RECALL INDEX 2021 EDITION 1

PRODUCT RECALL
EUROPEAN EDITION

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

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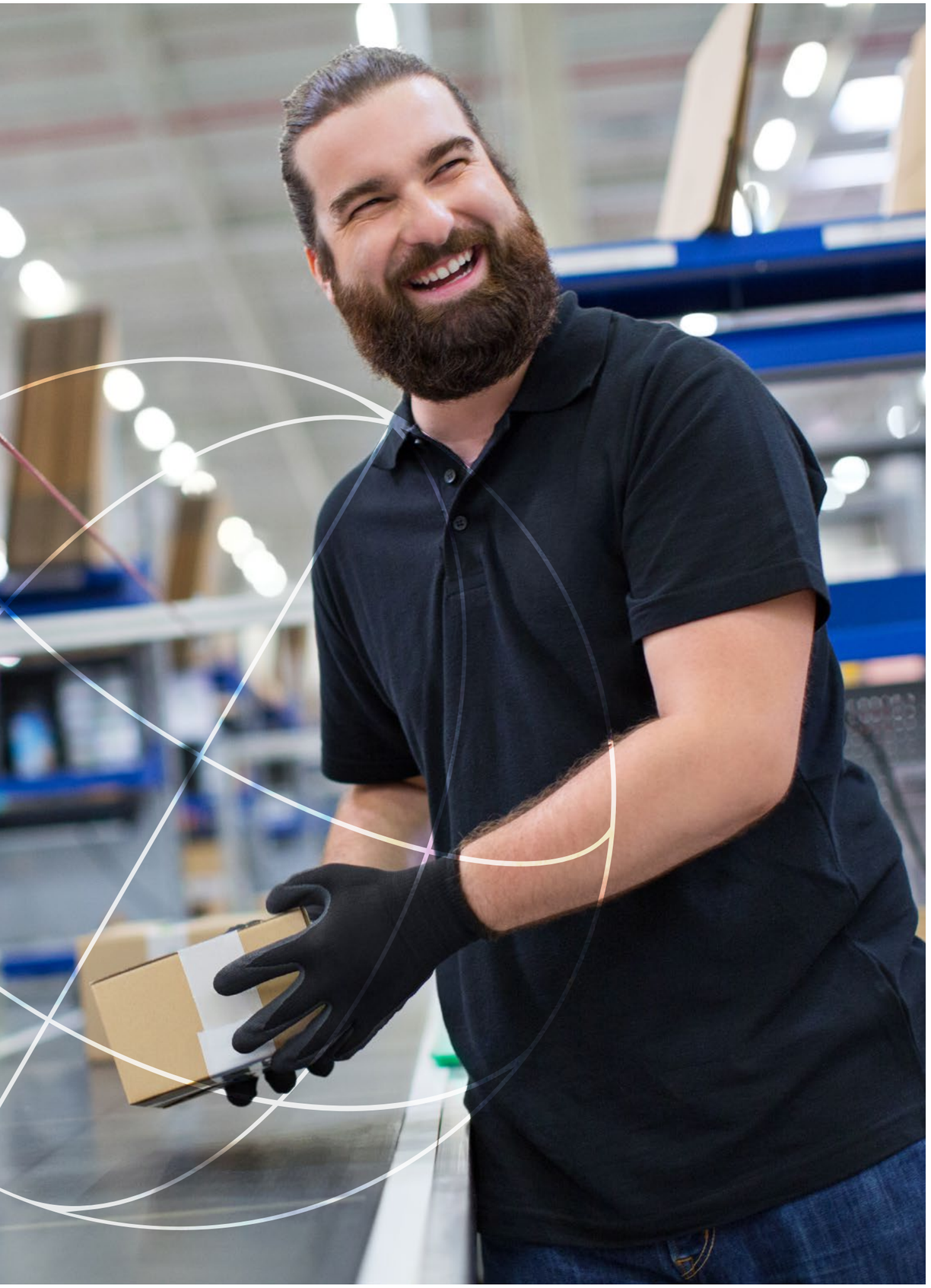

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The Sedgwick brand protection recall index is an essential reference for manufacturers and retailers seeking impartial and reliable perspectives on past, present and future recall data and product safety trends.

Over the course of 2020, Sedgwick's brand protection experts have compiled free and insightful quarterly index reports. This latest edition goes beyond our traditional reviews, bringing you not only information about the latest quarter, but also featuring legal and regulatory insight from some of our strategic partners at leading law firms. We are confident this combination of data and insight will help you further prepare for the increased risks created by product innovations and evolution in the regulation of automobiles, food and beverage, pharmaceuticals, medical devices, toys, electronics and clothing.

Furthermore, our analysis and predictions let you know what to expect in 2021 as lawmakers, regulators and business leaders alike look ahead to a post-pandemic world and a continuation of what has been one of the most turbulent eras for business.

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

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

There has never been a more important time for industries to be primed and ready for any recall or market withdrawal situation, and the information in this report can serve as your guide to ensure you are prepared.

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

US edition available here: LINK

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

2021 State of the Nation European recall index: LINK

Q3 2020 European recall index: LINK

Q2 2020 European recall index: LINK

Q1 2020 European recall index: LINK

CONTENTS

AUTOMOTIVE

Between Brexit and the global pandemic, the automotive industry has faced significant operations and sales challenges over the past 15 months. But as vaccine rollouts build momentum across the globe, these trials may turn out to be minor blips on the radar for an industry facing pressure to innovate and establish entirely new product lines to meet electric-vehicle demands.

On top of that, global automakers and original equipment manufacturers are frequently finding themselves under pressure for environmental requirements, the evolution from combustion engines to hybrid and electric vehicles, and safety risks associated with innovative technology and features. At the same time, they must contend with always changing regulatory environments across the EU and the UK.

Regardless of the risks, honesty and transparency will be key for effective crisis management. Recall plans, complaint investigation and effective customer engagement must be part of this process, particularly as innovative technology and newer vehicles are made available to consumers.

> *"Global automakers are frequently finding themselves under pressure for environmental requirements. A recent 12M Euro fine against a leading EV manufacturer serves as a reminder of the cost associated with noncompliance."*

Evolving regulatory environments

Brexit was on top of the agenda for many European manufacturers for the last few years, returning to the headlines as 2020 came to a close. When the Brexit trade deal ultimately kept the EU and UK markets free from tariffs and quotas, we saw relief across the industry. The automotive sector is also currently benefiting from a grace period over rules of origin, although this will expire at the end of this year.

But just as automakers have a global presence, regulators are having an increasingly global influence. In addition to EU and UK regulations, regulators within EU member states on occasion follow the lead of the U.S. National Highway Traffic Safety Administration (NHTSA) when responding to safety risks associated with products manufactured or sold in their nation-state. If NHTSA becomes more powerful in the coming months as predicted, the knock-on effect in European countries could be significant.

The bottom line is that the automotive industry is still adjusting to Brexit-driven changes, not to mention evolving regulations and policy changes in the EU, the UK and the U.S. Chief among them are proposals to tighten regulations related to emission standards.

Environmental concerns

As the EU seeks to pass tougher emission rules and encourage an ultimate phase-out of fossil fuel vehicles, European carmakers are pushing back. The final version of Euro 7, the proposed EU emissions standard, is expected to be announced this year. As we await the final version, France and Germany are among the countries that believe the initial proposed versions went too far in forcing European carmakers to shift away from combustion engines. On the other side, expect Euro 7 to be influenced by European Green Deal targets to reduce carbon dioxide emissions.

While automakers will likely have several years until the new standard comes into full force, there are undoubtedly significant emissions compliance challenges ahead for automakers. But bear in mind that environmental concerns also stretch beyond just emissions.

A recent 12 million Euro fine against a leading EV manufacturer levied by German authorities serves as a reminder of the cost associated with non-compliance with environmental obligations. The fine follows allegations that the brand failed “to make public notifications and properly fulfill their obligations to take back old batteries from customers,” according to CNBC. 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.

> *“Just as automakers have a global presence, regulators are having an increasingly global influence. If NHTSA becomes more powerful in the coming months as predicted, the knock-on effect in European countries could be significant.”*

Bumps in the road to a hybrid-and electric-dominated fleet

Recent recalls of the lithium-ion batteries powering hybrid and electric vehicles (EVs) are an indication that, for all their benefits, EVs are arguably no safer than their traditional combustion counterparts. But the pressure for the world to shift to these cleaner vehicles remains.

Automakers in Europe are among those most eager to increase global sales of their electric models. Realizing the business and consumer demand challenges in front of them, these companies are calling on European governments to increase taxes on gas-and diesel-fueled vehicles.

As The Wall Street Journal notes, "Traditional automakers face a dilemma. The bulk of their business is still building and selling cars with internal-combustion engines—including family cars, big sport-utility vehicles and sports cars. Raising fuel taxes could hurt sales of those vehicles. But unless EVs can compete on price with conventional cars, it will be hard for automakers to lure customers to them and recoup the vast investments manufacturers have made in the technology."

If automakers are to deliver on both self-imposed commitments and regulatory compliance, they will need to effectively manage consumer expectations and ensure satisfaction before, during and after the vehicle sale.

Safety risks posed by innovative technology

At the outset of 2021, safety concerns related to electric vehicles and new technology remained at the forefront. But adding to those risks are the increasingly cited safety concerns related to innovative and evolving automotive features – like autonomous driving technology. Consider concerns related to features and software rather than traditional tyres and airbags – risks like those associated with autonomous driving features and data privacy.

In one specific example, consider the inquiry by Germany's KBA motor vehicle into safety risks linked to touchscreen displays in Tesla cars, ultimately resulting in a recall initiated in February 2021.

While in some cases the remedies required for these safety issues may not require a trip to the mechanic, the shifting definition of "safety" (to include consumer privacy) and the availability of much-relied on features will create new reputational challenges for automakers. Likewise, these challenges will equally be felt by the technology companies delivering the software and programming to enable this new driving experience. Now consider how recalls are going to evolve with innovation and technology leading the way. These changes demand the same technology-led innovation in recall management. Your reputation depends on it.

FIRST QUARTER OVERVIEW

Despite the pandemic, automotive recalls in the first quarter of 2021 increased 26 percent, compared to average quarterly activity in 2020 (average 121 recalls to 153 recalls). In fact, first quarter 2021 activity exceeded 2019's quarterly average 128 recalls by 20 percent.

Compared with the first three months of 2020, the last pre-pandemic quarter saw 133 recall events, demonstrating recall events are on the rise despite ongoing operational challenges experienced by global automakers and original equipment manufacturers.

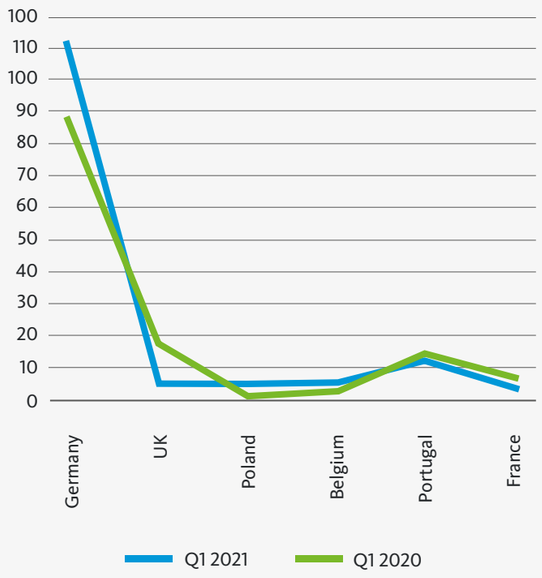
Germany once again dominated in terms of recalled vehicles by originating country, with 48 recalls or 31 percent of all notifications. The United States was responsible for the second most originating events (17), followed by France (16), Japan (14), and the Republic of Korea (8).

Consistent with previous quarters, injuries remained the leading risk associated with automotive recalls, accounting for 122 recalls or 80 percent of notifications. The next most common risk types were fire and fire and injuries, each cited in an additional 14 recalls. This follows the trends identified through 2020.

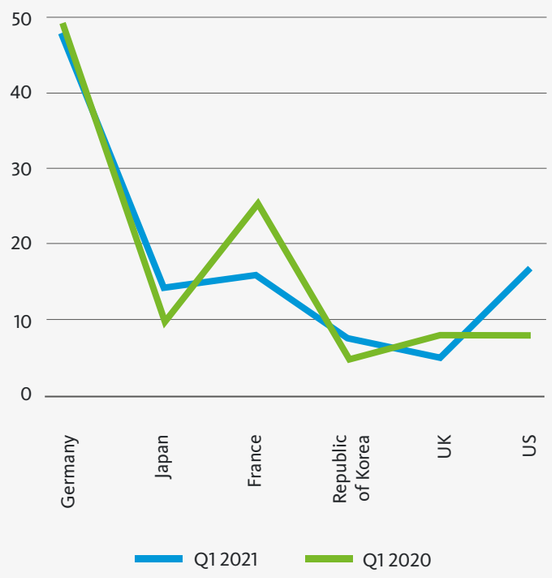
Of all first quarter recalls, 63 percent (96 events) impacted passenger cars. Passenger vans and light commercial vehicles were the second most-impacted category with 14 recalls, followed by motorcycles with 13 recalls.

