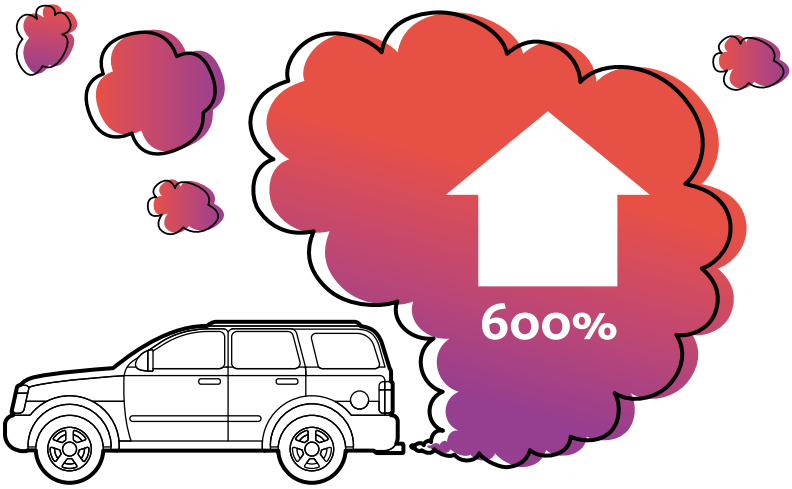




At 152 events, Q3 recalls **declined 14.1%** from Q2 at 177.



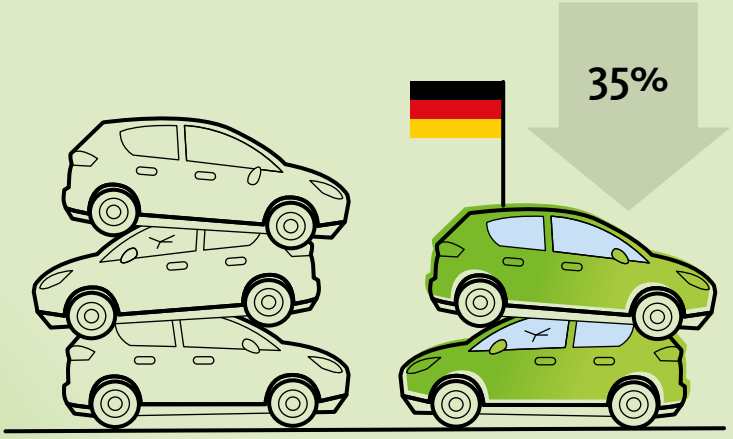
Despite this drop, Q3 recall events remain 141% above the quarterly average for the last 15 years.



While representing just 7 events, **Environmental concerns surged** by 600% from Q2.

This is the highest incident rate recorded YTD, and equal to all Environmental incidents reported in 2020.

While **Germany** remained the highest notifying country, alerts submitted fell by over a third (35%).



In contrast, notifications made by France more than doubled in Q3 from 19 to 46.

LEO FIELDING, SENIOR ASSOCIATE,
SHOOK, HARDY & BACON INTERNATIONAL LLP

WITH NEW INNOVATIVE FEATURES COME NEW RISKS, NEW REGULATION FOR AUTO INDUSTRY

From July 2022, Regulation (EU) 2019/2144 will require manufacturers to implement new safety measures in cars, including features to warn of driver drowsiness and distraction (e.g., smartphone use), intelligent speed assistance, and use of cameras or sensors to help drivers reverse their vehicles safely.

Whilst advancements in these areas will undoubtedly improve consumer safety in the long run, manufacturers must nevertheless remain alert to the challenges of commercialising products with increasing technical complexity. From a risk assessment perspective, many of the features that are required to be integrated – such as advanced emergency braking and lane keeping assistance – have the potential to affect control of the vehicle, creating potential risk to occupants and pedestrians if a safety defect arises.

Furthermore, the addition of such features will inevitably mean the inclusion of a greater number of third-party vendor components in the end-product (e.g., sensors and related electronics). National authorities may need increasingly detailed explanations from manufacturers in order to understand how such third-party components interact with one another in order to determine whether a safety defect in one component was, or contributed to, the root cause of the reported issue. To this end, numerous third parties may need to be involved in the investigation once the potential safety defect is better understood.

As investigation of reported issues in these circumstances is likely to prove increasingly complex – and time-consuming. In addition, the initial investigation by the manufacturer may become more challenging. For example, in the UK, the Driver and Vehicle Standards Agency (DVSA) guidance recommends that automakers keep the DVSA updated on the progress of investigation into potential issues, normally providing evidential and statistical information within 28 days. As such deadlines become increasingly challenging to meet - due to the length of the investigation required and/or the need to involve third-party vendors - working with the relevant national authority to manage expectations will be of paramount importance.

Impact of Brexit on UK vehicle recall reporting

Since leaving the EU and reaching the end of the Brexit transition period, there is no longer a requirement for UK authorities to notify EU authorities, or vice versa, about automotive safety issues via RAPEX. In addition, the UK government's Product Safety Database, which issues weekly reports on unsafe products supplied within the UK market, does not extend to motor vehicles. Whilst it is straightforward to check if a vehicle supplied in the UK is subject to a safety recall via the website of the DVSA – the UK authority responsible for product safety in the automotive sector – it is first necessary to know either the registration number of the vehicle, or the manufacturer, model and year of manufacture. It will be interesting to see in due course whether the DVSA will add additional features on its website to enhance recall communication (e.g. a weekly reports function covering vehicle safety issues following the model of the RAPEX weekly report).

Opportunities to address safety issues presented by autonomous driving

In 2022, there will be a number of opportunities for the European Commission to consider the implications of autonomous driving capabilities, whether in the context of the proposed Digital Services Act, the proposed Artificial Intelligence Act, or the revision of the General Product Safety Directive (GPSD). In the U.S., there have been reports of increased regulatory and political scrutiny of manufacturer statements about the autonomous driving capabilities offered by certain vehicles. Criticism has focused on concerns that overstated claims by automakers – for example, implying that driver assistance systems offer full autonomy – may give drivers a false sense of security in a vehicle's capabilities. With this comes the risk of potentially altering driver behavior in a way that could put other road users at risk. It will be interesting to see whether the Commission will take its cue from the debate taking place in the U.S. and come forward with its own measures regarding driver adaptation and, if so, which of the legislative proposals listed previously will be used to address the issue.

Remote vehicle updates

As the connectivity of vehicles continues to improve, component manufacturers will increasingly have the ability to monitor and update software remotely. Whilst this remote monitoring and repair capability is undoubtedly convenient for dealers and consumers from a recall implementation perspective, it can also create more safety issues long after the product was first placed on the market. As the GPSD also requires manufacturers to monitor the safety of their products after they have been placed on the market, and to take "appropriate action" if a safety issue arises, automakers will be watching to see the extent to which increased use of over-the-air updates may impact the cost of their market surveillance.

Vehicle-to-Vehicle (V2V) and Vehicle-to-Infrastructure (V2I) technology

Innovative Original Equipment Manufacturers (OEMs) are transforming how our vehicles connect with their surroundings. The development of V2V and V2I technologies – which will enable cars to communicate with other cars and surrounding infrastructure such as traffic signs – is expected to play an important role in improving road safety. As vehicles begin to communicate more frequently with the outside world, their functions are also likely to become increasingly dependent upon connectivity. These features are likely to require the use of Wi-Fi and cellular networks that may be subject to coverage, reception, environmental interruption, or similar issues. They are also likely to involve interaction with software located in the Cloud and/or installed on third-party smart devices, which may be subject to potential security vulnerabilities. We anticipate that national authorities will be watching closely to see how technologies such as V2V and V2I can be deployed in vehicle applications without exposing consumers to excessive risk.

Regulators are definitely focused on consumer safety and recognize how vehicles are driven and powered is changing. Manufacturers may have some challenges working to adapt to all the new requirements, but the goal of safer roads is worth working towards.

“Companies need to evaluate not only the supplier’s food safety culture and compliance record, but also the ingredient quality and safety risks.”

FOOD AND BEVERAGE

The food industry faces a growing number of challenges from supply chain disruptions and labor shortages, to an increasing number of laws and directives addressing a broad swathe of food safety concerns, including environmental issues. Making matters worse, food safety risks and recalls are only becoming more prevalent, putting more risks on brands than we have seen in recent history. Companies need to prepare now for any number of risks facing the brand, whether regulatory, legal, operational, or reputational in nature.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Safety risks created by supply chain challenges

As consumer stay-at-home guidance is lifted, restaurants open, and events return, demand for food rapidly increased, putting immense burden on the global food supply chain. But the resulting challenges are larger than product shortages and supply chain delays. The biggest threats to the industry are traditional food safety risks.

Consumers will see some of these challenges play out in the form of reduced variety or, worst case, empty shelves. These effects are in part because fresh or finished goods get caught in transit and don't make it to the market. But they are also an indication that food manufacturers cannot obtain the ingredients they need, triggering an unprecedented number of substitutions across the industry.

As companies scramble to find new suppliers, it will be important that risk assessments are not cut short. Companies need to evaluate not only the supplier's food safety culture and compliance record, but also the ingredient quality and safety risks. That includes less clear-cut analyses, like whether the ingredient has a cross-contamination risk that could put your final product over the allergen labelling requirements. Would you take the risk or invest in a new label? Too often when companies rush to get a product to market, something gets overlooked. When that happens, the potential for future recalls and enforcement increases.

Ethylene oxide, irradiation, and food safety

Every few years, a calendar year earns itself a recall-related designation. Last year (2020) was one of those years in the EU. After the Rapid Alert System for Food and Feed issued its Annual Report for 2020, media in September called 2020 the year of the ethylene oxide scandal.

The headlines seized upon the finding that pesticide-related recalls of products originating from EU member countries rose 492% in 2020, citing 166 notifications for the year. On top of that, 667 notifications covered products that originated from non-EU member countries. About half of those recalls cited Ethylene Oxide as the hazardous substance putting consumers at risk.

While the Annual Report provides some helpful historical insight and context, understand the problem is far from over. The pesticide and ethylene oxide recall designations for 2020 are not purely historical risks or phenomena. These risks continue to drive significant recall volume today. The data proves it.

But even more remarkable is that the food industry appears hesitant, if not unwilling, to utilize a safer alternative to ethylene oxide as a tool for reducing or eliminating bacterial contamination: irradiation. The process of food irradiation is viewed by regulators as a safe way to preserve food, reduce waste and eliminate bacteria that may lead to food poisoning. One of the reasons is likely that the EU requires companies that irradiate their food to label it accordingly. So, because consumers are reluctant about the process, and can differentiate between products due to the labelling requirement, a regulatory or legislative shift is unlikely to have a measurable impact on food safety and recalls.

Food and the environment

Consumer demand for environmentally friendly products is increasing across all product categories. At the same time, regulators are putting more pressure on companies to reduce their environmental impact. As food and beverage companies publicise environmental-impact product claims to both stakeholders, it will be important that facts are made crystal clear.

Why? A multi-pronged crackdown underway on greenwashing – the act of making misleading claims about the environmental impact of a product.

The Competitions and Markets Authority (CMA) in the UK recently issued a Green Claims Code to ensure that environmental claims are clear, unambiguous, and accurate. According to Food Navigator, businesses technically have until 1 January 2022 to ensure their green claims comply with the new code, at which point companies that are found to make misleading claims will face enforcement. But companies should expedite their green claims review as experts at Gibson Dunn warn that the CMA "is not required to wait until January 2022 to take action, and has noted that where there is evidence of breaches of consumer law, it may take action before the start of the formal review."

On a parallel track, the UK's Environment Agency launched a project to standardise the way food and beverage companies measure their environmental performance. The agency notes that the effort is designed to "help manufacturers to more effectively communicate their environmental performance to the public, minimizing the opportunity for green washing."

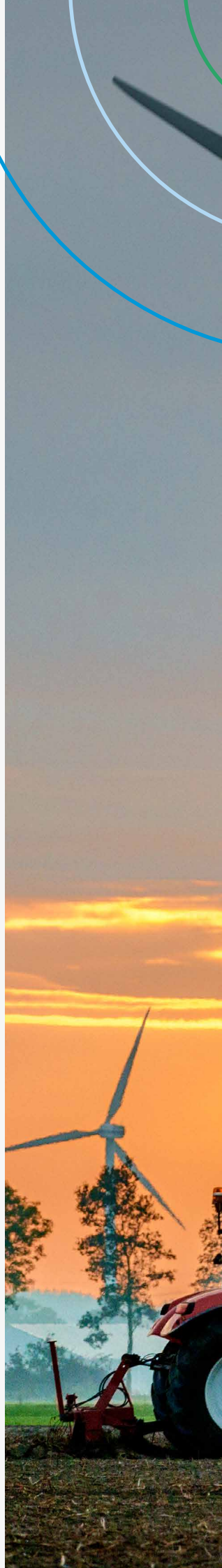
Meanwhile in the EU, the European Commission is expected to propose new regulation to remove misleading claims from the market as it urges greener food production.

As these initiatives get underway, food and drink companies should make a concerted effort to review product labelling and marketing claims, and to ensure environmental and sustainability claims are accurate and compliant with current, and expected, regulatory guidance.

A transatlantic "food fight"

When it comes to feeding a growing population, many believe that any plan to increase food production is a good strategy. But it turns out that the EU and U.S. have very different approaches in mind. The EU's Farm to Fork strategy seeks to prioritize sustainability by promoting organic food production and cutting pesticide use in half by 2030. Across the Atlantic, however, the U.S. contends this approach "will reduce crop yields, push up food prices and threaten food security," according to POLITICO. In fact, the U.S. Department of Agriculture "released economic models saying world food production would drop by 11 percent and prices would shoot up 89 percent if all countries followed the European model."

These conversations about food security are, by nature, forward-looking. But the disagreements mean more than uncertainty in future food security. New EU food standards could lead to barriers to trade, creating supply chain challenges and disruptions in the current markets. For example, France next year will consider whether to put restrictions in place on imports coming from countries that have different standards or positions on agrichemicals in food production.



> *The pesticide and ethylene oxide recall designations for 2020 are not purely historical risks or phenomena. These risks continue to drive significant recall volume today."*

THIRD QUARTER OVERVIEW

EU data collected from the Rapid Alert System for Food and Feed (RASFF) in the food & beverage category show that recalls continue their gradual return to pre-pandemic levels. Recalls continued to rise, from 1,120 recalls in the second quarter to 1,178 recalls in the third quarter.

Consistent with the second quarter, the leading cause of food and beverage recalls is contamination (other than bacterial), representing 441 events or 37.4 percent of recalls. This includes a variety of contaminants, the most common of which were Ethylene Oxide (150), Aflatoxins (80) and Chlorpyrifos (44).

Bacterial contamination logged 244 recalls, making it the second most common reason for third quarter recalls. Of these recalls, 170 were due to Salmonella concerns, followed by Listeria (29) and E. coli (25).

Unauthorized substances was the third-leading cause with 161 recalls.

The top two product categories impacted by recalls remained consistent with the second quarter. Fruits and vegetables were the most impacted product category with 137 recalls (11.6 percent), followed by nuts, nut products and seeds at 105 recalls.

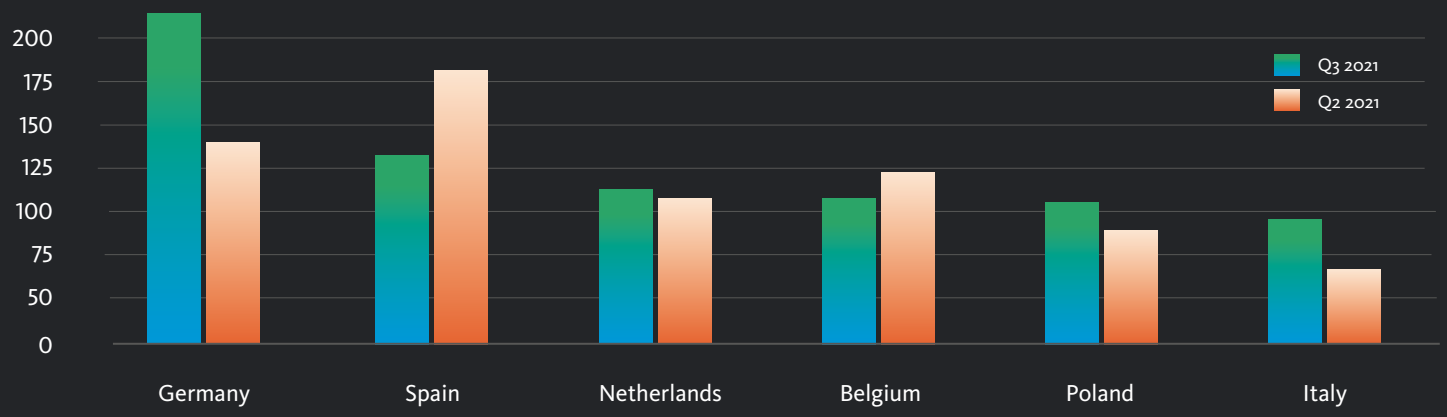
The most common reasons for Fruit and vegetable recalls were contamination (other than bacterial) (65) and unauthorized substances (31). Chlorpyrifos was the leading contaminant (22) followed by Aflatoxins (5). The leading unauthorized substances impacting fruit and vegetables were Paraffin coating (12).

In the case of both fruit and vegetables, and nuts, nut products and seeds recalls, the recall was most likely to take the form of a border rejection notification. This type of notification accounted for 64 fruit and vegetables recalls (46.7 percent) and 81 nuts, nut products and seeds recalls (77.1 percent). By comparison, border rejection notifications accounted for 299 of all third quarter notifications (25.4 percent).

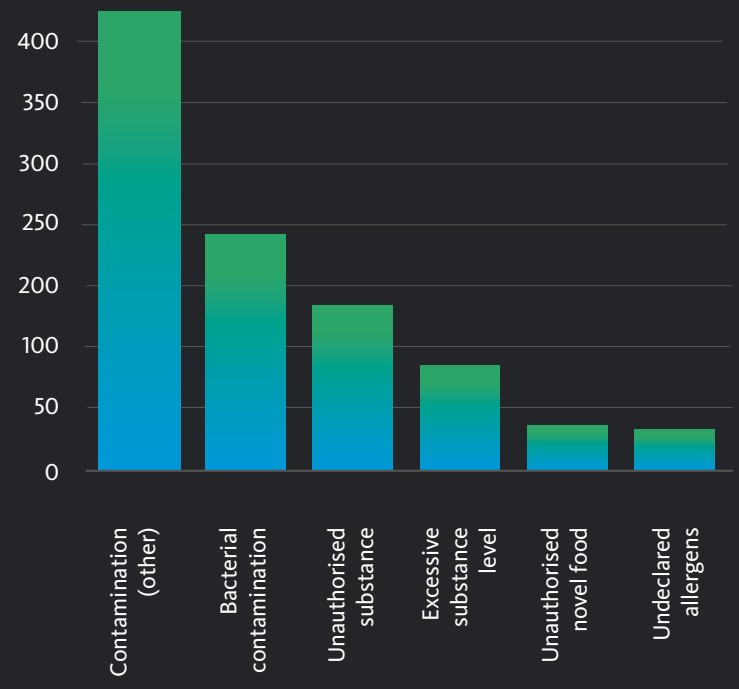
Rounding out the top five product categories impacted by recalls were dietetic foods, food supplements and fortified foods (101), poultry meat and poultry meat products (100), and herbs and spices (85).

Germany was the top notifying country in the second quarter (230), followed by Spain (129), the Netherlands (111), Belgium (106) and Poland (105).

