STATE OF THE NATION 2022

PRODUCT RECALL
EUROPEAN EDITION

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

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

The report reviews five product categories and three sub-categories: Automotive, Consumer Products – including Electronics, Clothing and Toys, Food and Drink, Pharmaceutical and Medical Devices. It collects and analyses data from regulators across Europe, including the UK and the European Union, to provide businesses with exclusive insights and guidance valuable to their operations.

This 2022 'State of the Nation' brand protection Recall Index goes beyond our traditional quarterly reviews. It provides not only information about the most recent quarter, but also offers a year-in-review look at recall data and trends from all of 2021. In addition, there is a look ahead into the most recent January recall numbers.

Our analysis and predictions help companies plan for 2022 as regulators and business leaders alike look ahead to the third calendar year of the pandemic and hope for some relief and a return to something that resembles normal. There are also insights on how new trade rules under Brexit are impacting business operations and commerce.

Additional insights from some of our strategic partners at leading law firms, insurance companies and communications firms offer expert analysis to help you prepare for new regulations facing your sector.

Both the EU and the UK are pushing for more consumer protections and safeguards. There also continues to be a focus on how to make commerce greener and more sustainable. That is why it is so important for companies at every level in the supply chain to be aware of changes and be ready for recalls and related threats to their businesses and reputations.

Whether you read the Recall Index cover-to-cover or focus on sections of particular importance to your company or industry, you're sure to learn something new about what is happening today, and what may be on the horizon.

As a reminder, this 2022 'State of the Nation' 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:

Q3 2021 European Recall Index: click here

Q2 2021 European Recall Index: click here

Q1 2021 European Recall Index: click here

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SUMMARY

There were two notable disruptions for the UK and EU markets in 2021 – Brexit and COVID-19. There have been supply chain challenges resulting from both of these, and businesses have been forced to adjust what would have been normal operations two years ago.

Recalls were up in every industry in 2021, with the exception of toys, which saw a 28% decline in events compared to 2020. The toy industry did however see the expected spike in the fourth quarter, which accounted for 38% of all recalls for the year.

The pharmaceutical industry saw the biggest jump with 372 recalls, a 48% increase over 2020. Electronics experienced a 45% year-over-year increase in product recalls. While clothing saw a 25% increase, children's sweatshirts alone experienced a 200% increase from the year previous.

As we outline in this report, there are sweeping changes ahead for all industries. In many cases, regulators are working to update laws written 20 years ago, before the widespread adoption of online marketplaces and connected devices.

While the goal of these changes is to protect consumers, and in some cases the environment, they are likely to cause challenges for businesses who may need to make significant adjustments to their business processes to comply with new regulations.

Key industry highlights for the year:

Automotive

The European Commission's focus on sustainability and the environment was clear in 2021 and will continue throughout 2022. One example of this is proposed changes to the Intelligent Transport Systems Directive. These revisions are part of the Commission's overall blueprint for making cities safer, connected and sustainable, and include regulations for data sharing, transport networks, and emissions. If adopted, these measures will affect how these systems are used in road transport and how they interface with other modes of transport.

In other environmental news, after being delayed from an ambitious target of June 2021, the European vehicle emissions standards, Euro 7/VII, are expected to go into effect in the first quarter of 2022. The regulations, which are part of the European Green Deal, will apply to all petrol and diesel cars, vans, lorries, and buses.

Regulators are taking notice of companies and their actions, or inactions, around green obligations. German authorities fined a leading EV manufacturer 22 million Euros in 2021, a stark reminder of the cost associated with non-compliance with environmental obligations. The fine follows allegations that the brand did not notify the public or properly meet its obligations to retrieve old batteries from customers.

The manufacturer objected to the fine, writing in its filing that this was primarily related to administrative requirements, but they had continued to take back battery packs. Regardless of the outcome, it is an example of the expansive safety related regulations and hard-hitting enforcement penalties facing global automakers. **For more in-depth analysis of the automotive industry in 2021, and our predictions for 2022, click here.**

Food and beverage

Labelling and packaging changes drove a lot of the conversation around food and beverages in 2021. We will undoubtedly see more activity here in the year ahead.

The European Union updated its food packaging rules last year in accordance with its Single Use Plastics directive to limit packaging waste, promote recycling, and establish traceability requirements. The European Food Safety Authority (EFSA) issued guidance to help food suppliers determine what information to give consumers about food storage and time limits for consumption.

The European and UK food and beverage industries are facing several regulatory updates in 2022, including the Competition and Markets Authority Green Claims Code, which is now in effect. Natasha's Law for ingredient labelling has also been enacted and 2022 will be the first full year it is enforced.

Natasha's Law is not the only legislations around food labels. The EU is seeking mandatory, harmonised food labelling. In December 2021, the European Commission published its public consultation about proposed changes on providing food information to consumers.

If enacted, these new rules would impact several aspects of food labelling: front-of-pack nutrition labelling and nutrient profiling criteria, extension of mandatory origin indications for certain products and a revision of the EU rules on "use by" and "best before" labels.

As in the automotive industry, food industry regulators are being more aggressive with enforcement. We saw the first sanction for greenwashing by the UK Advertising Standards Authority. In addition, there was a 7.56 million Euro fine against a grocery chain for selling food past its "use by" dates. **For more in-depth analysis of the food & beverage industry in 2021, and our predictions for 2022, click here.**

Pharmaceutical

A major change for the pharmaceutical industry is the European Union's new Clinical Trial Regulations, which went into effect on 31 January 2022. The new legislation is designed to harmonise the rules for conducting clinical trials in the European Union and European Economic Area. Under the new guidelines, clinical trial sponsors can submit one online application via a single platform to gain approval to run a clinical trial in several European countries.

Prior to the changes, sponsors were required to submit applications separately to national competent authorities and ethics committees in each country. The new law requires that the sponsor or legal representative for a clinical trial be established in the EU. Sponsors who are solely based in the UK can no longer conduct clinical trials in the EU on behalf of sponsors from the US or other non-European locations.

The UK Medicines and Healthcare products Regulatory Agency is also considering changes to its laws around clinical trials, but has yet to issue any formal proposals.

With the rise of the Omicron variant in 2021, global regulators are working together to drive a coordinated response and promote safe and efficient development of new vaccines and treatments.

Participants from 24 members and 13 associated members of the World Health Organization and the European Commission met to discuss the effectiveness of the approved COVID-19 vaccines. They also consulted about the key regulatory requirements for the development of a possible adapted vaccine specifically for the new, highly contagious Omicron variant.

We can expect changes throughout Europe regarding cannabis in 2022. Malta became the first country on the European continent to legalise recreational cannabis in December 2021. Other countries are also considering easing restrictions on recreational use of the substance. Germany, France, Italy, and Luxembourg are discussing some form of legalisation. Switzerland and the Netherlands have shared plans to expand current pilot programmes for adult use. **For more in-depth analysis of the pharmaceutical industry in 2021, and our predictions for 2022, click here.**

Medical devices

One of the major topics for medical device companies with business in the EU is changes to the transition periods required to take in vitro diagnostic medical devices (IVDs) to market. IVDs include both self-administered tests such as those for pregnancy or blood glucose levels, and more complex testing performed in clinical laboratories. HIV tests and COVID-19 tests are also examples of IVDs.

New rules were to go into effect in May 2022, but regulators realised that deadline was unrealistic. To avoid shortages of critical medical products that would be delayed awaiting compliance or assessments associated with the new regulations, the transitional periods were amended.

Certain classes of IVDs will still need to adhere to the original 26 May 2022 deadline. The IVD Regulation will not apply in Great Britain, but will apply in Northern Ireland.

The EU and UK are leading the way in regulating artificial intelligence/machine learning (AI/ML)-based software as a medical device. The EU issued a new Medical Device Regulation (MDR) last year that represented the first regulatory guidance for medical device software, commonly known as SaMD (Software as a Medical Device).

Among its changes, the MDR overhauled labelling requirements and outlined lifecycle traceability requirements. Soon after, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) released its new regulatory programme for medical devices, which bears many similarities to the MDR.

In terms of recalls, the volume of events in the medical device category rose sharply in 2021 compared to the previous year – up 40% to 2,886 in 2021. Quality issues were the most common reason listed for medical device recalls throughout the year, accounting for 21.8% of recalls. **For more in-depth analysis of the medical device industry in 2021, and our predictions for 2022, click here.**

Consumer products

We are seeing a flurry of legislative activity across the Consumer Products sector. Part of this is driven by the increase in new technologies – both in the way people shop and in the products themselves.

The change that will likely have the most far-reaching impact is the reforms to the Product Liability Directive (PLD). The PLD is the basis of EU product liability. Revisions are expected to include reforms to product liability legislation to explicitly cover software and other intangible products.

Proposed modifications would also lessen the burden of proof for consumers in cases dealing with complex technology. New rules will also make online marketplaces liable if they fail to identify suppliers. It is unclear if the UK will plan similar changes to update its Consumer Protection Act 1987 or wait and see how the EU addresses the issues first.

Another priority for the European Commission is updating the General Product Safety Directive. The proposed changes are designed to reflect advances in products and technological changes in commerce. It is meant to improve the safety of products linked to new technologies, mitigate risk for products purchased online, improve enforcement of the rules, increase the efficiency of market surveillance, and take steps to improve the recall of dangerous products.

In February 2021, the European Parliament adopted a resolution on the new circular economy action plan demanding additional measures to achieve a carbon-neutral, environmentally sustainable, toxic free, and fully circular economy by 2050, including tighter recycling rules and binding targets for materials use and consumption by 2030.

Another change that will impact the consumer products sector in 2022, but which will also have some effect on other product categories, is the new UK Conformity Assessed (UKCA) mark. The mark came into force on 1 January 2021 and is required for products for sale in England, Wales, and Scotland to show they meet required **safety, health, and environmental standards** and have been checked by the manufacturer. It replaces the European Union's CE marking, though that label will continue to be recognised until the end of 2022. **For more in-depth analysis of the consumer products industry in 2021, and our predictions for 2022, click here.**

Clothing

In June, 25 European non-governmental organisations (NGOs) pushed back against the "fast fashion" industry, considered one of the largest global polluters. Calling for the EU to hold brands accountable for their contribution to pollution, the organisations launched a Wardrobe Change campaign calling for "minimum standards for how long clothes should last, a ban on the destruction of unsold and returned goods, rules to verify and substantiate green claims, and ambitious targets for an absolute reduction in the amount of natural resources used across the supply chain,"

Environmentally friendly processes for production, packing, and shipping continue to be a theme across the clothing industry. More and more companies are highlighting ways they are using regenerative, responsibly sourced, renewable and/or recycled materials in their products and packaging.

The UK's Competition and Markets Authority (CMA) selected the fashion retail section as its target for the first review of environmental claims under the new Green Claims Code. As part of its evaluation, the CMA will look at environmental claims across the fashion retail sector in the UK to determine whether or not businesses are complying with consumer protection law. This includes being able to support claims of clothing as sustainable, the use of recycled materials in new clothing, and labelling materials as "organic." **For more in-depth analysis of the clothing industry in 2021, and our predictions for 2022, click here.**

Toys

Manufacturers are watching major changes in the EU Toy Safety Directive (TSD) work their way through the approval process. It is another example of how regulators are acknowledging how changes in both product technology and the way products are sold – notably online. The TSD regulates the safety criteria that toys must meet before they can be marketed in the EU. Revisions are expected to impact areas such as online sales, second-hand toys, and chemical testing models.

In addition to the regulatory changes that toy manufacturers will face from the revisions to the TSD itself, the European Commission also confirmed that the EU's new Market Surveillance Regulation will apply to products covered by the TSD. Under the new rules, any non-EU company, including toy manufacturers, must have an EU-based entity answerable for product compliance matters.

Consumers' growing desire to buy from local or small independent sellers applies to the toy industry, too. To help manufacturers on its site meet their legal obligations when selling and distributing into the EU market, the e-commerce giant Etsy published a primer about new requirements, the EU definition of toys, and a checklist of obligations manufacturers must meet before placing a toy in the EU market. **For more in-depth analysis of the toy industry in 2021, and our predictions for 2022, click here.**

Electronics

With more people working at home as a result of the pandemic, and more children forced to school remotely, electronics were used more frequently and in new ways in 2021.

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."

The UK's proposed Product Security and Telecommunications Infrastructure Bill (PSTI) is meant to protect consumers, but could end up being onerous for manufacturers and distributors. While the bill is still in its early changes, if passed, it has the potential to have a big impact on consumer electronics as well as telecommunications companies.

The proposal looks at "consumer connectable products," which include everything from smartphones and connected baby monitors, to connected smoke detectors and wearable connected fitness trackers. Even connected appliances such as refrigerators would be covered.

Under current laws, connectable consumer products must ensure that they will not directly cause physical harm. Under the PSTI's product security measures section, the proposed legislation would protect consumers from cyber harm. It will also provide an adaptable and flexible regulatory framework.

The electronics industry saw a nearly 45 percent increase in recalls in 2021 compared to 2020. This marks the second year in a row that figures have increased. This year's increase to 326 recalls is more significant than the increase between 2019 and 2020. **For more in-depth analysis of the electronics industry in 2021, and our predictions for 2022, click here.**

AUTOMOTIVE

Looking ahead in 2022, the European automotive industry is facing a number of regulations from the European Commission – some proposed and some soon to be enacted – that focus on sustainability and the environment.

The Commission sees many of these new actions as interconnected – all part of its overall blueprint for making cities safer, connected, and sustainable. There are also sweeping automotive safety rules taking effect this year, with requirements for all new cars and light commercial vehicles to have three advanced driver assist systems.

It will be interesting to see if these new regulations are able to lower the number of recalls due to injuries, which is typically the most common risk associated with the industry. In 2021, injuries were cited in almost 78% of total European recalls.

> *"As the ITS proposal works its way forward, automakers will want to monitor what regulations may apply to vehicle data, including any privacy protections for drivers."*

> *"The European vehicle emissions standards, Euro 7/VII, are expected to go into effect in the first quarter of 2022, and apply to all petrol and diesel cars, vans, lorries, and buses."*

Focus on intelligent transport systems

The European Commission proposed updates to its 2010 Intelligent Transport Systems (ITS) Directive in December 2021. The changes relate to how ITS are used in road transport and how they interface with other modes of transport.

One of the Commissions' recommendations is that ITS data should be digital, stating that digitalisation "will make the entire transport system seamless and more efficient," and "further increase levels of safety, security, reliability and comfort." It envisions ITS as a key factor in building a connected and automated multimodal mobility system, increasing the use of shared vehicle solutions as an alternative to private vehicle ownership, accelerating the adoption of zero-emission vehicles and reducing traffic congestion to create more sustainable transport. The Directive also notes a lack of coordination in ITS deployment across the EU and the often slow, risky, and costly roll-out of its deployment. It hopes that additional rules to improve alignment with current practices and standards will address some of the current challenges.

In its proposal, the Commission encourages an expansion of the scope of the 2010 Directive to cover new and emerging challenges and looks to mandate the use of essential ITS services across the EU.

As the proposal works its way forward, automotive manufacturers will want to monitor what regulations may apply to vehicle data, including any privacy protections for drivers.

European commission proposes new urban mobility framework

The European Commission announced its European Urban Mobility Framework in December 2021. The proposed framework is designed to complement recommended revisions to the Trans-European Transport Network (TEN-T revision). With the TEN-T updates, all major cities on that network must develop a sustainable urban mobility plan by 2025.

This new urban mobility framework complements changes in the TEN-T and outlines a common list of measures and programme's for cities on that transport network, as well as for other cities in the EU, to ensure their mobility is more sustainable.

The Commission identified the programme's key objectives as contributing to EU greenhouse gas reduction targets as set in the Climate Law, improving transport and mobility to, in and around cities, and improving the efficiency of goods and home deliveries.

There were 11 elements that the Commission outlined for the plan including "stronger action to create climate-neutral cities," "more targeted EU funding and better synergies between different programmes to support these action points," and "more effective zero-emission city freight logistics and last-mile deliveries" through the integration of sustainable urban logistics plans (SULPs) and Sustainable Urban Mobility Plans (SUMPs).

We can expect to see a lot more communication from the Commission around this framework and the TEN-T changes throughout 2022 as planning moves forward.

Regulations for stricter emissions standards coming soon

After being delayed from an ambitious target of June 2021, the European vehicle emissions standards, Euro 7/VII, are expected to go into effect in the first quarter of 2022. The regulations, which are part of the European Green Deal, will apply to all petrol and diesel cars, vans, lorries, and buses. The EU has stated that the proposed rules will consider new vehicle technologies and ensure emissions are measured in real-time as part of its commitment to accelerate the shift to sustainable and smart mobility.

New automotive safety regulations coming this year

The first phase of the EU's "General Safety Regulation" will go into effect in July 2022 mandating that all cars and light commercial vehicles registered in the EU for the first time must have three advanced driving assistants: intelligent speed assistant (ISA), lane change warning, and tyre pressure monitoring system. Trucks and buses will additionally have to have emergency braking systems capable of stopping the vehicle if a possible frontal collision with a stationary or moving vehicle is detected.

Even though the UK is no longer part of the EU, it is expected these new requirements will also apply in the UK since most driving laws have been transferred for ease of manufacturing.

The European Transport Safety Council (ETSC) is calling on vehicle manufacturers to go beyond the minimum requirements of the legislation to maximise the huge potential safety benefits of these technologies. Under the new regulations, automakers will have to report aggregate, anonymous data on how ISA systems are being used, and if they are being switched off by drivers.

Given that these regulations have been under discussion since 2019, it is hoped that manufacturers are already making preparations for both the technology and the required reporting.

European commission publishes first sanction of an anti-competitive agreement on technical development

In November 2021, the European Commission published its decision AT-40178 of July 8, 2021, fining four automotive makers a total of 875 million euros for their involvement in a cartel within the European Economic Area territory and giving full immunity to a fifth company that disclosed the existence of the cartel. The case centered on the assertion that the manufacturers postponed the introduction of techniques to clean exhaust gases generated by new diesel cars.

At issue was how all five manufacturers had a liquid solution that removes some of the nitrogen oxide (NOx) from car exhaust. This solution could be used to reduce harmful emissions from diesel car exhaust to a level below what was legally required by the European Union.

None of the automakers fully developed this technology, which would have made their diesel cars less harmful to the environment. Their reason was to intentionally avoid competing with each other. The Commission found that this reduced innovation and restricted competition on the technical features of the cars they will bring to market, even though many consumers are looking for vehicles with lower emissions.

This was the first cartel case based on the limitation of technical development under Article 101(1)(b) of the Treaty on the Functioning of the European Union. It is unclear if the Commission's focus on the European Green Deal – and the fact that this matter dealt with vehicle emissions – impacted the amount of the fine.

> *"Under the new EU's "General Safety Regulation", automakers will have to report aggregate, anonymous data on how ISA systems are being used, and if they are being switched off by drivers."*

2021 BY THE NUMBERS

Automotive recalls rose across Europe in 2021, reaching 571 for the year. This marked a nearly 18% increase compared to 2020 (485). Recalls rose from 152 in Q1 to 177 in Q2, before starting to fall. There were 152 in Q3 and then a 40.8% drop to only 90 recalls in Q4.

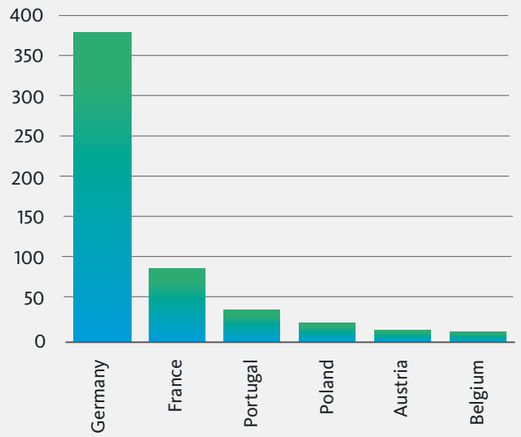
Once again, Germany led with the most recall notifications at 379, or 66.4% in 2021. France saw a dramatic rise, with 82 in 2021 compared to only 16 in 2020. Portugal had 37 for the year, a 14.0% decrease from 2020. The number of recall notifications in the UK dropped significantly, going from 62 in 2020 to only five in 2021.

In terms of country of origin, Germany recorded 214 recall events (38.0%) in 2021, this represents a 24.4% increase compared to 172 events in 2020. Vehicles originating in France accounted for 70 recalls, placing it second in terms of volume.

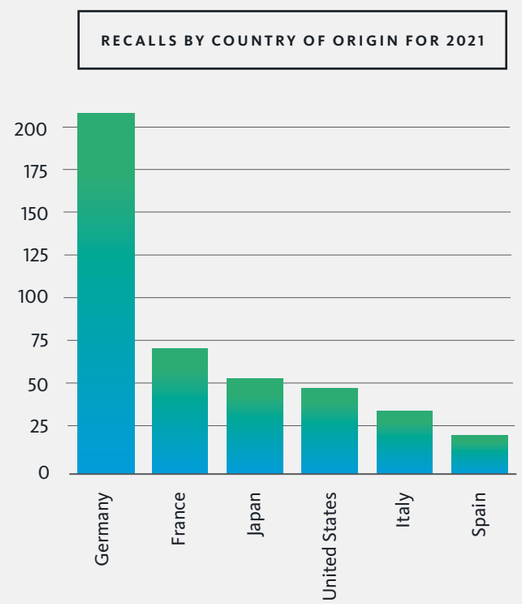
Consistent with recent years, the most common risk associated with automotive recalls across each quarter was injuries. Injuries were cited in almost 78% of total recalls, with 444 reported for the whole of 2021. Following patterns from 2019 and 2020, fire was the second most common risk type – listed in 79 recalls, and fire and injuries (combined) was cited in 27 recalls.