RISK TYPE	Q1 2021 RECALLS	Q1 2020 RECALLS
Injuries	122	110
Fire	14	12
Fire, injuries	14	8
Burns, fire	2	1
Environment	1	2

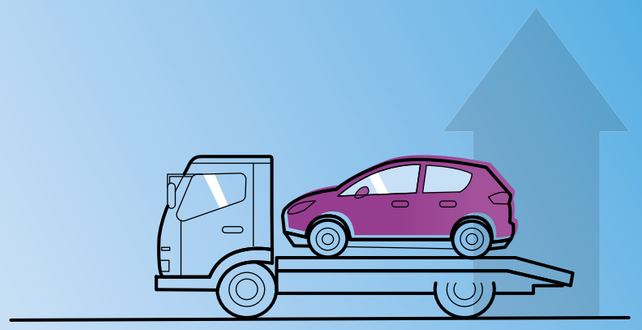
NOTIFICATIONS SUBMITTED BY COUNTRY



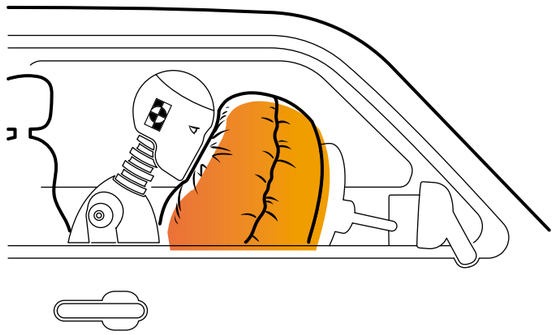
RECALLED VEHICLES BY COUNTRY OF ORIGIN



At 121 events, **Q1 recalls increased 26%** (compared to average quarterly activity in 2020)



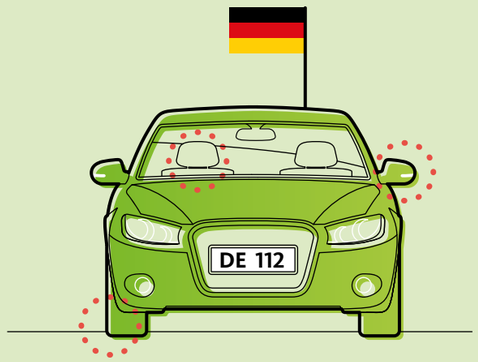
Despite the pandemic and ongoing operational challenges experienced by global automakers, recalls are on the rise.



Accounting for 122 recalls (80% of events), **Injuries** remained the top cause of automotive recalls

This was followed by Fire and Fire and Injuries, each cited in an additional 14 recalls.

Germany was the top notifier in Q1 with 112 events (accounting of 73% of all alerts submitted)



This figure represents a rise of 44% compared to average quarterly notifications made by Germany in 2020.

SIMON GARBETT, PARTNER,
SQUIRE PATTON BOGGS

DIGITIZATION OF THE AUTOMOTIVE INDUSTRY: THE ROAD AHEAD

The automotive industry experienced complex global supply chain challenges over the last 12 months as the Covid-19 pandemic and Brexit created significant disruptions and blocked shipping routes. But even as automakers and Original Equipment Manufacturers (OEMs) struggled to get the right parts to the right place at the right time, the automotive industry remained eager to get new vehicle makes and models on the road as quickly as possible. But this is not without significant risks.

Increased recall risk

Speed-testing and swift approvals increase the risks of recalls. This is particularly troublesome in light of known and unknown dangers associated with electrification, vehicle batteries and autonomous driving technologies. The chances of these safety issues leading to a recall is increased by the globalization of regulatory oversight and enforcement. This is evident in the increasingly coordinated approach to automotive and equipment recalls, particularly in the UK given the adoption of the EU Approval Regulations. While this set of standards will help mitigate product safety risks for passenger vehicles before gaining "type approval," the UK type approval authority is empowered to suspend or withdraw vehicles when standards are not met, including when the car poses a serious safety risk.

Data, privacy and security threats

In addition to risks related to rushing new vehicles and features to the market, cyber security vulnerabilities are on the rise as cars become more digitized. Widespread introduction of autonomous driving capabilities, for example, is likely to create a shift in liability from individuals to product manufacturers – a move that could increase recall risk. If a series of accidents raises safety concerns related to the artificial intelligence technology behind driverless cars, a recall is also likely to follow. And to the extent the safety risk is linked to software or technology shared by other makes and models, the impact will increase exponentially.

Given these risks, companies need to build expertise within big data analytics and develop actuarial and modelling techniques to prepare for increasingly autonomous features. That includes becoming familiar with the UK's Code of Practice for vehicle safety defects and recalls. The Code of Practice outlines expectations of UK enforcement authorities, with a particular focus on defect and recall management. This code also includes significant, detailed guidance on automotive recall requirements in the UK.

It is still unknown how insurance companies will react to the product liability risks. Automakers and OEMs should address privacy and data security risks with their specific insurance covers. Assuming coverage of these risks will be absorbed in conventional insurance products could leave OEMs and suppliers with significant gaps in coverage.

What's next?

As we approach year-end, the automotive industry can expect increased pressure to have more stringent regulations on safety concerns from environmental protection to data privacy and cybersecurity. Further restrictions on CO_2 emissions will serve to advance the electrification of automotive vehicles ahead of the UK's ban on petrol and diesel cars by 2030.

As the UK's Department for Transport prepares to relax autonomous driving restrictions by year-end, the Office for Product Safety and Standards is seeking evidence for ways to modernize UK product safety laws for the automotive industry. This could lead to greater flexibility in the regulatory framework while also supporting enhanced risk identification.

Finally, cybersecurity will become a more pressing issue for connected or 'smart' vehicle manufacturers. These companies face dual liabilities in the event of a data breach resulting in vehicle crash – liability as a 'producer' under the Consumer Protection Act 1987, and as a 'data controller' under the GDPR.

Given these evolving concerns, OEMs and suppliers should engage their insurers now to evaluate topics related to cyber security and autonomous driving liabilities. At the same time, companies would be wise to revisit their recall plans to ensure they will be effective in managing a new-age technology-driven recall.

> *“As companies continue to adjust to consumer-driven phenomenon, they must not lose sight of the basics – everyday concerns like contamination risks and undeclared allergens.”*

FOOD AND BEVERAGE

The food and beverage industry has faced a seemingly endless list of challenges that forced the sector to evolve over the last 15 months. Now, with the world slowly emerging from the pandemic, the trends we identified in our recent 2021 state of the nation recall index - conscious consumerism and eating for health and sustainability - are firmly here to stay.

As companies continue to adjust to consumer-driven phenomenon, they must not lose sight of the basics – everyday concerns like contamination risks and undeclared allergens. The first step in protecting your reputation is a strong culture that ensures food safety compliance, builds consumer trust and prepares the company for the times when a recall or corrective action is required is critical.

Contamination concerns

The leading cause of food and beverage recalls is contamination concerns. But as a point of clarification, we're not talking about the foodborne illness-related contaminations that are often top of consumers' minds. Instead, notifications in the first quarter showed a heightened level of recalls resulting from contaminants like ethylene oxide – the unauthorized substance at the center of a growing list of withdrawals and recalls for sesame seed products in many EU Member States, including hummus, bread and sauces containing sesame.

While these recall notifications started approximately six months ago, we are still feeling the impact. The industry would be wise to proactively evaluate their exposure to similar risks. A February 2021 briefing from the European Parliament noted that "at least some of the food safety authorities in Member States have also announced that they are continuing and expanding their investigations, scrutinizing further countries of origin as well as other products, such as spices." As additional contaminants of concern are identified in foodstuffs and widely used ingredients, this scrutiny will increase creating additional regulatory, legal and reputational risk for companies.

Consumer communication

According to survey data released by the European Institute of Innovation and Technology (EIT), more than half of consumers agree that the food supply in Europe is safe but, there is significant variation across countries. The survey looked at consumer confidence across a combination of five factors: taste, safety, healthiness, authenticity and sustainability – reflective of an intentionally broad definition of food safety.

"As we look to our economic recovery in the coming year, helping to build trust between consumers and the food sector will be critical to improving food for everyone," said Saskia Nuijten, director of communication and public engagement at EIT Food. "Ultimately, to create a future-fit food system, we must put consumers at the center of the development, production, distribution and promotion of food."

The European Food Safety Authority (EFSA) recently issued guidance designed to help the food industry determine what food safety information to share with consumers beyond simply use-by or best-before dates. This latest position suggests that food companies offer consumer-level directions related to storage conditions, consumption timelines before and after a package is opened and guidance on thawing and consuming of frozen items. The guidance, which takes the form of a five question decision tree, also warns companies that they must consider consumer behaviour and reasonably foreseeable conditions.

As businesses in every industry know, this "reasonably foreseeable condition" language is where businesses are exposed to the most risk, particularly because "reasonable" conditions evolve in response to any number of factors. One business's non-compliance could impact consumer trust across an entire category. Consumers in the Netherlands could have varying expectations about food safety than consumers in Germany or France. Or, perhaps more simply, consumers may have different expectations about how and when they will hear about a potential safety or quality issue.

In these cases, the most critical component to your crisis management is also the hardest to put your finger on – the beliefs, mindsets and expectations of your customers. But your ability to understand your consumer and effectively engage during crisis will directly correlate to the impact on your brand and reputation when food safety comes into question – especially during a recall.

Crisis planning

The European Commission began developing a contingency plan to ensure food supply and food security across the EU in response to the challenges experienced during the height of the pandemic. A chief tenant of the plan is a permanent forum including member states and food supply chain stakeholders working to find ways to enhance coordination. That includes recalls and withdrawals.

The team at Sidley Austin shared insight on the rules governing recalls and withdrawals of food products from the EU market, including procedures outlined by Regulation 178/2002 (General Food Law Regulation) and the European Commission's guidance on the implementation of that regulation. The attorneys note that determinations on whether a food is considered safe will be largely based on "information provided to consumers, including information on the label or other available information about avoidance of specific adverse health effects for a particular category of foods."

Should a recall be required, the General Food Law Regulation details obligations of food companies. While these obligations are the primary legal responsibility of the businesses, food industry entities must also consider their contractual obligations up and down the supply chain in order to ensure customer and partner retention during and after a recall.

The last piece of the puzzle is the risk of penalties for non-compliance with EU food legislation. Here again, the Sidley Austin team warns that the EU member states levy penalties at a national level, from administrative investigations to fines and injunctions. Criminal fines and criminal liability are also on the table in EU member states, including France, Italy and Ireland.

> *"More than half of consumers believe Europe's food supply to be safe. As we look to our economic recovery in the coming year, helping to build trust between consumers and the food sector will be critical to improving food for everyone*."*
>
> Source: European Institute of Innovation and Technology

FIRST QUARTER OVERVIEW

EU data collected from the Rapid Alert System for Food and Feed (RASFF) in the food & beverage category revealed 1,038 recalls, evidence that recall activity is returning to pre-pandemic levels. First quarter 2021 recalls were up 11 percent compared to quarterly averages in 2020 and 4 percent compared to average quarterly activity in 2019. It is worth noting that this volume is down from the fourth quarter's 1,448 recalls. But if first quarter activity continues, we'll see 2021 activity exceed volumes recorded over the last two years.

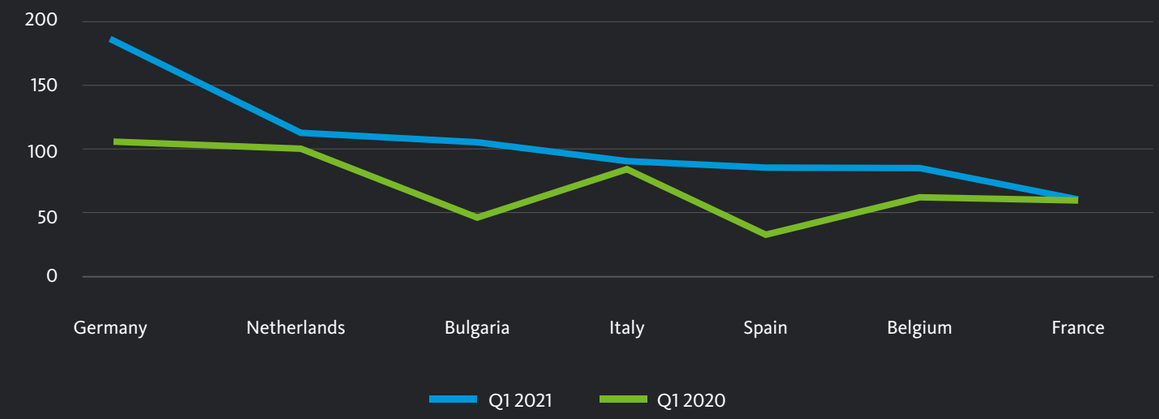
The leading cause of food and beverage recalls is contamination (other than bacterial), representing 390 events or 38 percent of recalls. This includes a variety of contaminants, the most common of which were Ethylene Oxide (144), Aflatoxins (95), Prochloraz (14) and Cadmium (12). Bacterial contamination was the second-leading cause with 195 recalls, followed by unauthorized substances accounting for 194 recalls.