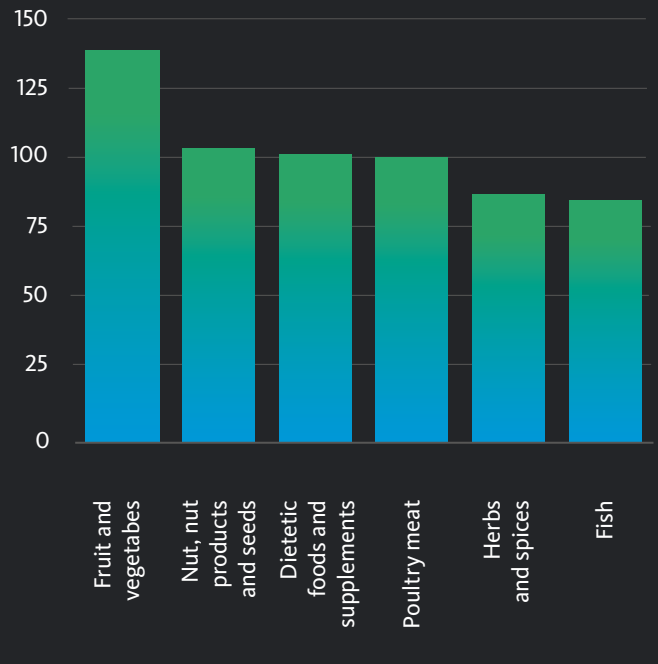
RECALLS BY NOTIFYING COUNTRY



RECALL EVENTS BY CATEGORY

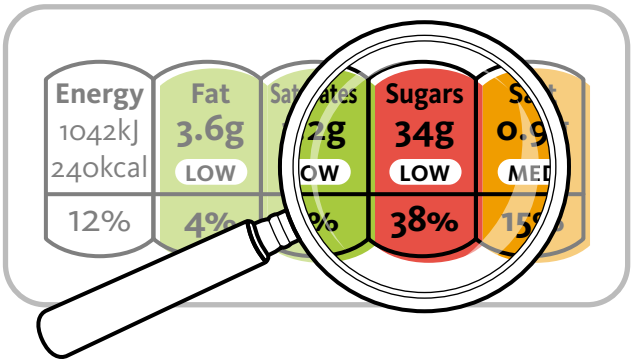


RECALL EVENTS BY PRODUCT TYPE



At 1,178 events, **Q3 recalls increased** for the third consecutive month.

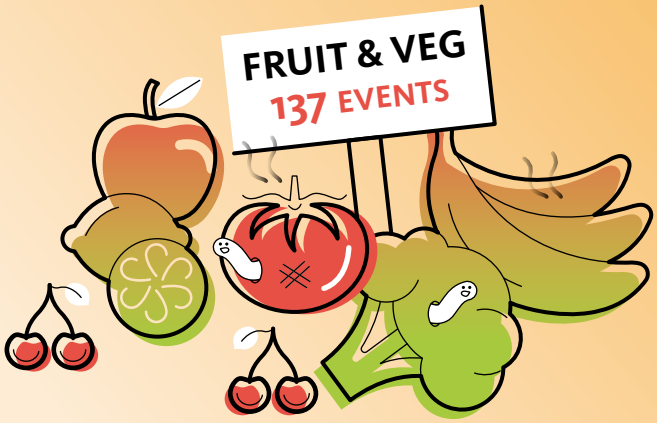
Continuing at this pace, 2021 is on-track to exceed 4,500 events. For context, the highest number of recalls recorded in a given year was 4,001 (in 2019).



Packaging & Mislabelling defects recorded the largest increases in Q3 recalls (433% and 57% respectively).

Contamination (other than bacterial) was the leading cause with 441 recalls, followed by Bacterial contamination (244), and Unauthorised substances (161).

Accounting for 137 events, **Fruit and vegetables** remains the top recalled product.



At this rate, Fruit and vegetables are firmly on track to end the reign of Nuts, nut products and seeds, which have dominated the recall charts for the last 2 years.

NICOLA A. SMITH, DIRECTOR,
SQUIRE PATTON BOGGS (UK) LLP

SPOTLIGHT ON THE BIGGEST FOOD SAFETY CHALLENGES OF TODAY AND TOMORROW

Food safety risks are becoming more prevalent as global supply chain and labour challenges, increased oversight and tougher regulation have the potential to create a chain reaction where a single recall can impact numerous manufacturers, brands and countries, causing reputational damage and large financial losses. We are likely to see more recalls - and at a larger scale - in the future as the strain on supply chains grows and legislation evolves.

Supply chain and labour challenges

Complex global supply chains, logistics issues and labour shortages have made getting the right products, to the right place, at the right time, incredibly difficult. With disruptions ranging from Brexit, to the pandemic, to blockages of shipping routes, cross-border checks creating delays, and political challenges, the disruption itself is only half the story. Companies need to be aware of the threats these issues pose to food safety.

For example, ingredient shortages may lead to substitutions, which in turn could impact on the accuracy of ingredient and allergen labelling. Delays in the supply chain may lead to deterioration of products and affect shelf-life, particularly if cold chains are not properly maintained.

At the same time, labour and skills shortages are having a compounding effect on food safety risks. The Food and Drink Federation published a report in August 2021 detailing the consequences of labour and skills shortages across the food chain. Among the risks are reduced choice and availability for consumers, increased prices, and reduced growth of the domestic food chain. Staff shortages and a reliance on temporary or agency staff may also mean that a greater proportion of the workforce have not received full food safety training, potentially putting product quality and safety at risk.

Brexit challenges remain and more are to come

The UK's timetable for businesses to implement post-Brexit steps when importing products of animal origin, has been pushed back to 2022. From 1 January 2022, businesses will be required to pre-notify authorities via the UK's Import of products, animals, food and feed system (IPAFFS) that their consignment will be entering Great Britain. From 1 July 2022 businesses will still need to ensure the arrival of animal products is pre-notified via

IPAFFS. In addition, consignments must be accompanied by a certified Export Health Certificate and enter via a point of entry with a Border Control Post (BCP) that has been designated to receive these goods. Consignments will also be subject to documentary, ID and physical checks; and businesses must ensure they are ready for these changes.

Looking further ahead, the requirement for a UK name and address on food and drink products exported from the EU will also kick in on 1 October 2022. From this date, pre-packaged food or caseins sold in Great Britain must include the name and address of a food business operator (FBO) established in the UK. If the FBO producing the product is not in the UK, the address of an importer, based in the UK, will be required.

There were no equivalent grace periods in the EU, so checks and additional documentation are already being required for products imported into the EU from Great Britain, and an EU (or Northern Ireland) name and address is required to be given for the FBO. The named FBO will have responsibility for compliance of the food and drink products with EU laws.

Procedures and agreements with suppliers may need to be adapted to reflect the additional obligations on distributors which have become 'importers' following Brexit (on both sides of the border).

It is possible that there may be divergence between legal requirements and minimum standards in the EU and those in Great Britain in future. The Trade and Co-Operation Agreement reached when the transition period ended did not require alignment of standards (except in the case of Northern Ireland, because of the effect of the Northern Ireland Protocol). We would not envisage any short-term changes to food safety standards in the UK, because the UK helped to develop the safety standards that apply in the EU. However, Lord Frost's statement to the House of Lords on 16 September 2021 indicated that the government is intending to critically review all retained law, so divergence is not impossible. If standards do diverge, this could have a detrimental impact on the levels of trade between the EU and the UK- and may contribute further to existing supply chain challenges.

Labelling is a hot topic

In addition to the business and market-driven challenges, there is a renewed focus on legislation governing product labelling and marketing requirements.

One such piece of legislation is the EU-wide 'dual quality' Directive. The intent of this legislation is to effectively blacklist products that are marketed in different countries identically front-of-pack, but are 'significantly different' in composition or characteristics. There are some exceptions, for example, where composition is different to ensure compliance with local legal requirements (such as beer purity laws in Germany). Member States have until November 2021 to publish their measures to comply with this Directive.

It is also possible that there will be a uniform front-of-pack labelling system for nutrition across the EU by the end of 2022. There are numerous front-of-pack systems used currently; and we have yet to see if there will be a compromise or mutual agreement on which to use. Press reports earlier this year indicated that the labelling framework most likely to get the nod from the Commission would be the colour-coded Nutri-Score, developed and backed by France. However, there have also been reports that Italy would ban products with the French Nutri-Score, because its system for categorizing nutritional value is seen as penalising some of the core products of the Mediterranean diet. In any event, it is not clear who would control the correct Nutri-Score labelling outside France.

Companies should undertake a thorough review of product labelling and marketing claims to ensure compliance with latest laws and guidance on 'dual quality', 'greenwashing', allergens and ingredients, then make revisions as necessary. In doing so, it is imperative to consider potential legislative changes in the UK and the EU – with an appreciation that it is possible that requirements could diverge between these markets in future.

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NICOLA A. SMITH, DIRECTOR,
SQUIRE PATTON BOGGS (UK) LLP
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GE and GMOs are back on the agenda

In another legislative development, the regulatory environment for gene editing (GE) and genetically modified organisms (GMOs) may change in the future. The UK's Department for Environment, Food and Rural Affairs (DEFRA) held a consultation on the regulation of genetic technologies in the UK earlier this year, with a focus on the regulation of GE organisms. DEFRA's view is that organisms produced by GE or other genetic technologies should not be regulated as GMOs when they possess genetic changes which could have been introduced by traditional breeding. Retained EU legislation, however, currently requires that all GE organisms are classified as GMOs irrespective of whether they could be produced by traditional breeding methods.

There is a myriad of potential issues involved with this development, but one of the most important is that it may become increasingly difficult for businesses to identify whether a product they are importing is GMO or not, particularly where an EU business imports product from the UK or vice versa. Businesses should be aware of the potential for divergence in the rules on GE and GMOs between the EU and UK, and begin to plan accordingly.

Preparing for current and upcoming challenges

Companies need to have a plan and strategy for addressing ongoing challenges and complying with new legislation and directives. This is especially important for UK businesses navigating continued post-Brexit changes. Set timeframes for compliance that ensure any teething issues can be fixed and full solutions can be implemented in time. This will avoid any further operational disruption and supply chain delays while also limiting any exposure to new risks.

PHARMACEUTICAL

The global pharmaceutical industry continues to face both opportunities and serious challenges related to the ongoing pandemic. While the industry is proving itself a formidable force in protecting consumers from COVID-19, the regulatory and reputational threats show no sign of abating. Even as extensions are granted and leeway is given to drug companies in response to the challenges created by the pandemic, regulators in the EU and the UK are finding time and resources to crack down on safety-related concerns while changing the way stakeholders collaborate and communicate on regulatory oversight activities.

> *"The pharmaceutical e-commerce market in Europe is set to grow by USD 12.81 billion by 2025. That is in a large part because e-commerce has the power to offer patients certain benefits."*

E-commerce boom threatens pharmaceutical supply chain security

E-commerce has long been a disruptor for the consumer product sector, but now its impact is being felt in the pharmaceutical industry – thanks in large part to the pandemic. Putting the impact in numbers, leading research and advisory company Technavio reported that the pharmaceutical e-commerce market in Europe is set to grow by USD 12.81 billion by 2025. That is in a large part because e-commerce has the power to offer patients certain benefits – such as increased accessibility, and greater speed and efficiency for greater speed and efficiency of purchasing.

But it also comes with risks. Among them is the challenges associated with verifying and validating prescription orders and medicines delivered. Another is the proliferation of counterfeit drugs. A third is the risks to your reputation if something goes wrong with a transaction, or global supply is tainted with counterfeits with no easy way to distinguish between products.

Drug companies should evaluate the impact of e-commerce on business on an ongoing basis, whether or not the product manufactured can be sold online. Identify both opportunities and risks associated with this growing distribution channel. It is the first step in effective risk management.

Overhauling drug safety reporting procedures

The European Commission (EC) is consulting on proposals that aim to improve a nearly decade-old regulation on pharmacovigilance activities. As part of this process, four primary proposals for updating the 2012 Implementing Regulation (IR) are on the table – all of which relate to the pharmacovigilance system master file (PSMF) and activities that must be carried out by marketing authorization holders (MAHs).

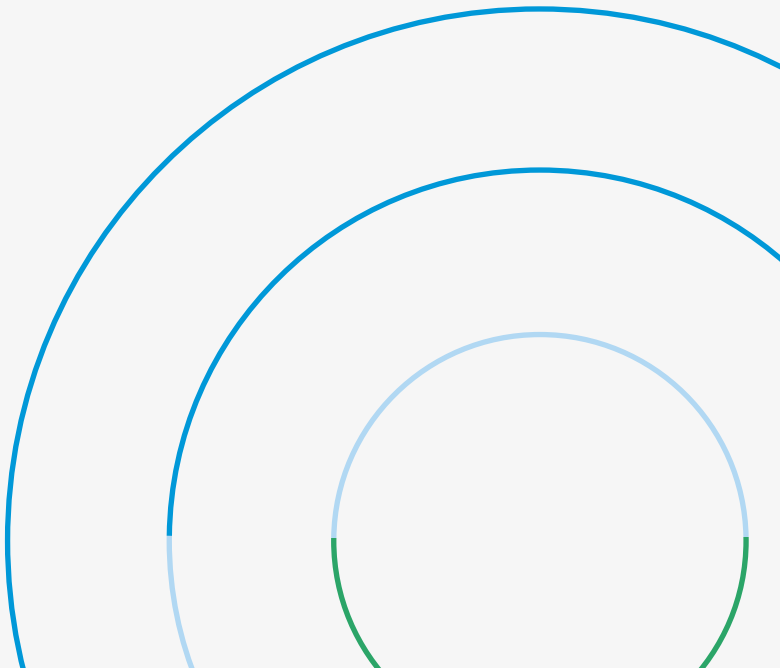
The first proposal relates directly to the PSMF. While the commission acknowledges the "enhanced efficiency and oversight" that came with the introduction of the PSMF, EU inspectors recognize an opportunity to improve the MAH's oversight of third parties responsible for pharmacovigilance activities.

A second proposed enhancement is to, quite simply, bring reporting requirements in line with the latest International Organization for Standardization (ISO) standards.

In addition, the commission is considering revisions that would require all individual case safety reports (ICSRs) and adverse reaction reports to include a "Digital Object Identifier" that can be used to connect data and information for easy access and tabulation.

The last proposal would change the way that post-authorization studies are disclosed, requiring MAHs to submit the study protocol before collecting data, and then disclosing the findings within 30 days of completion.

Whether one or all these proposals are adopted, the impact could increase EC awareness, as well as scrutiny and tracking of adverse effects, thereby leading to more investigations and recalls. Companies would be wise to evaluate these potential changes and start making plans for future compliance or else get caught flat-footed.

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European Medicines Agency's change in good manufacturing (GMP) inspections

The EU recently announced that good manufacturing practice (GMP) and good distribution practice (GDP) certificates will again be extended, this time through 2022.

According to Regulatory Focus, a publication of the Regulatory Affairs Professionals Society, "For sites located in the European Economic Area (EEA), the extensions should occur without any action on the part of the certificate holder, unless there are restrictions on the validity period stated in the clarifying remarks of the certificate. Similarly, the updated notice says that GMP certificates for manufacturing sites of active substances and finished ingredients should be automatically extended through 2022 without the need for any action from the certificate holder."

While no action is reportedly needed to prepare for the GMP certification extension, the EMA recently introduced changes in the way it communicates with drug companies regarding GMP inspections. Specifically, these changes are designed to allow MAHs and inspectorates in the EU and European Economic Area to engage with the EMA for GMP inspections, thereby streamlining the coordination process, allowing for secure information transfer, and improving data quality.

These changes are no surprise as they reflect the trend in increased collaboration across borders that we've discussed previously in the Index, and signal the potential desire for a more collective approach not just to oversight, but also enforcement.

> *"Even as leeway is given to drug companies in response to the challenges created by the pandemic, regulators in the EU and the UK are finding time and resources to crack down on safety-related concerns."*

THIRD QUARTER OVERVIEW

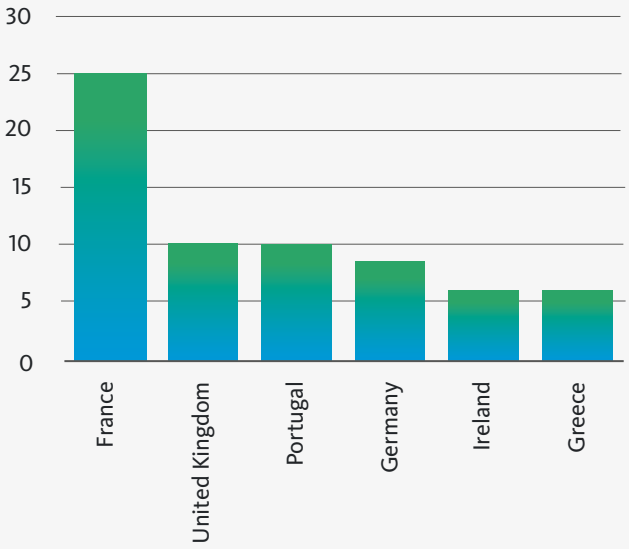
Pharmaceutical recalls dropped 29.2 percent to 75 recalls in the third quarter despite the incremental increases seen in previous quarters.

The most common reason for recall was cited as safety (18), followed by foreign materials and contamination (17) and failed specifications (15).

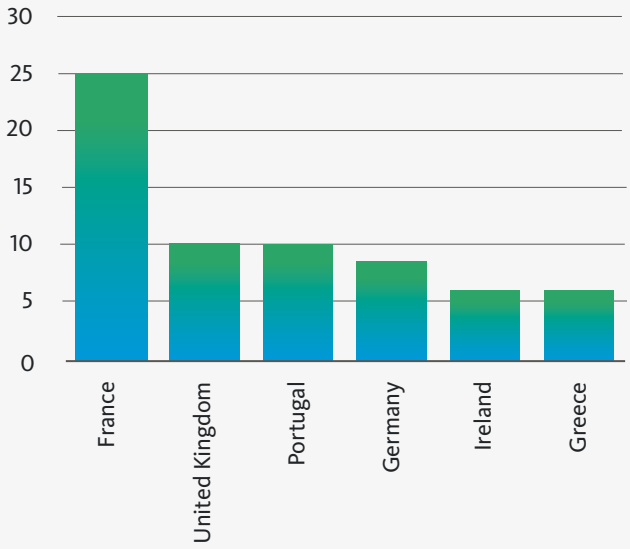
According to the data, pharmaceuticals produced in France continued to be the most likely to be recalled, accounting for one-third (25) of pharmaceutical recalls in the third quarter. This was driven by quality (6), foreign materials and contamination concerns (5), and failed specifications (4). Pharmaceuticals produced in Portugal were the second most likely to be recalled (10) followed by United Kingdom (10).

Likewise, France placed the highest number of notifications in the third quarter (25), followed by Portugal (10) and United Kingdom (10). In fact, every third quarter recall notification originated from the same country of origin.