While overall automotive recall patterns remained fairly stable in 2021, there were notable differences in some notifying countries, including increases in France and decreases in the UK. It is unclear if those changes can be attributed to shifts in production due to the pandemic, or to other factors.

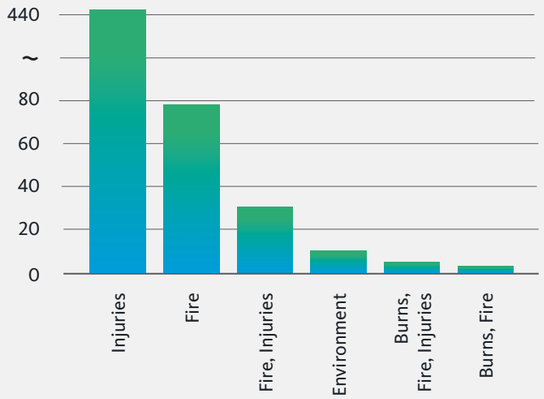
RECALLS BY NOTIFYING COUNTRY FOR 2021



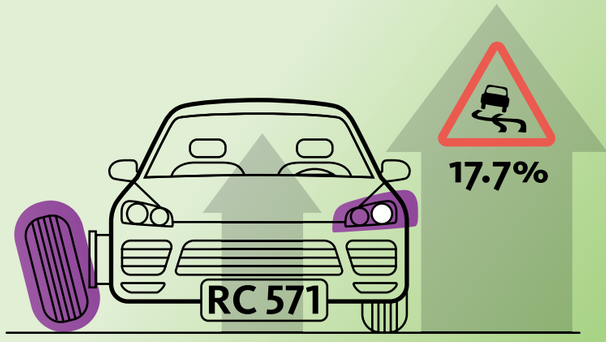
RECALLS BY COUNTRY OF ORIGIN FOR 2021



NUMBER OF EVENTS BY RISK TYPE FOR 2021



At 571 events, European automotive **recalls increased 17.7%** in 2021, from 485 in 2020.

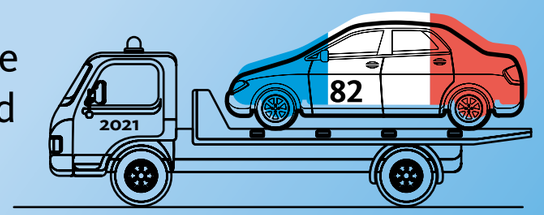


Recall events in 2021 sat 128% above the industry's annual average of the last 15 years.

For the last 10 years, **Injuries** have remained the leading annual cause of automotive recalls.

While this category accounted for 444 events (77.8%), recalls caused by fire risks increased by a third (29.9%) from the year previous (113 vs 87).

France experienced the highest increase in annual recall notifications (82 were recorded in 2021, compared to only 16 in 2020).



France recorded the second highest number of recall notifications in 2021, and was the second highest country of origin – following Germany in both instances.

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AUTOMOTIVE FORECAST – FAMILIAR HEADWINDS FOR 2022

UK automotive production hit a 65-year low in 2021 with fewer than 900,000 vehicles rolling off production lines, according to estimates from the Society of Motor Manufacturers and Traders (SMMT). Germany had its worst year since the 1970s.

Some of the factors that resulted in this slow down were shortages of labour, lockdowns, travel and border restrictions due to the COVID-19 pandemic, and product and component shortages. Furthermore, price and wage inflation, the increased administrative burdens from Brexit and other geo-political events such as U.S.-China relations, all impacted cross-border trade.

Even as the world emerges from the on-going grasp of the pandemic, many of these challenges linger. And whilst the impact of shortages across the automotive industry is expected to reduce later this year, most experts predict effects on production into 2023.

In addition, manufacturers are expected to see increased legal and regulatory burdens and scrutiny. These include new safety regulations, vehicle content and "rules of origin", Environmental, Social and Governance (ESG) rules around emissions targets and new guidance for self-driving technologies.

As if that wasn't enough, there are significant challenges for automotive businesses flowing from long-term structural changes in the industry. The push to electric vehicles (EVs), commitments to net-zero emissions by 2040, accelerating autonomous vehicle (AV) and in-cabin technologies, and new generations of production and automation technologies will all add more complexity and liability for automakers.

There are some bright spots, though. According to the SMMT, the UK automotive sector rebounded in 2021 following an especially damaging 2020. However, the rate of recovery was lower than the industry would have hoped for. Sales volumes were around 10% below 2019 levels, whilst registrations of new cars within the EU fell by 2.4%, representing the worst performance since 1990.

With challenges come opportunities. There are evolving solutions to deal with eminent supply chain issues and there are significant growth areas in the burgeoning EV market, particularly if energy costs and the present semi-conductor issues can be addressed head on.

One of the biggest areas for optimism is around electric and autonomous vehicles.

Growth of electric and autonomous vehicles

Consumer demand for and uptake in EVs is at an all-time high. And 2022 is likely to see a continued push towards increased electrification. With the political goodwill from COP26 in Glasgow late last year and with multiple jurisdictions setting targets to cut emissions by 2040 or sooner, the economic climate is becoming increasingly more favourable for EV growth.

UK government data showed that the number of public EV chargers rose 37% from 1 January 2021 to 1 January 2022, and BP recently revealed that their EV chargers will soon be more profitable than their fuel pumps. Statistics like these demonstrate the benefit to manufacturers in increasing their already significant investment in EVs and further seizing the opportunity this market presents.

AVs have not received similar acceptance, as evidenced by a recent national survey linked to a multi-city trial. Safety remains a key concern for drivers when it comes to AVs. Increasing numbers of product recalls are not relieving consumers' concerns. There have been high-profile and well-publicised issues with EV batteries and AV crashes.

Most notably, one of the leading U.S. EV and AV manufacturers issued two significant product recalls for different models of EVs. One recall around rear-view camera and trunk issues impacted more than 475,000 vehicles. Another recall of 54,000 vehicles addressed self-driving software issues.

With the increasing use of charging stations, cybersecurity continues to be an interesting and evolving area of risk. Manufacturers, infrastructure owners and other stakeholders must strengthen cybersecurity protections to meet emerging threats.

Both AV and EVs can be vulnerable to cyberattacks, including through charging station connections, shared mobility risks, over-the-airwaves vehicle IT/software updates etc. For instance, AVs may communicate with one another and share personal data. More traditional threats could also come from aftermarket and servicing checks.

Cyberattacks have the potential to cause fatal consequences, particularly for AVs, so safety and systems protections must continue to be at the heart of this technology revolution. There is also the risk from vehicle big data and data loss, which could provide a battleground for future litigation claims and, potentially, customer class-actions.

It is important to remember EVs are not just cars. There has been an increase in demand for e-scooters and e-bikes across major European cities throughout 2021. This trend is expected to continue. These vehicles offer an alternative to private driving and taxis, as well as the ability to bypass congestion. But high-profile e-scooter accidents and issues with regulation suggest it is an area where further legislation is urgently required.

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More regulation on the way

The drive to zero carbon and emissions commitments from COP26 are obvious areas for increased regulation, with carmakers faced with ever-increasing standards and rules to meet these ambitious environmental goals.

Manufacturers are also increasingly evolving the use of AV and in-car technologies within their models. In-car technology appeals to and competes for the driver's attention. The Transport Research Laboratory found that some in-car technology systems can need up to 20 seconds of concentration.

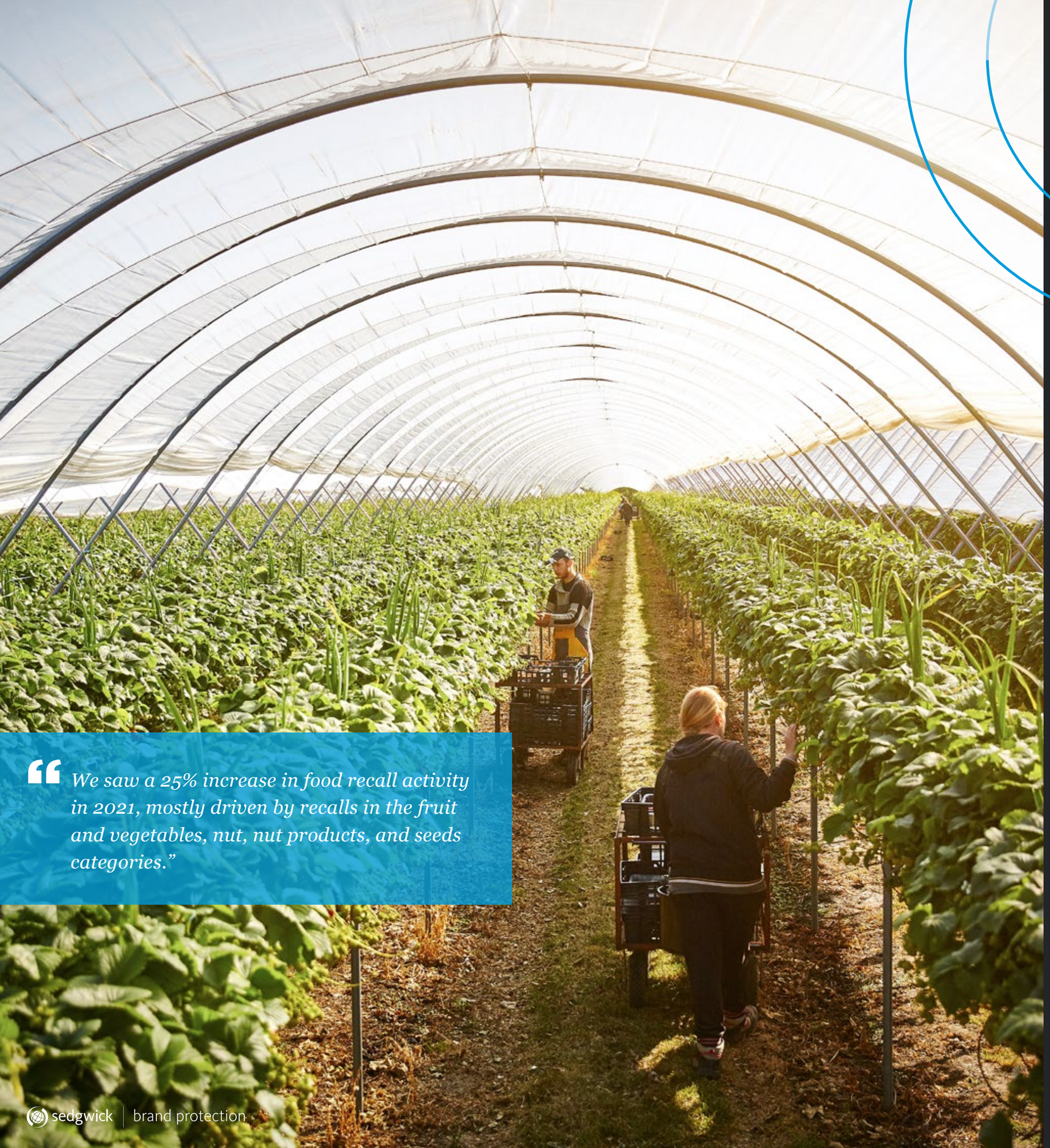
The industry needs to ensure this distraction does not lead to more accidents. In particular, there is a greater need for regulation of in-car technologies, particularly as self-regulation is currently the only form of governance over drivers. Such regulatory gaps may well be addressed by new EU legislation being introduced in July 2022. Regulation (EU) 2019/2144 will require manufacturers to implement three new safety measures in cars: intelligent speed assistant (ISA), lane change warning, and tyre pressure monitoring system. Trucks and busses will require emergency braking systems capable of stopping the vehicle if a possible frontal collision with a stationary or moving vehicle is detected.

A recent report by the Law Commission and the Scottish Law Commission importantly seeks to change the liability landscape for autonomous driving in the UK. The report recommends that manufacturers of AVs, not the person behind the wheel, should be liable for any driving aspects of the vehicle. It is recommended that the person is only liable for ancillary matters, such as insurance and wearing seatbelts.

Ultimately this report should be welcomed by the industry. Increased legal certainty encourages the safe and sustainable development of AVs, which in turn will build consumer confidence, as well as greater uptake and use. However, it also means more risk for automakers.

Regulators in the UK are still working to complete a considerable amount of legislation flowing from Brexit, including rules around marking and type approvals. The automotive industry must avoid divergence, particularly between the UK and the EU, if different products and product standards and greater market complexity is to be avoided. Less complexity, fewer variations and more global standards must remain the way forward to make things easier for manufacturers, regulators and consumers.

Despite the challenges ahead, the automotive industry is poised at the brink of big changes. Companies that are nimble enough to adapt, while keeping an eye for compliance in an ever-shifting regulatory environment, have a bright future ahead.



> *“We saw a 25% increase in food recall activity in 2021, mostly driven by recalls in the fruit and vegetables, nut, nut products, and seeds categories.”*

FOOD AND BEVERAGE

The European food and beverage industry is facing several regulatory updates in 2022, including the enactment of the UK’s Competition and Markets Authorities (CMA’s) Green Claims Code, Natasha’s Law for ingredient labelling, and proposed label changes from the European Commission planned for promulgation this year.

We saw a 25% increase in food recall activity in 2021 compared to 2020, mostly driven by recalls in the fruit and vegetables, nut, nut products, and seeds categories. We will continue to monitor this trend to see how it evolves in 2022.

We also witnessed more aggressive enforcement by regulators around food safety in 2021, including the first sanction for greenwashing by the UK Advertising Standards Authority (ASA). In addition, we saw a £7.56 million fine against a grocery chain for selling food past its “use by” dates. In fact, “use by” and “best by” dates are one of the topics the Commission will be looking at in 2022 and regulatory changes are expected.

Green claims code goes live

As of 1 January 2022, the CMA's "Green Claims Code" is in effect. The set of six rules is designed to help businesses be honest with their customers about their environmental credentials and protect consumers from false or misleading claims.

The CMA has already launched a review of environmental claims in the fashion retail sector, but will surely turn its attention to the food and beverage industry. Companies would be advised to review the guidelines the CMA has posted to ensure they are in compliance and start making any changes that might be needed if they are not.

First sanction for greenwashing

In October 2021, the UK Advertising Standards Authority (ASA) issued its first sanction under its expanded "greenwashing" provisions. It cited an alternative milk brand for using the claim "Good for the planet" in its ads. The authority stated that the brand had breached its Committee of Advertising Practice (CAP) Code because the ad was unclear, misleading, and lacked qualification.

The ASA ordered that the ads must not appear again in their current form. The agency also told the company to ensure that the basis of any environmental claims was clear. With the CMA's Green Claims Code now in effect, companies can also expect more careful scrutiny from other authorities including the ASA over unsupported "green claims."

Natasha's law fully in effect

After being discussed for years, Natasha's Law went into effect on 1 October 2021. The law is named after Natasha Ednan-Laperouse, a UK teenager who died from an allergic reaction in 2016, after eating a baguette with unlabelled sesame.

The law requires all food outlets to provide full ingredient lists with clear allergen labelling on Prepacked for Direct Sale foods (PPDS). PPDS is food that is prepared, prepacked, and offered or sold to consumers on the same premises. According to the new rules, PPDS food will have to clearly display the following information on the packaging:

- Name of the food
- Full ingredients list, with allergenic ingredients emphasised (for example in bold, italics, or a different colour)

These changes apply to businesses in England, Scotland, Wales and Northern Ireland. The Food Standards Agency developed a series of checklists and guidances to help companies ensure their compliance.

EU seeks mandatory, harmonized food labelling

In December 2021, the European Commission published its public consultation to gather the opinions of citizens and both professional and non-professional stakeholders about proposed changes to Regulation (EU) No 1169/2011 on providing food information to consumers (FIC Regulation).

This is part of the Commission's "Farm to Fork Strategy" (Farm to Fork) for a fair, healthy and environmentally-friendly food system, which was adopted in May 2020 as part of the European Green Deal. Farm to Fork targets the entire food chain, including ways to empower consumers through labelling information and actions to reduce food waste.

The proposed revision of the FIC Regulation will look at several aspects of food labelling:

- Front-of-pack nutrition labelling and nutrient profiling criteria to restrict claims: The proposal offers an EU harmonised and mandatory front-of-pack nutrition labelling and would set "nutrient profiling" criteria, which are thresholds of nutrients above or below which nutrition and health claims on foods are restricted.
- Origin labelling: Extension of mandatory origin indications for certain products.
- Date marking: A revision of the EU rules on "use by" and "best before" labels.

The discussion over "use by" and "best before" dates holds more impact now after a UK grocery store was fined £7.56 million earlier this year for selling food past its "use by" dates. There have also been discussions about the amount of good food that is wasted because of the labelling.

Another major UK supermarket chain has said that beginning in January 2022, it will change its "use by" dates to "best before" dates on 90% of its own-brand milk and encourage customers to use a "sniff test" to check quality in an attempt to reduce food waste.

Stakeholders have until 7 March 2022 to submit comments on the European Commission's website regarding the proposed regulatory changes. The goal is to adopt a proposal for EU-wide food labelling by the end of 2022.

EFSA actions suggest leeway in use of banned products

The European Food Safety Authority (EFSA) completed its assessments of emergency authorisations granted by 11 EU Member States for the use of neonicotinoid-based insecticides: clothianidin, imidacloprid, thiamethoxam, and thiacloprid on sugar beet crops in 2020 and 2021.

EFSA concluded in its November 2021 report that all 17 emergency authorisations were justified, either because no alternative products or methods were available, or because there was a risk the pest could become resistant to available alternative products.

Outdoor use of imidacloprid, thiamethoxam, and clothianidin in the EU was banned in 2018 and, in January 2020, the approval of thiacloprid was not renewed. The EFSA's decision suggests that growers do have some leeway in limited circumstances to use banned products. However, it is important that they carefully document factors such as all available pesticide products authorised in their territory to control that pest in their specific agricultural products, as well as research that was ongoing or planned regarding control of the pests with other methods.

Satellite kitchens must follow same food safety guidelines

With bans on indoor seating and a dramatic rise in takeaway food service and delivery due to the COVID-19 pandemic, many restaurants and chefs have opened smaller operations with fewer staff to prepare food for carryout. These satellite kitchens, also known as dark, cloud, or ghost kitchens, may be able to cut corners with amenities like seating and waitstaff, but they still must comply with the usual food safety, hygiene, and information laws in relation to the food production site, according to Nicola Smith, a Director at the law firm Squire Patton Boggs.

All of the usual requirements, including registration with the local authority, Hazard Analysis and Critical Control Point (HACCP) food safety principles, preventing contamination, controlling food temperature, personal hygiene of staff and cleaning regimes, still apply with these non-traditional kitchens.

It will also be critically important that information about food, such as potential allergens, a full list of ingredients, and the price of the dish are provided to consumers when they order. This is because most ordering will be done with an app or a website and there will be no way to ask questions to the restaurant staff.

While these satellite kitchens may be a huge benefit to operators who want to keep their business running when physical restaurants are closed or have limited seating, it is important to observe food safety standards.

> *"With the CMA's Green Claims Code now in effect, companies can expect more scrutiny from other authorities including the ASA over unsupported "green claims."*

2021 BY THE NUMBERS

Based on EU data collected from the Rapid Alert System for Food and Feed (RASFF), the number of recalls in the food and beverage category rose quarter-over-quarter in 2021, reaching a total of 4,676 for the year. That is a 25.1% increase compared to 3,737 recalls in 2020.

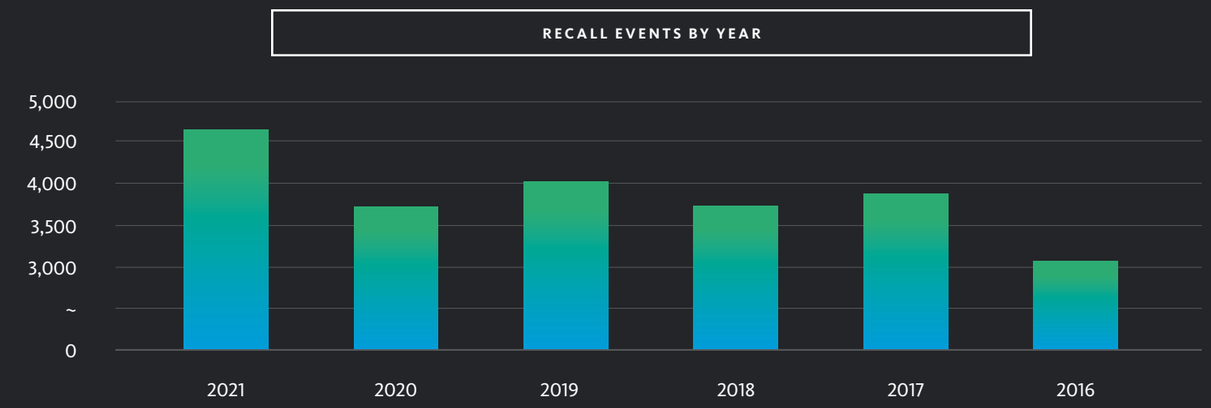
Throughout 2021, the prevailing reason for recalls in the food and beverage sector was "contamination – other," with 1,680 recalls of this nature. Among these contaminants, ethylene oxide were linked to 392 recalls, followed by aflatoxins (386), and chlorpyrifos (164).