Fruits and vegetables were the most impacted product category with 260 recalls (25 percent). The most common reasons for these recalls were unauthorized substances (129) and contamination other than bacterial (100). Specific unauthorized substances listed include Chlorpyrifos-Methyl (116), Carbendazim (7) and Colour (7). Nuts, nut products and seeds were the second-most impacted product category at 149 recalls, followed by cereals and bakery products with 76 recalls.

Germany remained the top country for notifications in the first quarter (184). This represents a 40 percent increase from 2020's quarterly average of 131 recalls. The Netherlands maintained its heightened level of activity in the first quarter, with 119 recalls compared with last year's quarterly average (125). Bulgaria rounded out the top three notifying countries with 109 events.

Undeclared allergens, while not a leading cause, resulted in 34 recall events in the first quarter. As we approach October 2021, when Natasha's Law will go into full effect, it is worth noting that only three of these events impacted prepared dishes. As a reminder, the Law will require businesses in England, Scotland, Wales and Northern Ireland to make available full ingredient lists and allergen labelling on all pre-packaged food available for direct sale. With a full commitment to compliance with this regulation, we will ideally see this recall cause become even rarer.

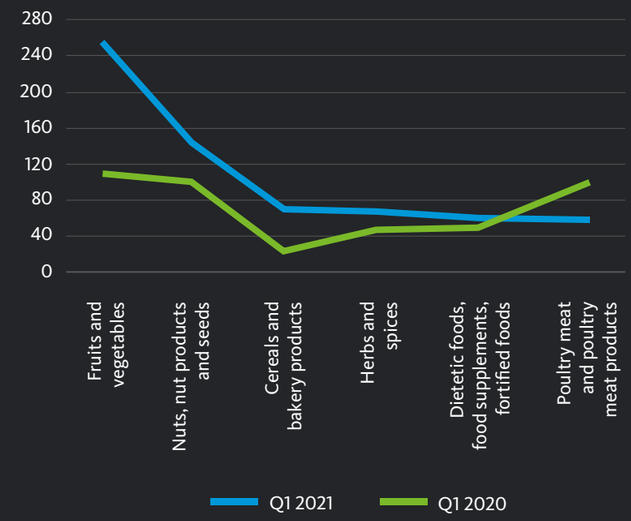
NOTIFICATION SUBMISSIONS BY COUNTRY*



**Top 7 notification submitting countries listed, out of 32*

ACTION TAKEN	Q1 2021	Q1 2020
Destruction	165	83
Withdrawal from the market	137	121
Official detention	103	83
Re-dispatch	99	75
Recall from consumers	98	99

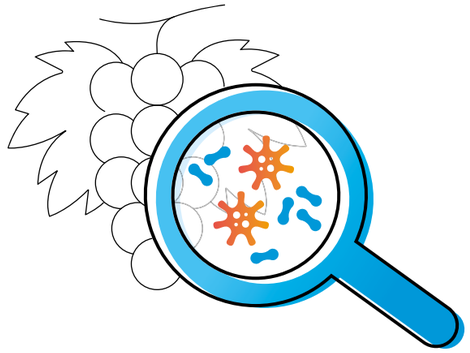
RECALLS BY PRODUCT TYPE



At 1,038 events, **Q1 recalls increased 11%** (compared to average quarterly activity in 2020)

Q1 2021

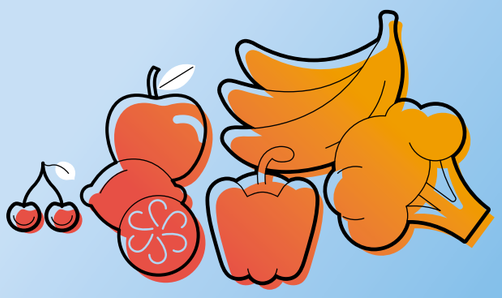
Despite this uplift, Q1's volume was down 24% from the 1,448 recalls experienced in Q4 2020.



Accounting for 390 events (38%), **Contamination** (other than bacterial) was the top category impacting Q1 recalls

Bacterial contamination was the second-leading cause with 195 recalls, followed by unauthorized substances (194).

Fruits and vegetables were the most impacted product category with 260 recalls (25%)



Nuts, nut products and seeds were the second-most impacted category at 149 recalls, followed by cereals and bakery products (76).

SARAH-JANE DOBSON, PARTNER AND **EMILIE CIVATTE**, SENIOR ASSOCIATE (FRENCH AND UK DUAL QUALIFIED), **KENNEDYS LAW**

PROTECTING YOUR REPUTATION IN A POST-PANDEMIC ERA

Amongst other challenges, three primary challenges transpired as a result of the Covid-19 pandemic, each making its own lasting impact on how companies interact with consumers, partners and regulators. The good news is that a close examination of these challenges can be beneficial in helping companies identify and mitigate reputational risks through careful planning.

Food safety and quality assurance challenges

It goes without saying that food manufacturers need to have solid quality control systems in place to protect consumers. But the pandemic taught us how important - and difficult - it is to ensure they work if no one is on-site monitoring or conducting inspections.

For companies with global operations and factories abroad, food safety programmes were put to the ultimate test during the pandemic. With travel restrictions firmly in place, food companies needed to find ways to conduct effective quality audits without stepping foot into a factory, processing site, partner facility or out-of-country supplier location.

This is a risk that isn't going anywhere any time soon. Companies should do the legwork now to build a network of trusted and reliable professionals or third-party partners for each factory, with a focus on those out-of-country. The same approach should apply for how you vet and audit your suppliers. The work you do now will be valuable long after the pandemic. Consider how a trusted food safety network will benefit you in the event of any unforeseen circumstances.

Addressing food safety concerns during Covid-19

At the outset of the pandemic, customers were quite scared about transmissibility of the coronavirus by food sources. There was a lot of uncertainty about the safety of food products. Combined with product shortages and changing consumer behavior, the industry has faced significant challenges maintaining trust.

In the end, everyone was able to find food and store shelves are back to full-stock. It is a testament to the strength of the industry. But that does not mean there are not areas for improvement and lessons to be taken from the experience.

Food businesses should conduct due diligence to critically examine what parts of their pandemic response worked and, more importantly, where the company can improve. If you turn a blind eye on something, an opportunity for preparation is lost. But if you realize that you had trouble sourcing materials or getting products to consumers, you can take steps now to mitigate that risk in the future.

Rebuilding consumer confidence

Consumers' concerns about the potential association between food or packaging and transmission of Covid-19 is in part a symptom of a much larger challenge: growing mistrust for everything that is mass produced, particularly involving the same suppliers.

This is not a new risk for the food industry, but it has been exacerbated by media coverage and headlines about food safety concerns and product recalls. Where consumer awareness and interest was once limited, people are much more aware of food safety concerns and the potential impact of a recall. While this is good because consumer safety increases, the industry must recognize the influence tabloid headlines and social media has on its reputation, particularly in the event of a recall.

Serious, irreparable damage can be done to your reputation if your recall communication and management fail to reassure consumers and build trust. Not to mention the gradual and significant increase in class action and claimant lawsuits in the UK and the EU.

As consumer behaviour evolves, safety will remain a driving factor. Food companies can expect to see a continued increase in demand for products from local growers and processors due to a perception of increased traceability and safety.

As they become more health conscious, consumers want to know more about where their food is coming from and how it is produced. With this increased attention, consumers are becoming more capable and willing to detect a food safety or quality issue. As this level of interest increases, there will be consequences. More customer complaints often lead to more recalls.

The industry is changing, and the regulatory environment is also evolving with it. From the adoption of blockchain to continued focus on genetically modified organisms (GMOs), at both an EU and UK level we may see new regulations in the future. But until then, there is plenty of work to be done to protect consumers and your reputation.

PHARMACEUTICAL

We are slowly emerging from an era in which regulatory oversight and enforcement actions were restricted, particularly in terms of on-site inspections. As time passes, expect EU, UK and Member State regulators to return to a more traditional approach to oversight activities, supplemented by the newly minted virtual approaches to audits. But regardless of the form taken, expect the focus to be on traditional pain points that lead to recalls.

> *"As we emerge from the COVID-19 pandemic, the pharmaceutical industry has significant challenges ahead, not the least of which will fall on the safety and efficacy of vaccines."*

Safety and efficacy risks

Pharmaceutical companies have some of the strongest quality control procedures in place. Even still, contamination concerns are a long-standing risk for the industry. Part of the reason is that contamination risks, like every other, are evolving. Companies not only need to control for known contaminants but also chemicals and substances previously unidentified. Consider N-nitrosodimethylamine (NDMA) – a contaminant that, until recently, companies didn't even know they should be looking for in pharmaceuticals.

In response to the discovery of NDMA back in 2018, the European Medicines Agency (EMA) launched a scientific review of "nitrosamine formation or presence during the manufacture of human medicines [and has] provided guidance to marketing authorisation holders to avoid the presence of nitrosamine impurities." That guidance was followed by an implementation plan establishing how the European medicines regulatory network and the European Directorate for the Quality of Medicines & HealthCare (EDQM) will monitor for and respond to nitrosamines in human medicine.

The EMA and Member State authorities will continue to monitor the presence of nitrosamine impurities in medicines, with support and in collaboration with regulators outside the EU. That continuous review led to a February 2021 request for marketing authorisation holders for rifampicin-containing medicines to test their products before releasing them onto the market.

While the investigation into potential NDMA in rifampicin-containing medicines is ongoing, there is the possibility that recalls will follow. If that happens, expect those notifications to be as global in nature as the distribution of the product in question.

Labelling, leaflets and marketing claims

Some of the leading recall causes and reputational risks facing pharmaceutical companies are almost purely documentation-related. We continue to see patient information leaflets and labels that have any number of mistakes requiring corrective actions, including language issues, omitted information that impacts traceability, missing warning labels or other straightforward inaccuracies or deficiencies.

The fact is mistakes happen, and we'll always see corrective action programs for these reasons. While errors in product labels and patient leaflets make a product non-compliant, these errors rarely cause significant increases in adverse event rates. That said, these issues can have a direct impact on the outcome of potential lawsuits, which are becoming more popular as we discuss next.

Increased litigation risk

Product liability lawsuits have become synonymous with recalls in the United States. That's no secret. Pharmaceutical companies are beginning to learn that similar risks are increasing in the EU and the UK, as we see an increase in group actions, likely sparked by growing consumer awareness by social media, opportunistic claimant lawyers and evolving consumer expectations of safety, quality and, in the case of vaccines, a lack of faith in medical research and the scientific process.

As we emerge from the COVID-19 pandemic, the pharmaceutical industry has significant challenges ahead, not the least of which will fall on the safety and efficacy of vaccines.

In the UK, claimant lawyers have already raised concerns that the Vaccine Damage Payments offered does not go far enough. In an exclusive with The Independent, "medicine experts, lawyers and families warn that the government needs to overhaul the UK's 'dated' compensation scheme and provide better support for people affected by vaccination." As long as this public opinion holds, manufacturers can expect claimants to test the legal waters via the court system.

In the EU, however, legal responsibility rests with the manufacturer unless the company is granted indemnification by Member States. But even then, a disagreement would be resolved in court.

FIRST QUARTER OVERVIEW

Pharmaceutical recall activity started returning to pre-pandemic levels. After a quarterly average of 63 recalls in 2020, pharmaceutical recalls increased 35 percent to 85 recalls in the first quarter. We expect this increase to coincide with the early stages of business-as-usual regulatory oversight.

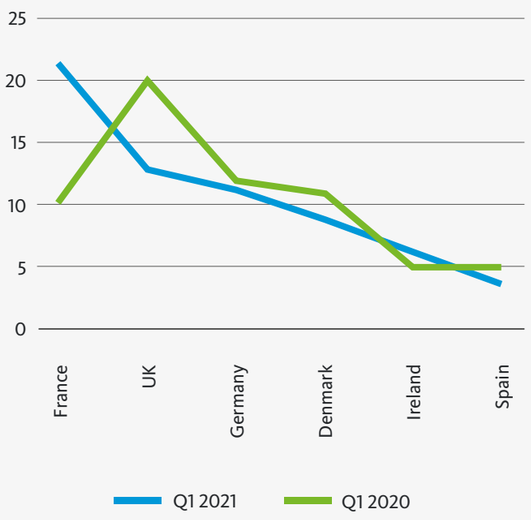
The most common reason for recall was cited as safety (27). This was followed by failed specifications (17), mislabelling (9), quality (8) and "notification only" (8). In our 2021 state of the nation recall index, we noted that foreign materials and contamination recalls dropped precipitously in 2020 to only eight recalls for the year. While recalls of this type have not fully returned to pre-pandemic levels, we saw 6 recalls due to foreign materials and contamination concerns in the first quarter alone. As regulators find innovative ways to audit and inspect manufacturers, there is a chance we will see recalls of this type continue to increase.