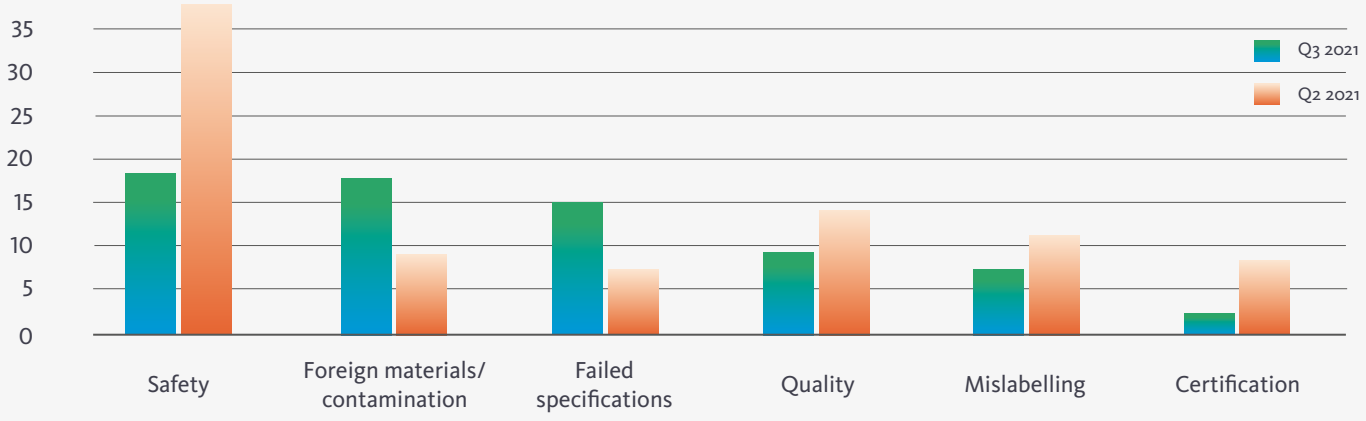
RECALLS BY NOTIFYING COUNTRY



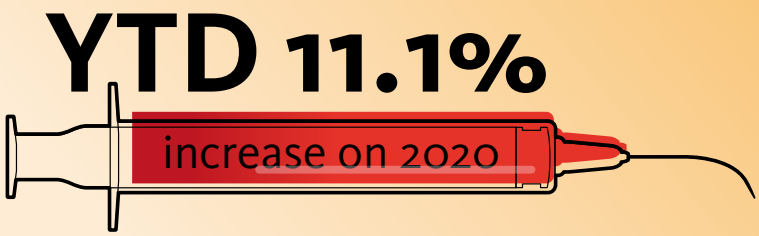
RECALLS BY COUNTRY OF ORIGIN



TOP REASONS FOR RECALL EVENT



While recalls declined 29.3% from Q2, **total recalls YTD** (Sep 2021) have now exceeded 2020's total by 11.1%.

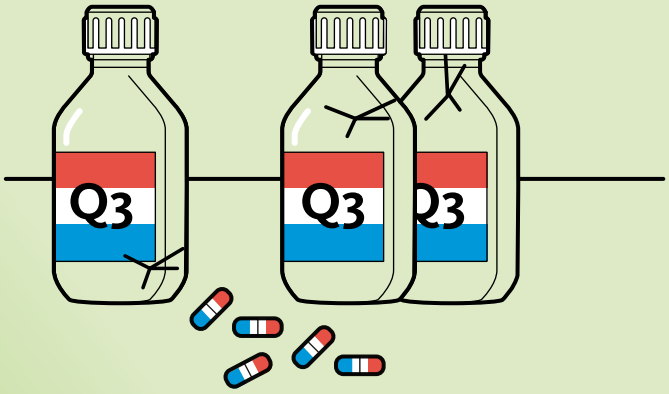


Continuing at this pace, 2021 should surpass the total number of events recorded in 2018 (380), signifying a return to pre-pandemic levels.

Accounting for 18 **recall events** (24.0%), Safety risks has now remained the leading cause for three consecutive quarters.

Safety concerns were followed by: Contamination / Foreign materials (17), Failed specs (15), Quality (9), and Mislabelling (7).

Pharmaceuticals manufactured in **France** accounted for exactly one third of all recalls in Q3.



YTD, France has accounted for 28% of all recalls, followed by the UK (15%), Republic of Ireland (14%), and Germany (10%).

SARAH-JANE DOBSON, PARTNER AND **EMILY BRETT,** SENIOR ASSOCIATE (FOREIGN QUALIFIED LAWYER – AUSTRALIA), **KENNEDYS**

SAFEGUARDING THE PHARMACEUTICAL INDUSTRY AHEAD OF EXPECTED LEGISLATIVE OVERHAUL

With legislative overhaul for the industry anticipated in 2022, we expect the pharmaceutical industry will enjoy continued growth despite the risks and challenges that can be expected in an increasingly digital world where the line between pharmaceuticals and technology continues to cross.

The proposed overhaul will seek to:

- ensure access to affordable medicines;
- foster innovation and sustainability, including in areas of unmet medical need;
- improve security of supply and avoid shortages; and
- adapt to new scientific and technological developments; and
- strengthen Europe's position on the global stage.

As the industry prepares for the changes to come, it will be important to stay updated on the latest regulatory, legal, industry developments while keeping patient safety as the cornerstone.

Supply shortages and meeting 'unmet needs'

While proving resilient despite the extraordinary challenges of the Covid-19 pandemic, the pharmaceutical industry, as with many other industries, continues to grapple with the disruption to supply chains and access to raw materials. These challenges are resulting in medicine shortages. The Covid-19 pandemic demonstrated in real terms how critical it is that manufacturers are not solely reliant on one or two primary suppliers of ingredients, especially when those entities reside in countries based outside of the EU. In response, pharmaceutical companies are evaluating whether and how to diversify and/or onshore supply to ensure consistent production so that people have the access to safe and reliable medicines that they expect.

Indeed, one of the key drivers of the EU Pharmaceutical Strategy, a European Commission (EC) document produced in late 2020 to future proof the EU's pharmaceutical regulatory framework, is meeting 'unmet needs.' That is providing access to reliable, affordable and safe medicines, particularly for underprivileged and minority groups and ensuring medicines and 'innovative therapies' can be deployed at speed without financial barriers to access.

One major issue we anticipate manufacturers will need to grapple with are the costs of innovation and scaling new therapies and technologies to ensure all patients continue to have access to affordable but innovative medicines. Furthermore, the consumer demand for sustainable approaches to manufacturing, production and reduced environmental footprints will be pressure points for manufacturers in the years to come as they balance supply and innovation demands with their environmental responsibilities.

Better understanding where roadblocks occur in the production life cycle, and why, will help inform policy-makers to tailor proposed legislative reforms appropriately, identify where investment can be best directed on an EU scale, and guide manufacturers to future proof their businesses.

Personalised medicines

Developments in genomics have enabled the concept of personalised medicine to enter the mainstream with industry actors and health services recognising the benefits of, and demand for, tailored therapies. The trade-offs are the raft of logistical, financial, legal and ethical implications of personalised medicines and how manufacturers might balance these challenges while serving to benefit financially from such therapies.

We expect that the costs associated with the development of personalised medicines, as well as the logistical challenges of scaling such products, will be a barrier to many patients. Further, the individualised nature of these products, and corresponding risk profile that is unique for each user, may present difficulties for insurers, manufacturers and healthcare providers. These stakeholders will invariably want appropriate cover against claims made by patients with respect of adverse outcomes, or otherwise to quantify their legal exposure in order to mitigate against it.

Enhanced digitisation and technological innovation

The EU's Pharmaceutical Strategy recognises the rapidly evolving technological landscape - particularly in the wake of the Covid-19 pandemic. Innovative design will be integral to developing drugs in the key areas of rare diseases, paediatric cancers and neurodegenerative diseases.

Also key to drug development in these relatively underfunded areas of research will be the utilisation of innovative technology and digitisation of health data that will enable manufacturers to synthesise the large swathes of data required during the research and development process to bring medicines to market. The potential for more rapid drug development circumvents many of the classic markers used for safety assessment, which invariably raises questions about long-term risks and any related legal exposure. Further, the increasing reliance on technology exposes the industry to cyber-attacks and data protection challenges as stakeholders and market actors move from a competitive approach to one of collaboration.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SARAH-JANE DOBSON, PARTNER AND **EMILY BRETT,** SENIOR ASSOCIATE (FOREIGN QUALIFIED LAWYER – AUSTRALIA), **KENNEDYS**

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The role of borderline medicinal products in the pharmaceutical space

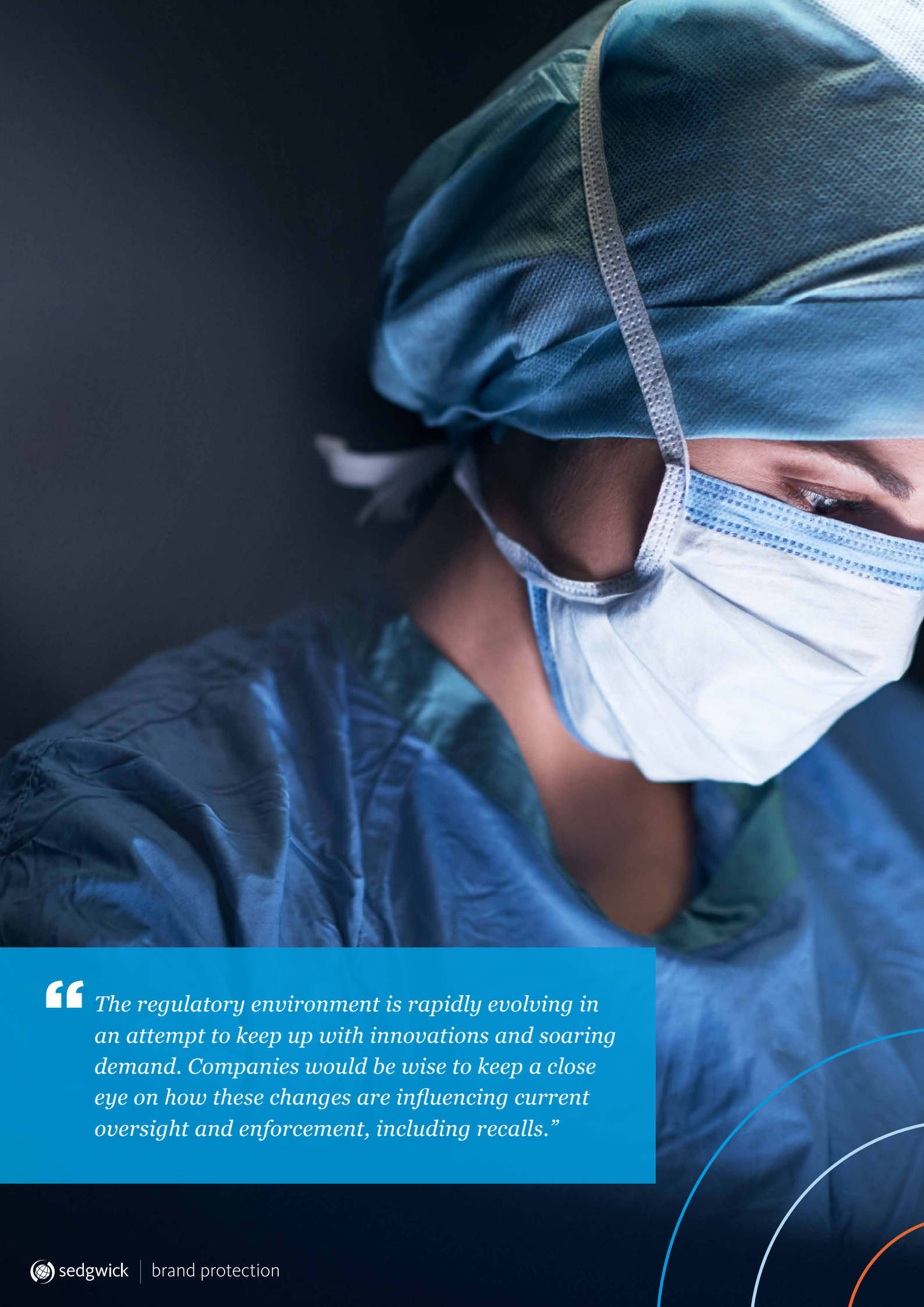
Recent media reports suggest a mounting pressure in the UK for regulation of borderline medicinal products such as Botox and cosmetic fillers, commonly referred to as cosmeceuticals. The UK has recently passed legislation banning the administration of Botox or cosmetic fillers in patients under the age of 18 (save in certain medical contexts); however, there are increasing calls for more extensive regulation of non-invasive cosmetic procedures using these products. As cosmeceutical products start to cross into the pharmaceutical sphere and attract regulatory attention, we anticipate stakeholders may start to see claims in the future.

The future of pharmaceutical regulation

The EC, European Medicines Agency (EMA) and EU countries have combined forces for the Pilot Project for the Market launch of Centrally Authorised Medicinal Products which aims to analyse data submitted confidentially and voluntarily by stakeholders regarding the reasons for delays to the launch of centrally authorised medicinal products (CAMPs). The hope is that this data will help regulators better understand the roadblocks to launch of CAMPs and certainly inform proposed policies regarding access to medicines for all patients across Europe.

Access to, and the sharing of, real time data will continue to prompt more rapid development and change than seen in the past. A perfect example of this is the rapid development of the Covid-19 vaccine by various manufacturers. This offered the industry a real-time example of how stakeholder collaboration and data sharing can produce rapid and effective results.

Lastly, while profit will always be a significant driver of development and innovation, we expect to see a shift from a purely competition driven industry to one of stakeholder collaboration with a renewed focus on patient-focused healthcare solutions.



“The regulatory environment is rapidly evolving in an attempt to keep up with innovations and soaring demand. Companies would be wise to keep a close eye on how these changes are influencing current oversight and enforcement, including recalls.”

MEDICAL DEVICE

Regulators around the world are increasingly willing to collaborate on matters related to product safety. While this shift in recall activity may not be a direct reflection of a collaborative regulatory environment, it is certainly a reminder that recalls are – more often than not – global events. Companies should be prepared to manage a recall accordingly.

Regulatory environment for artificial intelligence and machine learning

A lot of work is being done to understand the impact that AI and ML will have on the medical device industry – both in terms of benefits and risks. There is also ongoing debate about how the EU and UK will regulate the use of AI in medical devices, and how this guidance could alter existing directives.

In the meantime, companies should keep a close eye on the latest guidance and standards set by government agencies and industry groups around the world. These documents will serve as the leading indicator on how regulators are thinking about product approvals, continued oversight and future enforcement. One of those resources is a list of 10 guiding principles created by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), along with U.S. Food and Drug Administration (FDA) and Health Canada. The principles aim to help promote safe, effective, and high-quality medical devices that use AI and ML. The three agencies also expect these principles to guide regulatory collaboration on research, international harmonization, and consensus standards, which could inform regulatory policies, directives, and guidance. These are the types of documents that provide insight into how regulators are thinking about AI and ML. By extension, it should inform how you are approaching everything from product design to future compliance.

Mitigating cybersecurity risks

New EU legislation for medical devices and in-vitro diagnostic devices is paving the way for health and safety improvements across the medical device industry – from data collection during clinical studies to post-market surveillance requirements.

Both the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) also include requirements that address the cybersecurity of medical devices. There is also ongoing debate about how the EU will regulate the use of AI in medical devices, and how this guidance will alter existing directives.

Meanwhile, in the UK, the MHRA received £194,000 to research how adaptive AI algorithms in medical devices change and how to regulate their decisions.

All this to say the regulatory environment is rapidly evolving in an attempt to keep up with innovations and soaring demand. Companies would be wise to keep a close eye on how these changes are influencing current oversight and enforcement, including recalls.

Impact of European medical device regulations on the global market

In addition to the MDR and IVDR changes related to cybersecurity, the EU and UK are leading the way in regulating artificial intelligence/machine learning (AI/ML)-based software as a medical device.

Starting off was the EU, with its new MDR that represented the first regulatory guidance for medical device software, commonly known as SaMD. Among its changes, the MDR overhauled labelling requirements and outlined lifecycle traceability requirements. Soon after, the UK's MHRA recently released its new regulatory program for medical devices, which bears many similarities to the MDR.

The global market will be impacted by more than just the passage of the MDR and IVR in the simplest sense of regulatory compliance. These changes will impact how companies think about new product development and marketing. The regulatory environment may also influence decisions like when and how companies take new products to market in the EU, the UK, the United States, or other jurisdictions around the world.

As the EU and UK continue to bolster their regulatory programs and increase enforcement, medical device manufacturers must be prepared to comply. It will also be important for manufacturers to stay engaged with regulators across all markets to ensure that market approval and reporting requirements are met.

> *"The global market will be impacted by more than just the passage of the MDR and IVR in the simplest sense of regulatory compliance. These changes will impact how companies think about new product development and marketing."*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Supply chain challenges facing the medical device industry

The Covid-19 pandemic exposed weaknesses and risks in supply chains around the world and across industries. The medical device industry was no exception. With demand as high – if not higher – than ever before, medical device companies still find themselves stretched thin and often unable to meet demand.

As these supply chain crises continue, the companies that fare best generally have one thing in common: a steadfast commitment to risk mitigation that not only identifies potential issues, like product shortages or logistics challenges, but also identifies potential solutions and lays the groundwork to execution on those plans when needed.

But the shifting value chain will also create challenges and opportunities post-pandemic. KPMG writes in its report titled Medical devices 2030 that mounting pressures on the healthcare system are creating shifts in the care delivery model. "In the new normal, companies will need to step out of their conventional manufacturing role," the firm writes.

"Services and data intelligence will need to be integrated with products to offer holistic solutions, requiring a 'power play' across the value chain – strengthening existing business-to-business (B2B) plays and creating new ones, while introducing business-to-consumer (B2C) plays," KPMG continues. As the value chain evolves, so will the supply chain. As medical device companies look to take advantage of these opportunities, which have likely only grown larger in response to the pandemic, they should take the supply chain challenges into account.

THIRD QUARTER BY THE NUMBERS

Medical device recall activity bounced back to 709 recalls in the third quarter, representing a 5.8 percent increase quarter-over-quarter. As a reminder, this quarterly activity remains high compared to a quarterly average 515 recalls in 2020. Looking at the first three quarters of 2019, which averaged 700 recalls per quarter, it is clear we are seeing recall volume return to 2019's quarterly average recall volume of 710 notifications.

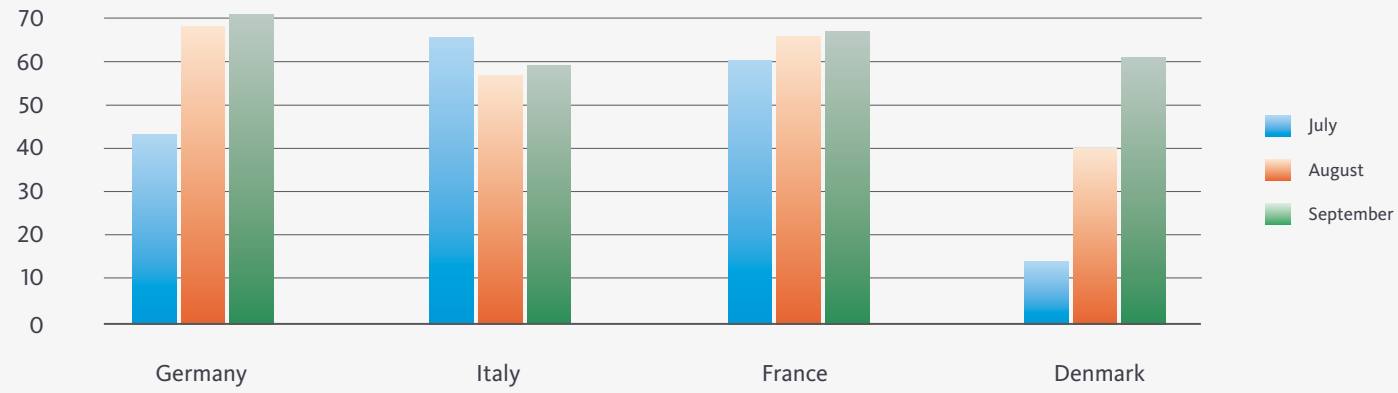
There was a broader range of recall causes in the third quarter compared to previous quarters. Software was the leading cause of medical device recalls in the third quarter at 99 events, followed by manufacturing defects (67), instructions updates (61), and sterility and quality concerns (60 each).