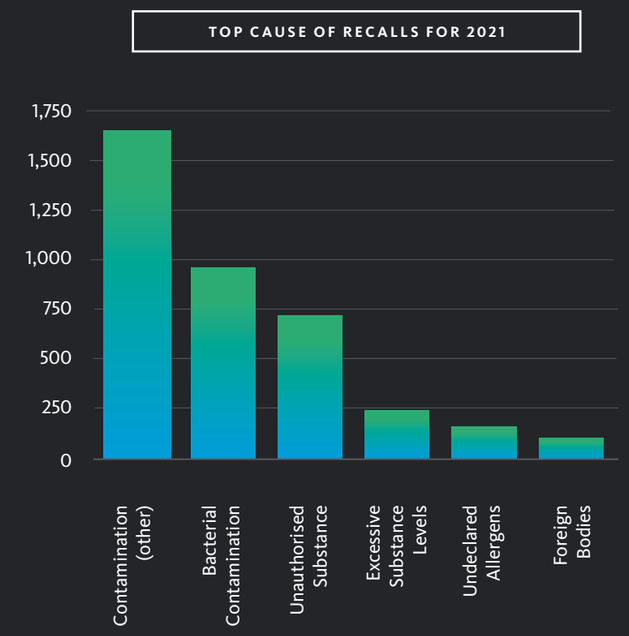
Bacterial contamination was the second most common cause across 2021, with 969 recalls in this category. In terms of specific reasons, salmonella was the most common concern both quarter-by-quarter and for the year as a whole, with 728 recalls attributed to this bacteria.

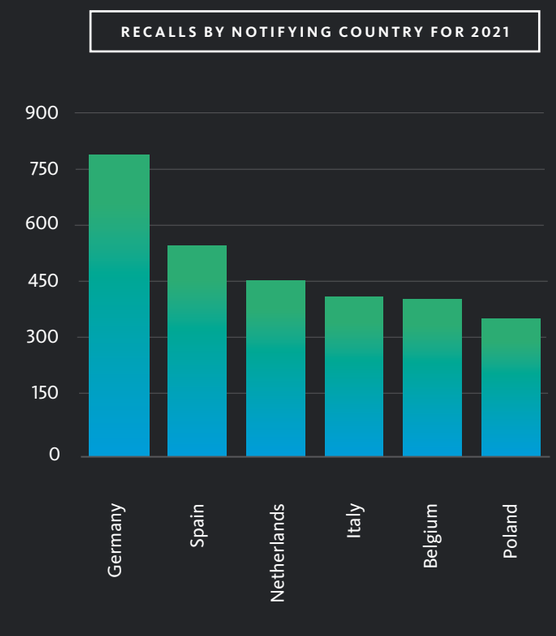
Germany remained the top country for notifications throughout 2021 with a 46% increase in recalls compared to 2020. Spain saw the second-largest number of recalls in 2021, with 549, followed by Netherlands (450), Italy (394), and Belgium (391).

From 2019 to 2020, the Netherlands saw a 33.7% increase in recalls (374 to 500) due to a large number of nuts, nut products and seeds that were contaminated with ethylene oxide – a sterilisation gas banned in Europe. While total notifications from the Netherlands dropped to 450 for 2021, ethylene oxide was still the cause of 23.3% (392) of the 1,680 recalls attributed to "contamination – other."

Poland saw a spike in poultry meat and poultry meat products contaminated with salmonella, leading to 158 recalls in that category, and a total of 339 notifications for the year, giving it the sixth largest number of recalls across the EU.

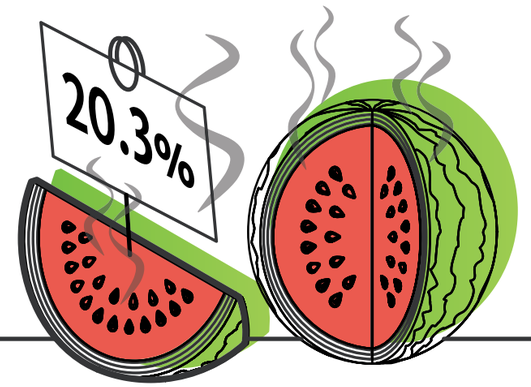






At 4,676 events, 2021 food and drink **recalls increased by a quarter** from 2020 (3,737).

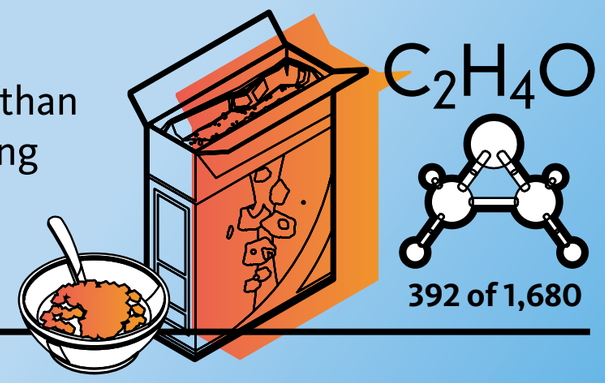
2021 also exceeded 2019's pre-pandemic levels by 16.9%, which recorded 4,001 events.



Accounting for 947 events (20.3%), **Fruit and vegetables** was the most impacted product category.

Fruit and vegetables ended the reign of Nuts, nut products and seeds, which have dominated the annual recall charts for the last 2 years.

Contamination (other than bacterial) was the leading cause of recalls in 2021 with 1,680 events.



The most prevalent contaminant was Ethylene oxide, with 392 events, followed by Aflatoxins (386), Chlorpyrifos (164), and Mercury (51).

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

FOOD SAFETY FORECAST HAS FAMILIAR CHALLENGES

The COVID-19 pandemic has made familiar challenges the food industry has been grappling with for years more acute. Food companies are seeing more regulatory enforcement, with fines increasing in some areas and a growing focus on safety of products sold online.

Supply chains remain disrupted

Restrictions, lockdowns and labour shortages caused by the pandemic, combined with damaging weather events and the impact of Brexit and other political events on cross-border trade, mean that supply chain disruptions are likely to continue throughout 2022.

Meanwhile, the desperate global search for alternative suppliers also poses new threats to the food supply, as producers may not practically be able to take the time to vet new suppliers with the same level of verification that they will normally apply with new vendors. In at least some cases, there may be travel restrictions that prevent supplier visits or inadequate time to conduct the standard audits. This is especially true for fast-moving consumer goods (FMCG).

Differing production and storage arrangements for ingredients among different suppliers also run the risk of introducing new allergens to processed foods. Because of this possibility, it's important that food manufacturers update their product labels to reflect new ingredients and include revised 'precautionary allergen labelling' where necessary. Overlooking this step could lead to more recalls for unsafe products due to undeclared, or mis-declared allergens and potential harm to consumers.

Language matters with safety warnings

Another important concern with food labelling is language. Instructions for use and safety warnings need to be readily understood by the consumers in the country where the product is sold. Similarly, ingredient and allergen information for food and drink products needs to be understood by consumers with sensitivities.

If a product was intended to be sold in Greece, but it is redirected to the UK because of a shortage in the UK market, the language on labels must therefore be changed to reflect the relevant market. Most consumers in the UK are unlikely to understand labels written only in Greek, so correct translations to English would likely be required to prevent a safety risk.

Similarly, if a label is incorrectly translated, safety risks could arise. Most national laws across the EU and in the UK prescribe a language or languages that ingredient and safety information must appear in.

Food supplements in the spotlight

Within the food and drink sector, we can also expect a continuing focus on the composition and safety of supplements, particularly those sold online. The UK's National Food Crime Unit's (NFCU's) priorities were reflected in a recent prosecution in the UK for the sale of a product described as a "diet pill" that was found to contain 2,4-dinitrophenol (DNP), which is considered a "toxic chemical." In a published strategy, the NFCU flagged dangerous "non-foods" as posing the highest risk of all areas of food crime and gave as examples DNP products sold for weight-loss and sodium chlorite solution marketed as a supplement.

Even producers and suppliers of supplements with strict procedures to ensure their products do not pose safety risks should take note: increased scrutiny and proactive scanning of supplements in the UK market are likely; along with intelligence collection by authorities on newly emerging products with purported health or other benefits, which could pose a risk to human health. Companies should be documenting how they are meeting the regulations and be prepared for closer surveillance.

CBD: a likely focus of the FSA

The Food Standards Agency (FSA) has stated previously that they review safety information on cannabidiol (CBD) as it becomes available. The FSA warns against "vulnerable groups" taking CBD, including pregnant women and those taking medication.

In the UK, food businesses were required to apply for authorisation of CBD extracts and isolates to be placed on the market in Great Britain using the FSA's regulated products application service by 31 March 2021. If an application was submitted for a CBD product and that application is still being assessed, the product can remain on the market in the interim. However, products classified as food for which no application was made are unauthorised for sale.

There are, of course, other categories of products containing CBD, which are not governed by the "novel food" requirements, including pet products and cosmetics. There may also be assessments of safety for such products over the coming months.

Use of "best before" dates growing

The ongoing focus on preventing food waste and the impact of the £7.5 million fine imposed on a supermarket in 2021 for selling food past its "sell by" date will likely lead to a rise in "best before" dates and a decrease in "use by" or "sell by" dates on food and drink products in 2022, where the nature of the food (or drink) makes that possible.

There have already been reports of UK supermarket chain Morrison's moving to "best before" dates for its milk. We predict that other operators may follow suit. There may also be a similar approach for other products when relevant assessments of safety and appropriate warning labelling have been made. The FSA published updated guidance in March 2021 on "use by" and "best before" dates, confirming that "use by" dates relate to food safety and "best before" dates relate to food quality.

The EU follows the same approach on the difference between "best before" and "use by." General EU food law prevents unsafe food from being placed on the market and EU food information and labelling laws, which also continue to apply in the UK, as 'retained laws' following Brexit, provide that after the "use by" date, food shall be deemed unsafe. EU law also makes it mandatory to label food with a "best before" or "use by" date, with certain exceptions. A "use by" date is mandatory for food and drinks that are highly perishable from a microbiological point of view.

If "use by" dates are maintained, operators may assess whether those dates can be extended. Currently most adopt a precautionary approach, which leads to good food being routinely disposed of both by businesses and within homes.

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Fines for food safety and product safety offences on the rise

The £7.5 million fine imposed against a supermarket for selling food past its "use by" date is the largest reported fine imposed for food safety offences. In fact, the fine is much higher than typical health and safety prosecution fines, even where a fatality occurs.

It's probable that we will see similar fines for other large organisations in connection with food safety offences. For example, the sale of food with mis-declared or undeclared allergens or the sale of food containing foreign bodies due to a manufacturing fault, could both be charged under the same legislation as that governing the sale of food past its "use by" date. The same Food Safety and Hygiene (England) Regulations 2013 sentencing guidelines will also apply.

Increasing fines will likely not be limited to the food industry, but will also extend to safety offences for other types of product, particularly for large and very large organisations. An organisation is classified as "large" if its turnover or equivalent is £50 million or more. In this category, the starting point for an offence in Harm Category 1, which many food safety offences will be, is £1.2 million, with a range for the sentencing judge to consider between £500,000 and £3 million. An offence will be committed for each product sold that breaches requirements. Usually, there will be multiple products involved and a sample will be charged to reflect that there is more than one breach.

Even where there is no specific sentencing guideline for an offence, magistrates' courts will typically follow a similar approach to that in the sentencing guideline for health and safety, corporate manslaughter and food safety offences.

More online sales means more enforcement

As with other product categories, online sales of food and drinks has increased with more people at home and more restaurants closed due to the COVID-19 pandemic. While there has been less media attention paid to the safety risks of food and drink sold online compared to other types of products such as toys and electrical goods, these risks still exist.

A primary safety concern is ensuring that accurate information on the product, including ingredient and allergen information, is provided online. Another thing to be aware of is safety risks with the product itself. In 2021, the FSA issued warnings about red meat sold online through Facebook by an unregistered and unapproved seller, which was deemed to be unsafe.

During the pandemic, the use of food delivery services has also skyrocketed. These may be associated with online sales since the food is often ordered through an app. For food deliveries, ensuring that the heat chain or cold chain is properly maintained, safeguarding against pests and confirming allergen and ingredient information is properly relayed are all safety factors that can't be overlooked. We predict that given the boom in online sales of food and drink over recent months, food safety challenges with such remote sales will become apparent in 2022 and increased enforcement may follow.

As we move into 2022, companies should be advised that regulators are perhaps watching certain areas of the sector more closely than in previous years. They should heed lessons learned in 2021 and expect enforcement in the year ahead in the areas of food safety that have been identified as most troublesome.

PHARMACEUTICAL

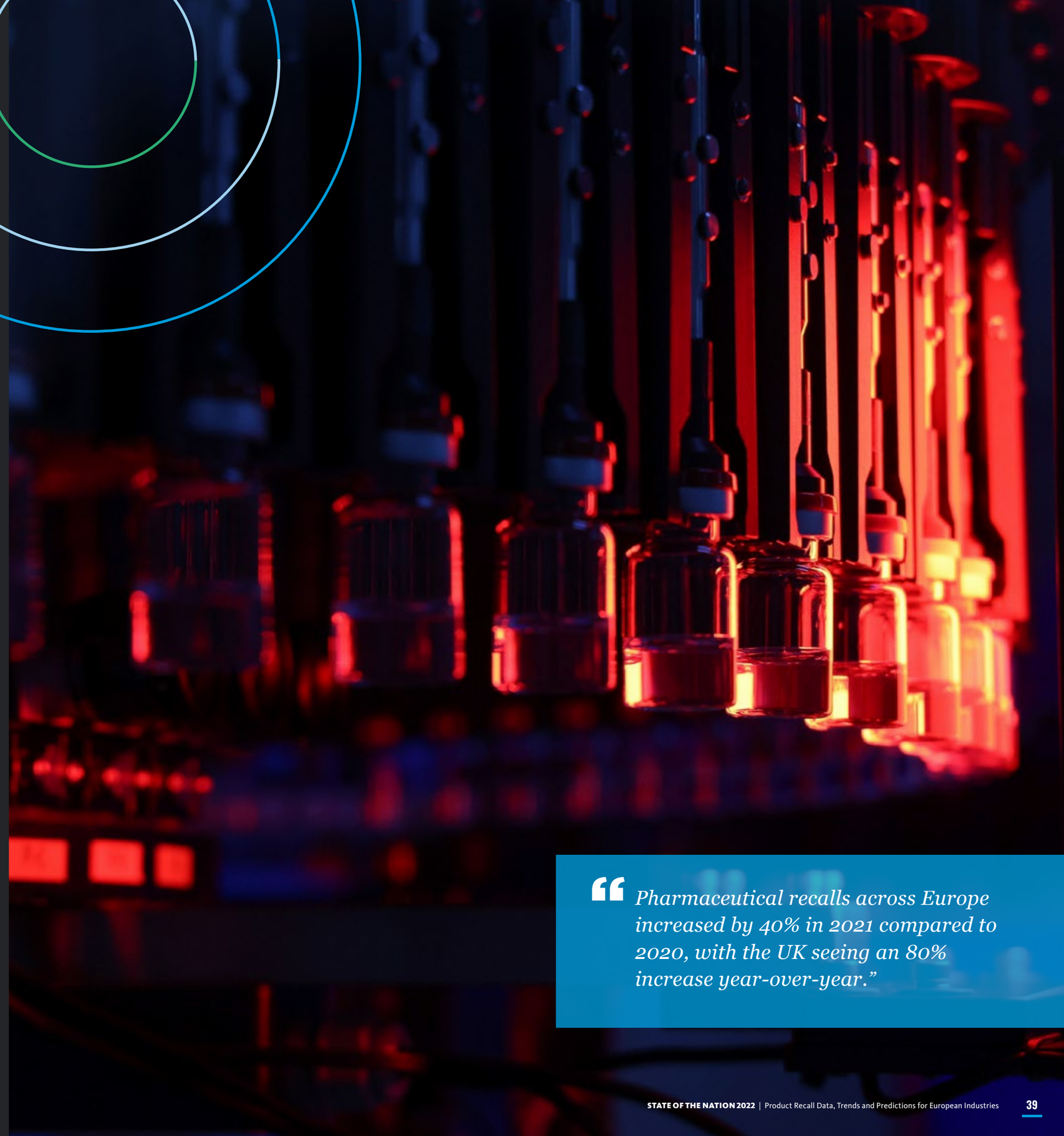
The COVID-19 pandemic continues to be a driving force across the pharmaceutical industry. With the rise of the Omicron variant in 2021, global regulators are working together to drive a coordinated response and promote safe and efficient development of new vaccines and treatments.

One change that may complicate these collaborative effects are new clinical trial regulations. EU law demands that the sponsor or legal representative for a clinical trial be established in the EU, which means that sponsors who are solely based in the UK can no longer conduct clinical trials in the EU on behalf of sponsors from the US, or other non-European locations.

To incentivise companies to conduct trials in the EU, a new streamlined system for administering clinical trials across multiple nations has been launched. The UK is working quickly to make its clinical trial regulations more attractive as well.

Brexit trade laws are being blamed for drug shortages in Northern Ireland because of the country's classification under Brexit agreements as being part of the EU. The European Commission has proposed some guidelines that, if passed, should help ease the shortages for everything from over-the-counter pain relievers to cancer-related drugs.

Pharmaceutical recalls across Europe increased by 40% in 2021 compared to 2020, with the UK seeing an 80% increase year-over-year. Recalls for which the reason was simply "other" fell from 154 in 2020 to 24 in 2021. The fact that regulators were able to trace recalls to a specific cause (instead of the reason being unknown) suggests an improving drug safety environment.



> *"Pharmaceutical recalls across Europe increased by 40% in 2021 compared to 2020, with the UK seeing an 80% increase year-over-year."*

Taking a global approach to fighting omicron

As the COVID-19 Omicron variant continues to fuel a global health emergency, regulators from around the world met in January 2022 to discuss the global regulatory response during a workshop (co-chaired by the European Medicines Agency (EMA) and US Food and Drug Administration), under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).

Participants from 24 members and 13 associated members of the World Health Organization (WHO) and the European Commission came together to review evidence around the effectiveness of the approved COVID-19 vaccines and reach alignment on the key regulatory requirements for the development of a possible adapted vaccine specifically for this new, highly contagious variant.

Emer Cooke, EMA's Executive Director and chair of ICMRA described the larger goal of the workshop as being, "part of setting the scene for a more strategic discussion about what types of vaccines might be needed in the long-term to adequately manage COVID-19."

This overview of EMA's rapid formal review procedures related to COVID-19 is mainly intended as a procedural guide for developers and looks at processes related to several factors including rapid scientific advice, rapid agreement of a paediatric investigation plan and rapid compliance check, rolling review, and marketing authorisation.

It follows updates in September 2021 from the EMA outlining initiatives to accelerate development support and evaluation procedures for COVID-19 treatments and vaccines. The agency is working towards having detailed procedures set-up to adapt different types of review activities in response to health threats.

Clinical trial regulations changing in UK and EU

The European Union's Regulation (EU) 563/2014 (the "Clinical Trial Regulation") regarding clinical trials on medicinal products for human use went into effect on 31 January 2022. The goal of this new legislation is to harmonise the rules for conducting clinical trials in the European Union (EU) and European Economic Area (EEA).

Under the new guidelines, clinical trial sponsors can submit one online application via a single platform, known as the Clinical Trials Information System (CTIS), to gain approval to run a clinical trial in several European countries.

Prior to the changes, if sponsors wanted to carry out multinational trials, they were required to submit applications separately to national competent authorities and ethics committees in each country to gain regulatory approval.

The hope is that conducting large clinical trials in multiple European countries will benefit medical innovation and patients.

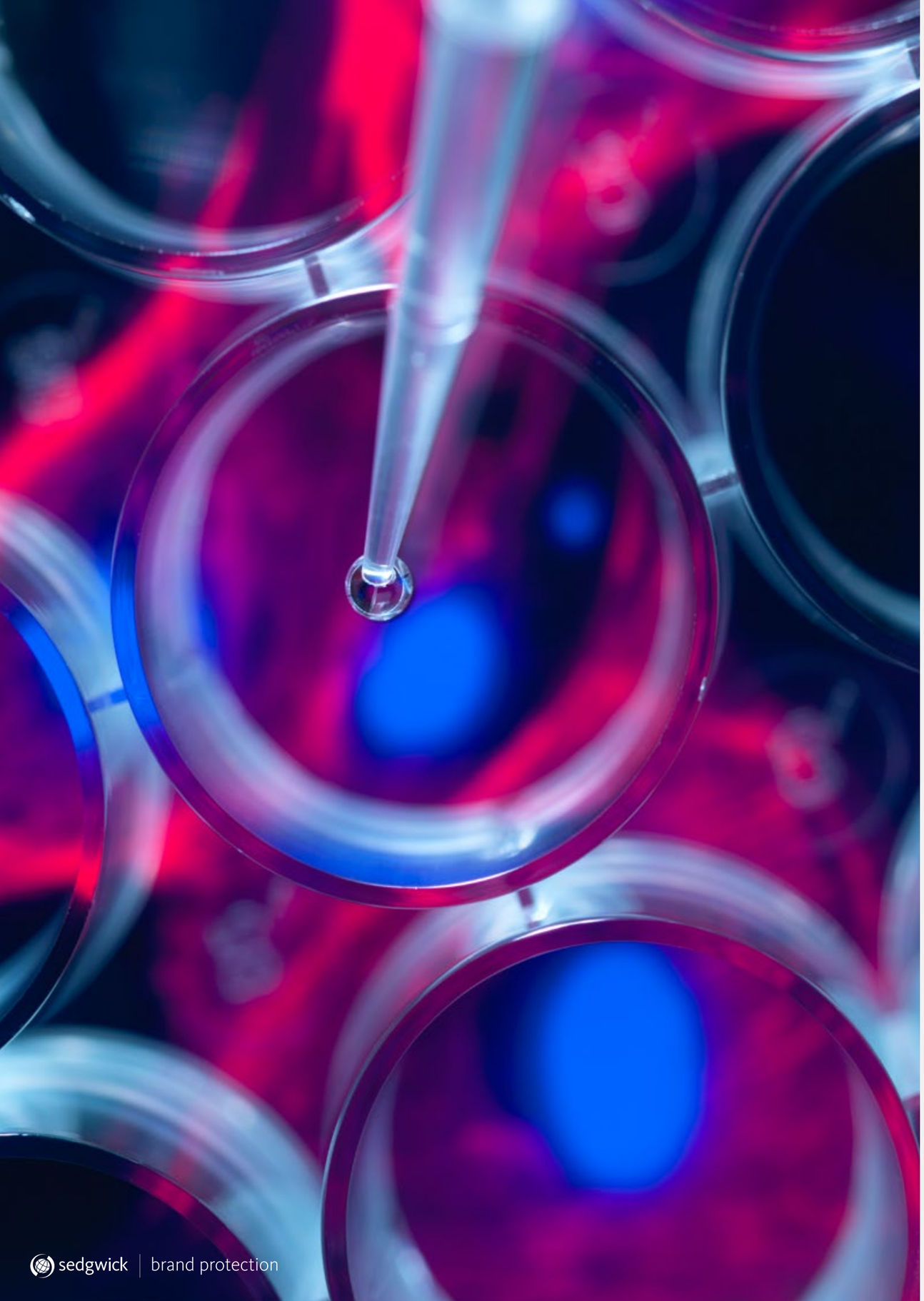
Not to be left behind, the UK Medicines and Healthcare products Regulatory Agency issued a consultation on proposals for legislative changes for clinical trials in January 2022.