According to the data, pharmaceuticals produced in France were most likely to be recalled, accounting for almost a quarter (21) of pharmaceutical recalls in the first quarter. This was driven by mislabelling concerns (5) followed by failed specifications (4), quality (3), safety (3) and sterility (3). Pharmaceuticals produced in the UK were the second most likely to be recalled (13) followed by Germany (11).

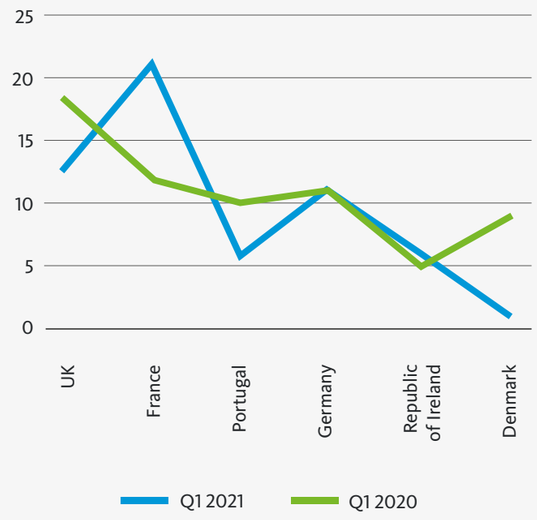
France placed the highest number of notifications in the first quarter (21), followed by the UK (13) and Germany (11).

It is also worth noting that Ireland placed 6 notifications in the first quarter, all as the result of safety concerns. All of these notifications impacted products produced in Ireland. Likewise, Spain issued 4 notifications in the first quarter, all as the result of safety concerns related to products produced in Spain.

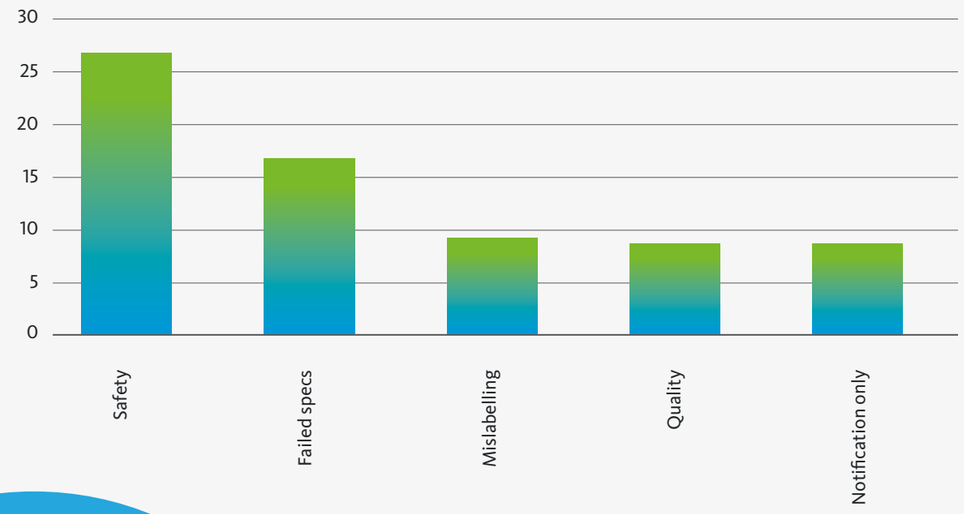
NOTIFICATIONS SUBMITTED BY COUNTRY

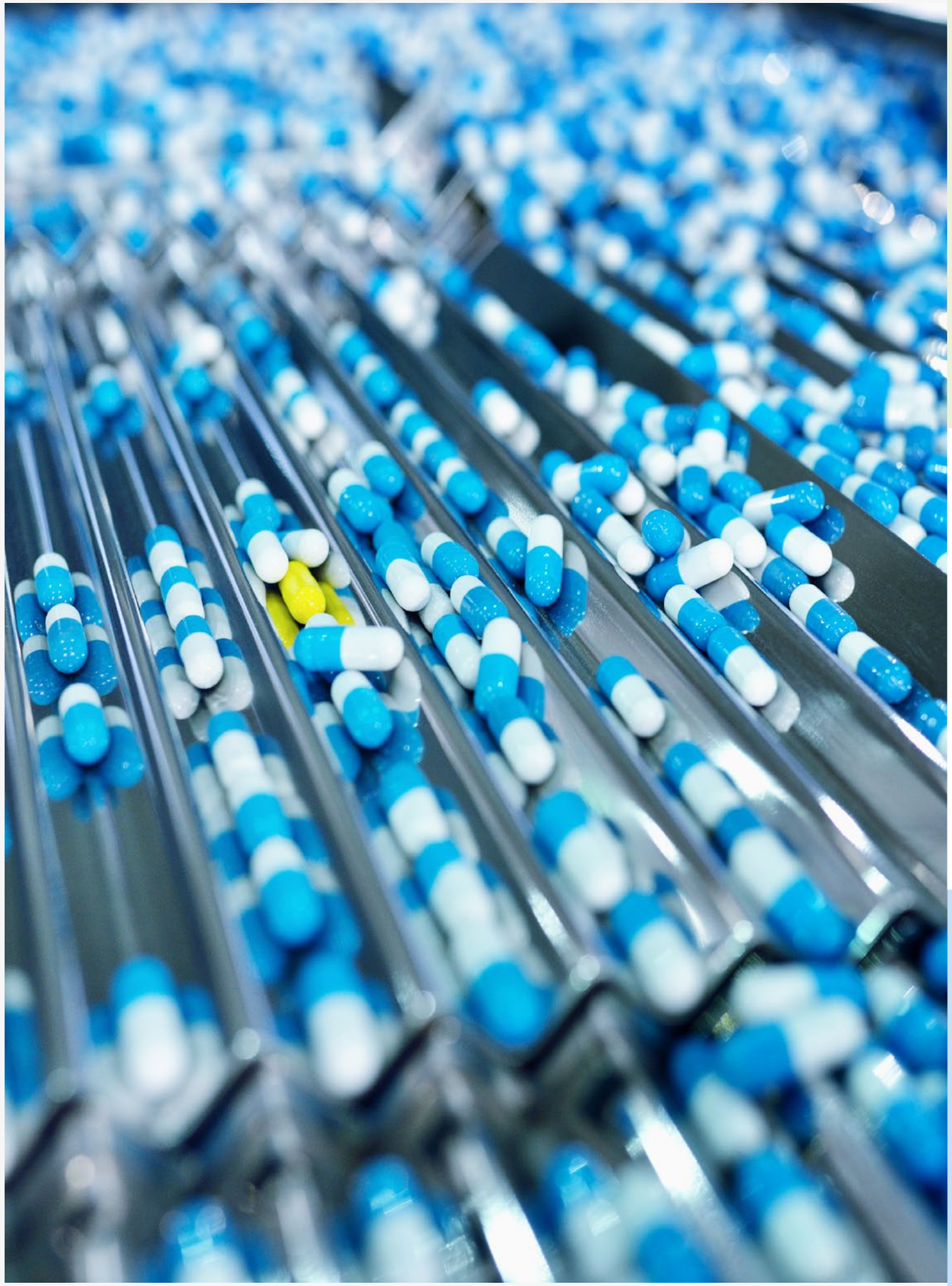


RECALLS BY COUNTRY OF ORIGIN

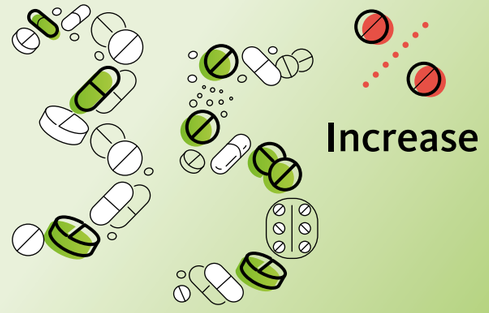


TOP REASONS FOR RECALL

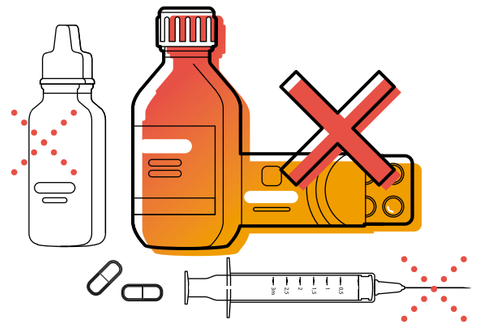




At 85 events, Q1 recalls **increased 35%** (compared to average quarterly activity in 2020)



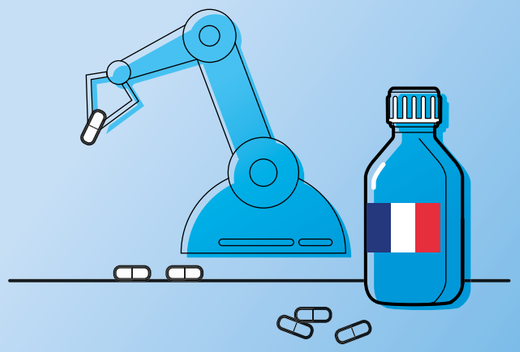
We expect this figure to increase further as European regulators return to more traditional approaches of oversight activities.



Accounting for 27 events (32%), **Safety** was the leading cause of recall activity in Q1 2021

This was followed by failed specifications (17), mislabelling (9), quality (8) and “notification only” (8).

Pharmaceuticals produced in **France** were most likely to be recalled, accounting for 21 Q1 events (25%)



This was driven by mislabelling (5), followed by failed specifications (4), quality (3), safety (3) and sterility (3).

ALISON NEWSTEAD, PARTNER/SOLICITOR,
SHOOK, HARDY & BACON

THE PHARMACEUTICAL INDUSTRY IN 2020 – RAPID RESPONSE AND REGULAR CHALLENGES

Over the last 15 months, we have seen unprecedented efforts by the pharmaceutical industry in supporting the global response to the coronavirus pandemic. This rapid response has posed – and will continue to pose – challenges to the pharmaceutical industry, which has also had to get on with its usual "day job" of bringing non-Covid products to market and responding to safety and compliance concerns.

Primary causes of pharmaceutical recall actions in 2020

When we think about recall of pharmaceutical products, we immediately consider that it is the safety or the efficacy of the active ingredient in the pharmaceutical product that is in issue. This is rarely the case. Although a few such examples can be noted in 2020, the majority of recalls in 2020 related to other types of issues. Indeed, notwithstanding the pressures of the Covid-19 pandemic, 2020 saw pharmaceutical companies reacting to familiar, pre-Covid, product safety and compliance issues:

1. **Deficiencies in Patient Information Leaflets (PIL's).** There are numerous examples of incorrect PIL's in 2020, most concerning the omission or inaccuracy of important safety information. Such deficiencies covered issues such as the omission of warnings about side effects, instructions as to how to take the product, and storage information. Notwithstanding the safety implications, shortcomings in patient information are problematic from the perspective of potential product liability claims, as the accuracy (or otherwise) of patient information will be closely scrutinized by Claimant lawyers and the Courts should there be an allegation of injury arising out of the use of the product.

2. **Labelling issues.** Labelling issues continue to be seen in various guises, including discrepancies between prescribed dosage on the product packaging and that stated on the vial, syringe or bottle. Labelling-related recalls also concern missing batch numbers (which impact traceability), expiry dates and language issues.

3. **Contamination.** Pharmaceutical companies consistently have robust quality control procedures. Even still, as with every year, 2020 saw a number of adulteration cases, both in terms of foreign bodies in finished products and cross contamination during the production process.

4. **Production and manufacturing errors.** These are the result of issues arising on the production floor, and are often picked up in routine testing and sampling. The results of such issues can be seen in the production of out-of-specification products, packaging issues such as blister packs not containing the correct number of tablets and bottles that do not have child-resistant caps.

All potential safety and compliance issues require investigation by the license holder to determine what, if any, action needs to be taken. Being aware of potential issues is crucial and pre and post-market vigilance is key. Of course, pharmaceutical products undergo an extremely vigorous pre-market evaluation before market authorization is granted and the production process is subject to strict quality assurance controls. However, in addition to this, it is important to have rehearsed internal processes to respond to a recall situation.

Recall planning as part of risk mitigation

Most companies have strong controls in place for pre-market risk mitigation, but ensuring that those in the business are ready if a recall situation arises is something that is often overlooked. A recall dry run – or recall drill – can be invaluable in preparing for such an eventuality. It can greatly assist in validating the recall plan, by helping the internal recall management team understand their roles and responsibilities, appreciate the speed at which a recall happens, better evaluate their insurance position, and prepare to execute on their recall notification, logistics, storage and disposal obligations. Identifying shortcomings in processes or the knowledge of key personnel will be possible outside of the high-pressured environment of a real-time recall event.

That said, even when companies conduct these drills, they are too often completed with one jurisdiction in mind (typically the home nation), and limited consideration is given to the interconnectedness of regulatory bodies across the globe. Forethought must be given to the entire global marketplace and what steps each regulatory body will expect a company to take, and when.