France was the leading country of origin for recalled products in the third quarter with 192 events, followed by Italy (183), Germany (182), and Denmark (115).

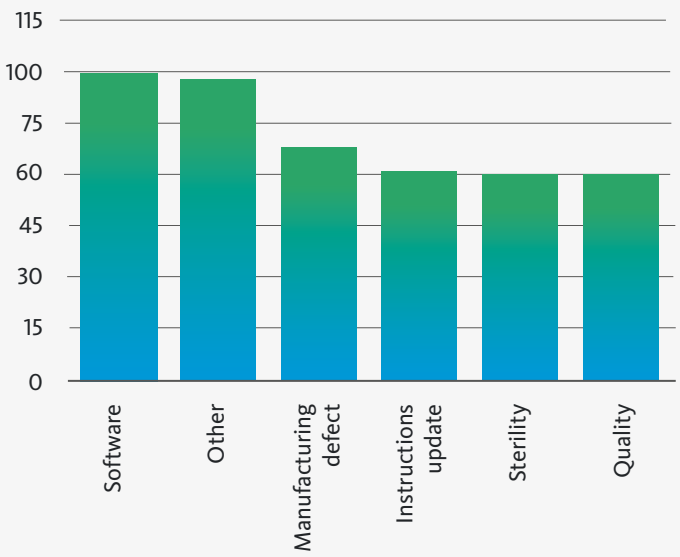
Italy was the leading country of notification at 158 recalls, followed by Germany (151), France (124), Denmark (119), and the United States of America (53).

Whereas only one second quarter medical device recall in the data analyzed listed independent jurisdictions as the notifying country and country of origin, this distinction was true for 174 third-quarter recalls (24.5 percent).

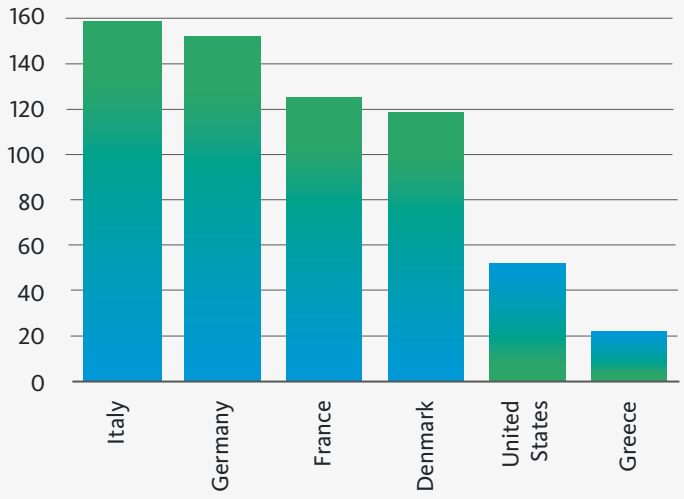
Q3 RECALLS BY COUNTRY OF ORIGIN



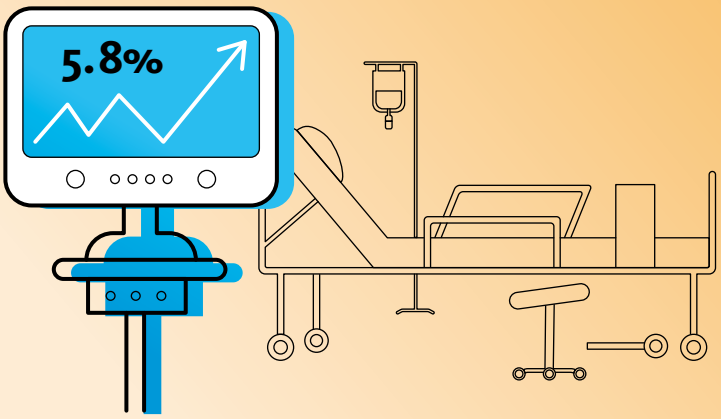
TOP REASONS FOR RECALL EVENT



RECALLS BY NOTIFYING COUNTRY



At **709 events**, Q3 recalls increased 5.8% from 670 in Q2.

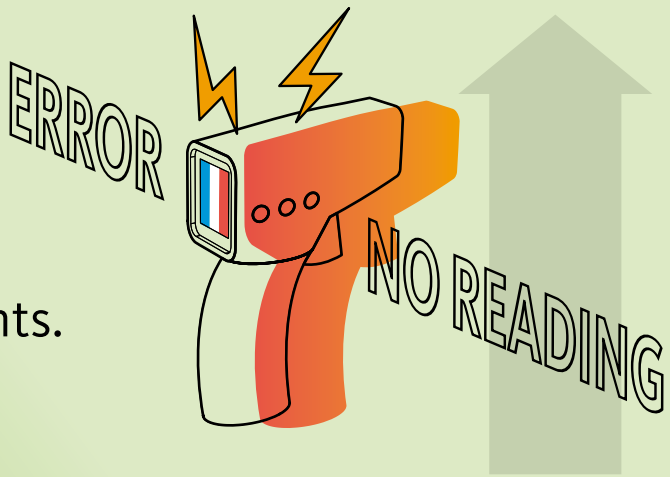


With this increase, total recalls in 2021 (to end of September) have already exceeded 2020's annual total by 40 events.

Accounting for 99 events (14.0%), **Software was the leading cause** of recall activity in Q3.

This was followed by Manufacturing defects (67), Instruction updates (61), Sterility (60), and Quality concerns (60).

Over a quarter (27.0%) of all recalled products originated from **France**, at 192 events.



This increase of 65.5% saw France replace Germany as the top originator, who experienced a decline of recalls by 27.5%.

ALISON NEWSTEAD, PARTNER,
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THE EXPANDED SCOPE OF THE NEW MEDICAL DEVICE REGULATION (MDR) – ARE YOUR PRODUCTS NOW SUBJECT TO THE GREATER SCRUTINY OF THE REGULATORS?

Medical device manufacturers in the EU have been busy preparing for, and now implementing, the changes introduced by the new Medical Device Regulation (MDR) (Regulation (EU) 2017/745) which came into force in May 2021. While there has been significant focus on ensuring compliance with the MDR's new requirements, the introduction of the MDR may lead to an increase in recall activity and regulatory action as the regulations start bedding in and regulators start working with the new regime.

A key driver of a potential increase in recall activity is that the new MDR substantially expands the scope of products covered. A new, broader definition of medical devices will now also cover certain products that do not have a medical intended purpose, but may be similar to a medical device in terms of the way that they function or their risk profile. Of particular concern here, is a product's ability to cause infection or injury.

The inclusion of such products within the scope of the Regulation is in response to concerns about various aesthetic products which have seen an exponential growth in use, particularly by the younger consumer demographic. This category of devices covers products such as cosmetic coloured contact lenses and iris implants; cosmetic implantable devices, such as implantable horns, buttock implants and silicone breast implants; and products such as dermal fillers used to fill facial lines and to add fullness to the lips and cheeks. The Regulation also extends to equipment used for liposuction and high-intensity radiation equipment used for tattoo and hair removal.

Many of these aesthetic products are widely available online, which means the range of products available is vast. More worryingly for consumers, the quality and safety profile of those products is also highly variable. Not having to comply with the MDR until now has meant that these products could often be produced relatively cheaply, easily and without the high standards of safety and significant vigilance requirements that apply to medical devices.

With reports of injuries growing (including major disfigurement and life-changing injuries), it is of little surprise that the EU has responded proactively to calls for increased regulation to protect consumers. Some commentators have indicated that certain products in this category should be regulated even more closely under the regime covering medicines. It will therefore be interesting to see how manufacturers respond, and regulators are able to better manage, the risks posed by these types of products, and whether we see further shifting of regulatory surveillance in this area.

Also significant, is that the scope of the MDR now covers devices designed for the purpose of "prediction and prognosis" of a disease or other health condition, including diagnostic tests for health and well-being. Whilst there are clear categories of products that will fall within this definition, there may be questions about interpretation as to what products are covered by the Regulation. Regulatory action may ensue if there is a discrepancy between manufacturer and regulator as to the interpretation of the MDR.

Manufacturers of products which were previously unregulated or regulated under a different regulatory regime may now find themselves forced to comply with a much more complex and stringent set of requirements – particularly in the manufacturing and post-market surveillance stage. They will also find themselves under the scrutiny of national EU medical device regulators, who often operate differently than regulators who are entrusted with ensuring the safety of general consumer products. Manufacturers can expect significantly more interest in their activities and closer scrutiny of their products, their market surveillance activities, and any corrective action that they propose.

Whilst some manufacturers will rise to the challenge of ensuring compliance, other manufacturers – many of whom are located outside the EU – may not be aware of the recent regulatory changes, or fail to act on them. This could lead to increased regulatory action to ensure that non-compliant products are not on the EU market.

With increased regulatory action, manufacturers and those in the supply chain are also likely to witness an increase in civil claims. That said, a proactive approach, under a tighter regulatory regime and scrutiny by regulators is more preferable than consumers having to seek redress through the Courts for injuries sustained.

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SHOOK, HARDY & BACON INTERNATIONAL L.L.P.
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What can we expect in the UK?

As a result of the timing of the Brexit departure, the new MDR is not applicable in Great Britain (England, Wales and Scotland). It will, however, apply to Northern Ireland.

Given that the MDR does not apply to Great Britain, the UK government is seizing the opportunity to carry out a consultation of existing medical devices legislation (implemented as the Medical Devices Regulations 2002), with the aim of having a new regulatory regime in place by 1 July 2023 (when the UK will stop accepting CE-marked products).

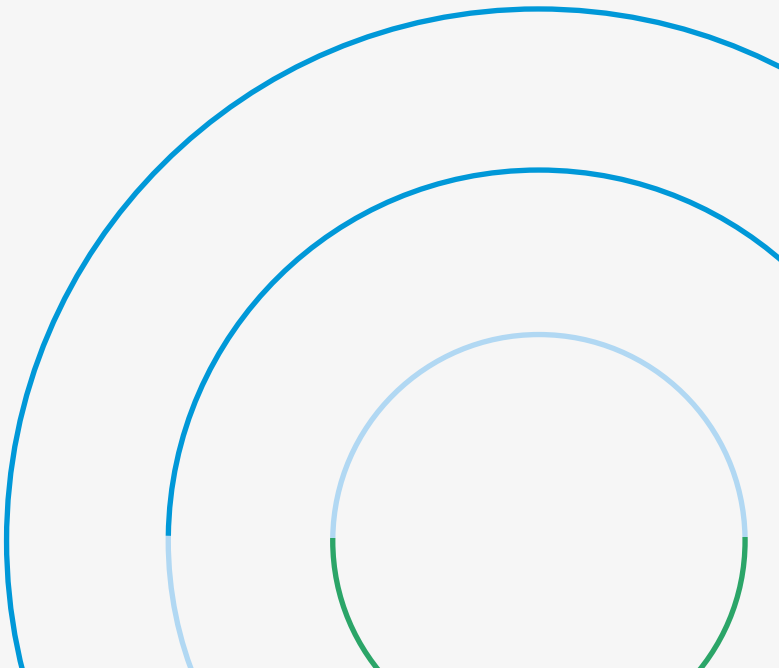
Whilst the consultation has a distinct focus on health technology and innovation, patient safety is at the core. Views are canvassed on a broad range of issues that were included in the new MDR in the EU, including scope, classification of products, economic operators, registration and Unique Device Identifiers (UDIs), conformity assessment, clinical investigations and performance studies, post-market surveillance and vigilance, in vitro diagnostic medical devices (IVDs), software and implantable devices.

The consultation states that ***"in many areas, gaining and maintaining competitiveness in a global market will be best supported by alignment with internationally recognised best practice and standards."*** Therefore, it will be interesting to see just how far any new regulations in Great Britain deviate from the changes in the EU.

It appears that the UK government is open to proposals for additional products to fall within a new regulatory regime in Great Britain beyond those covered by the new MDR at EU level. To this end, the position in Great Britain may be more stringent for certain products than is currently the case in the EU.

Will the new regime be more flexible than we have previously seen? Will this make the regulatory landscape more easily navigable for manufacturers? The UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), has emphasized that in any future regime it intends to ***"use both regulations and guidance to establish a fluid and effective approach to the oversight of medical devices and technologies. In some cases, this is likely to involve greater use of guidance than under the existing regulatory framework to ensure that we can keep pace with dynamic innovation in medical technologies, whilst maintaining high standards of patient safety."*** To this end, there may be less grey regulatory areas in Great Britain than in the EU, meaning that there is less risk of regulatory action with respect of new, innovative products that do not fit neatly within legislative definitions.

Manufacturers supplying products in the EU and Great Britain will need to keep a close eye on the consultation and determine whether any deviations need to be acted upon. Regulatory approaches may differ for the same products and care will need to be taken to ensure that compliance is achieved.



CONSUMER PRODUCTS

One of the most threatening product safety risks facing the entire consumer product industry is the increasing prevalence of counterfeit products, brought on by a perfect storm of insatiable demand, limited supply, and increased adoption of e-commerce.

It is estimated that 6.8% of EU imports, worth €121 billion, are counterfeit. As online shopping grows — and copying and adulterating becomes more sophisticated — consumers are struggling to differentiate between what is genuine and what is fake. In fact, one in 10 Europeans has been duped into buying counterfeit products, with the majority coming from Asia, according to the EU's Intellectual Property Office.

Counterfeit goods have always been considered a brand infringement or intellectual property right issue but they're increasingly raising red flags for product safety. In October 2021, in response to the European Commission's public consultation on the General Product Safety Directive, the International Trademark Association advocated that the regulation's scope be extended to include counterfeit goods. This recommendation was made on the basis that all fake products are inherently unsafe since they do not comply with existing EU health and safety guidelines.

While traditionally our focus in this Index has been on three of the top product categories impacted by consumer product recalls, we want to take the opportunity to highlight some important recall data that falls outside the scope of electronic, toy and apparel recalls. While these three categories combined accounted for 182 recalls in the third quarter, the broader consumer product category faced an additional 161 recalls across categories like fireworks, jewellery and – a new commonly-recalled product closely associated with the pandemic – face masks.

Here are some highlights:

- Fireworks accounted for 33 third quarter recalls, up significantly from zero events in the second quarter and 10 recalls in the first quarter. Of third quarter recalls, 20 originated from the People's Republic of China.
- Particle filter masks accounted for 22 third quarter recalls. This is down from 60 recalls in the second quarter and 28 recalls in the first quarter. Of these 110 recalls, 89 impacted products that originated in the People's Republic of China.
- In another COVID-19-driven product category, the third quarter also logged three recalls of hand disinfectants within the jurisdiction of consumer product recalls. All three products originated from Portugal. This activity continues a downward trend of recalls, following 4 second quarter recalls and 9 first quarter recalls.
- Jewellery, including bracelets, necklaces, and earrings, accounted for 12 third quarter recalls, down from 49 recalls in the second quarter and 33 in the first.

Now let's dive into clothing, electronics and toys.

> *"It is estimated that 6.8% of EU imports, worth €121B, are counterfeit."*

SARAH-JANE DOBSON, PARTNER AND
CAMILLE HEPSWORTH, ASSOCIATE, **KENNEDYS**

REGULATORY AND LEGAL OVERHAUL LOOMING OVER CONSUMER PRODUCTS INDUSTRY

The legal framework for the consumer products industry in the EU and the UK is at an important juncture. There are significant changes looming regarding product safety laws, enforcement practices of regulators and the increased involvement of consumers in pre-existing systems. Changes in any one of these areas could be disruptive, but changes across all would place serious burdens on companies.

Focus on overseas manufacturers and e-selling practices

In recent years, EU legislatures tried several times to improve the enforcement of product safety laws, a historically weak link in what was otherwise a widely well-regarded system. The overall aim of increased enforcement is to ensure only safe products reach the EU market.

In this vein, the EU's Market Surveillance Regulation (MSR), which came into force in July 2021, aims to significantly bolster existing market surveillance provisions. Some of the most significant new developments, which target e-commerce practices in particular and/or overseas manufacturers, include the following:

- Online marketing targeted at the EU is required to place a product on the market, even if there is no physical presence in the EU (i.e., solely distance selling or e-commerce platforms).
- An EU-based economic operator must exist (manufacturer, distributor, retailer, etc.), even when overseas manufacturers supply products directly to consumers via e-commerce. That EU entity is responsible for all compliance tasks and must provide their contact details for those purposes.
- Fulfilment service providers will become responsible if no other economic operator is located.
- Increased custom control measures, including increased information-sharing of such Member State authorities amongst themselves.

Consumer participation with and perception of product safety matters in the UK

It is thought that weak consumer engagement with product safety is likely to lead to an increased risk of unsafe products remaining on the market and decreased consumer awareness of product safety generally. Recently conducted research from the UK's overarching product safety regulator, the Office for Product Safety and Standards (OPSS), estimates only 17% of consumers consider product safety when making purchase decisions. In addition, product safety was found to be considered less important than price or ease of purchase.

Historically, regulators' efforts to influence consumers have been limited to specific campaigns, such as fireworks and Halloween costumes, rather than being driven by an assessment of gaps in consumer knowledge or efforts to improve general product safety awareness. In addition, proactive efforts by the OPSS have been limited because the agency has been focused on national incident responses around pressing issues, rather than a broader assessment of risk.

For example, a September 2021 a study by the OPSS title "Public Perceptions of Smart Products" evaluated three issues – but only as they relate to smart products:

- How price, care and risk perceptions affect blame attributions
- Do safety commitments decrease blame for third parties?

- Do perceived product intentions affect blame attributions?

Similar public perception studies on other product categories have also been produced in what appears to be a growing body of research in this area being undertaken by the OPSS. This work illustrates an increased focus by the OPSS on participation of consumers in assisting with market surveillance and enforcement practices in the UK.

Changes in the regulatory landscape for innovative products

It has long been recognised that product safety laws in the EU must effectively balance minimizing risk to consumers with a commitment to avoid stifling innovation in product developments.

The EU has announced several initiatives, including most notably the revision of the mainstay piece of product safety legislation, the General Product Safety Directive (GPSD), to include concepts of privacy and cyber security more expressly in light of technological developments in the years since the drafting of the original laws, to make them "fit for purpose" in our modern, technological world.

Supply chain complexity

The global COVID-19 pandemic laid bare issues with modern, global supply chains that are increasingly complex, but increasingly reliant on few suppliers in overseas jurisdictions for key, core components for a range of everyday consumer products that are central to daily modern life.

These increasingly complex supply chains, including offshoring and outsourcing, can lead to difficulties in traceability and product safety compliance, particularly if new vendors need to be on-boarded because traditional suppliers can't get components.

The changing recall landscape

Proposed revisions to the EU's GPSD mentioned previously will bring with them changes to the recall landscape in the EU by implementing additional obligations to facilitate successful recalls. For example, obligations on Economic Operators to issue notification of an "accident" within two working days after becoming aware of the incident, obligations to establish frameworks for traceability for products that present a high risk to health and safety, and specific requirements for recall notices including clear descriptions of the products and hazards and prohibition of the terms "precautionary" or "voluntary."