In its announcement, the Agency stated it is developing a set of proposals to "improve and strengthen the UK clinical trials legislation" with the goal of making the UK "the best place to research and develop safe and innovative medicines."

According to the Agency, the proposed changes are designed to streamline clinical trial approvals, enable innovation, enhance clinical trial transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials.

The battle over clinical trial sites is a result of Brexit. The EU-UK Trade Agreement and Cooperation Agreement that went into effect in May 2021 states that while EU sponsors or clinical research organisation (CRO) partners based in the EU can conduct a clinical trial for medicinal products in both the EU and the UK, solely UK-based CROs can no longer conduct clinical trials in the EU on behalf of sponsors from the US or other non-European locations. EU law demands that the sponsor or legal representative be established in the EU.

It will be interesting to see what happens to pharmaceutical testing in both the EU and the UK and which jurisdiction sponsors will select for new drug trials.



Brexit-related drug shortages in Northern Ireland continue

Due to certain considerations under the Brexit agreement, Northern Ireland, is subject to European Union regulations. An unintended consequence of this unusual classification is a disruption in the supply of drugs to Northern Ireland that are readily available in England, Scotland, and Wales.

In December 2021, the European Commission put forth a proposal to stop this supply chain interruption. One of the provisions of this proposal is that the same medicines will continue to be available in Northern Ireland at the same time as in the rest of the United Kingdom, while specific conditions ensure that UK-authorised medicines do not enter the EU Single Market.

The recommendations include guidelines for authorising generic medicines under national UK procedures in compliance with EU rules, and the elimination of a requirement to batch test medicines brought in from the rest of the UK – if that testing has already been conducted in Great Britain or the EU. Furthermore, the recommendations outline that the UK will assume sole responsibility for authorising medicines for Northern Ireland.

While the proposals are being considered in the European Parliament and the Council, the Commission extended its interpretive note to ensure a continuation of the supply of medicines to Northern Ireland as well as to Cyprus, Ireland, and Malta – which similarly face disruption.

It is unclear when the proposal will be passed and how long it will take for the markets to normalise, or if simply an extension of the current note will help alleviate the issues.

Changes expected for cannabis regulation in Europe

Malta became the first country on the European continent to legalise recreational cannabis in December 2021. The UN's Commission on Narcotic Drugs recognised cannabis' therapeutic uses in December 2020 and removed it from its harshest schedule, where it had sat alongside deadly drugs. That change was one factor in Malta's decision to make it legal.

Other countries are also considering easing restrictions on recreational use of the substance. In December 2021, the new German coalition government announced plans to pass laws to make it easier to sell cannabis for recreational use to adults from licensed shops. In January 2022, the French parliament introduced Bill 4746 that, if passed, will legalise adult cannabis use at the federal level and establish a regulated market.

Italy and Luxemburg have also discussed legalisation, while Switzerland and the Netherlands have shared plans to expand current pilot programmes for adult use. It is too soon to tell how similar the laws will be across jurisdictions, but there seems to be widespread support for changes.

> *"Malta became the first country on the European continent to legalise recreational cannabis in December 2021."*

2021 BY THE NUMBERS

After seeing a 40% drop in pharmaceutical recalls in 2020, the number of events rose 48% to 372 for 2021. There was a dip in the third quarter, with recall numbers fairly balanced across the other three quarters.

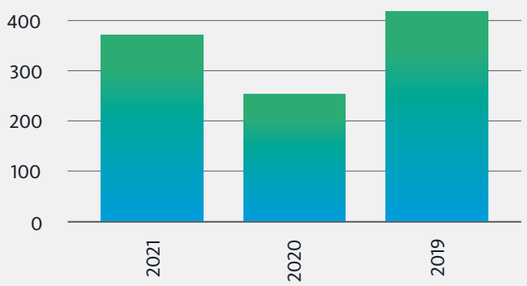
The most common cause for recalls was safety, which accounted for 123 (33%) of pharmaceutical recalls for the year. This was followed by failed specifications (56), quality (49), mislabelling (38), and foreign materials and contamination (35). This represents a big spike in recalls for foreign materials and contamination, which were cited for only eight recalls last year.

Another observed shift is in those events recorded with no specific reason. In 2020, "other" was the most common reason for pharmaceutical recall, with 154 events. That number fell to 19 in 2021, a nearly 88% decrease. It is not clear why this number dropped, though it could be that manufacturers have improved their safety and reporting processes; so even though there were more recalls in 2021 compared to last year, the reason for those events is now better understood.

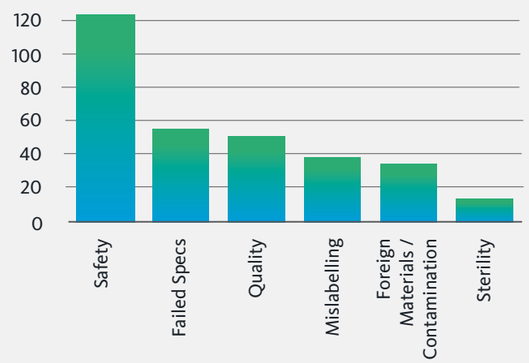
France was the top country for both origin and notification of pharmaceutical recalls, with 108 (29%) in each category. The UK was second with 64 recalls both as the country of notification and the country of origin. Ireland (43), Germany (33) and Portugal (33) were the other countries who saw the largest numbers of recall events with the same pattern.

There were no Class I recalls last year across the EU or the UK. The majority of the recalls (87%) were not assigned a Class. There were 20 pharmaceutical recalls classified as Class II, 11 as Class III, and 18 as Class IV for the year.

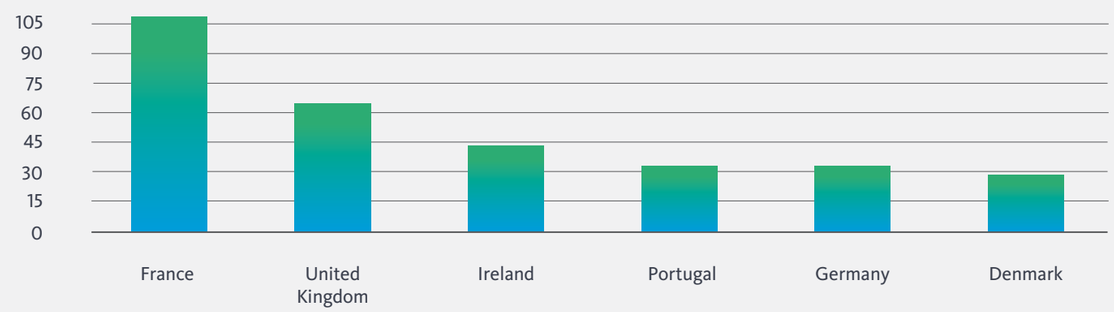
RECALL EVENTS BY YEAR



TOP CAUSE OF RECALLS FOR 2021

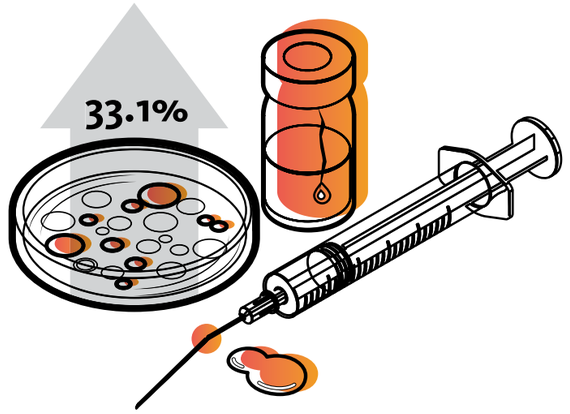


RECALLS BY NOTIFYING COUNTRY FOR 2021



At 372 events, 2021 pharmaceutical recalls **increased 48.2%** from 2020 (251).

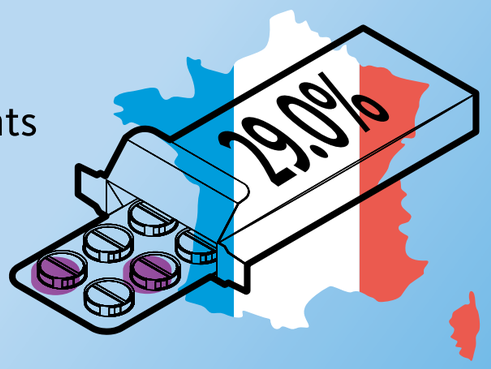
With this uplift, total annual recalls are gradually returning to 2019's pre-pandemic levels (417).



Accounting for one third of all recalls (33.1%), **Safety concerns** were the leading cause of recall activity in 2021.

At 123 events, Safety concerns were followed by: Failed specs (56), Quality (49), Mislabelling (38), and Foreign materials / contamination (35).

France was the leading country of origin for events in 2021, recording 29.0% of all recalls.



Pharmaceuticals manufactured in France have experienced a surge of 191.9% from 2020, and 52.1% from 2019.

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TECHNOLOGY AND AI: REVOLUTIONISING THE PHARMACEUTICAL INDUSTRY

The COVID-19 pandemic put unprecedented pressure on the pharmaceutical industry. Demand for newly approved vaccines and alternative drug treatments sky-rocketed while supply chain and manufacturing bottlenecks slowed the delivery of products.

As manufacturers plan for production within a "new normal," technology, and specifically artificial intelligence (AI)-driven technology, will play an increasingly crucial role in the pharmaceutical industry.

Digitisation of healthcare and data

Health technology in the form of digital platforms, virtual consultations, the digitisation of health data and increased patient engagement with remote therapies became mainstream during the pandemic.

Real-time online consultations, remote diagnostics and smart devices have enabled patients and healthcare providers to bridge not only the physical limitations caused by the pandemic, but also offered workable solutions to some of the barriers caused by appointment backlogs and both staff and supply shortages.

It is likely that the adoption of technology in the healthcare and pharmaceutical space will continue to increase in 2022 even after we are through the public health emergency.

Among pharmaceutical industry investments in 2021, it has been widely reported that deals that included digital therapeutics saw the biggest increase in ranking, apparently jumping up 19 slots in terms of themes CEOs were focused on. The momentum for investment into technology and AI shows no sign of slowing.

Virtual GPs, e-pharmacies and borderline products where drugs are administered by smart medical devices outside of the clinical setting are more examples how technology and AI are bringing healthcare into the home and into the hands of patients.

Crucially, digital platforms and devices enable manufacturers to capture vital data on drug safety, user engagement, efficacy and side effects. This, in turn, will provide the foundation for technology-powered drug development. This data may also be a vital tool for any future product recalls.

The proposed "European Health Data Space," a platform built by the European Commission in collaboration with Member States, highlights the vital role of data. This tool is intended to promote access to, and sharing of, health data to inform public health, treatment, research, innovation, healthcare delivery and policy making in Europe.

Drug development & novel therapies

The rapid development and roll-out of the COVID-19 vaccines demonstrate the profound benefits of technology and its ability to facilitate the sharing of data and promote stakeholder collaboration.

Supercomputers and quantum computing enable manufacturers to synthesise large volumes of data required during the R&D process, identify potential new drug therapies and bring these products to market.

The shift towards the digitisation of healthcare records, coupled with AI technologies such as machine learning (ML) and language recognition software, provides pharmaceutical companies with access to large volumes of potentially untapped patient data to help facilitate predicative analysis and further accelerate drug development.

AI-driven technology solutions are also making headway in alternative clinical trial settings. Even before the pandemic,

traditional clinical trial settings struggled with securing long-term participant engagement due to logistical hurdles. With the development of patient administered drug-delivery devices, virtual and/or alternative venue consultations and smart devices that can record patient data, drug trials are moving beyond the traditional clinical setting. Patients are becoming increasingly conversant and comfortable with the role of technology in monitoring and managing their health.

Looking ahead, technology is driving the growth of novel innovations such as gene writing and the use of mRNA technologies beyond vaccine development, which offer manufacturers alternative routes to drug development. In particular, investor interest in mRNA is gaining significant traction in the wake of the success of the COVID-19 vaccines.

Regulatory reform

As technology changes, regulations will need to change too to keep up. Over the course of this year, we expect to see increased regulatory activity which will impact the use of technology and AI within the pharmaceutical sector.

Following on from years of incremental change in this space, specific to medical devices but generally for consumer products in Europe too, the foundations for this were laid in April 2021 when the European Commission published its proposals to harmonise rules on AI. A consultation on the proposed regulation closed on 8 August 2021 and is awaiting review by the European Parliament and Council. A draft report on the proposal is expected to be published later this year. While the proposed regime focuses primarily on AI, pharmaceutical manufacturers and stakeholders utilising AI-driven technologies will be impacted and should follow the developments closely.

More recently, the European Parliament confirmed its support of the European Commission's Pharmaceutical Strategy ("the Strategy") on 24 November 2021. The Strategy aims to streamline innovation and promote and support competition within the sector. Technological solutions and AI-driven technologies, such as supercomputers, virtual clinical trial approaches and virtual monitoring platforms will play a role in achieving these initiatives.

As part of the implementation of the Strategy, the European Commission launched the "Combined Evaluation roadmap/ Inception Impact Assessment." This initiative will evaluate the EU's general pharmaceutical legislation on medicines for human use "to ensure a future-proof and crisis-resistant regulatory system." The European Commission is expected to publish its legislative proposals later this year, which will invariably have a significant impact on the existing regulatory framework.

While COVID-19 may have forced healthcare professionals, consumers and pharmaceutical companies to embrace technology more quickly than they might have planned, it is clear that the sector is keeping up the momentum and building upon this head start granted by the pandemic.

> *“Given the significant cost of bringing a new product to market, having tools to help companies avoid the need to re-run a product trial is crucial.”*

MEDICAL DEVICE

Most medical device companies with business in the EU are closely following changes to the transition periods required to take in vitro diagnostic medical devices to market. New rules were due to go into effect in May 2022, however – owing to the necessary shift taken by manufacturers to satisfy increasing demands for pandemic-related products (including COVID-19 test kits) – this deadline was subsequently deemed too optimistic.

To avoid shortages of critical medical products that could be subject to delays (while awaiting compliance or assessments associated with the new regulations), the European Commission, the Council of Europe (the Council), and the European Parliament passed legislation to extend and amend the transitional periods.

In addition to proposed legislative change, the medical device industry also continues to feel the impact of Brexit, notably in regulation variance between the UK and EU markets, and ongoing complications in trade and supply chains.

As manufacturers consider lessons learned from the pandemic, the European Medicines Agency (EMA) has revised its mandate to incorporate a larger focus on preventing, resolving, and communicating medicine and medical device shortages.

In terms of medical device recalls, there was a 40% rise in events from 2020, with 2,886 across the UK and EU in 2021. In more positive news, regulators’ ability to determine the cause of recalls appeared to improve. In 2020, “other” was the reason attributed to nearly 40% of the total medical device recalls. In 2021, that figure dropped to only 7.2%.

Revisions to in vitro diagnostic medical device transitional periods

The In Vitro Diagnostic Medical Device Regulation (IVD Regulation/ EU Regulation 2017/746) – approved in May 2017 – was due to take effect on 26 May 2022. However, with the ongoing pandemic impeding manufacturers' abilities to ensure full compliance, many stakeholders, including Member States' authorities, health institutions, notified bodies, and economic operators, agreed to extend transitional periods for its introduction.

In vitro diagnostic medical devices (IVDs) are tests used on biological samples to determine the status of a person's health. They include both self-administered tests – such as those for pregnancy or blood glucose levels – and more complex testing performed in clinical laboratories. HIV tests and COVID-19 tests are also examples of IVDs.

The goal of the IVD Regulation adjustment is to improve the safety of medical devices brought to market, and reflects the substantial scientific and technological progress achieved since the original legislation was drafted in the 1990s.

Another challenge in meeting the original timeline is that there are only six notified bodies designated so far under the IVD Regulation. IVDs are not subject to a pre-market authorisation by a regulatory authority the way medicinal products are. But some devices are required to undergo a conformity assessment procedure involving an independent third party known as a "notified body."

Recognising these challenges and wanting to avoid supply shortages, the European Commission, the Council, and the European Parliament worked quickly to propose, adopt, and approve amendments to the transitional implementation periods.

Now, while the IVD Regulation will still apply from 26 May 2022, IVDs that are currently on the market by virtue of a certificate from a notified body can continue to be on the market until the certificate expires or until May 2024.

Because there are so few notified bodies to grant certificates, the Commission has granted additional transitional periods for devices that have to undergo a conformity assessment. The IVD Regulation differentiates between risk classes. The transition period for high risk devices (class D) is May 2025. The longest period is for class B and A sterile IVDs which have until May 2027 to meet all the new rules.

However, for IVDs that do not require the involvement of a notified body, such as a class A non-sterile device, and other products not covered by a certificate or a manufacturer's declaration of conformity issued prior to 26 May 2022, the 26 May 2022 deadline still applies.

It is also worth noting that the IVD Regulation will not apply in Great Britain, and this proposal is not relevant to the supply of devices in this territory, but it, and any amendment to it, will apply in Northern Ireland.

EU takes steps to address medical device and medical product shortages

On January 25, 2022, the Council adopted a Regulation revising the mandate of the (EMA). The Council described this action as "an important step towards EMA's reinforcement in crisis preparedness and management for medicinal products and medical devices." Under the new rules, the EMA will be able to closely monitor and mitigate shortages of medicines and medical devices during public health emergencies or other major events, and enable faster approval of medicines.

The new mandate allows the EMA to create and manage the European Shortages Monitoring Platform to streamline the collection of information on shortages, supply, and demand of medicinal products. A public website to share information about shortages and two steering groups to coordinate actions and monitor critical products are also part of the plan.

The hope is that if there is another pandemic – or if the current one takes another turn as it did from Delta to Omicron – there will not be considerable supply shortages as we have witnessed in some stages of the COVID-19 crisis.

> *"MHRA states that it is the sponsor's "safety net" to check that the trial protocol, procedures, training, and other factors necessary to conduct the trial right the first time are all functioning correctly."*

MHRA suspends accounts of Great Britain-based authorised representatives

The UK Medicines and Healthcare products Regulatory Agency (MHRA) requires that any medical device manufacturer that wants to sell a product in the UK register with them. If that manufacturer is not established in the UK, they must appoint a UK Responsible Person to register and act on their behalf.

With the changes from Brexit, the MHRA announced that effective 1 January 2022, it would suspend the accounts of any former Great Britain-based Authorised Representatives (the term used by the EMA for medical device registration) that have not updated their role to UK Responsible Person on the MHRA registration system, as well as the accounts of any represented manufacturers.

Because of the complicated position of Northern Ireland under the Brexit trade agreements, requirements for registration of medical devices is also more complex. The MHRA does allow for a single entity to act as both an Authorised Representative based in Northern Ireland and a UK Responsible Person, but that entity still must register with the MHRA.

New requirements around medical device instructions

In December 2021, the European Commission published requirements regarding electronic instructions for the use of medical devices. The Commission recognised the environmental benefits of paperless instructions and the lower costs to manufacturers.

However, the Commission also stated that for safety and efficiency, users should always be able to receive instructions in paper form if they request them. It further emphasised that paperless instructions should be limited to "certain medical devices and accessories intended to be used under specific conditions."

The types of devices covered by this new regulation are clearly outlined and include, but are not limited to, certain implantable and active implantable medical devices and their accessories, and fixed installed medical devices and their accessories, providing certain conditions are met.

Before they try to change their safety instructions and documentation policies, medical device manufacturers should make sure their products are eligible under the new rules.

MHRA provides guidelines for medical product trials

In January 2022, the MHRA published recommendations about implementing adequate oversight and monitoring processes for sponsors and companies conducting trials of investigational medical products.

While not official regulations, the advice is designed to help companies adhere to the principles of Good Clinical Practice (GCP), trial protocol and procedures, and relevant legislation. Following the guidelines will also increase the likelihood of authorisation from the competent authority and a favourable opinion from the ethics committee.

The agency states that it is the sponsor's "safety net" to check that the trial protocol, procedures, training, and other factors necessary to conduct the trial right the first time are all functioning correctly.

Given the significant cost of bringing a new product to market, having tools to help companies avoid the need to re-run a product trial is crucial, and could potentially save considerable resources in terms of both time and money.

2021 BY THE NUMBERS

The volume of recalls in the medical device category rose sharply in 2021 compared to the previous year – up 40% from 2,061 to 2,886. Quality issues were the most common reason listed for medical device recalls throughout the year, accounting for 21.8% (630) of recalls.

Software was the leading cause of recalls in Q3 and Q4 and finished the year as the second most common reason for medical device recalls with 408, followed by sterility (275).