Similarly, all too often, a company quickly becomes engrossed in the details of the recall process in one jurisdiction, and fails to consider triggers related to obligations in other countries. Supplying a product to a global marketplace requires a coordinated response at a global level. Failure to do so, puts the company at risk of civil and criminal sanctions.

The Covid-19 context

It is not possible to comment on 2020, without examining the impact of Covid-19. Inevitably, both the pharmaceutical industry and global regulators were keen to ensure that Covid-19 vaccines were made available as soon as possible as the virus continued to spread around the world. The usual timescales for researching, testing, manufacturing and obtaining regulatory approvals for vaccines were significantly condensed. Unsurprisingly, questions as to the legal liability for the safety of vaccines was an issue that was raised in many jurisdictions and which has been handled differently around the world. In the UK, those allegedly injured by Covid vaccines are likely to have to turn to the Vaccine Damage Act for compensation. In terms of drugs, concerns have been raised about products that have been used off-label for Covid-19 prevention or treatment.

While claims have been limited in number so far, it is naïve to consider that claims will not be pursued in respect of vaccines or drug therapies and companies should prepare for potential Claimant action in the future.

Of course, regulators continue to monitor vaccines and drugs placed on the market to treat Covid-19 and take the action they consider necessary to address any potential safety concerns.

What does the future hold?

2020 has taught us that it really is not possible to predict what might happen in the future and how individuals, businesses and the legal community will need to pivot quickly to respond. What is certain, however, is that the pharmaceutical industry will continue to evolve and technology will present ever more complex and ground-breaking ways in which to address health issues. With these new innovations will come new legal challenges and inherent risks. Being informed as to what these risks may be, and how to respond to them quickly if they arise, is the most effective form of risk mitigation that a company can undertake.

> *“In addition to traditional oversight activities, authorities are becoming proactive in their monitoring for potential safety issues, including using social media to monitor for potential safety concerns and adverse events.”*

MEDICAL DEVICE

As we previewed in our 2021 state of the nation recall index, two major developments in the medical device technology industry will have a direct impact on your business and products:

1. **Expectations of impervious quality control procedures – covering software and hardware – across your supply chain**

2. **New European Medical Device Regulations which are due to come into play in May**

But these developments also give rise to a host of reputational risks facing medical device manufacturers, particularly in a legal environment that is showing signs of being increasingly friendly to claimant actions.

Software and emerging technology

The COVID-19 crisis placed unprecedented strain on our healthcare systems, creating a perfect storm of increased demand and limited supply for devices from face masks to ventilators. At the same time, these shifts have highlighted the need to develop new technology that can manage and treat patients remotely and safely.

Right now, medical device companies are operating without significant oversight or regulatory enforcement, with the biggest threat coming from emerging technologies. Smart devices have long been known for introducing a host of risks, from standard software vulnerabilities and increased maintenance demands to privacy concerns and threats of cyberattacks.

It is worth noting that these challenges pose even more reputational risk to your company when the healthcare professional is removed from the picture. Whose responsibility is it then to ensure the product's software is updated? That the product is used according to its specifications? These are questions companies need to consider as they evaluate new regulatory obligations and their future patient and consumer engagement strategies. And yet, only recently has the EU started working on how the integration of artificial intelligence into medical devices, including In Vitro Diagnostics (IVDs), will be regulated. Companies in this space, and the broader electronics category, should watch closely how the EU approaches future regulation of innovative technology. It will undoubtedly have influence beyond the EU and its Member States.

Evolution in regulatory oversight

The Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) are scheduled to take effect from May 26, 2021, and May 26, 2022, respectively. The impact of these regulations will be numerous and have arguably already begun. For starters, the European Union announced in January 2021 that it will allow remote audits of medical devices and IVDs on a temporary basis.

In addition to formal regulations and traditional oversight activities, authorities are becoming proactive in their monitoring for potential safety issues, including using social media to monitor for potential safety concerns and hints about adverse events. This is likely because online and social media platforms serve as centralized clearinghouses where consumers, patients or healthcare professionals can share information about products. Companies are likely already doing the same, but our experience tells us that online complaints and reports are increasingly the leading indicators of regulatory scrutiny and, ultimately, recalls.

Evolving recall obligations

Even more substantive to our analysis here, manufacturers and other economic operators would be wise to pay special attention to requirements for recalls and withdrawals of nonconforming medical devices.

By now companies should be fully aware of the recall obligations outlined in the MDR IVDR – it is a topic discussed frequently, including by the team at Sidley Austin. If you need a briefer, you can refer to Sidley Austin's full article on the topic. But the challenges we'd like to dissect here are the potential increases in regulatory exposure, enforcement and legal liability as a result of these obligations.

Under the MDR IDVR, withdrawals or recalls made as part of a field safety corrective action will require the manufacturer to publish a field safety notice (FSN) that will be made available through Eudamed, the future European database on medical devices.

Once this database is in place, expect regulators in every EU member state and non-member country to be watching. To the extent you take corrective action in one member state, you would be wise to ensure that (1) your communication is effective across borders and (2) you fully understand your obligations in every jurisdiction in which you produce or distribute your product. If the regulator learns about a potential issue through Eudamed, you will face increased scrutiny and potential enforcement penalties at the national level.

Simply put, expect FSNs to be a driver of increased regulatory scrutiny, enforcement action and litigation across jurisdictions. As the Sidley Austin team noted, enforcement actions "may include administrative investigations, fines, and injunctions. In cases of fraud or serious negligence, economic operators may also face criminal fines and criminal liability." In addition, "civil liability may be imposed based on the EU member states' national rules."

Enforcement in the UK

Significant shifts in regulatory oversight are not limited to the EU. Tougher enforcement is on the way in the UK. In addition to making the Medicines and Healthcare products Regulatory Agency responsible for medical devices currently in the EU regulatory system, new medical device directives set to go in effect in July 2022 will also allow the government to step in and announce a recall. Similarly, the Secretary of State in the UK may soon have the power to disclose safety-related information about medical devices.

Increased litigation risk

Product liability lawsuits have become synonymous with recalls in the United States. That's no secret. But global medical device makers need to understand that similar types of risks are increasing in the EU and the UK. We are seeing an increase in group actions, likely sparked by growing consumer awareness by social media.

Given the medical device industry's critically important role in preventing and treating the transmission of COVID-19, significant challenges lie ahead in the wake of the global pandemic. As consumers became increasingly aware of the importance of Personal Protective Equipment (PPE), from face masks to ventilators, their expectations and perceptions evolved.

FIRST QUARTER OVERVIEW

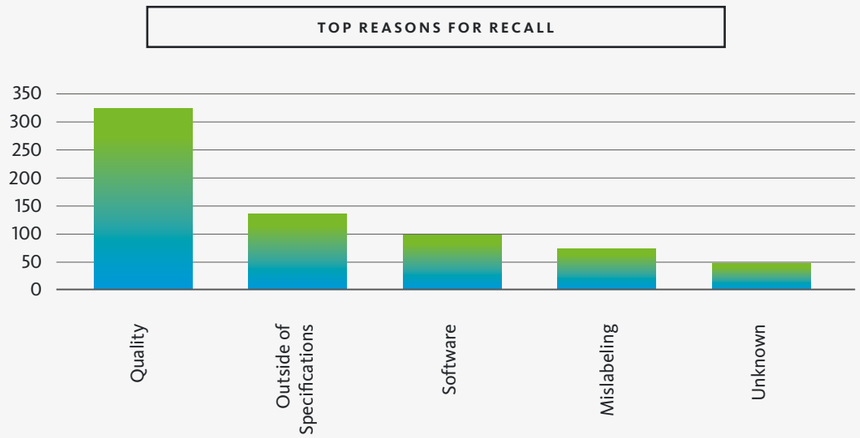
Medical device recall activity is returning to pre-pandemic levels in the first quarter of 2021. At 721 recalls, first quarter activity represented a 40 percent increase compared to the quarterly average 515 recalls in 2020. For context, the quarterly average recall volume in 2019 was 710 notifications.

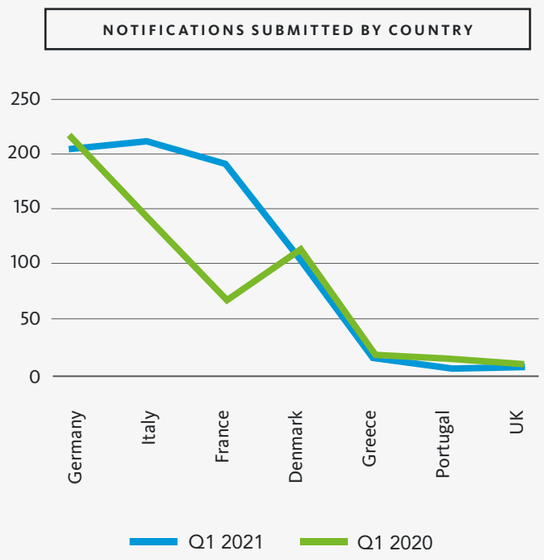
Quality issues remained the most common listed reason for medical device recalls at 323 events, followed by outside of specifications (131), software (98) and mislabelling (74).

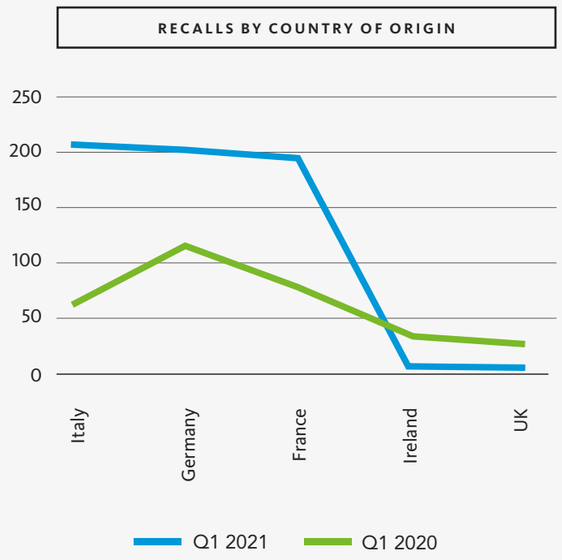
Italy was the top country for notifications in the first quarter with 203 events, all of which were for products produced in country. This made Italy the top origin country for recalled products. Of these recalls, the leading causes of recalls were quality (95), outside of specifications (30) and software (25).

Germany (201) and France (190) rounded out the top three countries for medical device recall notifications.

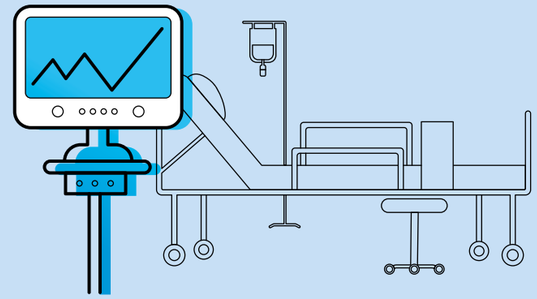
Of all medical device recalls in the first quarter, there were only 10 occasions in which the notifying country announced a recall of a product produced outside its jurisdiction. In 5 of these events, France issued the notification for products made in Australia.



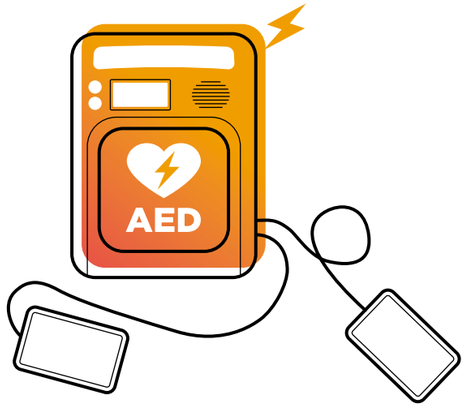




At 721 events, **Q1 recalls increased 40%** (compared to average quarterly activity in 2020)



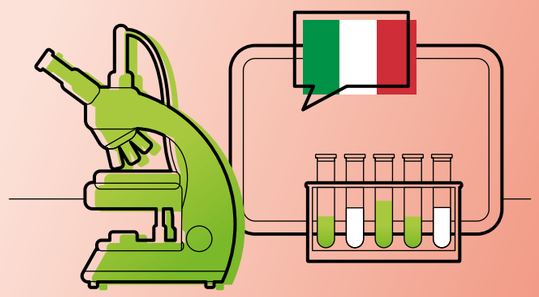
For context, the quarterly (pre-pandemic) average recall volume in 2019 was 710 notifications.



Accounting for 323 events (45%), **Quality** was the leading cause of recall activity in Q1 2021

This was followed by outside of specifications (131), software (98) and mislabelling (74).

Italy was the top notifier in Q1 with 203 events (28%), all were for products produced in country



This also made Italy the top origin country. Italy's leading causes were quality (95), outside of specifications (30) and software (25).

SARAH-JANE DOBSON , PARTNER AND **KARISHMA PAROHA AND NATHALIE SMYTH,** SENIOR ASSOCIATES, **KENNEDYS LAW**

PREPARING FOR YOUR MEDICAL DEVICE CRISIS

While smart, connected devices offer significant benefits to patients and physicians within the healthcare system, their increased adoption at the individual patient level poses risks to all stakeholders. This is because any vulnerability in a medical device could lead to an adverse event and even death.