These changes will also bolster the evolving practices for recalls of connected products including the emergence of novel mechanisms such as software updates, bricking devices, as well as direct communications through devices and service providers. It remains to be seen if this will be the new threshold for recall expectations across categories, but companies should begin to prepare to comply if required.

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Increased consumer exposure

The growth of consumer exposure to recalls can be attributed to a variety of factors, including social media and heightened consumer awareness, the rise of large multinational corporations, increasingly complex and consolidated supply chains, the increasing threat of litigation, and technological advances in product testing. It is anticipated that this exposure will only increase in years to come, with the behaviours and responses of manufacturers and suppliers to unsafe products being analysed to a greater degree.

Expanding scope of recalls

The nature of risks is continually changing and expanding which has led to the convergence of numerous types of regulations to create the concept of risk in relation to privacy/cybersecurity, non-physical/purely psychiatric harm, and supply chain issues. These issues significantly increase the potential "triggers" for product safety recalls, as the concept of what is a "safe" product expands to include cybersecurity, data privacy, and non-physical injury.

Increased cooperation between EU Member State authorities

The EU MSR will aid in the successful facilitation of recalls and withdrawal of non-compliant products with various introductions in the legislation having that express purpose, including:

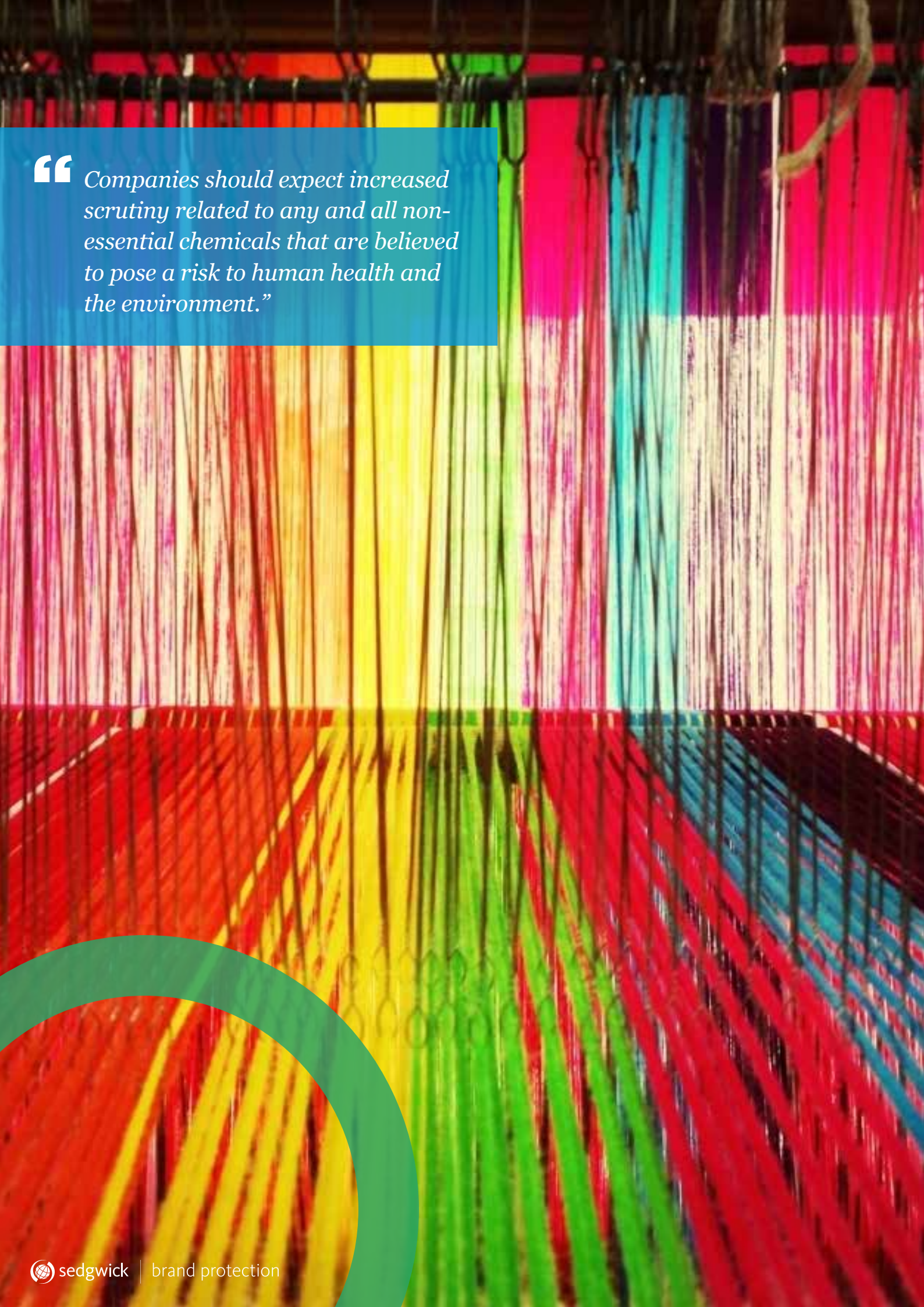
- Creating a database for national Market Surveillance Authorities ("MSAs") to share compliance data;
- Establishing new frameworks and processes for market surveillance and enabling the collaboration between national MSAs to remove non-compliant products from the EU market, focusing on e-commerce and online sales; and
- Determining how product warnings are to be shown on websites

Preparing for challenges related to changing regulations

It is clear that there are many challenges and risks ahead for consumer product companies with respect to product safety laws and recall practices in the EU and UK. There are several actions companies can take now to prepare for success:

- Reassess product portfolios to determine compliance with the proposed revisions for the EU's GPSD, particularly in respect of smart, connected devices;
- Re-evaluate selling practices to determine compliance with changes introduced by the EU's MSR, especially online selling practices;
- Incorporate cybersecurity risks as part of basic product safety and compliance requirement;
- Anticipate the broadening scope of what is considered a "safe" product, including within the revisions proposed to the EU GPSD;
- Enhance focus on compliance with product safety regimes across the board to mitigate risk of increased enforcement practices, including those foreshadowed by the EU's MSR;
- Enhance recall management strategies to reduce the need for regulator involvement (including using modern technology to improve traceability and developing recall plans in the event of a product recall); and
- Assess and enhance supply chain traceability, especially as it relates to complex global supply chains.

By taking these steps, companies will be well-positioned to adapt to the new regulations and minimize risk to consumer safety and their own reputation.



> *Companies should expect increased scrutiny related to any and all non-essential chemicals that are believed to pose a risk to human health and the environment."*

CONSUMER PRODUCTS

CLOTHING

The European Union's Circular Action Plan has lofty goals for the apparel and textile industries – at the same time the industry is evolving and innovating in its own ways. While we covered the Plan in our last Index, there are still several question marks when it comes to implementation.

For example, as part of the Plan, the EU is expected to establish rules that encourage manufacturers to use recyclable materials. Another possible requirement is that a manufacturer must take back, recycle, or otherwise dispose of products once they've reached the end of their useful life.

And while these types of discussions have not yet explicitly mentioned the impact on apparel and textile recalls, manufacturers and retailers would be wise to consider how these end-of-life requirements also influence recall expectations, requirements, and strategy.

> *67% of consumers consider the use of sustainable materials to be an important purchasing factor, and 63% consider a brand's promotion of sustainability in the same way."*

Crackdown on chemicals in clothing

The EU has been focused on the removal of "forever chemicals," not just from clothing and textiles, but from all products. And it appears that the clock for chemicals is starting to run out.

In September 2021, the EU announced a ban of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) subgroups, which is schedule to go into effect starting February 2023. The class of chemicals will also be under review as a part of the Commission's Chemicals Strategy for Sustainability next year.

Around the same time, according to Politico EU, a group of 11 countries called on the European Commission to take action that would ultimately force the clothing industry to move away from the use of "forever chemicals" including PFAS.

As more consultations occur and regulations are proposed, companies should expect increased scrutiny related to any and all non-essential chemicals that are believed to pose a risk to human health and the environment.

The ongoing influence of the #PayUp and Clean Clothes Campaign on the garment and sportswear industries

During the height of the pandemic, news broke that popular mass-market brands were refusing to pay factories and workers for completed orders. In response, journalist Elizabeth Cline joined fashion industry activists in launching #PayUp, a campaign that called on the industry to pay what they owed. Not only was it a success, but it put an even brighter spotlight on issues plaguing the fashion industry and the way to force change. The industry should expect a growing number of campaigns like #PayUp and others by Clean Clothes Campaign to target both companies and regulators to take action.

Consider activists' desire for France's ban on burning or destroying unsold clothing en-masse to take hold across the EU and beyond. Activists also support the Circular Action Plan's extended producer responsibility that would force companies to be responsible for the reuse or disposal of products that are at the end of their lifecycle.

As long as the fashion industry continues to be a leading contributor to global warming, activists will continue to push the EU and UK to hold brands accountable for product safety, human rights, and sustainability in any way they can. As we discussed in a recent Index, those activist victories may even mean recalls.

Impact of fashion start-ups on sustainability

As committed as consumers remain to staying on top of the latest fashion trends, they are also becoming more informed about sustainability and environmental risks associated with the apparel and brands they turn to for the latest fashion trends.

According to a McKinsey survey on consumer sentiment on sustainability in fashion, 67 percent of consumers "consider the use of sustainable materials to be an important purchasing factor, and 63 percent consider a brand's promotion of sustainability in the same way."

Consumers are beginning to hold clothing manufacturers more accountable for its supply chain and product lifecycle, from both an environmental and societal perspective. But that doesn't mean they need to turn their back on fashion and trends.

In the EU, innovative startups are putting their own mark on the fashion industry by leveraging tech-enabled solutions to create sustainability throughout the lifecycle, whether by the development of renewable textiles or the launch of platforms that facilitate clothing rental, clothes sharing, and second-hand re-selling. While fast fashion will continue to provide consumers access to the latest trends for the foreseeable future, increased adoption of these tech-based solutions may even help high street fashion brands meet their sustainability and social commitments.

THIRD QUARTER OVERVIEW

After almost doubling in the second quarter (from 32 in Q1 to 57 in Q2), clothing recalls dropped to 30 recalls in the third quarter.

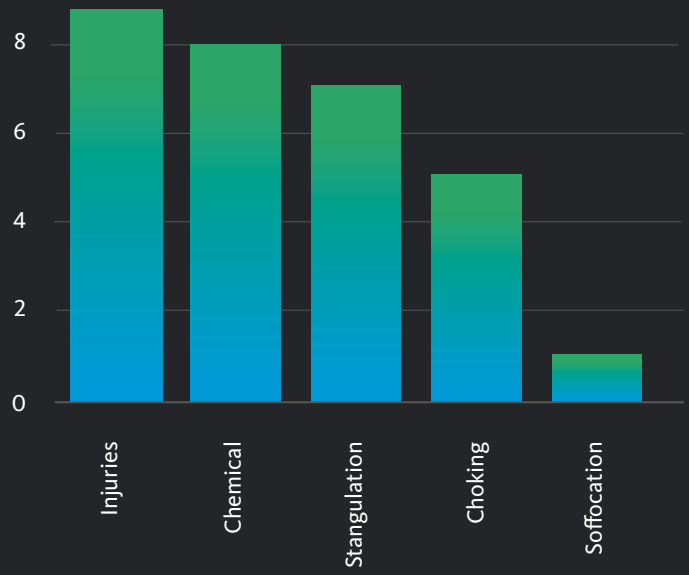
It remains clear that a focus remains on children's products when it comes to clothing recalls. Children's apparel and products dominated third quarter notifications at 20 events or 66.6 percent of recall events. Of these recalls, 8 were due to injury risk, 6 resulted from strangulation hazards and 5 were the result of choking hazards.

An analysis of the category in its entirety reveals that injury risks were the leading cause of recalls at 9 events, followed by chemical risks (8), strangulation (7), choking (5) and suffocation (1).

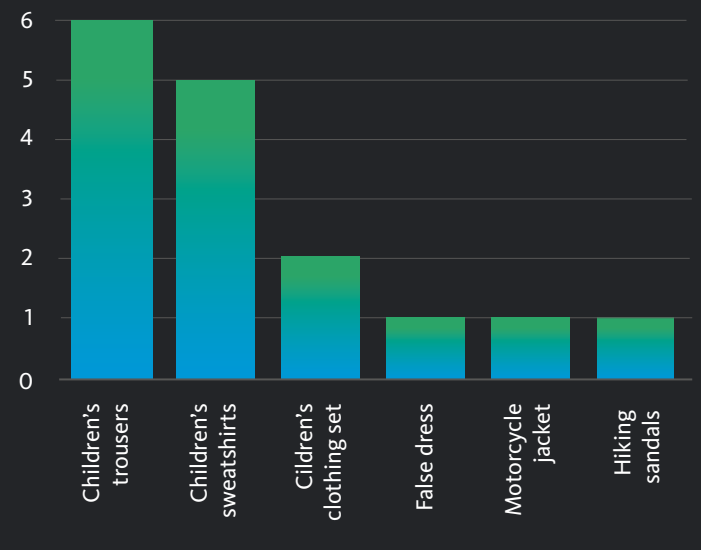
Turkey was the leading country of origin for recalled products in the third quarter, accounting for 16 events. All but one of these events impacted apparel for children. The People's Republic of China was the country for origin for an additional 5 recalls.

Bulgaria again issued the most notifications at 14, followed by Germany (5), Finland (3), Cyprus (2), and Romania (2).

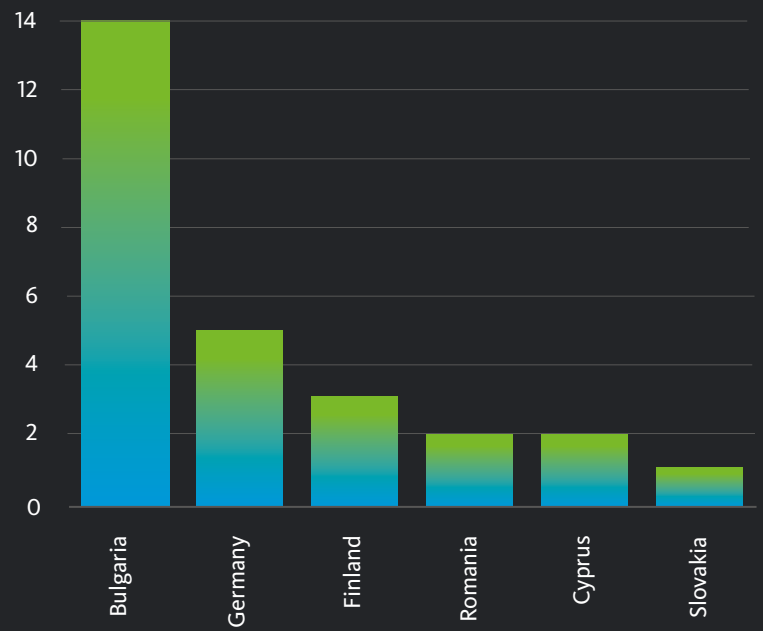
TOP CAUSE OF RECALL BY RISK TYPE



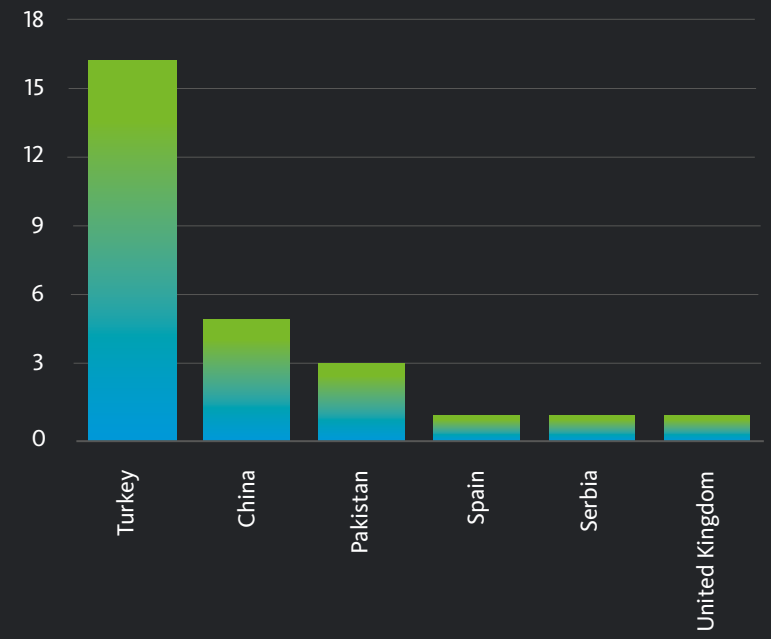
TOP RECALS BY PRODUCT



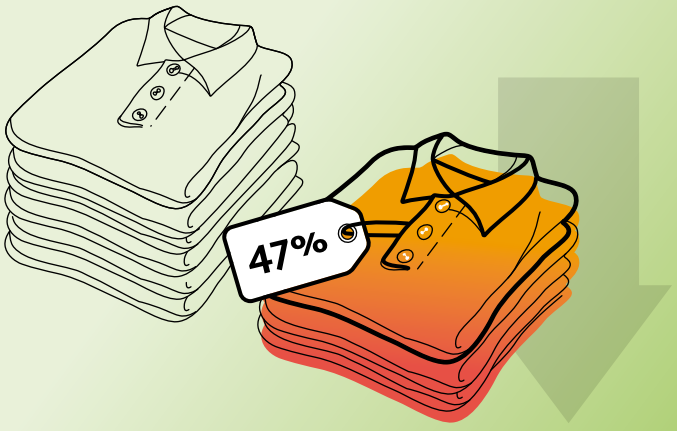
RECALLS BY NOTIFYING COUNTRY



RECALLS BY COUNTRY OF ORIGIN



Whilst **recalls halved** from Q2 (47%), average quarterly events in 2021 remain 11% greater than 2020.



Despite this decline, clothing recalls are set to exceed 2020's total of 142 recalls by approximately 13%.

Injuries was the most common risk type, impacting almost a third of Q3 recalls (9).

This was followed by Chemical (8), Strangulation (7), Choking (5), and Suffocation (1).

At 20 events, **Children's apparel** has remained the top recalled item for the last 7 quarters.

Delving deeper into Children's products, Trousers and Sweatshirts recorded 5 recalls each, followed by Clothing set (2).

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APPAREL RISKS HIGHEST AT THE INTERSECTION OF INNOVATION, CHEMICALS AND SUSTAINABILITY

When it comes to the future of the clothing industry, companies need to think far beyond fashion – especially when identifying and preparing for potential risks. When it comes to smart clothing, in-demand textile features (made possible using chemicals), and high expectations for environmental safety and sustainability, clothing companies need to ensure they are devoting adequate resources to the types of risks that, until recent years, did not apply to shirts and trousers.

Smart Clothing

Arguably the biggest and most apparent safety challenges and risks for the smart clothing category relate to cybersecurity and data protection. Wearable garments today can have the ability to interact with the user, collecting and processing health data regarded as sensitive under the General Data Protection Regulation (GDPR), the EU's mainstay data privacy legislation.

For this reason, smart clothing can be grouped with other smart wearable technology, such as smartwatches and fitness devices, in terms of privacy concerns and cybersecurity vulnerabilities. For one, cybersecurity breaches can result in the theft or nefarious use of the user's personal data by a threat actor. In the classic example, GPS location data obtained via compromise of a smart product can be used to blackmail or otherwise exert pressure on a user. In turn, this breach can result in negative psychological effects for the user, and even the potential for physical harm depending on the level of interaction the smart clothing has with the user.