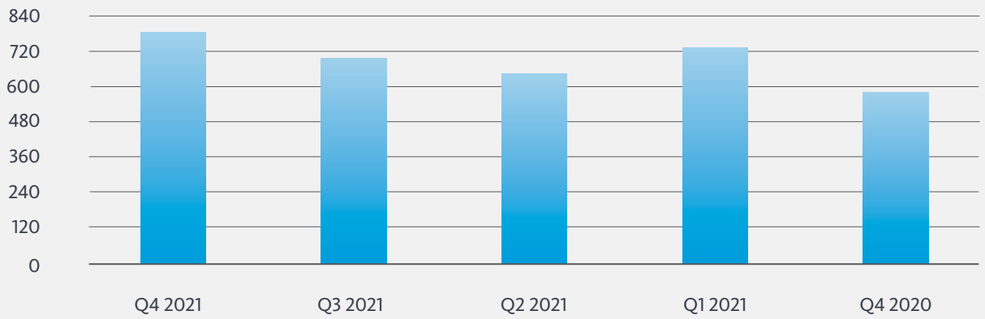
In 2020, nearly 40% of the total recalls submitted were flagged as "other" as their reason, meaning no specific reason was listed. Statistics normalised in 2021 with only 7.2% (208) of events receiving this classification.

Germany was the top country for notifications, submitting 857, up from 780 in 2020. Italy and France had similar numbers, with 786 and 728 respectively. After a drop last year to only 25, the UK's downward trend continued with only 10 notifications for the year.

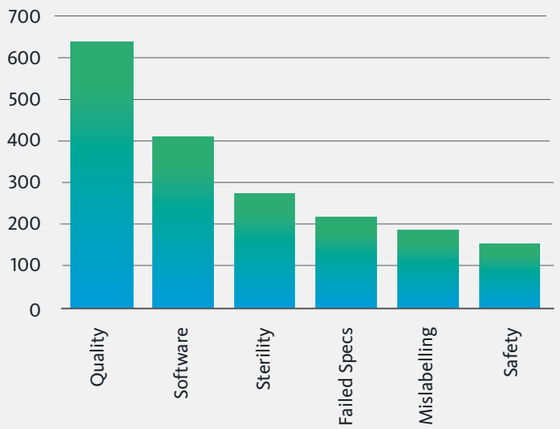
In terms of country of origin for recalled medical device products, the same three countries topped the list. Medical devices originating in Germany had 790 recalls, or 27.4%. Italy saw 668 recalls and France saw 604.

While there were no medical devices recalled in Europe that originated in the United States in the first half of 2021, there was a jump in the second half of the year to finish with 169 events.

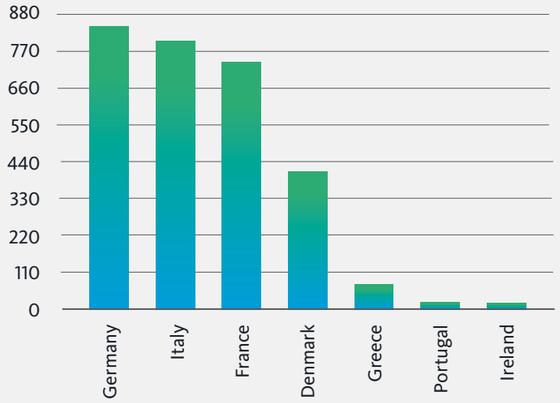
MEDICAL DEVICE RECALL EVENTS BY QUARTER



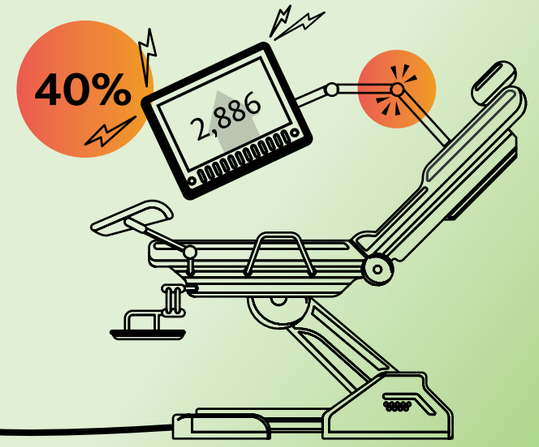
TOP CAUSE OF RECALLS FOR 2021



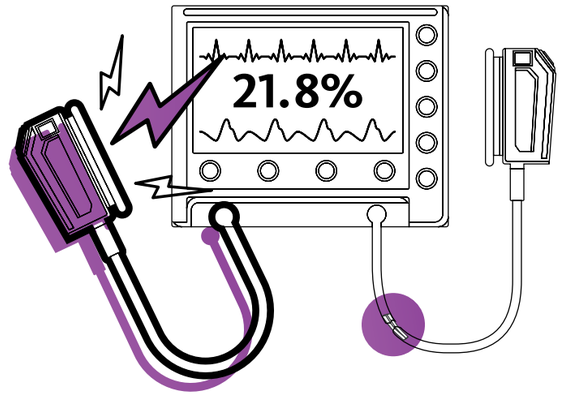
RECALLS BY NOTIFYING COUNTRY FOR 2021



At 2,886 events, 2021 medical device recalls **increased 40%** from 2020 (2,061).



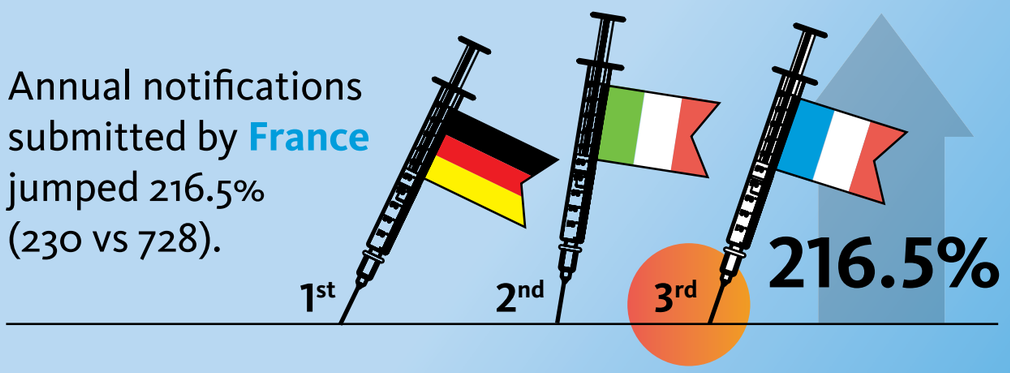
With this uplift in events, total annual recalls have now returned to 2019's pre-pandemic levels (2,841).



Accounting for **630 events (21.8%)**, Quality remains the leading cause of recall activity in 2021.

While remaining the leading cause, Quality concerns decreased 14.6% from 2020 (at 738 events). In contrast, annual Software concerns almost doubled (279 vs 408).

Annual notifications submitted by **France** jumped 216.5% (230 vs 728).



With this increase, France became the third highest notifying country, following Germany first (with 857), and Italy second (786).

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UK CONSIDERING CHANGES TO MEDICAL DEVICE REGULATION

Since the EU Medical Devices Regulation (Regulation 2017/745) ("MDR") came into force in May 2021, industry participants have been adapting, but regulators and other observers expect to see further queries as companies continue to operate under the new rules. This is likely to lead to further guidance from the European Commission to help companies with the practical implementation of the MDR.

Many of the changes being made at the EU level will also inevitably inform the shape of future reforms at the UK level. On 16 September 2021, the UK Medicines and Healthcare products Regulatory Agency (MHRA) announced a consultation to examine how best to overhaul the current regulatory regime for medical devices. The UK government is currently in the process of analysing industry feedback. Updated regulations are scheduled to apply from 1 July 2023 with appropriate transitional arrangements.

That means we can expect further discussion of possible changes to the regulatory framework for medical devices placed on the market in the UK, especially as they learn from what went right and what went wrong in the EU. Manufacturers in particular should expect to see increasing regulatory interest in subjecting certain products to UK medical device regulations that were not previously within scope and/or moving existing devices into classifications associated with higher risks and increased levels of scrutiny.

The survey questions for the UK consultation are helpful in providing clues about which topics might be the subject of future reform. Some of the specific initiatives under consideration by the MHRA that device manufacturers should be watching include the following:

- **Regulation of products with no medical purpose** – Products with no claimed medical purpose that still present some risk to consumers, such as coloured (i.e. non-prescription) contact lenses, buttock implants, microneedling products, dermal fillers, equipment for liposuction and hair or tattoo removal lasers, currently are not regulated. Under the new MDR, that is likely to change. It is expected that they will be regulated under the UK medical devices regulations to ensure they meet appropriate safety and performance requirements.
- **Changes to classification of existing devices based on risk** – Implantable devices such as surgical mesh and joint replacements have been flagged by the MHRA as devices that it believes need to be moved into the highest risk category (Class III) in order to better align such devices with the level of risk they present. In addition, the MHRA is considering introducing new rules for software and in vitro diagnostic medical devices (IVDs). It is considering changing the classification of software as a medical device in order to bring it into line with IMDRF guidance on software classification. In addition, it may move away from using a list-based approach for IVDs and instead implement rules that focus on the risk that different types of IVDs give rise to.
- **Greater role for importers and distributors of devices** – The MHRA is also interested in medical device importers and distributors assuming a greater role in ensuring the safe supply of devices to the UK market. This could include meeting additional requirements, such as ensuring the medical devices that they import or supply are accompanied by the correct documents, that they are correctly stored and handled and checking labelling or certificates to ensure that the device meets the requirements of UK medical device regulations.

- **Improvements to how medical devices are identified and traced** – The MHRA has expressed an interest in improving its ability to trace medical devices back to the relevant manufacturer, especially through the use of a Unique Device Identifier (UDI) number that the manufacturer would assign to each device. It believes this could assist healthcare professionals, economic operators and the wider public in reporting incidents. In this context, the MHRA has asked whether manufacturers should be required to assign UDI numbers to medical devices before they enter the UK market, and whether manufacturers, importers, distributors and health institutions should be required to store the UDI numbers of certain medical devices that they have supplied or purchased.
- **Engagement with patients when investigating device incidents** – The MHRA is considering whether manufacturers should be required to consult with patients when investigating device incidents. Currently, when an incident occurs in the UK involving a device, the manufacturer will investigate the incident to work out the root cause and any necessary corrections. It may issue a Field Safety Notice (FSN) to tell customers what the problem is, the risks involved and what actions the customer needs to take. However, there is currently no requirement for manufacturers to consult with patients and the public in these investigations. It will be interesting to hear stakeholders' views on if and how exactly manufacturers should consult with patients when investigating such incidents. There are a lot of factors to consider including how the manufacturer would find patients, methods of communication and how the manufacturer would demonstrate that they have taken into account patient views, to name a few.
- **Extra patient information requirements for implantable devices** – Whether manufacturers of implantable devices, such as pacemakers and hip replacements, should be required to provide additional patient implant information is also under consideration. Such information could include information or warnings on any potential negative interactions (e.g., with MRI scanners), information about the expected length of time the device will work for and any necessary follow-up (e.g., where the patient might require repeat scans) and any other information to ensure safe use of the medical device by the patient.
- **Possible new routes to market** - The MHRA is considering introducing different tailored pathways that manufacturers might be able to follow to obtain approval for placing a medical device on the UK market. One of the possible pathways currently identified is for manufacturers whose quality management systems have been certified (e.g., under the international Medical Device Single Audit Programme). Another pathway would be for manufacturers with approval to market their devices from another jurisdiction (e.g., from an EU Notified Body, the U.S. FDA or Health Canada).

The question of how closely the UK medical devices regime will track that of the EU and the wider international community will be watched with much anticipation. There is risk that significant divergence from international regulatory peers may lead to added complexity and friction for manufacturers in the short term. It is clear from the proposed changes that the MHRA is focused on patient safety, risk mitigation and holding manufacturers and suppliers accountable.

CONSUMER PRODUCTS

As the UK starts its second year apart from the EU, consumer product manufacturers are facing challenges to keep up with all the regulatory changes in both jurisdictions. The UK and the EU are each considering – or have already proposed – new product liability rules and general product safety regulations.

Part of the reason for the flurry of legislative activity is the increase in new technologies in the way people shop and in the products themselves. Much of the legislation around product safety, including the EU Product Liability Directive, are decades old and were not designed for enforcement based on software and third-party online sales.

In addition, the focus on sustainable living and a greener economy continues and is being reflected in proposed legislation. Protecting consumers against false “eco” claims is also top-of-mind, especially in the UK as the new "Green Claims Code” regulations go into effect.

The impact of the pandemic continues to be felt across the industry. Out of the 1,605 consumer product recalls across all categories – 134 of them were for particle filter masks. Plastic dolls were the second most common product to be recalled, associated with 79 recall events.

Overall, recall trends were mixed across the consumer sector. Clothing saw a slight uptick of 6.3%, primarily around children’s clothing. Recalls for electrical appliances rose sharply up 44.9% compared to last year. The number of toy recalls declined by 28.1%.

It will be interesting to see how recall numbers are impacted as more and more regulations go into effect. Will increased enforcement result in more recalls? Or will companies step up their compliance procedures and revamp their recall plans? Might we even see a decline in recall events?

> *“The COVID-19 pandemic, related lockdowns and restrictions have caused a dramatic rise in online sales. That has spurred the Commission’s urgency in updating the regulations."*

“Overall, recall trends were mixed across the consumer sector. Clothing saw a slight uptick of 6.3%. Recalls for electrical appliances rose sharply up 44.9% compared to last year. The number of toy recalls declined by 28.1%.”

Reforms to product liability rules coming

In early January 2022, the European Commission concluded its public consultation on proposed changes to the Product Liability Directive (85/374/EEC) (the “PLD”). The PLD is the basis of EU product liability regulations and establishes the EU-wide approach for determining who is liable if defective products cause personal injury or damage to consumers, and what recourse parties have.

The Commission intends to publish draft legislations in the third quarter of 2022, based on information gathered in the public consultation as well as findings from a formal evaluation and an external study.

The final proposal won’t be clear for several months. But its revisions are expected to include reforms to product liability legislation so that it explicitly covers software and other intangible products. Proposed modifications would also lessen the burden of proof for consumers in cases dealing with complex technology, including special consideration for artificial intelligence (AI) products regarding the “development risks defence” and the addition of rules to make **online marketplaces** liable if they fail **to identify suppliers**.

It is unclear if the UK will plan similar changes to update its Consumer Protection Act 1987, or wait and see how the EU addresses the issues first.

New general product safety regulations

Another priority for the European Commission is updating the General Product Safety Directive (GPSD). The Commission is currently revising the Directive with a goal of completing the revised regulation this year. The proposed changes are designed to reflect advances in products and commerce including the safety of products linked to new technologies, ways to mitigate risk for products purchased online, improving enforcement of the rules, increasing the efficiency of market surveillance, and steps to improve the recall of dangerous products.

The COVID-19 pandemic, related lockdowns and restrictions have caused a dramatic rise in online sales. That has spurred the Commission’s urgency in updating the regulations. The GPSD will apply to manufactured non-food consumer products.

The proposed updates will also make general consumer product safety regulations more aligned with the provisions of the New Legislative Framework (primarily Decision No. 768/2008) and the newly-introduced Market Surveillance Regulation (EU) 2019/1020.

Product safety also a UK focus

The European Commission is not the only governing body looking at product safety. The UK government’s product safety authority, the Office for Product Safety and Standards (OPSS), sought opinions early last year about the UK’s product safety framework. The OPSS published its response in November 2021, setting the stage for potentially aggressive changes.

While no legislation proposals have been introduced yet, reforms under consideration cover a range of issues. They include e-labelling for products, ensuring online marketplaces and third-party sellers are following appropriate UK product safety rules, expanding regulations to include software and AI products, and ensuring that processes for consumer recourse are accessible to everyone.

Promoting repair and reuse of products

On January 11, 2022, the European Commission published a Call for Evidence to get input on its initiative to provide incentives and tools to consumers who use goods for a longer time, including by repairing defective goods to extend their life. The initiative complements earlier actions including the New Consumer Agenda and the Circular Economy Action Plan, which aim to promote repair and more sustainable products.

In the consultation, the Commission says that "businesses have limited economic interest to produce or supply more environmentally sustainable goods," and it wants to address this. Some of the tactics may include amending the Sale of Goods Act Directive and possibly creating legislation specifically around the right to repair.

New EU consumer laws in effect

In addition to all the legislation being proposed, several changes went into effect on 1 January 2022. The EU's Digital Content and Services Directive and Sale of Goods Directive are required to be applied under local transposed law. With a few exceptions, these regulations are relevant to all digital content and services and goods supplied in the EU.

While the new EU laws share some similarities with the rules in the UK under the Consumer Rights Act, there are some differences and companies need to review the regulations to the jurisdiction in which they are selling their digital goods and services.

> *"The initiative complements earlier actions including the New Consumer Agenda and the Circular Economy Action Plan, which aim to promote repair and more sustainable products."*

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

A TIME FOR CHANGE AND CAUTION IN THE CONSUMER PRODUCTS INDUSTRY

The consumer product landscape is at an important juncture. An increase in the prevalence of socially conscious consumers and technology-enabled products is resulting in fast-paced changes to the industry globally. While regulators are doing more to address those changes, there are also increased litigation risks for companies.

The demand for socially conscious products

Companies must prove eco-claims

Growing consumer preference for sustainable products is creating pressure on both industry and government sectors to lower the carbon footprint of all products. As companies try to attract socially conscious consumers, the market has seen a rise in companies making exaggerated and misleading environmental claims to promote sales, a practice known as "greenwashing."

In September 2021, the UK's competition regulator, the Competition and Markets Authority (CMA), published the Green Claims Code ("the Code") to combat the rise in greenwashing. The Code provides guidance to businesses across all sectors, including consumer goods, on environmental claims in advertising, product labelling and branding so that products and services are marketed responsibly and honestly. The Code is a complement to existing product-specific requirements for making product claims, including environmental claims, for cosmetics, nutritional products and other categories.

Breach of the Code, whilst not legally binding, can be seen as non-compliance with a company's overriding legal obligations. This may result in "enhanced consumer protection orders" against companies that fail to comply with the Code. In addition to fines, companies who practice greenwashing risk reputational damage and potential legal action by consumers or environmental action groups.

Companies should review their claims around sustainability and Environmental, Social and Governance (ESG) promises to make sure they can back them up.

PFAS Raise More Risks

Perfluoroalkyl and Polyfluoroalkyl substances ("PFAS"), or "forever chemicals," are an expanding group of man-made chemicals found in a wide range of products. Policy makers and leading insurance providers have categorised PFAS as an emerging risk. Increasing concern over their use has prompted widescale investigations and studies, and regulators in multiple jurisdictions are considering steps to address the potential risks they pose. Businesses and the insurance market have voiced concerns over the potential for a tidal wave of PFAS contamination claims.

In the U.S., California State Assembly Bill 652 will prohibit a person from selling or distributing any new children's products that contain regulated PFAS on or after 1 July 2023, specifically products designed for use for infants and children under 12 years of age. It is anticipated that further regulation of PFAS will be imposed as more information in relation to these chemicals comes to light. Already U.S. litigation is underway, with multi-million-dollar verdicts and settlements already being reached over PFAS.

In the EU, increased monitoring of the use of these chemicals is contained in proposed revisions to the REACH Regulation and in the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (CSS) document.

Diversity and Inclusion Matter

Another area in which we are seeing a shift in the consumer products industry is towards diversity and inclusion. Notably in the production, marketing and advertising of children's products. In one example, the Mattel-owned Barbie franchise has expanded to include differently abled dolls.

In November 2021, the UK Office for Product Safety and Standards ("OPSS") responded to comments from the public that stated some consumer groups, including older people, children, disabled people, people with lower socio-economic status and those for whom English is not a first language, felt the current legislative framework impacted them differently.

In response, the OPSS has committed to working with the British Safety Standards Group (BSI) to improve the inclusiveness of data used in standards-making. The goal is to create inclusive standards that better meet the range of needs across society. This initiative is mirrored in respect of specific products, such as medical devices.

Modern products, changing regulations

New Technologies Drive New rules

New technologies continue to shape the landscape of consumer products, particularly those driven by artificial intelligence ("AI"), the Internet of Things (IoT) and software that allows for connected devices and the harnessing of data.

Whilst these novel technologies create opportunities for growth and innovation within consumer industries, their inherent complexities could give rise to a myriad of potential liabilities, notably in relation to privacy, security and product liability. Legislative and regulatory bodies in the EU and UK are taking notice.

In April 2021, the EU Commission published proposed regulations that would impose potential civil liabilities for AI. It also recommended proposals to revise the EU Product Liability Directive ("PLD") and the EU legislation governing liability for defective products to ensure it reflects today's digital age, AI and the circular economy.

A public consultation about the effectiveness of the PLD in the context of new technologies recently concluded on 10 January 2022. In a similar vein, the UK is also considering the potential reform of its Consumer Protection Act 1987, which transposed the original PLD into UK law. In tandem, the proposed revisions to the EU General Product Safety Directive ("the EU GPSD") and the UK's proposals to strengthen its current product safety framework spearhead several wider regulatory proposals addressing the safety of new technologies and supply chain management.

Whilst adapting the existing frameworks to reflect new technologies and new marketplaces is necessary to protect consumers, there remain challenges for organisations seeking to produce, market and supply these new technologies. The proposed regulatory changes are seemingly unable to keep pace with their rapid development.

SARAH-JANE DOBSON, PARTNER AND
CAMILLE HEPSWORTH, ASSOCIATE, **KENNEDYS LAW LLP**
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Increased legal exposure

Collective Redress Regimes

As part of a sweeping collective redress reform, the EU Directive (2020/1828) on representative actions for the protection of the collective interests of consumers ("the Directive") establishes an EU-wide mechanism for collective redress. The use of collective redress, a legal mechanism which may stop or prevent unlawful business practices that affect multiple claimants or compensate for the harm caused by these practices, has never been available to EU consumers before. It is similar to a class action lawsuit, which is more prevalent in the U.S.