Recall planning

As we enter the post-pandemic era, software and emerging technologies present significant risks to both medical device companies and the patients they treat and protect.

In these cases, like any other, recall prevention is always the goal. But there are several steps companies can take now to help streamline the process in the event a corrective action is required.

1. **Ensure strong traceability of product.** Keep detailed records of the batching and lot codes of distributed products and consider the use of Unique Device Identifiers (UDIs) and further tracking details. This is particularly helpful where companies face divergent requirements.
2. **Create onward traceability mechanisms to the end user.** Where appropriate, this can be accomplished through contracts and business agreements.
3. **Understand where your products are in the market.** Looking into the future, individualization of traceability is key.
4. **Protect your financial and reputational interests.** Evaluate your insurance policies to ensure adequate coverage for risks such as product recall and cybersecurity risks.
5. **Review device warnings and labels.** Careful review of relevant wording may serve to mitigate future regulatory compliance and legal risks.

Post-market surveillance

As companies return to business as usual, medical device manufacturers must be vigilant when monitoring adverse event reports. When a potential quality or safety concern is identified, manufacturers would be well served by investigating the potential risks and exposure. This is particularly important for medical devices utilized as part of the pandemic response.

But this effort should go beyond those incidents reported to safety regulators. To provide most protection to both consumers and the companies involved, post-market surveillance should be a proactive, thorough effort. This is especially true for products distributed to consumers. With the involvement of a healthcare system, hospital or physician, recall notification, repair and/or retrieval become even more challenging.

Regulatory authorities are also monitoring social media for insight into potential product quality or safety risks. We can therefore expect them to share anything worrisome they find as part of an inquiry into a product.

Litigation risk

Historically, Europe-based group actions have always targeted medical devices.

Group actions targeting medical device manufacturers are now even more on the rise. This is the result of increased consumer awareness and social media conversation, paired with an increasing degree of sophistication of claimant law firms.

As product liability claims grow in popularity in the EU and the UK, claimant law firms are collaborating with their counterparts in the US. These entities are sharing information, expert evidence and resources. As this process continues, and with the introduction of Europe collective redress mechanisms recently, we are likely to see a clear movement in the EU to allow consumers to access collective actions. As medical device manufacturers consider how the legal environment in the EU and the UK will evolve, they would be wise to watch how cases play out across the pond.

From the first step in the research and development process, companies will benefit from ensuring that their risk and quality assessments are as robust as possible. That includes vetting suppliers and component part manufacturers, identifying reliable partners in each jurisdiction, and carefully reviewing the quality and safety of the final product with regulatory compliance and litigation risk mitigation in mind. This type of crisis and recall planning is critical to protecting your reputation when the safety of your device is questioned.

CONSUMER PRODUCTS

With continued lockdown measures keeping people at home during the first quarter, businesses continued to evolve in response to changing consumer behaviour and shifting demand. As consumers begin returning to previous shopping and purchase habits, retailers and manufacturers would be wise to reflect on the past year and learn from the challenges presented by the pandemic.

This includes conducting a full risk assessment to understand evolving safety risks and how they could be applied to your product, re-vetting your suppliers and their quality assurance programmes, and updating your crisis plans, then testing them with mock recalls.

While the consumer product category is diverse, just three categories - clothing, electronics and toys - comprise 53 percent of all consumer product recalls. Each of these categories faces unique challenges that manufacturers must take into careful consideration. But before we dive into specific data, trends and insights for these three sectors, Kennedys Law partner Sarah-Jane Dobson shares insight into the evolving regulatory and legal environment across all consumer product categories.

> *"As consumers begin returning to previous shopping and purchase habits, retailers and manufacturers would be wise to reflect on the past year and learn from the challenges presented by the pandemic."*

SARAH-JANE DOBSON,
PARTNER, **KENNEDYS**

MELTING POT OF REGULATIONS MEANS INCREASED RISKS FOR CONSUMER PRODUCT INDUSTRY

The European regulatory framework for consumer products is in a state of flux.

Over the last few years, the European regulators have been reviewing every aspect of the regulatory framework with three primary goals in mind: improving sustainability and considering environmental impact, regulating new technologies, and modernizing the system to incorporate, for example, new modes of sale or practices.

New laws in this space are increasingly convergent on the one hand. The laws often continue to seek, as a central component of the original system, maximum harmonization across parallel pieces of legislation in the region. Sector-specific legislation is also increasingly borrowing from other pieces of product safety legislation in different areas. For example, cosmetics legislation now considers food contact material legislation for its packaging laws.

On the other hand, product safety laws across Europe are increasingly divergent in respect of EU and non-EU laws, as well as there being increasingly disparate enforcement practices across even EU countries. Regulatory compliance is in that way becoming an increasingly a country-by-country challenge.

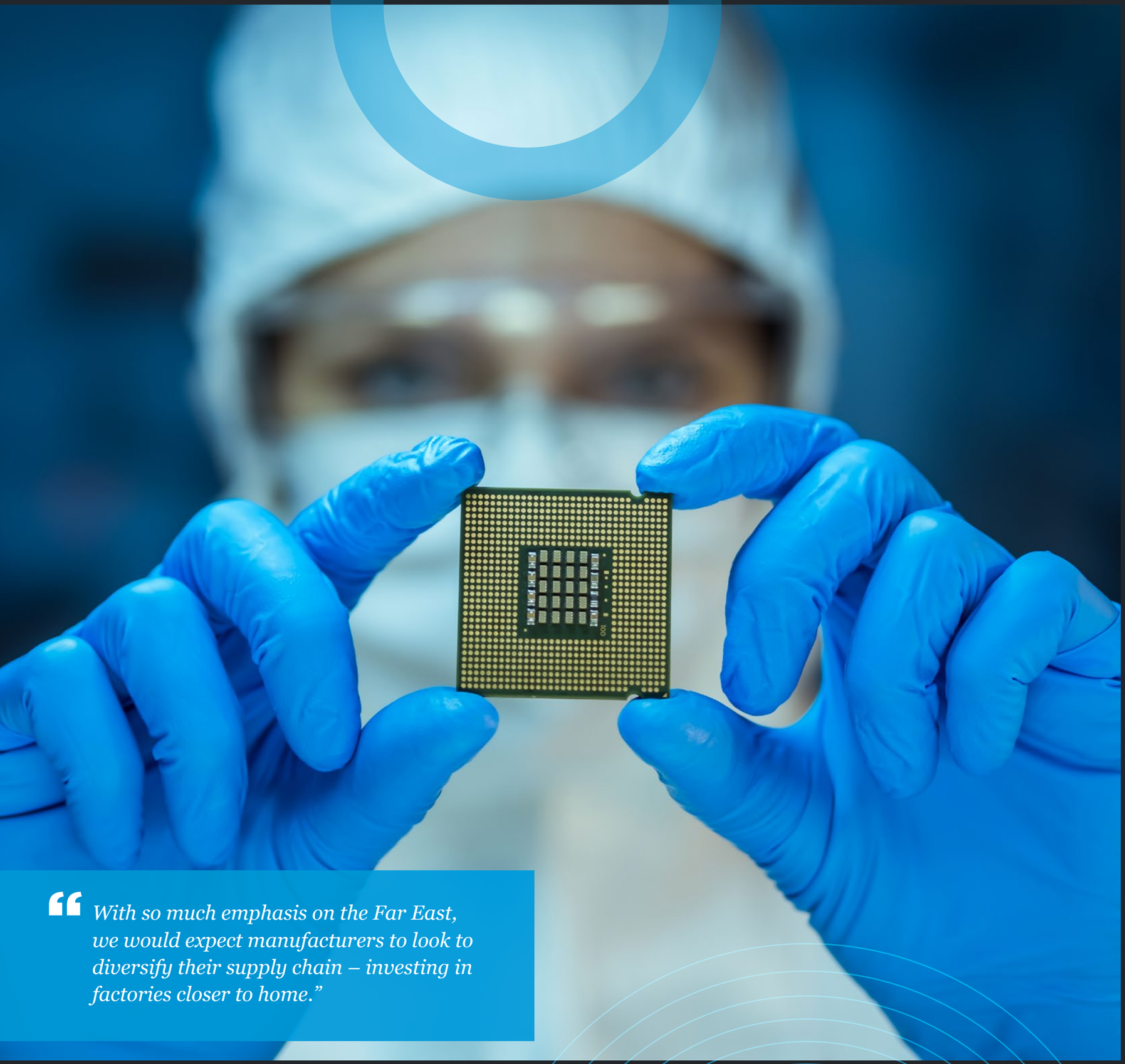
In the UK Brexit has resulted in a new set of compliance obligations. Dual requirements therefore now apply to companies selling in the EU and UK simultaneously. Where EU-based laws were already fully legally applicable in the UK well before Brexit, the position regarding these laws has not changed much – other than additional legislation being adopted to amend incorrect references to EU and UK and similar, and to empower UK rather than EU law makers to continue to make new laws or amend the old. However, where EU-based laws were not fully implemented in the UK prior to Brexit (which given the wholesale review of the regimes is not uncommon), the EU and UK positions may be immediately divergent at the time of the end of the Brexit transition period.

But differences are also being introduced across Europe as a result of different practices undertaken by each EU member state regulator. Whilst historically enforcement is always a Member-State-level power, it is even more so the case today that each EU member state wanting to enforce even harmonized laws in its own unique manner.

For example, when it comes to recalls, Safety Gate (formerly RAPEX), was established on the premise that it would serve as an EU-wide notification system for member states, removing the need for separate notification to the EU27 regulators. Under the system, companies can theoretically discharge their legal obligations to notify EU regulators through one single portal, and regulators in the affected Member States cooperate to determine what, if any, individual country-specific actions were warranted. The notion of a lead authority, now called the Main Member State on the Safety Gate forms (previously Home Authority), was to act as a central point of liaison for colleagues from other regulatory agencies across Europe. Today discharging of reporting obligations has become much less streamlined and more complicated in Europe, with many regulators in Europe expecting their own direct notification or applying their own unique risk assessment data and sometimes methodology. The overall result of this is a reduction on the focus of a EU-wide notification and the concept of a Main Member State also seems to have less significance.

There is also an increased focus on country-specific laws, often reflective of unique political or historical aspects of the country, that intersect or sit within the broader category of product safety. Take Germany, where privacy is a top priority - surveillance features of products are particularly focused upon in local laws, which are enforced strictly by local regulators. Meanwhile, France has specific regulations aimed at preservation of French language, and violations of these laws can lead to criminal prosecution.

The growing differences in opinions and approaches, and country-specific approach, among European countries has become even more evident during the pandemic. Deviating from a Europe-wide approach usually taken, responses to the pandemic were, in some instances necessarily, local to address the specific COVID-19 situation that country faced. Sector-specific regulators also had very varied practices, based on their position in the fight against the pandemic. Where life sciences regulators were particularly active and focused, at least initially, on projects bringing new products to market to use in the pandemic efforts, consumer regulators more focused on trying to introduce as small a changes as necessary to keep product safety matters running as business as usual, whilst also continuing their own important enforcement activities, arguably more online than ever before, from their own home offices.



> *“With so much emphasis on the Far East, we would expect manufacturers to look to diversify their supply chain – investing in factories closer to home.”*

CONSUMER PRODUCTS

ELECTRONICS

The electronics sector spans a wide cross-section of products, from power tools and toys to washing machines to wearables. Each product category faces its own unique set of product safety and consumer engagement challenges, particularly during the global pandemic. As we move forward, we expect to see product segments that suffered during COVID-19 to rebound, particularly as businesses and consumers seek to establish a new sense of normality.

And while brighter days are nearing, manufacturers will be learning some key lessons from the pandemic and putting in place steps to avoid exposure to further unforeseen events. The supply chain is likely to be the key focus. With so much emphasis on the Far East, we would expect manufacturers to look to diversify their supply chain – investing in factories closer to home, albeit not necessarily in their own country. That, however, has a consequence for consumers who may see the price of products rise in the short term as adjustments are made.

Smart technology

The number one trend in the electronics industry – from USB chargers and smart devices to automated vehicles and medical devices – is smart technology. But that trend is indicative of more than just consumer behaviour and preferences. It reflects the increasingly threatening product safety profile coupled with a growing number of regulations and safety standards from fire prevention to cybersecurity.

While clear regulatory guidance on smart technology may still be in the distant future, electronics companies would be wise to closely follow the EU's work to determine how to regulate the integration of AI into medical devices. We can expect this regulatory framework to serve as a guide for how all smart technology is regulated in the future.

If manufacturers can keep a close eye on their supply chain partners, or better yet find partners in the same geographic region, they will be better positioned to identify potential safety or quality pitfalls and avert issues before they reach the marketplace. Recalls, though, will be inevitable – and with online sales predicted to grow in the coming years, governments across Europe must work together to eradicate the risk of dangerous and counterfeit products reaching our shores.

Ongoing shortages

The pinch point created by COVID-19 was felt across industries up and down the supply chain and even directly noticed by consumers. But the electronics sector is arguably facing the longest-lasting supply chain impact in the form of semiconductor microchips.