To that end, clothing companies face the same regulatory and reputational vulnerabilities that arise if users' personal data or health are sufficiently jeopardised. Manufacturers may voluntarily recall their smart products or risk a regulator ordering a recall.

To prepare for these challenges and mitigate these risks, companies should ensure that:

- Smart clothing is secure by design through the use of effective encryption and multi-factor authentication.
- All those involved in processing data are well-versed on the relevant provisions of the GDPR (including, for example, Articles 33 and 34 regarding data breach notifications), and any national legislation.
- An effective plan for data breach management is in place.
- The consumer is aware of the types of data collected on them, their consent is collected, and they are able to exercise their rights under the GDPR and other relevant legislation.

Clothing companies should keep in mind revisions to the EU's GPSD and new UK legislation on the cybersecurity of products is in the pipeline as part of the EU-and-UK-wide regulatory focus on cybersecurity. This will mean greater regulation of internet-connected products, particularly Internet of Things (IoT) devices which smart clothing often falls under given its interconnectivity with other devices in a user's network.

Furthermore, we have seen a clear innovative progression of smart clothing as we now enter into what is regarded as the fourth-generation. These clothes are now developed to be as natural as possible, contrasting to the earliest generation where the electronic devices needed to be attached. This suggests that we will start to see smart clothing become increasingly normalised within the textiles industry.

Chemicals in clothing

Supply chains across every product category have faced scrutiny and challenges related to chemical use or contamination. The clothing industry is no different, facing a steady flow of allegations of using chemicals that may be considered dangerous. With increased consumer scrutiny as to the chemicals used as part of the manufacturing of clothing, expect the EU and UK chemicals regimes to continue adding chemicals to a growing list of restricted substances. Key categories of chemicals to watch out for include:

- Endocrine disruptors (commonly used to prevent staining);
- PFAs (commonly used for waterproofing);
- AZO dyes (used for dyeing fabric at lower temperatures);
- Chromium (used as a catalyst for dyeing); and
- Formaldehydes (used to increase fabric wrinkle and crease resistance).

As noted above, chemicals can offer various benefits when used in apparel. Making matters more complex, the use of these chemicals in certain clothing, such as sportswear, can also create challenges from a product compliance perspective. To the extent apparel is considered to serve some additional benefit, the product may be categorised as "Borderline". In such cases, it may fall within several applicable frameworks, including those more traditionally thought to apply to medical devices or chemical products, such as the biocidal products regulations. For this reason, consideration of all applicable product frameworks to chemical-containing products including in particular, anti-wicking or other anti-microbial textiles, should be considered carefully to ensure fully compliant products are manufactured.

Also important, not all of these chemicals are on the list solely due to risks to end users, such as skin irritations and aggravation of existing allergies due to chemical exposure. Chemical-related concerns in the clothing industry also include employment issues. There is concern that workers within the supply chain may be exposed to chemical risks and thereby require the use of adequate PPE.

Clothing manufacturers should ensure that they fully understand all aspects of their supply chain, including knowledge of the chemicals used in products (and their sources). Supply chain audits should be carried out by manufacturers (or services provided by a third party) to identify and mitigate risks. Many brands have found that developing a policy that defines commitment to operating in a way that helps the environment, often through less use of potentially dangerous chemicals, has not only decreased their risk of exposure to claims arising from product safety issues, but also increased customer sales.

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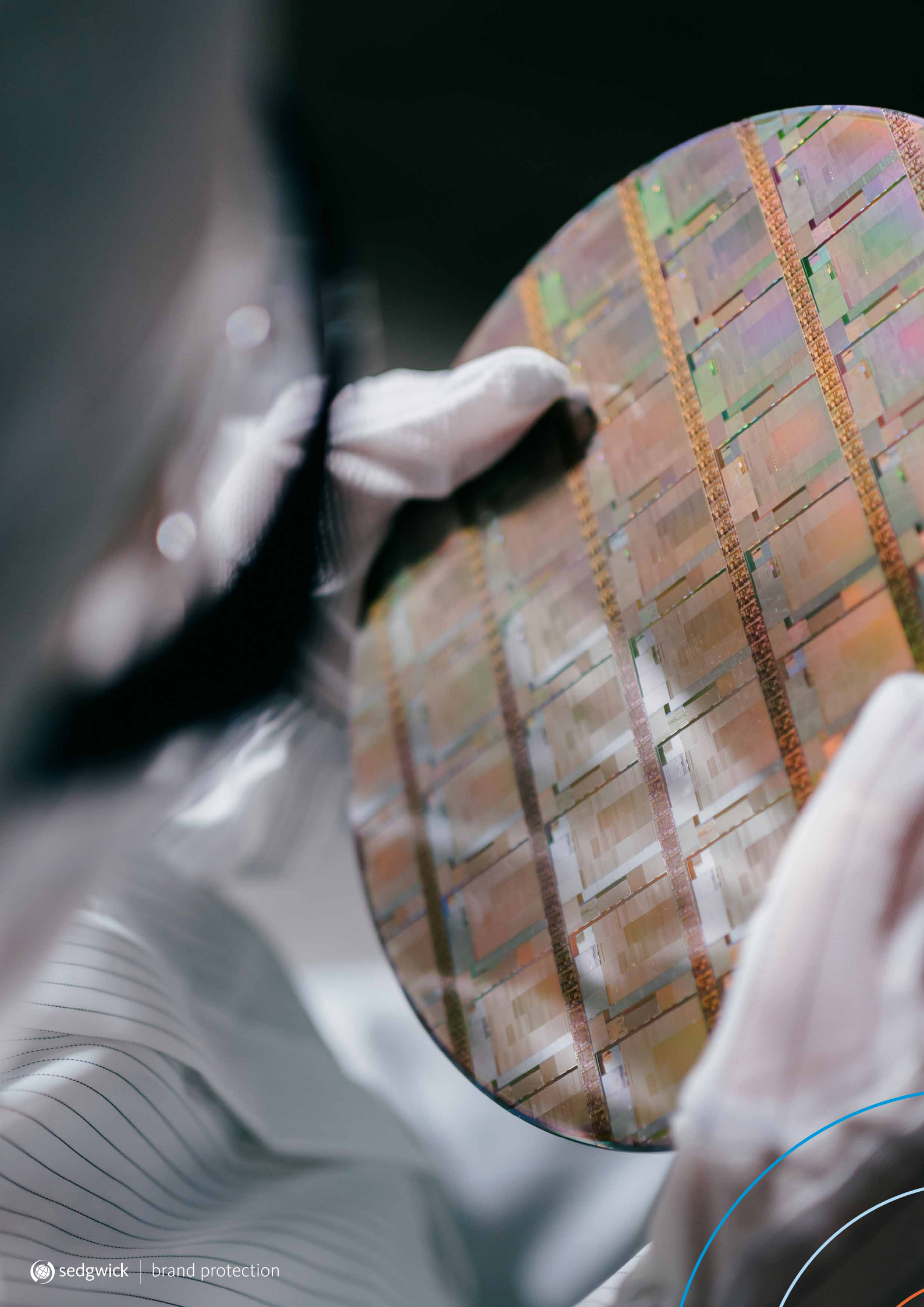
Environmental and sustainability considerations

The impact of the fashion industry is being felt worldwide, with 10% of global greenhouse emissions and nearly 20% of wastewater being attributed to clothing and footwear production. While sustainability is not a new issue, the EU's ambition to reach net zero by 2050, combined with a shift in consumer attitudes, is placing increasing pressure on the clothing sector to uphold its environmental, social and governance responsibilities.

With that said, companies should also remain alert to "greenwashing" in light of the UK's Green Claims Code, published by the Competition Markets Authority (CMA) in September 2021. This sets out to protect consumers and combat companies making misleading environmental claims about their products. Part and parcel with the Green Claims Code, the CMA announced that, from early 2022, it will carry out full compliance reviews of misleading green claims (i.e., greenwashing) made through both online or offline channels, with the intention to bring enforcement action against companies making such claims.

Innovative technology will also play an important role in increasing consumer awareness on the sustainability of clothing products. As announced in last month's Rome G-20 summit, the Sustainable Markets Initiative's Fashion Taskforce is currently creating a Digital ID system, which will allow consumers to scan a QR Code embedded into a clothing label to access the sustainability credentials of a clothing product. We predict that similar technologies will be created to allow consumers to make more informed ethical purchasing decisions.

In order to compete with changing consumer behaviour and succeed even under increased scrutiny, companies will need to continue evaluating their business models and increase product reporting. In addition, clothing companies need to embrace circularity, which is predicted to be one of the key business trends of the next decade. By adopting a circular business model, clothing companies can implement a number of strategies to reduce waste and make more efficient use of resources, such as offering rental or repair services and restoring returned items for re-sale.



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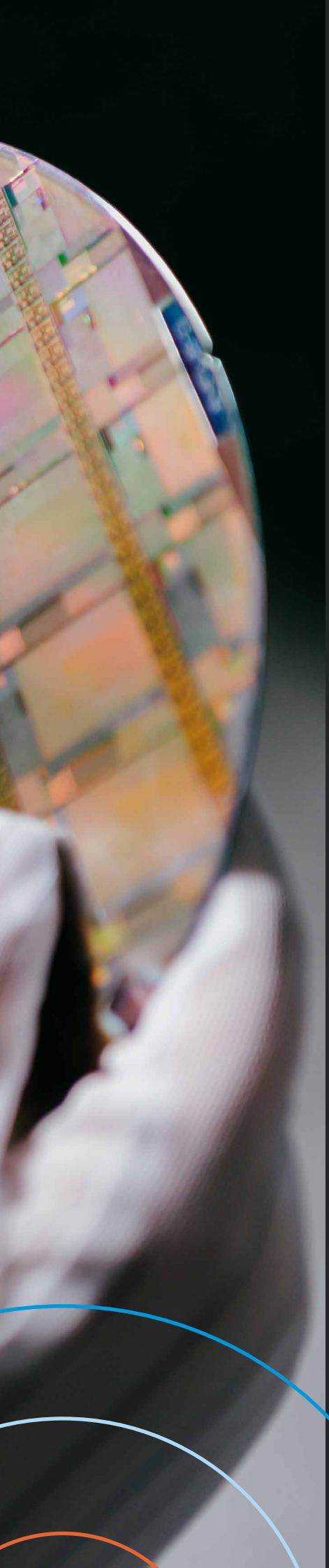


CONSUMER PRODUCTS

ELECTRONICS

The electronics industry is often at the cutting edge of innovation, but it finds itself at the heart of several major consumer safety issues as a result.

> *"While there are apparent leaders in AI development, staying ahead of any enforcement curve is critical, particularly since the EU Commission is proposing fines of up to 6% of global revenues."*

> *Manufacturers must take a more fulsome approach to incorporating 'reparability' into product designs and processes – not just to ensure compliance, but also to mitigate the product safety and liability risk that comes with consumers opting to repair products on their own."*

Artificial intelligence and the electronics industry

AI and ML continue to be two of the hottest topics in consumer product evolution. Consumer demand is high and the technology is advancing. As a result, regulators are focused on translating general guidelines or principles to enforceable legislation and directives. Among the frontrunners, the U.K. guidance on understanding AI ethics began to shape the way companies and regulators thought about the development of responsible AI.

Then the EU launched the first comprehensive legislative package on AI - the Artificial Intelligence Act (AIA). As the first mover, the EU likely hopes its policy becomes the gold standard for the world. The AIA aims to "establish a risk-based framework for regulating use of AI anywhere within the EU, including by companies based outside the EU." There are some challenges, however.

While there are apparent leaders in AI development – both in terms of technology and policy – collaboration will be key if the technology is to be a success. But arguably more critical is staying ahead of any enforcement curve, particularly since the EU Commission is proposing fines of up to 6% of global revenues for non-compliance. "This eye-watering number should catch the attention of global boards and other business stakeholders in Europe and across the world," attorneys at Squire Patton Boggs (US) LLP write.

Impact of the EU's market surveillance regulation

The EU Market Surveillance Regulation (MSR) that went into effect earlier this year was designed to strengthen the EU's ability to ensure that products sold in the EU were safe. According to that objective, the Regulation includes measures intended to strengthen compliance controls and improve product traceability.

The MSR also seeks to monitor products sold online. That said, there is a growing desire to increase accountability for online marketplaces and online services under further pieces of proposed EU legislation. To the extent the MSR is a stopgap, expect significantly stricter policies in the future.

"Right to repair" regulations

In July 2021, provisions of the UK Ecodesign Regulation were put in place that effectively maintained the region's alignment with the EU's current regime post-Brexit. Among the requirements are new 'right to repair' rules that compel manufacturers to make spare parts, repair instructions and maintenance information available for certain appliances – even beyond the warranty period or expected product lifespan.

On a similar track, the EU published a consultation on its sustainable products initiative (SPI), a measure designed to help meet Green Deal objectives. The SPI would broaden the scope of the existing Ecodesign for Energy-Related Products Directive beyond just energy-related products. In addition to a wider range of products, the SPI would also add new requirements linked to environmental and social factors aspects. For example, the EU has already shown support for adding personal electronics including laptops, tablets, and smartphones to the regulation in the future.

While offering possible environmental and consumer cost benefits, keep in mind that these regulations also have the potential to increase the prevalence of long-term safety risks. To that end, manufacturers must take a more fulsome approach to incorporating 'reparability' into product designs and processes – not just to ensure compliance, but also to mitigate the product safety and liability risk that comes with consumers opting to repair products on their own rather than soliciting help from an expert.

THIRD QUARTER OVERVIEW

Electronic recalls in the third quarter continued to drop, from 86 in Q1, to 75 in Q2, to 71 events in Q3. While representing a 6.6 percent decrease from Q2, current recall levels still sit 26.8 percent higher than 2020's quarterly average of 56 recalls. This heightened activity may be reflective of a continued focus on electronics safety as workers and students continue to navigate in-person and remote work and learning environments.

As is typically the case with electronics recalls, a wide variety of products were recalled. USB chargers accounted for 12 recalls, followed by extension leads (8), lighting chains (4), and laser pointers (3). The remaining product categories were impacted by just one or two recalls throughout the entire quarter.

Electric shock was by far the most cited single risk, accounting for 45 recalls. Consistent with previous quarters, electric shock was also listed as one of two or more reasons cited in 12 additional recalls.

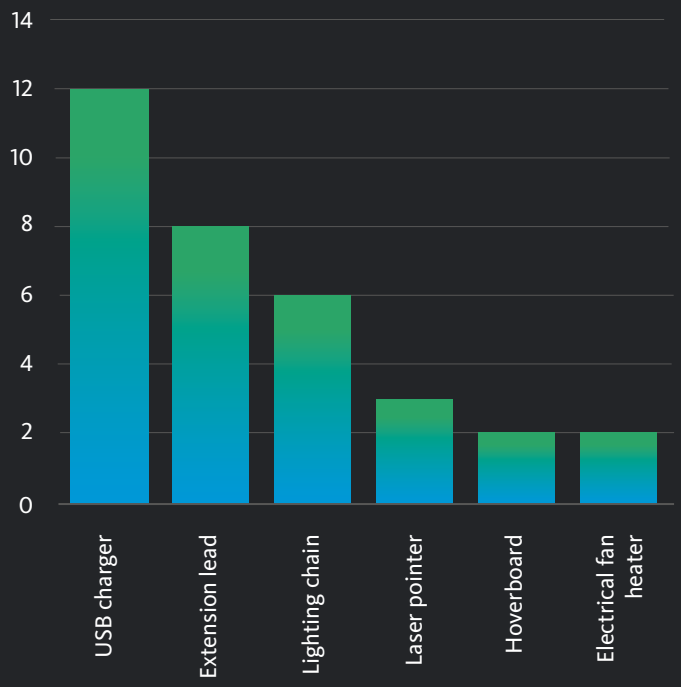
In sum, electric shock contributed to 57 recalls, or 80% of third quarter events. These recalls commonly impacted products such as electric cords (including USB chargers and adapters), and kitchen appliances.

In terms of notifications, Hungary was the top notifying country with 26 events, followed by Italy (8), Finland & Ireland (6 each), and France (5).

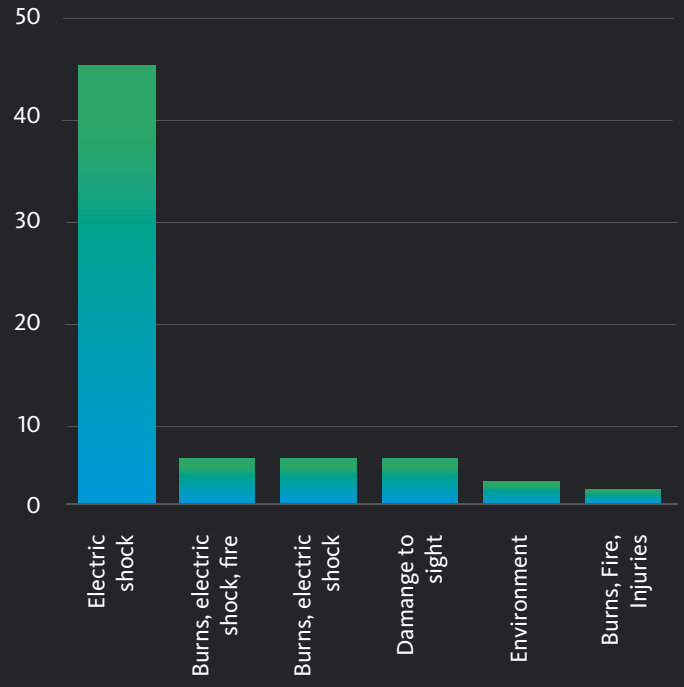
Consistent with the first quarter, most recalled products originated from the People's Republic of China, accounting for 64 recalls or 90.1 percent. Three recalls were from an unknown country.

Of all electronics recall notifications, one was known to be counterfeit product from the People's Republic of China. Another 28 events listed counterfeit status as "unknown;" 25 of which originated from the People's Republic of China.