The Directive came into force on 24 December 2020 with member states being given two years to transpose the Directive into their domestic laws. As access to collective mechanisms are widened, it is likely that the impact of this Directive will continue to be reflected in proliferation of larger legal actions across the EU for consumer products, and specifically in member states where domestic courts are particularly attractive for litigants. Although the Directive is not applicable in the UK post-Brexit, the UK has seen a surge of group actions over the last couple of years and may follow suit with similar legislation.

Increased Regulatory Enforcement

It is expected that in this new era of increased regulation of consumer products, we will continue to see more aggressive enforcement from regulators. Supporting this belief are the recent enforcement strategy developments published by the OPSS which have sought to increase and clarify powers in respect of online platforms, customs/ border checks and advisory functions for businesses with product compliance obligations. These strategies focus on proportionate and code-compliant enforcement activities.

Online Platforms Under Scrutiny

There is growing concern over the risks posed by online marketplaces and other platforms. In 2021 alone in the UK, 10,000 unsafe products, including toys, were taken down from online platforms. This concern has been addressed at EU level by virtue of the Market Surveillance Regulation ("the MSR") (Regulation (EU) 2019/1020), that came into force from 16 July 2021. The MSR brings online platforms such as marketplaces, within the remit of the EU's product safety framework and seeks to establish more robust processes, surveillance and enforcement of these platforms, particularly for consumer product sales.

Whilst the proposed revisions to the EU GPSD will help regulate the conduct of online marketplaces, the increased use of such platforms is already giving rise to product liability litigation in the U.S. It is likely the UK and EU will follow the same trend.

In particular, U.S. findings that e-commerce platforms can be considered a key part of the supply chain and are therefore integral to the sale of a defective product will inevitably impact any answers to similar questions posed to UK or EU regulators and/or courts.

Companies Need to Take Note

With all the changes ahead – both in terms of regulations and consumer buying habits – consumer products companies need to re-examine their operations and their risk mitigation processes and determine where the biggest weaknesses may lie and where the opportunities exist for growth.

> *“By the Competition and Markets Authority’s estimates, UK consumers spend £54 billion annually on clothing and footwear, and there are no signs of this abating.”*

CONSUMER PRODUCTS

CLOTHING

Environmentally friendly processes for production, packing, and shipping continue to be a theme across the clothing industry. More and more companies are highlighting ways they are using regenerative, responsibly sourced, renewable and/or recycled materials in their products, and packaging.

The Jeans Redesign project which launched in 2019 continues to grow. The organisation updated its guidelines in 2021 around how to manufacture jeans that “are used more, made to be made again, and made from safe and recycled or renewable inputs.”

Companies in the UK will see their eco-claims examined more closely now that the Competition and Markets Authority’s (CMA) new Green Claims Code is in effect.

Clothing recalls in 2021 were up slightly compared to 2020 with 151 events for the year. Children’s clothing – across several different apparel types – was most effected by recalls. The majority of events were focused on strangulation risks from cords/drawstrings on clothing.

> *"Companies in the UK will see their eco-claims examined more closely now that the Competition and Markets Authority's (CMA) new Green Claims Code is in effect."*

Green claim codes review underway for fashion sector

The UK's CMA selected the fashion retail section as its target for the first review of environmental claims under the new Green Claims Code.

By the CMA's estimates, UK consumers spend £54 billion annually on clothing and footwear, and there are no signs of this abating. However, that has a big environmental impact. According to some sources, between two and eight percent of global carbon emissions come from the fashion industry.

As part of its review, the CMA will look at environmental claims across the fashion retail sector in the UK to determine whether or not businesses are complying with consumer protection law. This includes being able to support claims of clothing as sustainable, the use of recycled materials in new clothing, and labelling materials as "organic."

The CMA is also actively soliciting input from consumers who have experience with issues covered in new code. They have published a dedicated email address to share information. Smart companies will want to be aware that in addition to CMA investigators, they may have other people looking at their claims and will need to have evidence to support them.

Sustainability spreads to bridal fashion

A major theme of the sustainability movement is "reduce, reuse and recycle." One sign that fashion companies are taking that motto seriously is an initiative launched by a global luxury bridal gown company to have brides repurpose their wedding gowns.

Wedding gowns can be notoriously expensive and the idea that a bride wears it for a day and never again has long been considered wasteful. While some brides have become creative on their own, this new programme makes it easier. The designer is offering a collection of redesigned gowns along with an alteration service that is free of charge for brides who want to change their dress after the wedding.

Some fashion companies are already recycling material from old clothes to create new fabrics, but this takes that idea in another interesting direction.

Global supply chain shows its resilience

Supply chain payment platform Tradeshift recently published its Index of Global Trade Health. Contrary to predictions, it found that cumulative transaction volume growth across its systems (which include a number of apparel companies), stayed flat in the fourth quarter of 2021.

The report showed that activity across the global transport and logistics sector last quarter exceeded the expected range for the first time in six months. This gives some hope that supply chain bottlenecks are beginning to ease and there seems to be more predictable ordering activity.

According to the latest data, supply chains across the UK and the Eurozone did see a drop in activity levels in Q4. Every region also saw low invoice volumes, which suggests that suppliers may still have cash flow and capacity challenges, even as fulfillment issues improve.

The overall steady activity is encouraging because Chinese supply chains saw less activity last quarter than at any point since the start of the pandemic. While that is not good for China, it does suggest that the global supply chain as a whole may be better able to withstand fluctuations, especially when one of the largest players slows down.

However, there is still reason to be cautious. If there are lockdowns in key industrial regions across China, we could see more shortages of crucial manufacturing components and long backlogs for orders. As we have learned over the past two years, the impact of COVID can be unpredictable.

2021 BY THE NUMBERS

The number of recalls for the clothing sector were up slightly in 2021 to 151. Unlike the past two years that experienced a spike in events in Q4, the most recalls in 2021 came in Q2 with 57 events, mostly fueled by 16 recalls for children's sweatshirts.

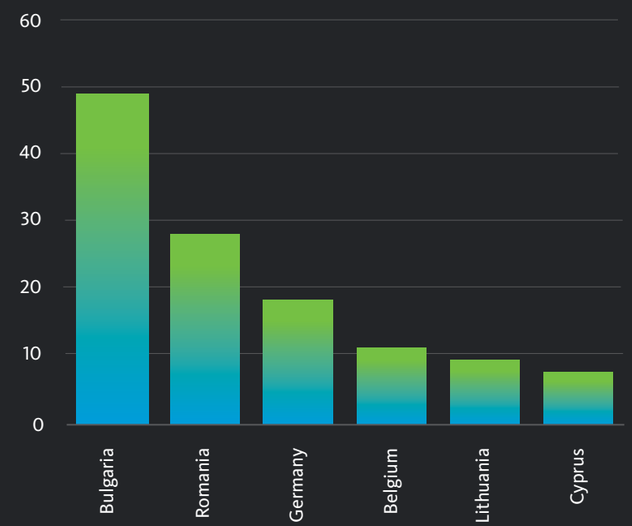
For the second year in a row, children's sweatshirts were the most recalled items, though the 27 recalls in 2021 represent a 200% increase compared to nine in 2020. There were 13 recalls for children's trousers, the second most common product in this category.

There were eight recalls for false nails, all notified by Romania. The cause cited was "chemical risk" which was due to the presence of dibutyl phthalate (DBP) in the glue - which use is forbidden in cosmetic products as well as children's articles and toys in the European Union.

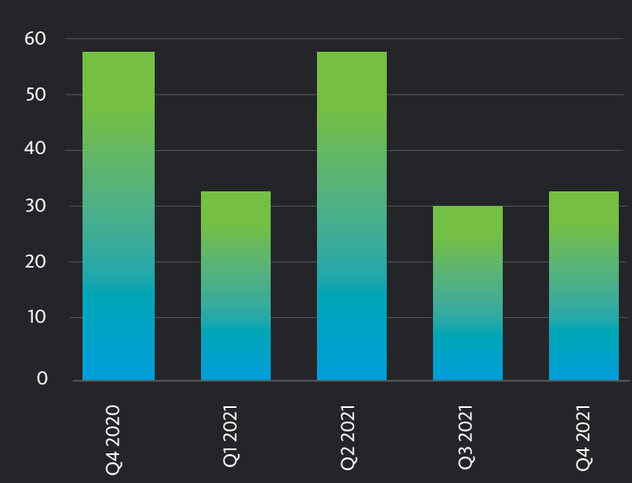
Bulgaria had significantly more recall notifications than any other country with 49, nearly one-third of all recall events for the year. These related to a range of children's products including sweatshirts, trousers and clothing sets. We noted in 2020 that Cyprus had dramatically reduced its number of notifications from 70 in 2019 to 18 in 2020. That trends continued in 2021 with its notifications falling further to seven.

The most common risk associated with recalls was chemical, accounting for 37 events, and a total of 41 when combined with other factors. Strangulation was noted as the sole reason for 36 recalls, but that number jumps to 48 if combined with injuries. Most of those recalls were due to cords/drawstrings on a range of children's clothing products.

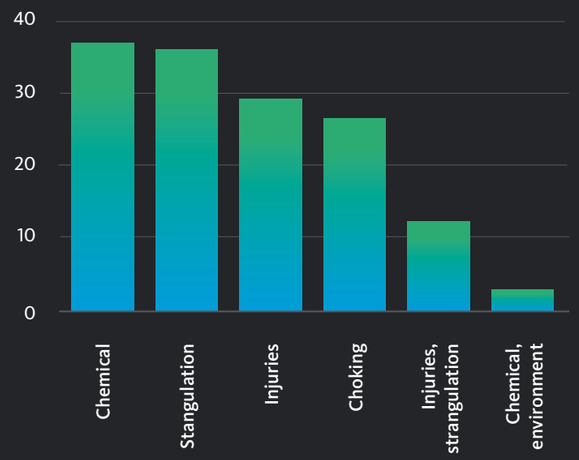
RECALLS BY NOTIFYING COUNTRY FOR 2021



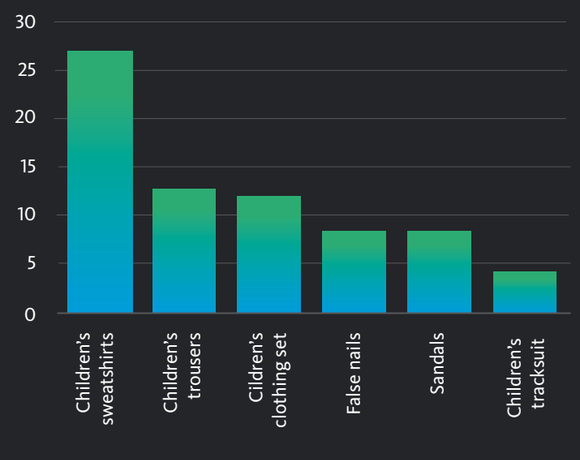
CLOTHING RECALL EVENTS BY QUARTER



TOP CAUSE OF RECALL FOR 2021

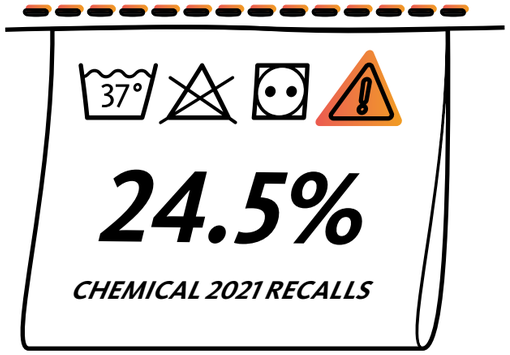


TOP RECALLS BY PRODUCT FOR 2021



Clothing recalls in 2021 remain down on 2019's pre-pandemic levels (151 vs 172).

Despite this decline, recall events exceeded 2020's total of 142 recalls by 6.3%.



Chemical remains the most common risk type per quarter of 2021 recalls (37 or 24.5%).

The risk landscape remains consistent with 2020, with Strangulation accounting for 36 events, and Injuries at 29 events.

At 93 events, **Children's apparel** remains the most impacted product category.

Delving deeper into Children's products, Sweatshirts recorded 26 recalls, followed by Trousers (13), and Clothing sets (8).

SARAH-JANE DOBSON, PARTNER; **ELAINE BARKER,**
SENIOR ASSOCIATE, **KENNEDYS LAW LLP**

FASHION FORWARD – WHAT DOES THE FUTURE HOLD?

The fashion industry is projected to return to growth at pre-pandemic levels in 2022, so there is good reason to be optimistic. Of course, plenty of challenges remain, including material shortages, supply chain bottlenecks, rising shipping costs and uneven customer demands.

Fashion companies will have to focus on how best to safeguard recovery whilst maximising opportunities. And that means being ready for changing regulations in response to new technology and consumer focus on environmentally friendly operations.

Fashion going green

New York City has long been considered a global fashion capital. The state of New York introduced legislation on 7 January 2022 that would force fashion brands to be as sustainable as they are stylish.

The U.S. Fashion Sustainability and Social Accountability Act (the "Fashion Act") is proceeding through the state legislative process. If implemented in its current form, the law would have a broad-ranging and significant impact on the fashion industry selling in the state. New York would become the first U.S. state to legally hold fashion brands accountable for their role in generating greenhouse emissions. This would include some of the biggest and most prominent brands in the world. Because of New York's influence on global fashion, it is likely that other jurisdictions will take notice and may consider similar legislation.

Provisions in the bill include the following:

- It would apply to global apparel and footwear companies with more than $100 million in annual revenue that do business in the state.
- Companies would be required to map out, within 12 months of introduction of the bill, at least 50% of their supply chain, from raw materials to factory locations and shipping.
- No more than 18 months after the law takes force, companies would need to provide an "impact disclosure," outlining the stages of their operations that have the greatest social and environmental impact and set binding targets to improve.

Companies could be fined up to 2% of their company's annual revenue for violations. In addition, the State Attorney may "name and shame" non-compliant companies in a report. Another big risk for companies, both financially and to their reputation, is that consumers could bring claims directly against offending companies to enforce compliance.

The introduction of this new law reflects the growing demand for greater climate awareness and positive action from an industry that has historically been considered a significant contributor to global emissions.

Over the lst few years, we have seen regulators around the world increasingly incorporate environmental considerations in legislation, particularly in the UK, the EU and Latin America. Some of these rules have impacted the fashion industry already. We expect the industry will see even more laws to mandate more accountable and sustainable operations.

Blockchain as a tool for sustainability

The fashion industry was an early adopter of blockchain technology and the pandemic has pushed companies to embrace its use more widely and in new ways. One use that is becoming increasingly popular is to provide details of traceability and ethical sourcing by way of "product passports."

The fashion industry has already implemented blockchain as a secure way for companies to track and record all steps of clothing production through the supply chain. It can help trace raw materials and finished products through the production cycle from farming the cotton, sewing the garment and transporting finished products to the consumer.

Companies are using "smart clothes" and e-labelling methods to strengthen their Environmental, Social and Governance (ESG) credentials in several ways:

- Near Field Communications (NFC) Tags: NFC tags, usually in the form of a sticker, allow consumers to use their phone and launch a digital experience showcasing sustainable credentials authenticated by blockchain.
- Quick Response (QR) Code: Like NFC tags, QR codes can be easily scanned with a phone's camera to access a digital experience. Consumers can receive different information depending on when and how many times they scan the code. In addition, QR codes can be used to make payments, authenticate the customer's identity and allow consumers to use any offers or rewards in their account.

As well as addressing 'green' concerns, blockchain could help in the fight against counterfeit goods that have long plagued the luxury industry. The recent explosion in online shopping, including foreign online marketplace platforms, has made consumers more vulnerable to fake products.

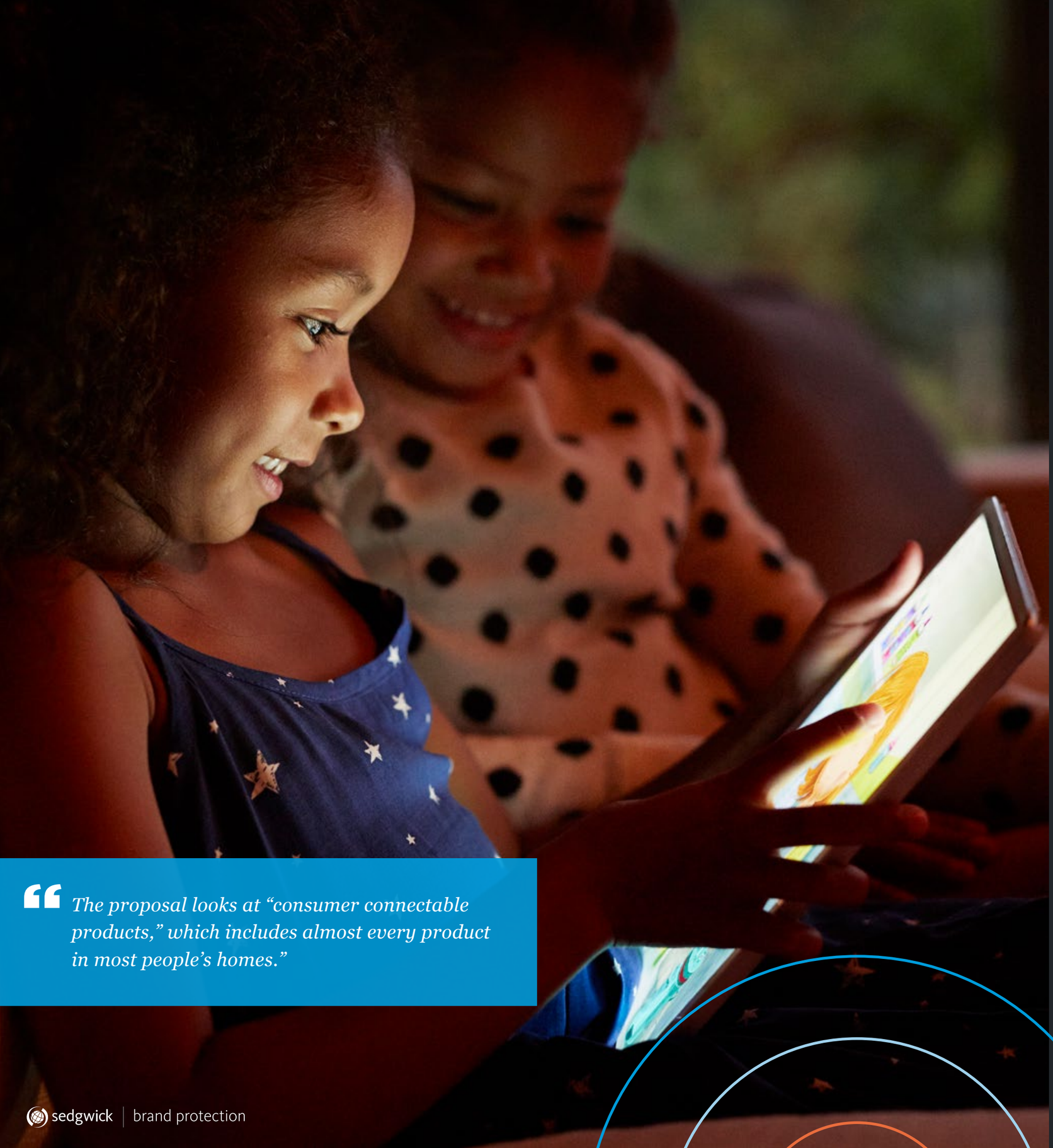
Fashion enters the metaverse

Another technology trend that could be significant for fashion retailing in 2022 is the metaverse. This virtual environment offers consumers an immersive, interactive and shared digital experience for a variety of activities. Some platforms even enable users to purchase physical items in the digital world. Use of technology may help retailers overcomes several hurdles that we have seen from the pandemic, including the need for physical distancing and the closure of brick and mortar stores.

The metaverse already looks like a lucrative revenue stream for the fashion industry. Some high-end fashion brands are already using digital fashion to drive sales of physical items, and this will be another channel for purchases.

Fashion forward 2022

The use of technology will allow brands to offer customers experienced-based retail. The hope is that these new ways of shopping and a frictionless online experience will get consumers excited. As exciting as these new tools are, there are also some challenges ahead for fashion brands as regulators try to hold them accountable for sustainable practices and a lower carbon footprint. If New York's Fashion Act moves forward and other states, and possibility countries, follow suit, we could see a monumental shift in how the fashion industry operates globally. Watch this space.