As consumers adapted their lives amid lockdowns and forced remote learning, demand skyrocketed for laptops, gaming consoles and other electronic products. On top of that increased demand, consumers purchased more vehicles than expected last spring, resulting in even tighter inventory.

Compounding the issue, sanctions against Chinese tech companies impacted supply, causing the shortage, which originally affected primarily the auto industry, to impact consumer electronics, such as smartphones, refrigerators and microwaves.

But when this happens, at least one company will inevitably fall victim to purchasing counterfeit, fraudulent or substandard components that put their entire inventory at risk.

> *"The pinch point created by COVID-19 was felt across industries up and down the supply chain. But the electronics sector is arguably facing the longest-lasting supply chain impact in the form of semiconductor microchips."*

FIRST QUARTER OVERVIEW

Quarterly recall activity remains high at 62 events in the first quarter of 2021. While this represents a 24 percent decrease from Q4 2020, the activity is 10 percent higher than 2020's quarterly average 56 recalls. The continued heightened activity suggests a continued focus on the safety of electronic products as the result of continued stay-at-home restrictions.

Electric shock was the most cited single risk, accounting for 21 recalls. However, electric shock was also listed as one of two or more reasons cited in an additional 29 events. Seventeen of these events listed the combination of electric shock and fire as the risk leading to the recall. Another 11 events listed burns along with electric shock and fire, and one event listed both electric shock and microbiological.

In terms of notifications, Sweden was the top notifying country with 16 events, followed by Poland (12) and the UK (11). The remaining 23 notifications were spread across 11 countries.

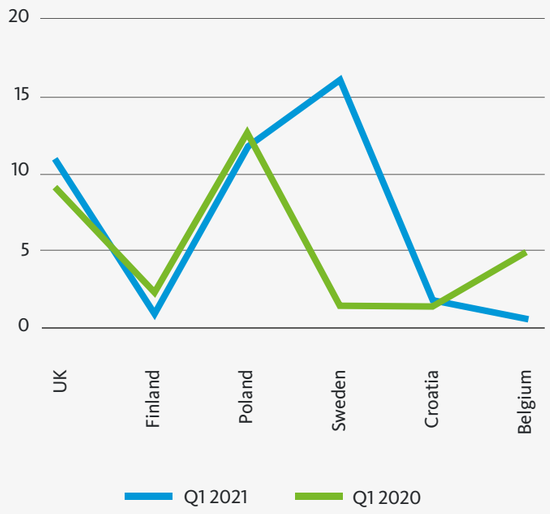
Of all recall notifications, two were known to be counterfeit products. Another 35 events listed counterfeit status as "unknown."

Products made in China remain the most likely to be recalled, representing 84 percent of all first quarter recalls (52). By comparison, Chinese products represented more than two thirds of all 2020 recalls in the sector. Five recalls came from an unknown country. The remaining five recalls impacted products from Vietnam (2), Czechia (1), Germany (1) and the United States (1).

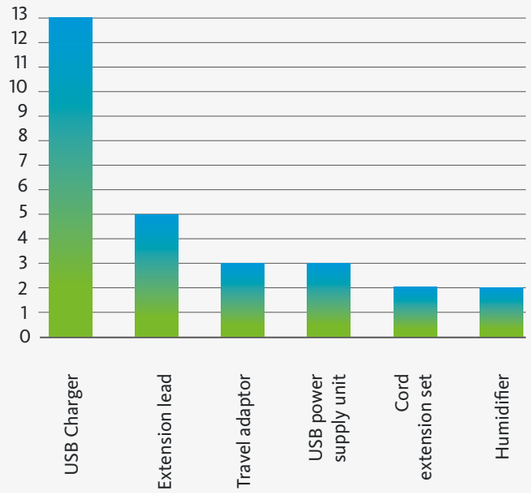
USB power supply products remained the most recalled electrical appliance, leading to a striking 19 recalls, just two events shy of the 21 USB charger recalls announced in 2020.

RISK TYPE	Q1 2021 RECALLS	Q1 2020 RECALLS
Electric shock	21	34
Electric shock, fire	17	2
Burns, electric shock, fire	11	1
Chemical, environment	5	1
Fire	4	1

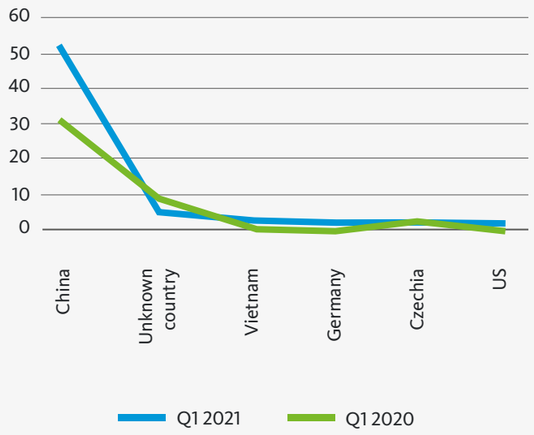
NOTIFICATIONS SUBMITTED BY COUNTRY

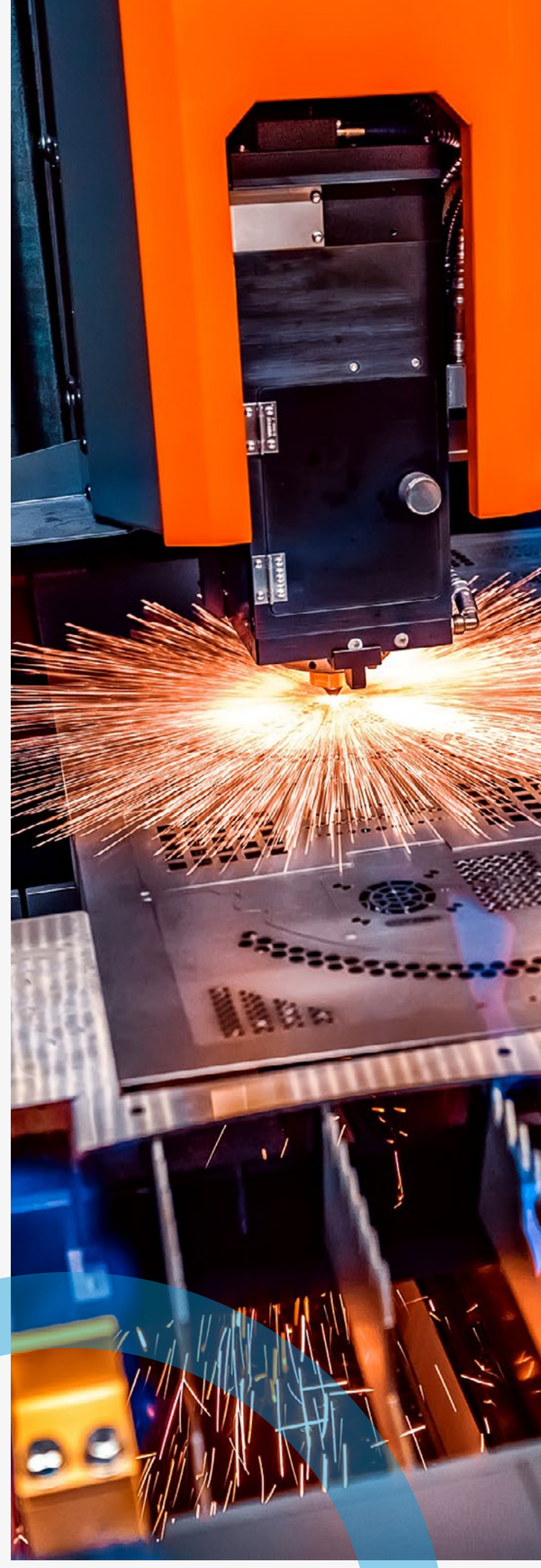


ELECTRICAL PRODUCT RECALLS Q1 2021

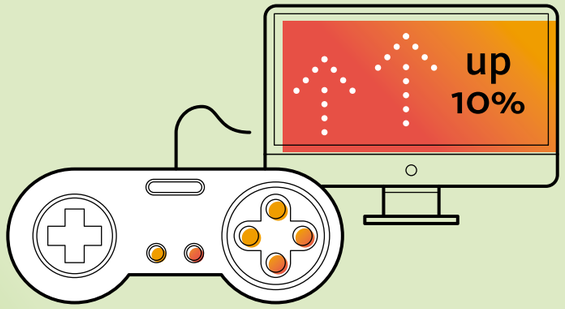


COUNTRY OF ORIGIN

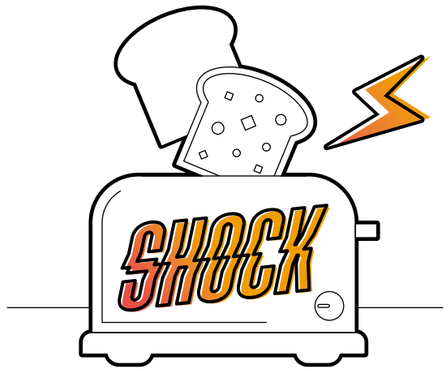




At 62 events, **Q1 recalls increased 10%** (compared to average quarterly activity in 2020)



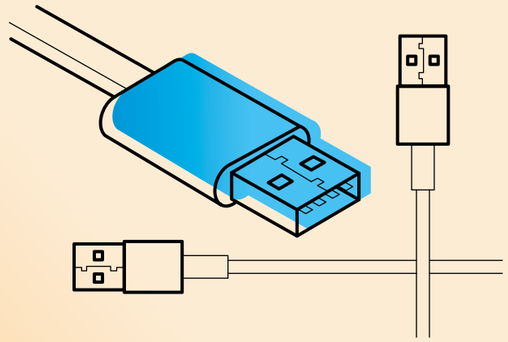
Despite this uplift, Q1's volume was down 24% from the 82 recalls experienced in Q4 2020.



Accounting for 21 events (34%), **Electric shock** was the leading cause of recall activity in Q1 2021

Electric shock also listed in an additional 29 events. Seventeen alongside fire, another 11 alongside burns and fire and 1 against microbiological.

USB power supply products were the most impacted electrical appliance with 19 recalls (31%)



This Q1 figure sits just two events shy of the total number of USB charger recalls for the whole of 2020 (21).

NATHALIE SMYTH AND KARISHMA PAROHA,
SENIOR ASSOCIATES, **KENNEDYS LAW**

SMARTER ELECTRONICS POSE INCREASED RISK

Consumers want smart devices, smaller electronics, and innovative products. But these products come with great risk: from manufacturing challenges and supply chain disruptions to fire hazards and data security and privacy concerns. Add in the complexity of the regulatory environment and the growing number of group legal actions, and the electronics industry may be facing an unprecedented level of uncertainty in a post-pandemic era.

Determining responsible parties

New-age electronics like personal 3D printers introduce complex questions about regulatory compliance and legal obligations. Consider consumers who may use a 3D printer to make any number of products from face masks and phone stands to puzzles or toys for children. Perhaps they set up a small business to sell the products they make. If the filament used is later found to be toxic, who is responsible? Is it the company that made the printer or the filament? What are the obligations of the small business owner? What steps need to be taken to reduce the safety risk?

Identifying and managing second-hand sales and third-party sellers

Manufacturers can begin to lose track of a product the moment it is purchased. As long as the original buyer maintains ownership, the manufacturer maintains visibility of that product in the marketplace. However, the challenge is that electronics are often sold and resold through secondary markets. The more often they change hands, the harder it is to track down products.

In the EU, the responsibility for these products during a recall falls on the manufacturer. Historically this has been a source of tension, particularly where the manufacturer has no relationship with the third-party seller.

In the UK, however, a review of the existing product safety regime is underway. That review includes a focus on online marketplaces. The UK realizes that online retailers and marketplaces have long been a topic of concern, but the increased reliance on ecommerce during the global pandemic has made the UK's safety evaluation a priority. While the final guidance is currently unknown, there is a significant push toward holding the online seller responsible for dangerous, counterfeit and fraudulent products sold online.

Planning for future regulatory requirements

The EU is taking a unique approach to regulating product development, encouraging consumer product manufacturers, and electronics companies to move towards the adoption of universal products. Under the Red directive, this would require all mobile phones to use the same charger. While having this choice sounds enticing to consumers, the adoption of this approach is not without product quality and safety risks.

Manufacturers will need to think carefully about compatibility concerns, not just from a compliance perspective but also to ensure that the electronic device is capable of working safely and effectively using the universal component. Electronic companies know too well that you cannot always foresee all product safety risks.

Understanding legal risks

Product liability claims are growing in popularity in the EU and the UK as claimant law firms are becoming more collaborative with their counterparts in the US. As these entities share information, expert evidence and resources, the financial and reputational risks for companies operating in the EU and the UK increase exponentially.