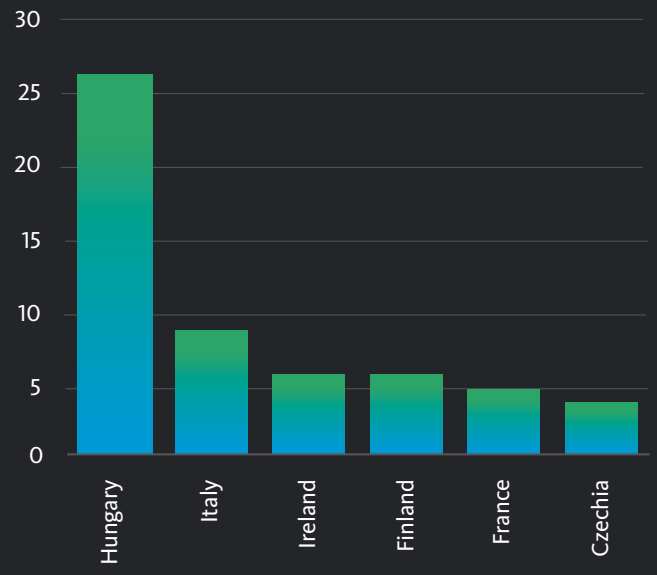
TOP ELECTRONIC PRODUCTS RECALLED



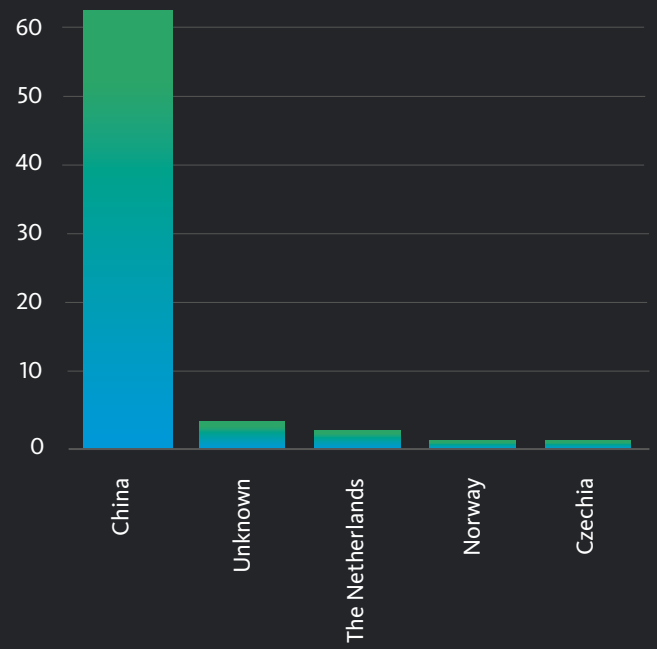
TOP CAUSE OF RECALLS

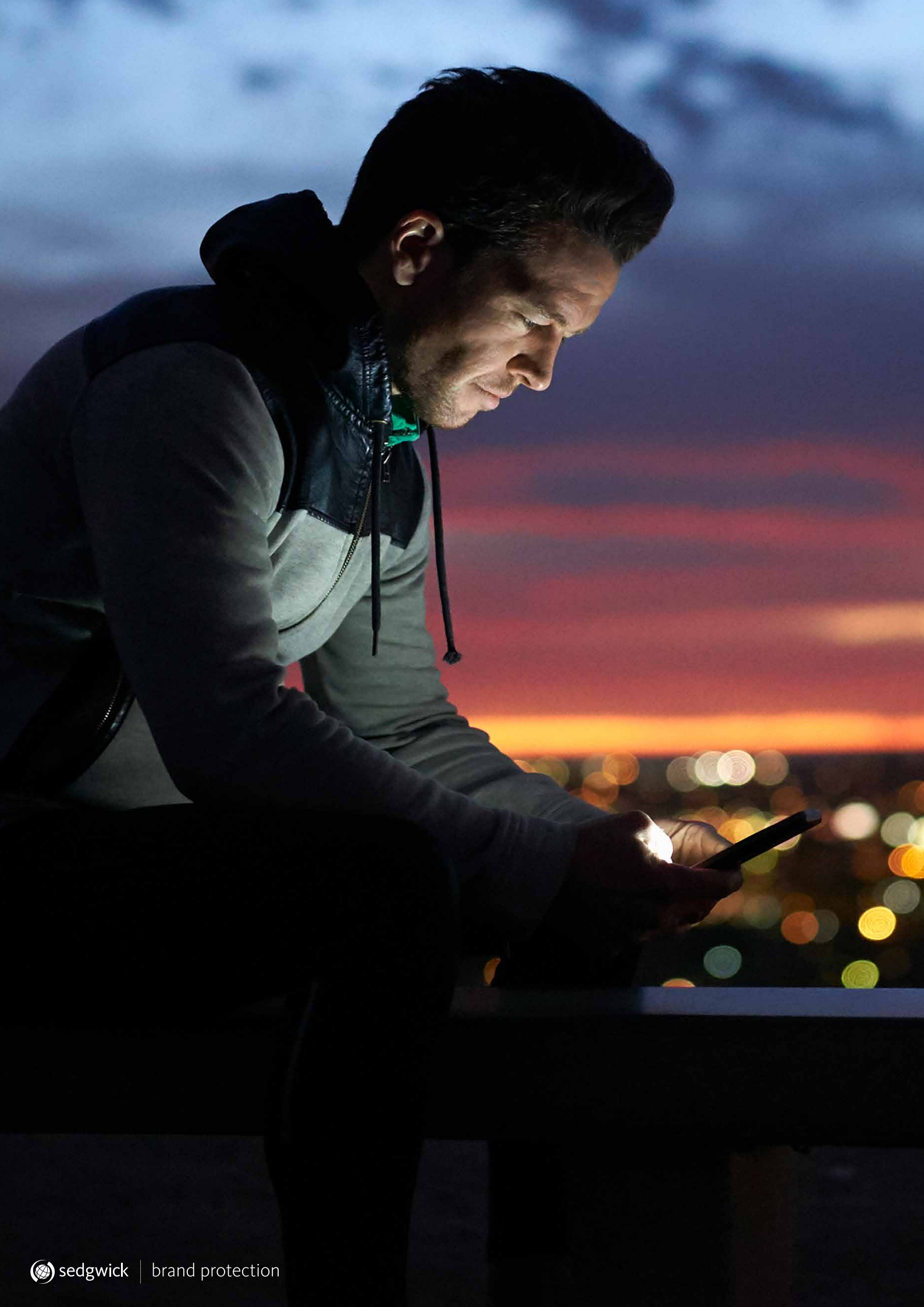


RECALLS BY NOTIFYING COUNTRY



RECALLS BY COUNTRY OF ORIGIN





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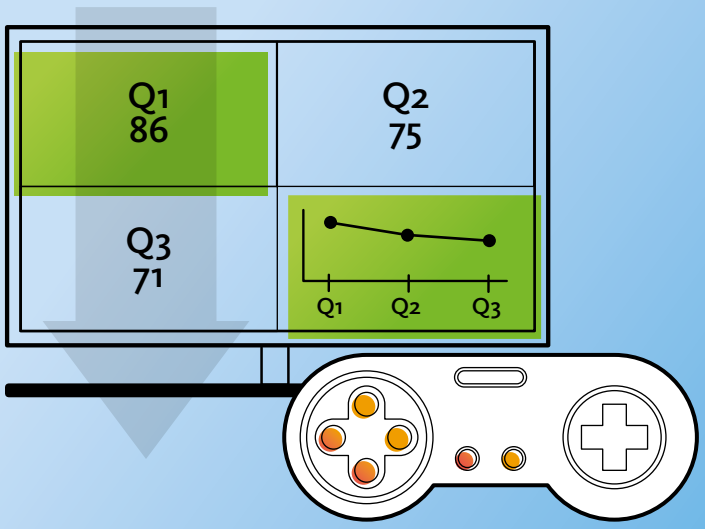
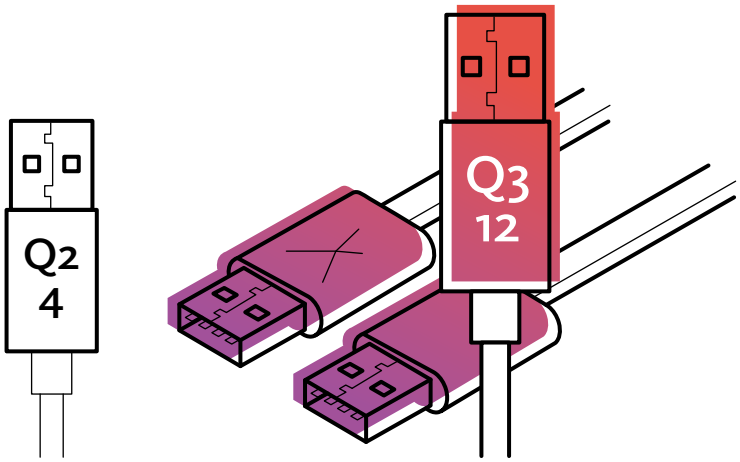
At 71 events, **recalls declined** for the third consecutive quarter (Q1 at 86, and Q2 at 75).



Despite this, Q3's total still stands 21.1% above 2020's quarterly average of 56 recalls.



USB chargers reclaimed the title of most recalled item, increasing three-fold (from 4 events in Q2, to 12).

Extension leads and Lighting chains followed with 8 and 4 recalls respectively. Hair dryers (the most impacted appliance of last quarter) did not recall this quarter.

Accounting for 45 events (63.4%), **Electric shock** was the leading cause of recall activity in Q3 2021.

Electric shock also featured in an additional 12 events, including: Burns (5), Burns & Fire (5), Fire (2).

MARISA PEARCE, ASSOCIATE, AND **ALISON NEWSTEAD,** PARTNER,
SHOOK, HARDY & BACON INTERNATIONAL L.L.P.

THE RIGHT TO REPAIR – A NEW DIMENSION TO THE RECALL LANDSCAPE?

The EU has recently witnessed the introduction of "right to repair" rules, which flow from the Ecodesign Directive. The rules are aimed at facilitating the availability of spare parts to enable the repair of a specific set of products, including household dishwashers, household washing-machines and washer-driers, refrigerating appliances, electric motors, and electronic displays. In short, manufacturers must now ensure the availability of spare parts within two years after the launch of a product, and then for between seven and ten years, depending on the type of product.

These new measures are intended to contribute to the EU's transition to a circular economy which involves the reduction of waste and pressure on natural resources by, for example, influencing product designs to improve product lifespans, maintenance, repair, reuse, upgrades, recyclability, and waste handling.

A shift in product safety management, recall, and litigation

Although the focus of this new approach is primarily the environment and sustainability, there will inevitably be product safety and recall considerations arising from these changes. Manufacturers will need to be alert to new issues that may emerge. For example, with an increasing number of consumers installing spare parts on their own, there is likely to be an increase in product failures and product liability claims.

When product safety issues like these arise, it has always been customary to investigate whether any repairs have been carried out and, if so, by whom. If repairs were not carried out by authorised repair centres, then further investigations are often undertaken. It will be important to continue to ask such questions, but investigations may require an additional dimension to determine what repairs the consumer carried out, what spare parts were used and whether the repair was completed correctly. Tensions may arise given that, in some circumstances, the person complaining of damage may be the very person who has carried out the repairs.

Similarly, with increased availability of spare parts, many products may remain in circulation for far longer than anticipated at the design stage. Where manufacturers could previously predict when most products would have reached their end of life, the duration of the product lifecycle may now be unknown. This could have several knock-on effects.

For example, if there is a potential safety issue in a product that has been on the market for some time, regulators will want to know how many products are on the market and how many are still likely to be in use. The latter question may well influence the corrective action taken and the expected response rate from the regulatory authorities. Additionally, with the expected lifetime of a product lengthening, the likelihood of product issues arising due to long-term use may also increase, leading to more safety issues that manufacturers need to investigate, notify, and undertake corrective action on.

These challenges raise an interesting issue with regard to product liability claims. Any claims under national legislation implementing the Product Liability Directive (PLD) will have a ten-year "long-stop", meaning a consumer will not be able to bring a product liability claim ten years after a product is first placed on the EU market. Products which have seen an extended life due to the right of repair, will not be able to use the PLD as a means of redress if an issue arises with the product ten years after it is placed on the market (whether related to the repair or not). It is likely to still be possible to bring actions under other legal principles, such as negligence, but one could anticipate that such actions would face difficulties. For example, is it negligent to design or manufacture a product that does not last more than ten years?

A Closer Jurisdictional Focus

France has become the first EU country to introduce a "reparability index", designed to encourage consumers to purchase more durable goods and manufacturers to produce more reparable products. The index assesses documentation, disassembly, spare parts availability, spare parts pricing and product-specific aspects such as software. The five pilot products that will be evaluated include smartphones, portable computers, washing machines, televisions, and electric lawn mowers.

The manufacturer, distributor or importer will be responsible for selecting and sharing reparability ratings with retailers, and retailers will have an obligation to display so that consumers may make an informed decision about the products that they purchase. By 2024, it is expected that new criteria will be added in relation to the robustness or reliability of products and the index widened to include other categories of products.

If France's reparability index means that more reparable products are produced and sold in that jurisdiction than other countries in the EU, then the outcome could be an indicator as to what the rest of the EU could expect in terms of the implications of the right to repair. For that reason, as part of its commitment to establish a right to repair under its Circular Economy Action Plan, the European Commission is contemplating the implementation of a similar reparability index that would be valid across the EU.

In **Germany**, the federal government is pushing to strengthen its right to repair laws over and above the EU requirements and is hoping to convince the EU to follow suit. Germany is promoting the implementation of legislation relating to smartphones and tablets, requiring manufacturers to provide reasonably priced spare parts and to make security updates available for seven years.

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MARISA PEARCE, ASSOCIATE, AND **ALISON NEWSTEAD,** PARTNER,
SHOOK, HARDY & BACON INTERNATIONAL L.L.P.
CONTINUED FROM PREVIOUS PAGE

What does the future hold?

As part of its Sustainable Products Initiative, the European Commission has indicated its intention to extend the scope of the EU regime by revising the Ecodesign Directive to include "the broadest possible range of products". A public consultation was held this year and the response to it and a legislative proposal are expected before the end of 2021. It may be that an increased range of products will fall into the scope of those covered by the "right to repair" and command the attention of manufacturers in terms of new types of recall and litigation risk.

Access by consumers to information on product durability, reparability, and even upgradability, at the point of sale is considered by some as the appropriate next step in fulfilling the EU's intention to promote a fully circular economy. This would complement the new "right to repair".

However, there remains an opposing view that such reforms on a broad range of products may impact product and consumer safety. If manufacturers have systems in place to identify repairs by inexperienced consumers that lead to product failures, then the risk of product liability claims and corrective action could be minimised.

However, given that the right to repair is likely to give products a longer lifespan, there may well be a rise in recalls of products that would have previously been considered as unlikely to be in use. Manufacturers will need to take this into account when evaluating product designs. In addition, manufacturers will need to consider the length of time for which product-related documentation is preserved, verify that documentation for historic products for which spare parts are available is well managed and identifiable, and ensure that the usual recall measures such as traceability and recall plans take this new dimension into account.

CONSUMER PRODUCTS

TOYS

Holiday shopping looks different this year as supply chain and logistics challenges are having a trickle-down effect on product ranges and selection, as well as pricing, discounting, and promotional offers, according to a report in the Financial Times. While this phenomenon is not limited to toys, the category is one of the most impacted.

In the same way, these supply chain challenges span the globe. As a result, we are deep into the throes of the holiday shopping season. Demand for products is high. And consumers are eager to secure their holiday gifts with a combination of guaranteed delivery and best price. In doing so, shoppers are turning to all forms of e-commerce – whether shopping their favorite brick-and-mortar shops online or relying on third-party marketplaces – and unknowingly walking into a dangerous situation.

> *A recent study by the British Toy and Hobby Association found that 88% of toys sold by third parties websites were not compliant with UK safety standards."*

Adoption of e-commerce leading to more unsafe toys

Toys, clothing, medicine, motor parts, and food are all subject to counterfeit products and other fraudulent activity – and these risks are even more prevalent in the rapid adoption of e-commerce. Unfortunately, fake goods are not often discernible to the average consumer – and the ability to differentiate between authentic and fake products is even more challenging when shopping online marketplaces and third-party sellers. Making matters worse, these products often seem like an attractive bargain.

From a regulatory perspective, it is important to understand that counterfeit goods have always been considered a brand infringement or intellectual property issue, but they're increasingly raising red flags for product safety. So much so that regulators are adopting the mindset that all counterfeit and fraudulent products are inherently unsafe since they do not comply with EU health and safety guidelines.

It comes down to this: while the counterfeiter is the bad actor in these cases, the brand whose authenticity is compromised is the one left to deal with regulatory investigations, potential claimant actions, and reputational fallout.

But what they don't always realise is that those channels are increasingly fraught with counterfeit, fraudulent, and unsafe products. In fact, a recent study by the British Toy and Hobby Association (BTHA) found that 88% of toys sold by third parties on websites like Amazon and eBay were not compliant with UK safety standards. Making matters worse, 48% of the products evaluated were deemed unsafe for children.

While counterfeit and fraudulent products are a safety risk for children and consumers, they are also a reputational risk for manufacturers. Companies should be prepared to respond to any concerns from consumers, regulators, or retail partners if the safety of your products are called into question because of another organization's criminal actions.

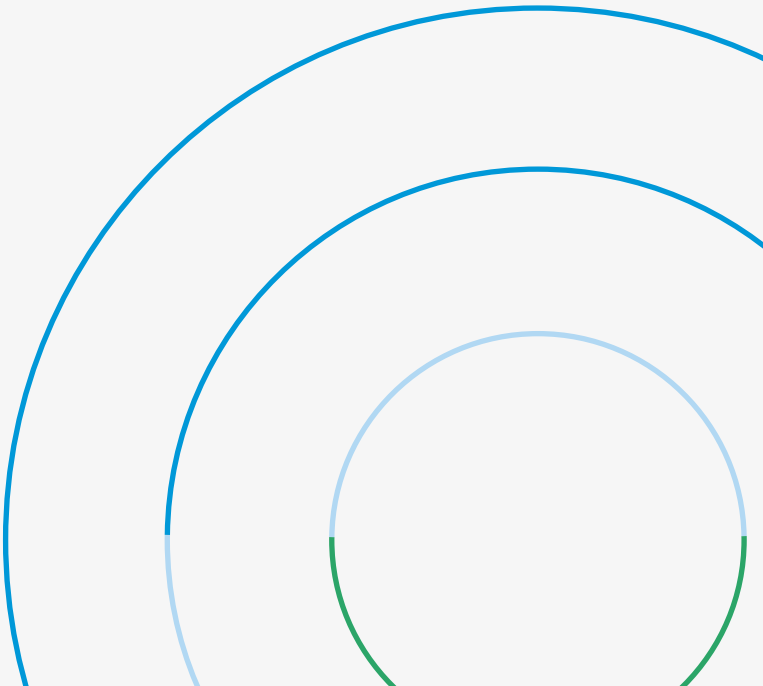
UK's new standards for children's digital services

The UK's Age-Appropriate Design Code (referred to as the "Children's Code") took effect in September, providing 15 standards that apply to online services that children are likely to access. While not explicitly legislation, the Children's Code is designed to help companies create and maintain online services that are age-appropriate and take data and privacy into account.

"The regulatory stick to make them do so is that the watchdog is explicitly linking compliance with its children's privacy standards to passing muster with wider data protection requirements that are baked into U.K. law," TechCrunch+ aptly warns. "The risk for apps that ignore the standards is thus that they draw the attention of the watchdog — either through a complaint or proactive investigation — with the potential of a wider ICO audit delving into their whole approach to privacy and data protection."

But the risk also is not contained to the UK. In addition to UK regulators expecting compliance with the Children's Code, regulators in the U.S. and elsewhere are also watching with the intention of formulating their own similar guidance or legislation. In fact, France's data watchdog issued child-protection-focused recommendations in June.

Before long, the definition of "toy safety" could explicitly address cybersecurity and privacy, leading to recalls and enforcement actions when products fail to protect data and privacy of children.



THIRD QUARTER OVERVIEW

Third quarter toy recalls remained consistent with last quarter at 81 events. This remains 22.9 percent down from Q1, which recorded 105.

Choking risk was the leading cause of third quarter recalls at 24 events, accounting for 29.6 percent of recalls. Various types of soft or plush toys accounted for 11 of these recalls.

Chemical concerns were the second most common cause at 21 recalls, followed by injuries (9), burns (5), and entrapment/injuries (4).