> *The proposal looks at "consumer connectable products," which includes almost every product in most people's homes."*

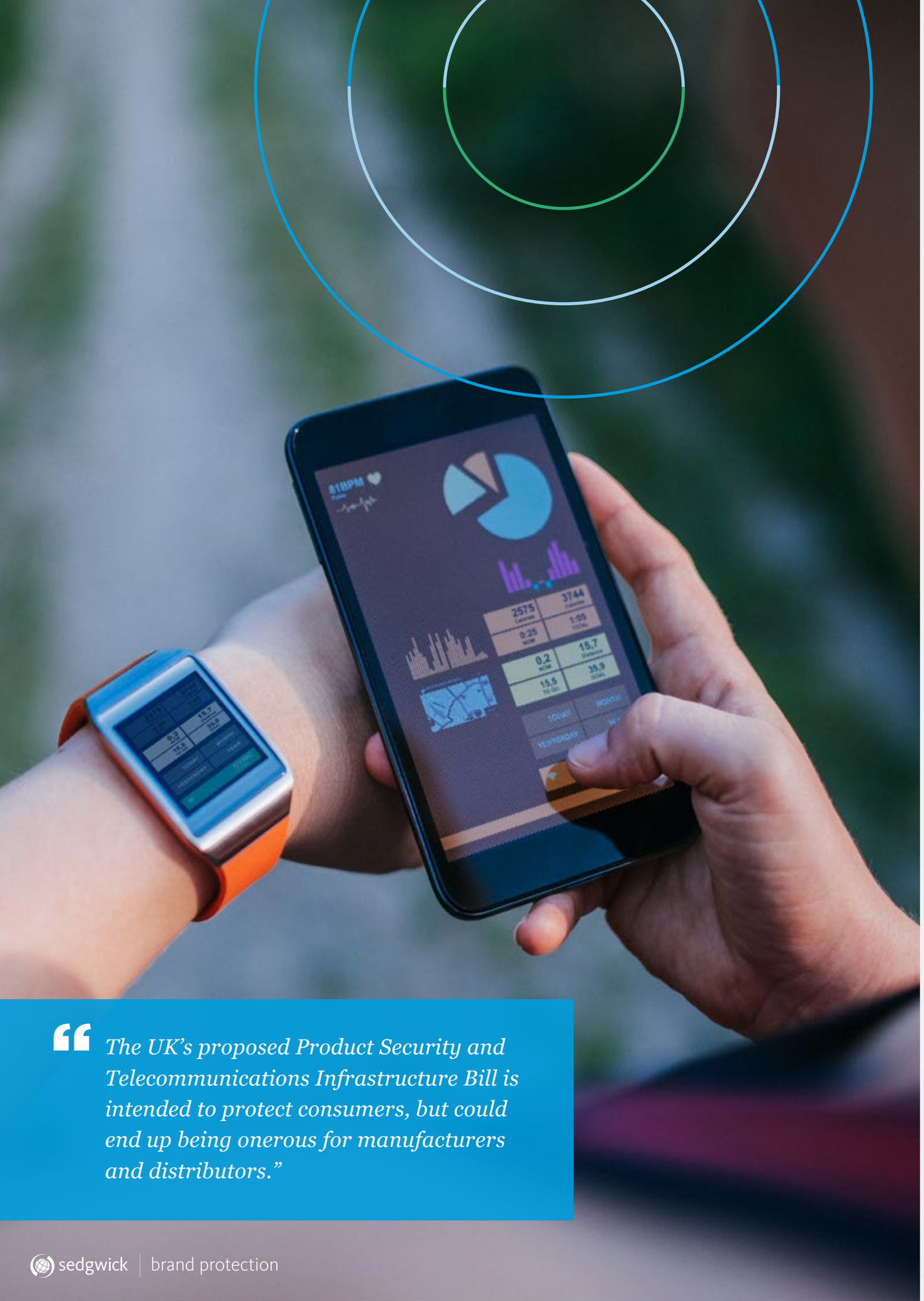
CONSUMER PRODUCTS

ELECTRONICS

With more people working at home due to the pandemic, and more children forced to school remotely, electronics were used more frequently and in new ways in 2021. People were watching movies on tablets and big screen televisions instead of going to movies.

Regulators are working to update legislation to reflect the changes in electronics usage and the expanded capabilities of things like artificial intelligence (AI) and the Internet of Things (IoT).

The UK's proposed Product Security and Telecommunications Infrastructure Bill (PSTI) is intended to protect consumers, but could end up being onerous for manufacturers and distributors.



> *“The UK’s proposed Product Security and Telecommunications Infrastructure Bill is intended to protect consumers, but could end up being onerous for manufacturers and distributors.”*

More regulation for connected products

In November 2021, the UK Government proposed PSTI, which aims to protect consumer connectable devices from cyber-attacks. While the bill is still in its early changes, if passed, it has the potential to have a big impact on consumer electronics as well as telecommunications companies.

The PSTI is divided into two sections: product security measures (Part 1) and telecommunications infrastructure measures (Part 2). It is the first section that will affect consumer electronics the most.

The proposal looks at “consumer connectable products,” which include smartphones, connected cameras; TVs and speakers; connected children’s toys and baby monitors; connected safety-relevant products – such as smoke detectors and door locks; IoT base stations and hubs to which multiple devices connect; wearable connected fitness trackers; outdoor leisure products – such as handheld connected GPS devices that are not wearables; connected home automation and alarm systems; connected appliances – such as washing machines and refrigerators and smart home assistants. These days, this list includes almost every product in most people’s homes.

Under current laws, consumer connectable products must ensure that they will not directly cause physical harm through overheating, environmental damage, or electrical interference.

The proposed legislation would protect consumers from cyber harm such as loss of privacy and personal data in two ways. Firstly, it mandates minimum security requirements for manufacturers, importers, and distributors. Secondly, it will provide a regulatory framework that is adaptive and flexible to respond to changes in technology, including the ways that malicious actors may try to harm consumers.

EU moves to standardise chargers

In January 2022, the Council of Europe (the Council) took a step towards requiring a common port standard for all smartphones, tablets, digital cameras, headphones, portable speakers, and video game consoles.

If passed, the law would require the sale of chargers to be unbundled from the sale of electronic devices. Consumers would no longer need to buy a new charger with every new device purchased. With the new common standard, all devices would work off the same charger.

The Council says these changes will reduce the electronic waste associated with the production, transportation, and disposal of chargers. It is not yet clear if electronics manufacturers will push back against this change.

French authorities crack down on cookies

The French Data Protection Authority (CNIL) fined two major US technology companies a total of €210 million for breaching Article 82 of the French Data Protection Act relating to the use of cookies.

After receiving a number of complaints, the CNIL decided that three websites associated with the companies do not provide users with a simple, one-click option to refuse cookies. The CNIL stated that because more work was placed on them to opt-out of cookies, that users would most likely accept all cookies. This, according to the CNIL, constitutes a violation of the freedom of consent.

In addition to paying the fines, the CNIL ordered the companies to change the process to opt-out of cookies on their sites within three months of being notified of the decision, or face being penalized €100,000 per day of delay.

All online services providers should review their policies on valid consent and ensure they are being applied correctly.

2021 BY THE NUMBERS

The electronics industry saw a nearly 45 percent increase in recalls in 2021 compared to 2020. This marks the second year in a row that figures have increased, though the jump to 326 events for the year is more significant than the increase between 2019 and 2020.

Unlike the past two years, the increase wasn't steady quarter-over-quarter, though we did see the most recall activity in Q4, which is consistent with the past two years. However, the 94 recalls in Q4 of 2021 is almost 15% higher than what we saw in the last quarter of 2020.

For the third consecutive year, USB charges were the most commonly recalled electronic appliance. They were cited in 36 recalls, compared to just 21 recall events a year prior. Lighting chains were the cause of 32 recalls, and LED lights and extension cords were cited in 30 and 26 events respectively in 2021.

In terms of notifications, Hungary was by far the top notifying country with 104 recall notifications, or 31.9% of all notifications for the year. Most of these were linked to burns or electric shock risk across several different types of products. The country with the second-most notifications was Sweden with 45 (13.8%).

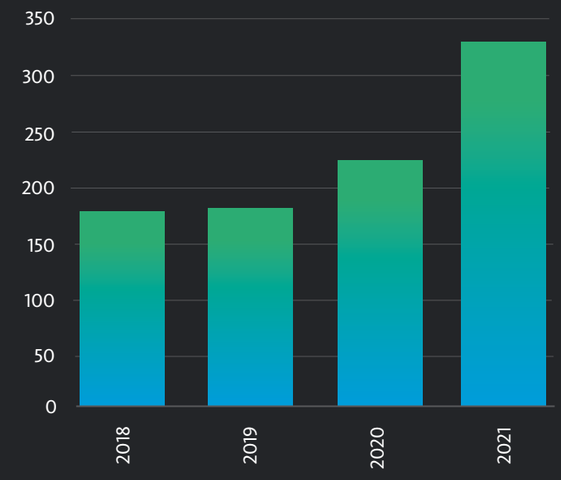
The UK had been the top notifying country in 2020 with 88 recall notifications. In 2021, it only registered 18 notifications, a three-year low.

As we have come to expect, the vast majority of electronics products recalled were made in China. Of the 326 recalls for the year, 265 (or 81.3%), were produced here. While it is not surprising to see China at the top of the list, the 265 recalls represent a 74% increase compared to 2020. The sixteen other countries mentioned as being a country of origin all had between one and four recalls each.

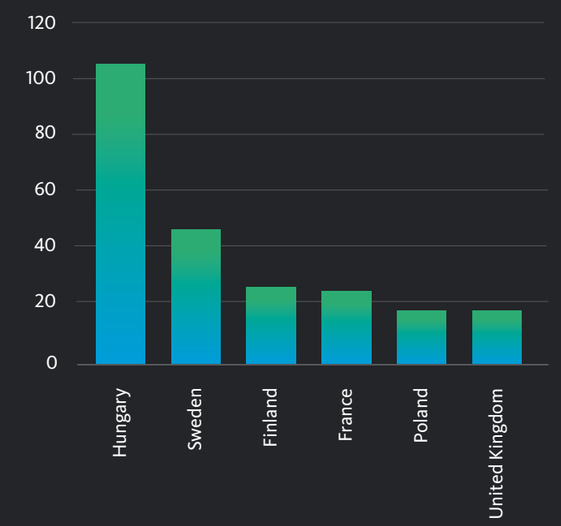
The number of recalls from products whose country of origin is unknown fell in 2021 to 32 (from 57). That is a 43.9 decrease and suggests that tracking is improving for counterfeit products.

Electric shock was the most common risk involved in electrical appliance recalls in 2021, accounting for 151 as a sole cause. If you add electric shock with other factors such as fire and injury, the number rises to 237. There were also 17 recalls linked to "damage to sight," most of which were associated with laser pointers.

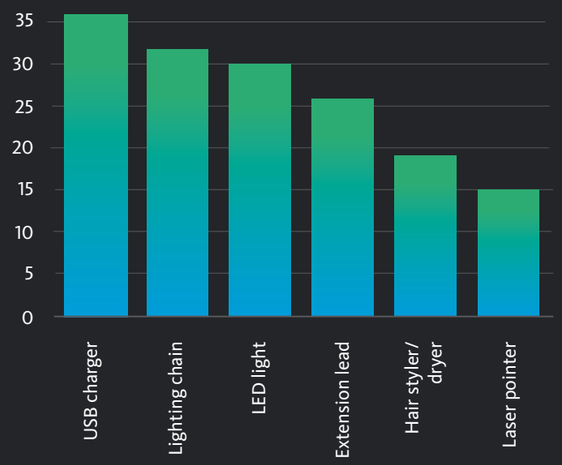
ELECTRONIC RECALL EVENTS BY YEAR



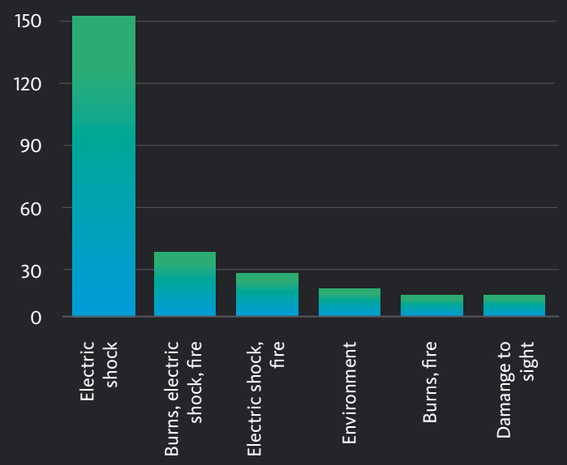
RECALLS BY NOTIFYING COUNTRY FOR 2021



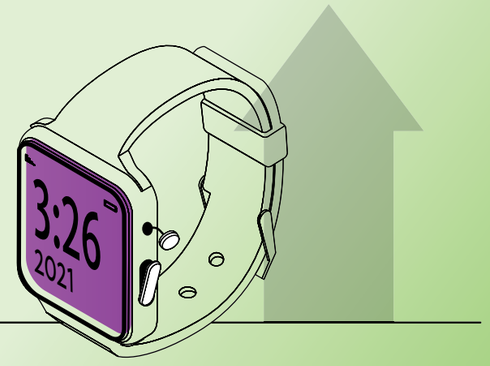
TOP ELECTRONIC PRODUCTS RECALLED FOR 2021



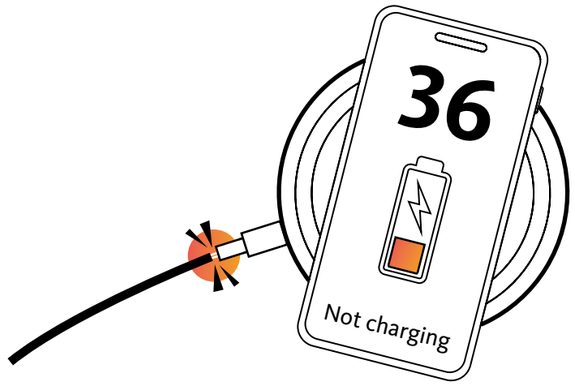
TOP CAUSE OF RECALLS FOR 2021



At 326 events, **recalls increased** for the second consecutive year (183 in 2019, and 225 in 2020).



In terms of quarters, Q4 accounted for the highest number of recalls in 2021. At 94 events, this stands 14.6% higher than the same quarter the year before (82).



USB chargers have remained the most recalled product over the last three years, recording 36 events in 2021.

Extension leads and Lighting chains followed with 32 and 26 recalls respectively.

Accounting for 151 events (46.3%), **Electric shock** was the leading cause of recall activity in 2021.

The second leading cause was a combination 'Burns, Electric shock, and Fire', which collectively impacted 43 events.

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SHOOK, HARDY & BACON INTERNATIONAL LLP

"CIRCULAR ECONOMY ACTION PLAN" TO HAVE SIGNIFICANT IMPACT ON ELECTRONICS INDUSTRY

There are three initiatives related to the European Commission's "Circular Economy Action Plan" that we expect to hear more about in 2022. The plan focuses on creating a more climate-neutral and resource-efficient EU economy in which products are sustainable, safe and recyclable.

While this vision is admirable, it is likely to put an increased regulatory burden on manufacturers, producers, importers and distributors of consumer electronics, who will need to take necessary steps to ensure compliance with new regulations.

The proposed changes include requirements for consumer electronics to be increasingly energy and resource efficient. They will also need to have longer product lifecycles, cleaner waste streams and be easier to repair.

Common USB-C charger standards proposed

A key initiative set out in the Commission's plan is to develop regulatory measures on chargers for mobile phones and similar devices. These measures include the introduction of a common charger, improvements to the durability of charging cables and incentives to unbundle the purchase of chargers from the purchase of new devices. The draft legislation that the Commission put forward in September 2021 revised the Radio Equipment Directive to establish a common charging solution.

Under the proposed Directive, USB-C will become the standard port for all smartphones, tablets, cameras, headphones, portable speakers and handheld videogame consoles. However, other devices, such as earbuds, smart-watches and fitness trackers have not been included for technical reasons related to their size, use conditions and power requirements. Additionally, consumers will be able to choose whether to purchase a new electronic device with or without a new charger. This measure is intended to limit the number of unwanted chargers purchased or left unused.

While the European Commission hopes that the proposed measures will deliver improved interoperability for consumers and less e-waste, concerns have been expressed that unless the Commission monitors and remains ready to rapidly embrace new and improved charging solutions in the future, the revision might inadvertently reduce incentives for manufacturers to innovate.

The updated Directive needs to be adopted by the European Parliament and the Council as the next step. The legislation is expected to be scrutinised by the European Parliament's Committee for Internal Market and Consumer Protection (IMCO) in April 2022. A transition period of 24 months from the date of adoption suggests an implementation date of mid/late-2024 at the earliest. The hope is that this will give the industry time to adapt to meet the changes.

Tackling electronic waste and recovery of critical raw materials

Increasing attention is likely to be paid by the European Commission to the recycling of electronic equipment and components that contain high concentrations of critical raw materials (CRMs). A report published by the EU-funded CEWASTE consortium in April 2021 recommended introducing legislation at the European Union level to require the recovery of specific CRMs such as palladium from printed circuit boards and cobalt from lithium-ion batteries. These two materials are essential for the manufacture of electronic equipment. Collection and treatment of CRMs are currently required by the WEEE Directive and the Battery Directive. However, these directives do not have specific requirements focusing on recovery of valuable materials or CRMs.

The report also emphasises the importance of getting tough on illegal e-waste exports from the EU, investing in the development of recycling technology and creating incentives for manufacturers to recover CRMs. These incentives may include reduced tax on products that incorporate recycled CRMs. As the report points out, a key challenge will be how to make recycling economically attractive for most CRMs. There are capital costs involved in the recycling process, volatile prices of the CRM minerals and challenges with achieving high-quality secondary materials that are suitable to be incorporated into new products.

Sustainable Batteries Regulation will bring big changes

According to the European Commission, global demand for batteries is set to increase 14 fold by 2030 and the EU could account for 17% of that demand. In addition, the exponential global growth in the demand for batteries will lead to an equivalent increase in demand for raw materials, notably cobalt, lithium, nickel and manganese, which will have a significant environmental impact.

Consequently, the Commission has proposed a Sustainable Batteries Regulation that will bring widespread changes to the existing framework for batteries marketed in the EU. If adopted by the European Parliament and Council, the legislative proposal will repeal the existing EU legislation on waste batteries set out in the Batteries Directive 2006/66/EC and impose new requirements across the entire life-cycle of batteries covering manufacturing, design, labelling, collection, re-use and recycling.

Portable batteries commonly used in consumer electronics will have requirements around sustainability and safety considerations, such as carbon footprint rules, minimum recycled content, performance and durability criteria. In addition, safety parameters will increasingly be in the spotlight.

From 1 January 2026, portable batteries of general use may only be placed on the market if electrochemical performance and durability parameters are fulfilled. This requirement will apply to many common formats: 4,5 Volts (3R12), D, C, AA, AAA, AAAA, A23, 9 Volts (PP3).

Additionally, regulators have proposed various labelling requirements that would apply to different types of batteries, including information relating to lifetime, charging capacity, presence of hazardous substances and safety risks. In addition to the CE mark, starting in 2023 batteries will need to be labelled with a QR code to access the information relevant to the type of battery in question.

The proposal will also require the collection rates of waste portable batteries to gradually increase. The measures will aim to ensure that by the end of 2025, 65% of waste portable batteries are collected and by the end of 2030, 70% of such batteries are collected.

The growing amount of electronic waste is a concern that must be addressed – whether that waste is in a mountain of incompatible chargers or old batteries or other sources. However, electronics manufacturers will have a lot of operational, manufacturing and supply chain changes to consider to meet the new regulations. And consumers may need to prepare for higher prices as companies make these shifts to remain in compliance.

CONSUMER PRODUCTS

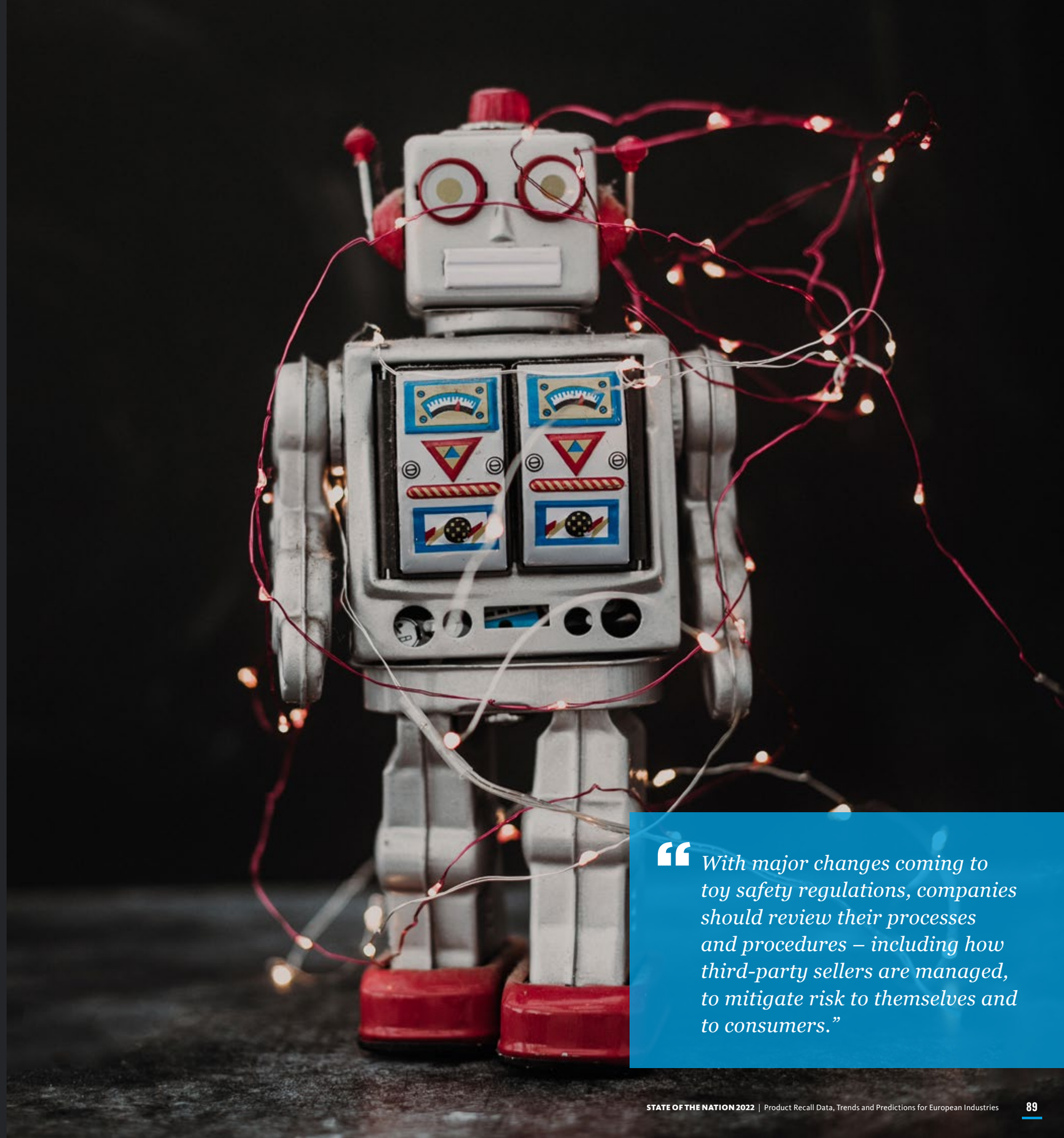
TOYS

Safety is the top issue across the toy industry. Manufacturers are watching major changes in the EU Toy Safety Directive work their way through the approval process. It is another example of how regulators are acknowledging changes in both product technology and the way products are sold – with online sales continuing to rise.

The proposed regulations could be a big burden on manufacturers and retailers, meaning companies should be following the developments carefully.

Another cultural shift that is being acknowledged in the toy industry is a focus on inclusion and diversity. While there have not been any regulations implemented in the UK or EU, from a branding standpoint, companies should assess their product offerings and marketing strategies as they relate to gender and other stereotypes.

Despite a significant jump in the fourth quarter, which is unsurprising due to holiday shopping (and new products rolling out in this timeframe), overall, the number of toy recalls in 2021 was down by 28% compared to 2020.



> *"With major changes coming to toy safety regulations, companies should review their processes and procedures – including how third-party sellers are managed, to mitigate risk to themselves and to consumers."*

Holiday shopping fuels warnings about toy safety and online purchases

Ahead of the 2021 Christmas season, the UK Office of Product Safety and Standards (OPSS) issued a warning message to consumers around product safety risks when shopping online. The agency issued additional guidance to help consumers make safe choices when buying toys, whether from an online source or in person. A few weeks later, another notification was published, announcing that the OPSS was testing more than 1,000 products from major online marketplaces to try to ensure a safe holiday.

As with other industries, toy manufacturers have little control over what information is provided if their products are sold by a third party. However, that doesn't absolve them of responsibility if injuries result. With major changes coming to toy safety regulations, companies should review their processes and procedures – including how third-party sellers are managed, to mitigate risk to themselves and to consumers.

Major changes to EU Toy Safety Directive

The European Commission has proposed major changes to its Toy Safety Directive (TSD), which regulates the safety criteria that toys must meet before they can be marketed in the EU.

As the revisions move through the regulatory process, the Commission has been providing documents to help companies know what to expect so they can begin to prepare. It issued a guidance document in September 2021 to help clarify which products do not fit the standard definition of what constitutes a "toy", and highlight revisions to topics such as online sales, second-hand toys, and chemical testing models.

In December 2021, the European Parliament adopted a report in support of the revisions to the TSD, highlighting concerns over children's exposure to chemicals, risks posed by connected toys, and the increasing number of unsafe toys sold online.

The report also calls for the European Commission to ensure the safety of toys sold on the EU market – whether produced in the EU, or made in other markets and sold online. This would be done by strengthening current legal obligations and market surveillance activities.

The next step in the process is launching an Impact Assessment to identify any problems with the proposed TSD revisions and set out the policy option. Even though the regulations are not yet approved, companies should be reviewing the guidance from the Commission and starting to plan any adjustments they may need to make in their business processes.

Legal obligations increase for foreign toy companies

In addition to the regulatory changes that toy manufacturers will face from the revisions to the TSD itself, the European Commission also confirmed that the EU's new Market Surveillance Regulation (MSR) 2019/1020 will apply to products covered by the TSD.

The goal of the MSR is to provide a uniform and efficient implementation and enforcement of product regulatory requirements across all Member States. However, it can create significant obligations for manufacturers, especially for foreign-based companies selling to the EU. Under the MSR, any non-EU company must have an EU-based entity answerable for product compliance matters.

Diversity and Inclusion Matters in Children's Products

A survey commissioned by one of world's largest toy companies highlighted the need for changing gender stereotypes. The study found that girls are being held back from engaging in creative activities due to societal stereotypes and that caregivers are three times more likely to encourage boys to participate in programming games, sports, and other play than girls. It also showed that caregivers are significantly more likely to think of "scientist" and "engineer" as a career path for men instead of women.

Following the release of this survey, UNICEF published their Promoting Diversity and Inclusion in Advertising Playbook (the Playbook) to call attention to how different types of stereotyping can have a negative impact on a child's development. It also provides strategies that companies can deploy to help combat these issues.

There are other initiatives around this issue including the long-running Let Toys be Toys campaign in the UK, and programmes by the COFACE Families Europe Network. In the US, the state of California passed a law requiring retailers to display toys and childcare items in a gender neutral way, a break from the traditional "boys" and "girls" sections.

While it may take time for other regulators to institute rules around diversity and inclusion, from a brand reputation standpoint, companies may want to consider exploring ways to consider these issues in their products and product marketing.

> *"The goal of the Market Surveillance Regulation is to provide a uniform and efficient implementation and enforcement of product regulatory requirements across all Member States."*

2021 BY THE NUMBERS

The number of toy recalls dropped by 28.1% in 2021 compared to 2020, with 433 recalls notified for the year. Last year did follow the year-over-year trend of having the number of toy recalls in Q4 spike compared to the rest of the year. We saw 166 toy recalls in Q4, or 38% of the full year and more than double the number in Q2 or Q3, which each saw 81 recalls.

The most common category of toys recalled was plastic dolls, with 79 recall events. If plush toys and soft toys recalls are combined, they account for 42 of all 2021 toy recalls.

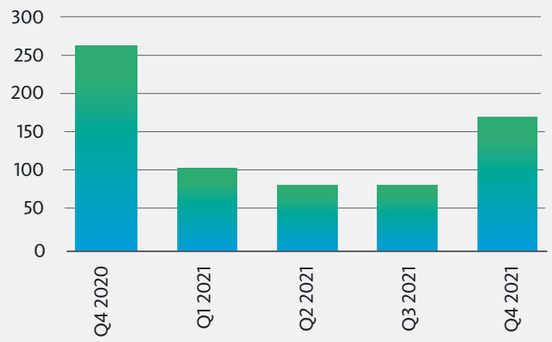
The most common risk type was chemical with 153 recalls as the sole cause and a total of 172 if combined with other factors. Choking alone was noted in 132 toy recalls, but if other factors such as injuries, strangulation or suffocation are also included with choking, the number of associated recalls increases to 175.

Poland took over the top spot in 2021 from the UK with 102 toy recalls. Hungary was second with 45.

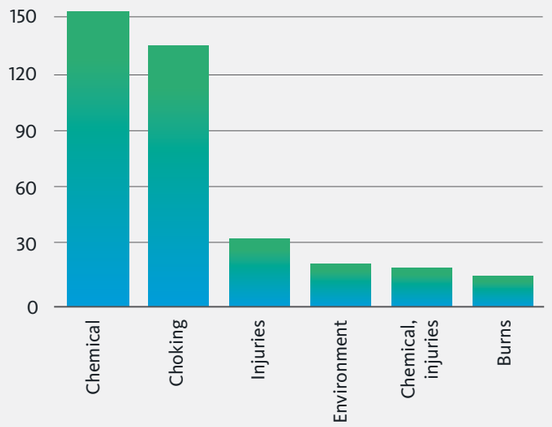
After seeing a dramatic reduction in recalls in 2020, the number of notifications from France rose to 34, a 30% increase but still much lower than the 56 notifications in 2019. The Netherlands, which has seen its number of notifications rise from five in 2019 to 64 in 2020 was back to more normal levels with nine in 2021.

The vast majority of toys recalled in 2021 were manufactured in China. That country was responsible for toys involved in 350 of last year's recalls, or 80.8%. Products of unknown origin were connected with 32 recalls (7.4%).

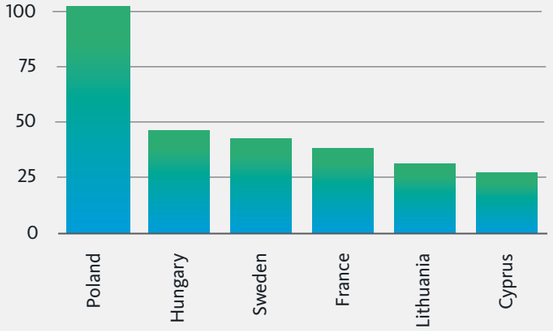
TOY RECALL EVENTS BY QUARTER



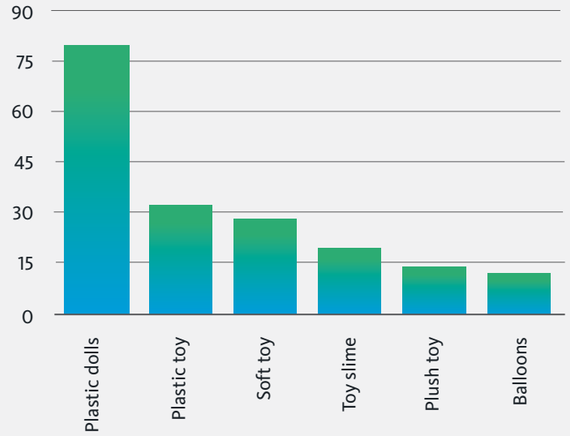
TOP CAUSE OF RECALL BY RISK TYPE FOR 2021



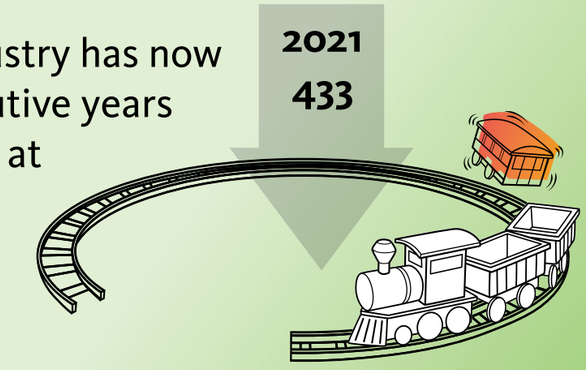
RECALLS BY NOTIFYING COUNTRY FOR 2021



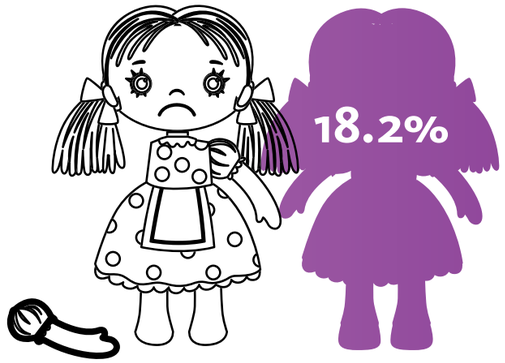
TOP RECALLS BY PRODUCT FOR 2021



The European toy industry has now experienced 2 consecutive years of **recall decline**: 2019 at 645 events, 2020 at 602, and 2021 at 433.



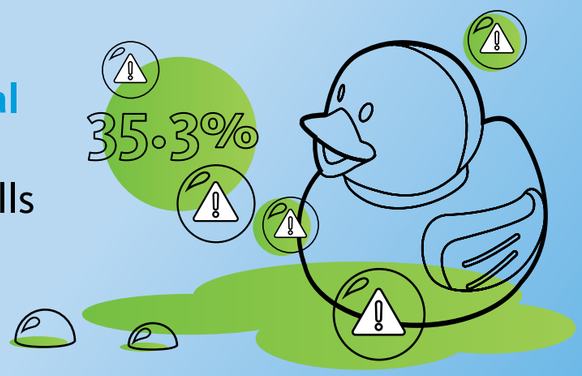
Q4 remains the most dominant quarter for toy recalls, with 38% (166) of all 2021 events recorded in this quarter alone.



Accounting for 79 events (18.2%), **Plastic dolls** remain the most recalled toy over the last 3 years.

Despite toy recalls declining, Plastic doll recall events surged 64.6% from last year, and exceeded levels recorded in 2019 by 25.4%.

At 153 events, **Chemical risks** were the most common cause of recalls in 2021 (35.3%).



Choking concerns followed with 132 recalls. Of these, Soft/Plush toys accounted for 29 events, with Wooden toys and Plastic dolls accounting for 4 recalls each.

ALISON NEWSTEAD, PARTNER,
SHOOK HARDY & BACON INTERNATIONAL LLP

TOY SAFETY – 2022 AND BEYOND

Engaged and environmentally conscious consumers, advancements in technology, new supply chain models and changes to EU legislation will all pose specific challenges to the toy industry in 2022 and beyond.

Sustainability is top focus for consumers

Consumers continue to want toys that are more environmentally-friendly and sustainability will remain a buzz word in 2022. As the ***"throw away"*** culture continues to diminish, there is likely to be a growing tension between sustainability and safety across all product sectors, including toys.

Toys that are made to last longer and be repaired and reused may remain in the hands of children for many more years compared to previous generations. Manufacturers will not only need to take this into account at the design stage, but also when considering any corrective action. In particular, the anticipated lifespan of a product may now need to be reevaluated by manufacturers and regulators when assessing residual risk and recall response rates. In terms of litigation, sustainability is likely to raise questions about how long a manufacturer may reasonably be expected to be responsible for the safety of a product.

The EU Product Liability Directive (Directive 85/394/EEC) has a 10-year "long-stop", which prevents claims being commenced more than 10 years after a product is first placed on the market. This time limit is already being called into question in light of sustainability aspirations. Should it be extended? Will innovation be affected as a result if manufacturers fear being liable for longer periods of time after the product has left their facility?

Increasing risks from connected toys

For the immediate future, toys will continue to excite purchasers with their remarkable technological capabilities.

The range of "connected products" can only be set to expand, with **cybersecurity** issues continuing to feature in safety alerts and recalls. To avoid recall action, those producing connected toys should be giving due consideration to security features at the design stage. However, while there remains the risk of cybersecurity breaches, purchasers will also need to remain vigilant and tech-savvy in protecting children in this ever-complex playground.

Expect more regulation of online marketplaces

Changes in supply models have led to particular challenges in policing product safety. Regulators recognise that those looking to buy toys at the most competitive prices often turn to online marketplaces. Such marketplaces have a much greater volume of unsafe products than traditional brick and mortar outlets. That has led regulators to look for more effective enforcement models.

In the UK, for example, consideration is being given to whether there is a need to revise the definition of an "economic operator," to make it inclusive of online marketplaces and to treat these channels in much the same way as a distributor in terms of liability and accountability. Consideration is also being given as to whether non-UK companies should have an economic operator based in the UK who would be charged with meeting all the necessary regulatory requirements, whilst also providing an easily identifiable entity against whom enforcement action could be taken and complaints addressed. Other market sectors such as medical devices require this.

"Micro-businesses" are another group to consider in online marketplace regulations. These operators make and sell

toys in very small numbers for sale online. Regulators have recognised that there is often confusion with sellers as to whether this category of business falls in the category of consumer-to-consumer sales or business-to-consumer sales. There is also concern that some businesses are suggesting that they are micro-business and masking their activities as consumer-to-consumer sales when they are actually full-scale businesses. Given that toys are destined for a vulnerable group, regulators are likely to be increasingly vigilant in ensuring compliance with regulatory requirements for everyone, including micro-businesses.

Changes to online marketplaces are also included in proposed changes to the EU's Toy Safety Directive (TSD). There are calls for greater coordination between, and increased action by, enforcement authorities – particularly with regard to online marketplaces who are frequently criticised for the tardiness of their actions in removing unsafe toys and preventing them from being relisted. However, it is questionable whether, in practice, the additional cooperation and resources needed to strengthen enforcement will be available in departments which are commonly underfunded and over-stretched.

Toy safety in the forefront

Manufacturers placing toys on the EU market should prepare themselves for potential changes to the regulatory landscape, both in terms of their obligations and the approach of regulators.

In December 2021, the European Parliament adopted a report calling for major changes to the Toy Safety Directive (TSD), which sets out the safety criteria that toys must meet before they can be marketed in the EU. The revisions focus on ways to reduce children's exposure to chemicals, address risks posed by connected toys and tackle the growing number of unsafe toys sold via online marketplaces.

The prevailing opinion is that the existing Directive, although providing a high level of safety, needs to be brought-up-to-date and be more nimble in responding to new safety risks. A call was made to the European Commission to strengthen current legal obligations and market surveillance activities to ensure the safety of toys sold on the EU market, whether originating from EU manufacturers, non-EU manufacturers or via online routes.

The presence of chemicals in toys – and, in particular, the varying chemical restrictions for those toys intended for children under 36 months old and toys that are destined to be put in the mouth – are a particular focus for revision. Current limits for the values for potentially dangerous substances such as nitrosamines and nitrosatable substances are deemed to be too high. It is also widely believed that certain exemptions from the prohibition of chemicals that are carcinogenic, mutagenic or toxic for reproduction will be challenged. Stricter compliance requirements and consolidation of all applicable chemical limits across all toys may be ahead.

Suggested revisions to the current Directive also include introducing new labelling requirements to require the inclusion of allergenic fragrances and dangerous chemicals, durability and reparability and obligations to address cyber threats at the design stage. Using technology such as e-labelling and artificial intelligence is also recognised as being part of the future armour in addressing toy safety.

Brando Benifei, Rapporteur for the Report on the implementation of the Toy Safety Directive, recently commented that ***"Our children deserve to benefit from highest level of protection when they play"***. Such sentiment will undoubtedly influence the future regulation of toys that are sold in the EU, leading to tighter regulation and increased corrective action.

CONCLUSION

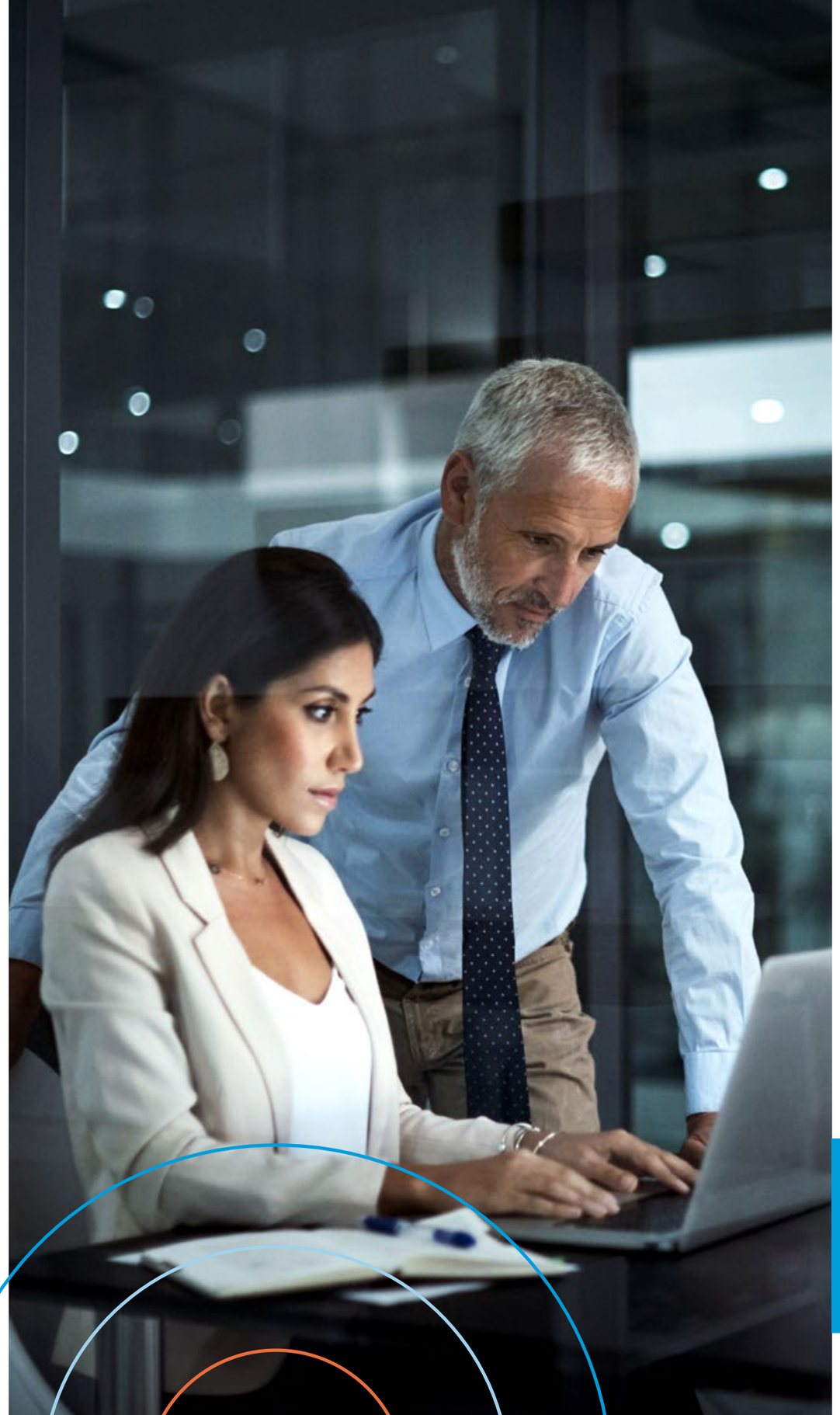
The ongoing global health crisis means continued uncertainty in terms of supply chains, normal business operations and regulatory oversight. Regulators in the UK and EU are looking at updates to old legislation across several industries to reflect risk to consumers from technologies that were not in use when the regulations were written. This includes threats from the technology itself – such as data being hacked from connected devices. It also means technology shifts in how goods are sourced and purchased thanks to online shopping.

While it is impossible to know all the longer-term impacts of these regulatory changes, it is clear that companies need to plan for risks across a variety of areas, including the following:

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

While no one wants to admit that they will face a product recall, if plans to mitigate such instances are tested and updated – and become as routine as other business processes – then when the inevitable occurs, both your brand and bottom-line will remain protected.

Working with an expert partner to leverage their experience and insights can help deliver significant saving in regulatory and litigation costs, as well as time and internal resources. In addition, their expertise will help you honor 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.

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