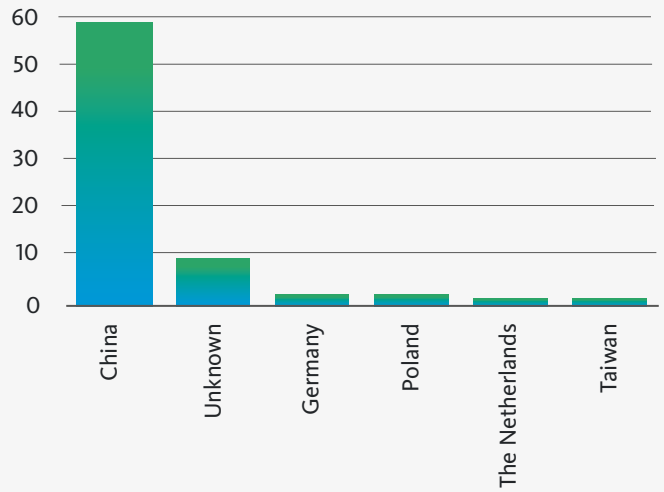
Like we see with electronics recalls, a wide variety of products were recalled with no one product type accounting for a significant percentage of recalls in the broader category. Plastic dolls were the most common recalled toy with just 12 recalls – all due to chemical concerns. Soft toys (9) and toy scooters (3) were the next most common products impacted by third quarters recalls.

Poland notified most at 20 events, followed by Hungary (8), Latvia (8), and Denmark (7).

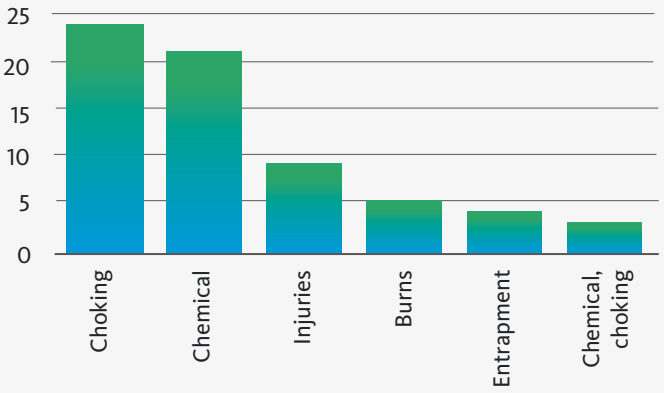
The People's Republic of China was listed as the country of origin in 58 third quarter recalls. Germany and Poland were each the country of origin for 2 events, while another 11 countries were the origin of just one product recalled. The origin of an additional 8 was unknown.

Of all recall notifications impacting toys, none were known to be counterfeit products, but 50 events listed counterfeit status as "unknown."

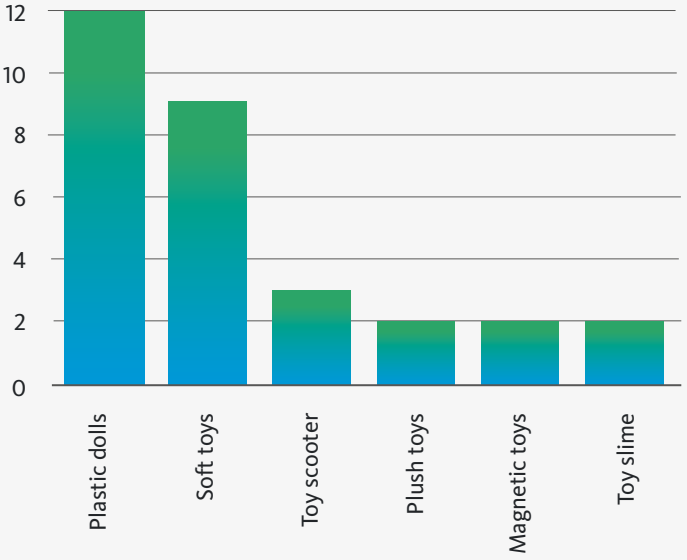
RECALLS BY COUNTRY OF ORIGIN



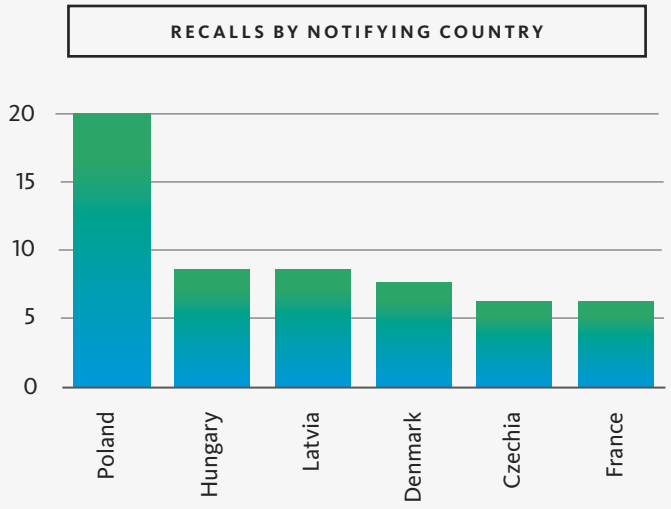
TOP CAUSE OF RECALL BY RISK TYPE



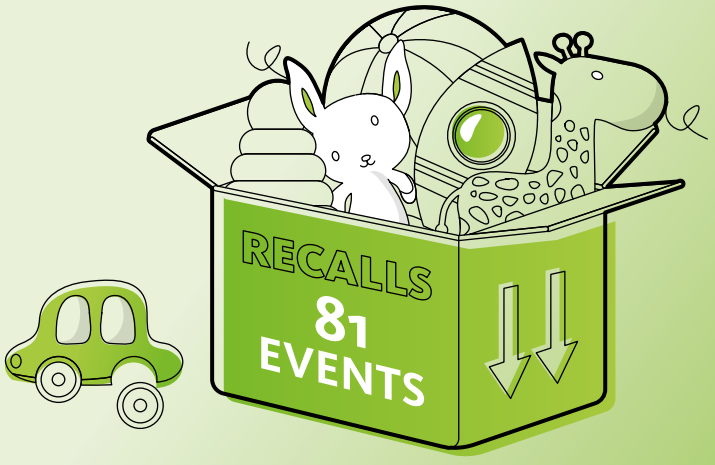
TOP RECALS BY PRODUCT



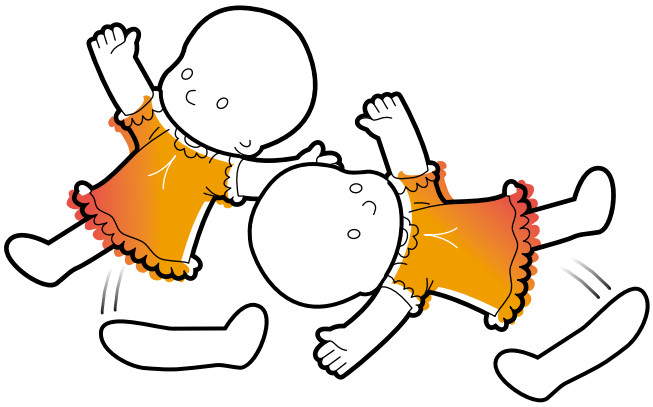
RECALLS BY NOTIFYING COUNTRY



Following two consecutive quarters of **significant decline**, recalls plateaued at 81 events.



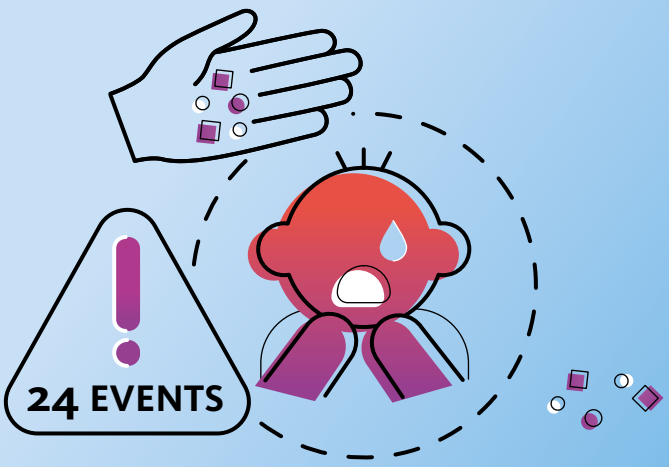
With the festive period fast approaching, we expect this number to climb noticeably.



Accounting for 12 events (14.8%), **Plastic dolls** remain the most recalled toy in Q3 2021.

At 48 recall events YTD, Plastic dolls have already exceeded their 2020 total of 47, making it the top recalled product of last year.

At 24 events, **Choking risks** were the most common cause of recalls in Q3 (29.6%).



Chemical concerns followed with 21 recalls. Of these, Plastic dolls accounted for 11 events, with Toy slime accounting for 2.

SARAH-JANE DOBSON, PARTNER AND
HOLLY WALDREN, ASSOCIATE, **KENNEDYS**

THE BIGGEST PRODUCT SAFETY CHALLENGES AND RISKS FACING THE TOY INDUSTRY

In Europe, toys are still considered one of the highest-risk product categories from a safety perspective, and therefore pose a significant challenge to manufacturers. This is due to the fact that these products are marketed to and used by a very vulnerable consumer group – children and infants. Against this backdrop, product safety has been the focus of legislative reform.

Changes to mainstay laws in the EU

The European Union's (EU's) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ("Toy Safety Directive, TSD") is in the process of being evaluated by the European Commission (EC) to strengthen its protection of toys and children's products. The recent evaluation of the TSD by the EC has identified several inadequacies that may compromise the health and safety of toys in the EU, particularly in respect of the chemicals contained in these products. As a result, several revisions have been proposed to address these issues with legislation applicable to toy safety in Europe. For example, the Chemicals Strategy for Sustainability was adopted by the Commission on 14 October 2020. This initiative is committed to strengthening the TSD with regard to contents of the most hazardous chemicals and combination effects of chemicals.

On 5 October 2021, the EC adopted an Inception Impact Assessment (IIA) Roadmap outlining measures for the Commission to assess and evaluate whether any improvements can be made to the safety rules for toys, particularly as in relation to compliance and enforcement. The IIA Roadmap will inform the Commission's expected revision of the current TSD.

The feedback period for stakeholders to provide their responses in respect of this consultation ran until 2 November 2021. It will become clearer over the next few months what parts of the TSD the industry considers too restrictive. An Impact Assessment is anticipated to be launched by the end of this year. It will set out the policy options laid down in the IIA Roadmap. Stakeholders will then be asked to share their views in dedicated meetings of the Expert Group on the revision of the TSD.

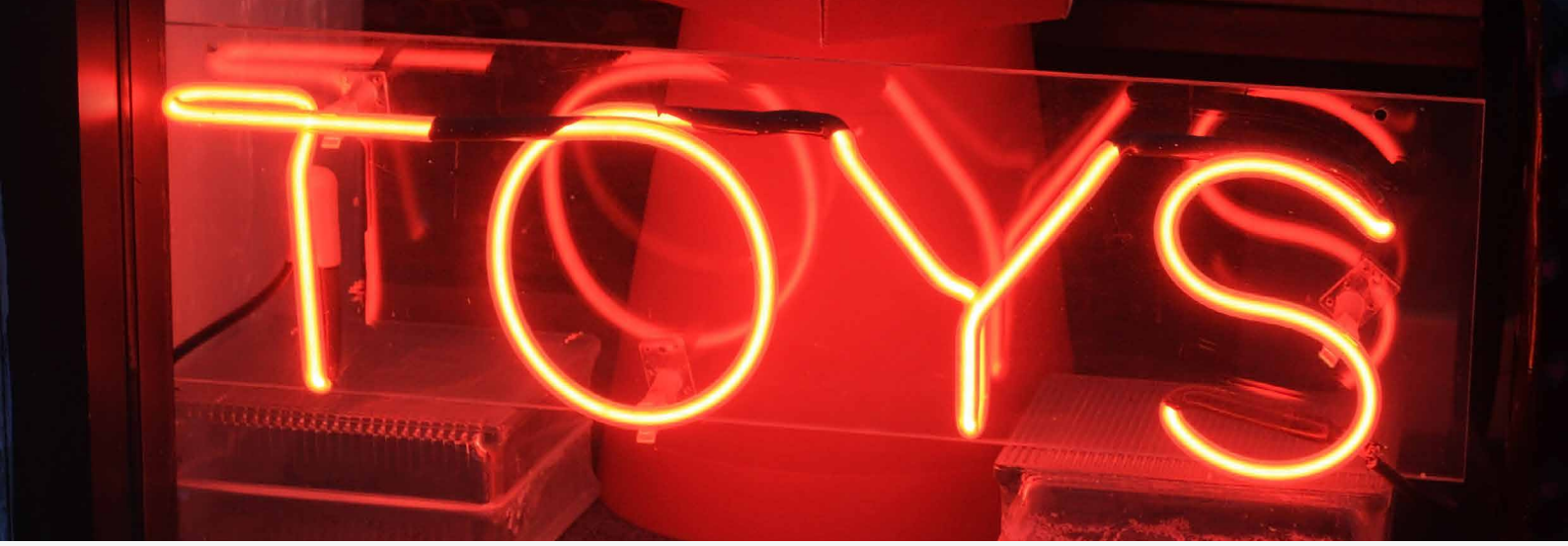
It is likely that a four-week consultation on the IIA and a 12-week public consultation on the internet will take place. However, the adoption of a proposal for a Regulation revising the TSD is predicted to take place in Q4 of 2022.

Impact of other product safety laws on the toy industry

Significant changes to the enforcement and applicability aspects of general product safety laws in the EU are imminent – and these impact the toy industry specifically. For example, the application of the EU's new Market Surveillance Regulation (MSR) to the TSD was announced by way of opinion by Advocate General on behalf of the European Commission as recently as September 2021. This reconfirmed the fact that, as per Article 4 of the MSR, the MSR applies to toys covered under the TSD and therefore requires relevant manufacturers of said toys to have an EU-based economic operator to ensure local product compliance and be answerable to authorities and report via Safety Gate, the EU rapid alert system, in the event of non-compliant products.

Online shopping and supply chain challenges

Currently the biggest challenge concerning toys is ensuring toys sold in-store and online are safe leading up to Christmas.



As the festive season approaches, it is predicted that many people across the UK will be concerned about toy shortages amid supply chain challenges created by the pandemic and Brexit. Many consumers are already thinking about where to purchase toys for their children, and considering turning to third-party sellers online. Unfortunately, this comes with risks.

There is no guarantee that online sellers comply with product safety laws, resulting in a high number of unsafe products being sold online. In fact, a report commissioned by the British Toy and Hobby Association (BTHA) showed that 88% of toys sold on third-party e-commerce platforms were non-compliant and 48% were deemed unsafe for children.

Online sales is a broad policy focus of EU and UK regulators. The long-standing voluntary EU Product Safety pledge by which online marketplaces commit to improving safety or products sold online may not go far enough, especially when it comes to toys.

The future of the recall landscape

Europe could see an increase in toy recalls in Q3 2021 as regulators push towards a greater level of compliance and safety in the lead-up to the revisions of the TSD.

The expected clarification of guidelines relating to required toy safety warnings for consumers is likely to impact the recall landscape. These changes will likely take time for manufacturers and consumers to adjust to new terms of the TSD whilst navigating post-pandemic market effects. However, it is likely recall numbers will plateau fairly quickly and the toy industry will see further decline in recalls for traditional risks over the long term as the market adopts higher safety standards.

That doesn't mean market participants can relax. As the toy market continues to be flooded with new technology, we may see toy recalls in new areas related to cybersecurity risks and previously unheard of dangers that have existed in other product categories but are new to the toy industry.

Preparing for new challenges

There are several proactive steps companies in the toy industry in the EU and the UK can take in light of the developing trends in product safety and recalls:

- Monitor the potential changes arising from the EC's roadmap to prepare for revisions of the TSD to assess how this may affect their business.
- Get familiar with the updated guidance on how to ensure information in instructions and warnings about how to use the toys safely are accessible and can be understood by consumers and those who play with the toys. This will help reduce the number of complaints and potential recalls.
- Reassess the use of toys by different ages of children in different contexts and adopt warnings accordingly. One ongoing difficulty for manufacturers is that one product may be safe for one category of child or under certain use conditions but hazardous for other children and under other use circumstances. Conditions of use should therefore be addressed and made very clear to the consumer.
- Anticipate potential product recalls and have in place an efficient process to address these issues as quickly and as easily as possible. These processes should be based on overall best practice but also industry-specific best practices.

While it can be difficult to make clear strategic plans with so many regulatory uncertainties and changes pending, following these recommendations can help players across the toy industry make the best decisions for their companies and their customers.

CONCLUSION

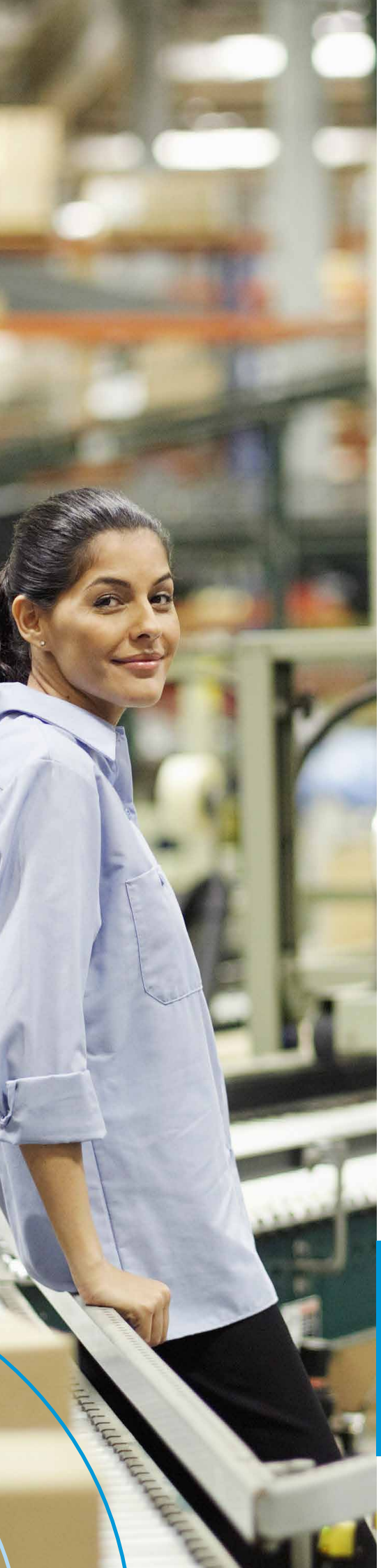
Manufacturers are operating in one of the most turbulent and uncertain times in recent history. There appears to be a light and the end of the COVID-19 tunnel and economists predict a business boom for the remainder of the year. But while consumers may be eager for a return to normal, the 2019 "business-as-usual" posture for regulators and legislators is a thing of the past.

We stand by the prediction we made in our state of the nation report. The only thing we can be sure of in 2021 is the expanding reputational risks to companies across all sectors. From a product-safety standpoint, the risks are numerous:

- 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
- Constantly shifting consumer demand
- Customer and partner apprehension

Companies across all industries need to closely re-evaluate all manufacturing processes and vet supply chain partners. We urge you to invest some time and resources now to prepare your recall management, crisis, and communications plans. Review your insurance policies to ensure they protect you in the event of a recall or safety inquiry. And in doing so, remember to turn to expert partners for their experience and expert insights that can save you millions of dollars in regulatory and litigation costs.

Given how quickly our business and regulatory environments are evolving, expert partners have become essential in helping you uphold 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

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.

But we haven't just watched it, 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.

So, while we predict continued change in 2022, it's nothing we haven't seen or dealt with before. In fact, it's often that these events, even what feels like a devastating product recall, offer opportunities to demonstrate trustworthiness and to build greater customer loyalty.

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.

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