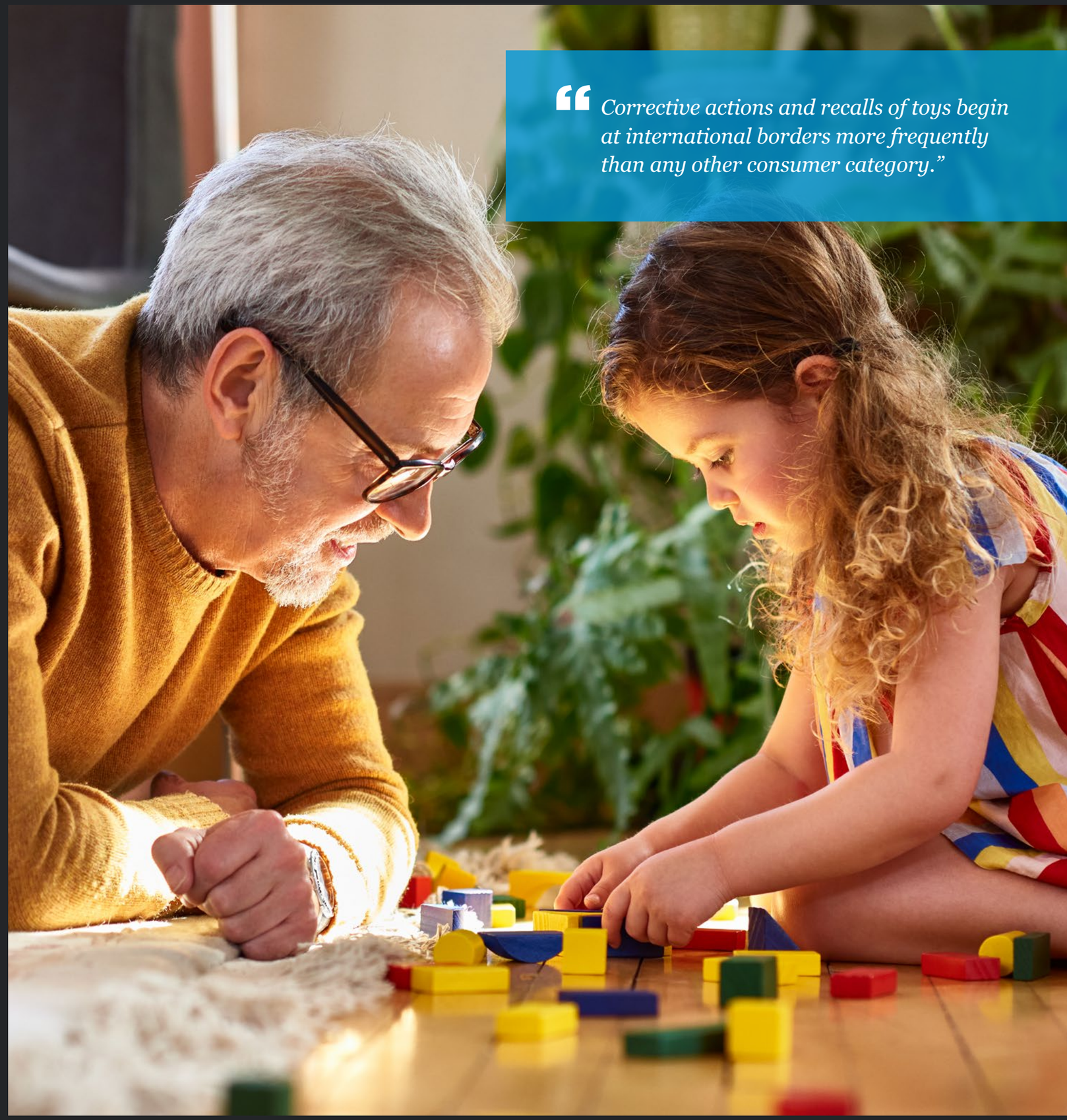
From the first step of the research and development process, companies will benefit from ensuring that risk and quality assessments are as robust as possible. That includes vetting suppliers and component part manufacturers, identifying reliable partners in each jurisdiction, and carefully reviewing the quality and safety of the final product with regulatory compliance and litigation risk mitigation in mind.

CONSUMER PRODUCTS

TOYS

Unsurprisingly, the toy industry has been the most resilient amid the global pandemic as schools shut down and parents and caregivers assumed the role of teacher or educator. Apartments and homes gave way to an influx of additional at-home learning toys and supplies. While this is not an entirely new phenomenon in Europe, the demand for safe, environmentally friendly and educational children's products intensified.

As we discussed in our 2021 state of the nation recall index, learning through play is a leading approach to education and psychology. As educators, medical practitioners and parents seek to understand how the pandemic is affecting children's mental health, we can expect increased investment into toys and resources that support children's emotional and social development when they are sequestered from friends and authority figures outside the four walls of their homes.



> *"Corrective actions and recalls of toys begin at international borders more frequently than any other consumer category."*

Growth for global toymakers

We are starting to see the measurable impacts of increased learning from home, and a need to maintain children's mental health and wellbeing. For example, the first quarter of 2021 was Mattel's best quarter in six years. According to RetailDetail EU, "The company also gained market share and recorded double-digit sales growth for quarters in a row." A significant portion of that growth is the result of e-commerce, but in-store sales are also picking up as lockdowns are slowly lifted and students return to classrooms.

New economic operator requirements coming into effect

Starting in July 2021, toys subject to the Toy Safety Directive require an economic operator in the EU who is responsible for certain safety-related tasks, including holding and supplying compliance documentation, informing authorities of product safety risks, and cooperating with corrective action programmes.

Chances are most international toy manufacturers have already started complying with this directive. However, compliance is only half the battle. To the extent you are relying on a supply chain partner to serve as your economic operator, ensure you update your recall management plans to reflect the changes to communication and logistics workflows. Once those plans are updated, conduct a recall drill to allow all parties to validate the new plan and practice their respective roles and responsibilities.

The fact is that corrective actions and recalls of toys begin at international borders more frequently than any other consumer category. To the extent customs know that toys are coming across the border, don't be surprised if a regulatory crackdown starts the day these economic operator requirements come into effect.

The intersection of safety, independent toymakers and e-commerce

The toy industry is not immune to consumer preferences to buy local or from small, independent sellers. But too often, consumers may not realize that these products do not come without risk. That's not to say that craftsmen, artisans and independent toymakers produce dangerous products, but it should serve as a reminder that the same safety regulations apply to all retailers – from global brands such as Amazon to a single Etsy storefront.

In early March, Etsy published a primer on manufacturers' legal obligations when selling and distributing into the EU market. EcommerceBytes noted that the e-commerce platform "advised sellers about new requirements outlined above, noting that listings on its marketplace are automatically set to ship worldwide unless updated by the seller, regardless of the seller's location." Etsy further elaborated on the items classified as toys in the EU and offered a "manufacturer's checklist of obligations before placing a toy in the EU market."

FIRST QUARTER OVERVIEW

Toy recalls plummeted in the first quarter, from 262 recalls in Q4 2020 to 105 events in Q1 2021.

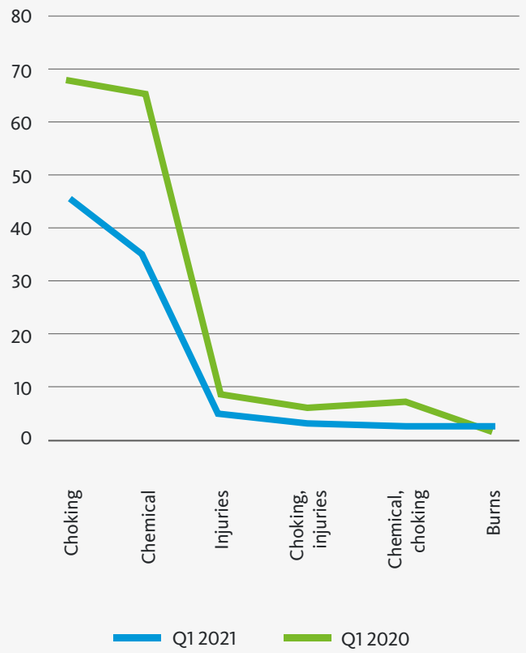
Plastic dolls were the most common recalled toy accounting for 14 notifications in the first quarter. Soft toys (11), plastic toys (10), balloons (6) and wooden toys (6) rounded out the top five product categories impacted.

Choking was the most common risk type in the first quarter at 44 recalls, accounting for 42 percent of recalls. Chemical concerns were close behind at 35 notifications. Of these chemical recalls, 17 impacted plastic dolls or toys and 6 impacted toy slime products.

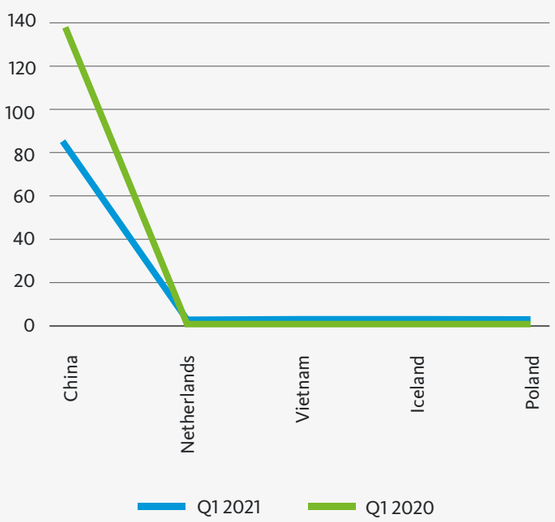
Poland notified most at 21 events, followed by Sweden (15), Hungary (11), Belgium (9) and Germany (8).

As we noted in our 2021 state of the nation recall index, chemical risks are a cause for concern because they correlate with upcoming buying trends (namely plastic dolls and characters). As the likes of Disney+ and Hollywood prepare for a bumper year of movie releases, we expect to see a surge in demand for these types of toys, coupled with increased risks of counterfeit and fraudulent products.

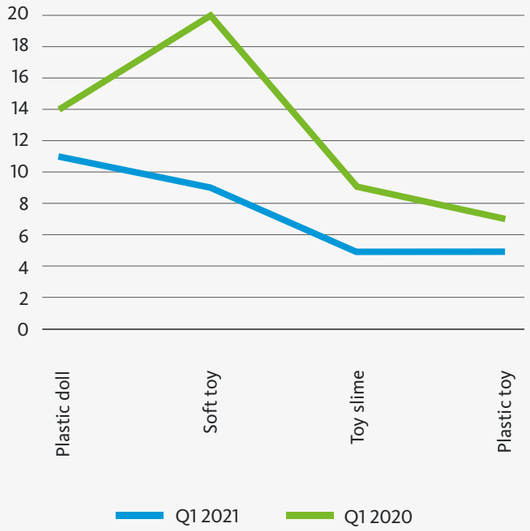
RECALLS BY RISK TYPE



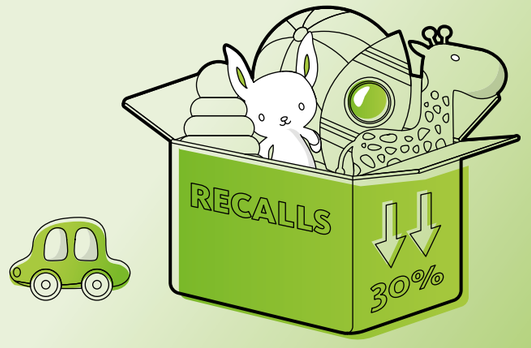
RECALLS BY COUNTRY OF ORIGIN



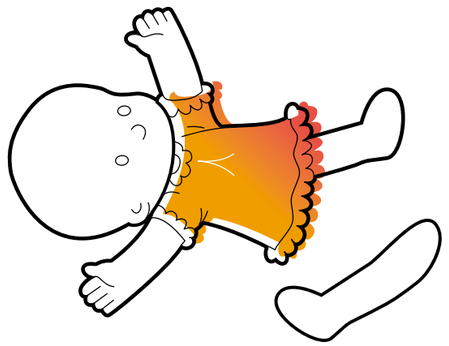
RECALLS BY PRODUCT TYPE



At just 105 events, **Q1 recalls fell 30%** (compared to average quarterly activity in 2020)



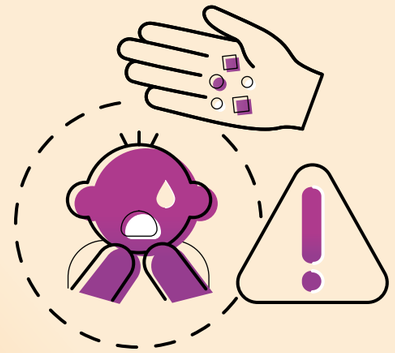
This figure also represents a fall of 60% from the 262 recalls experienced in Q4 2020.



Accounting for 14 events (13%), **Plastic dolls** were the most recalled toy in Q1 2021

Soft toys (11), plastic toys (10), balloons (6) and wooden toys (6) rounded out the top 5 categories impacted.

Choking was the most common risk type in Q1 at 44 events, accounting for 42% of recalls



Chemical concerns followed with 35 recalls. Of these, 17 impacted plastic dolls or toys and 6 impacted toy slime products.

SARAH-JANE DOBSON,
PARTNER, **KENNEDYS**

REGULATORS' KEEN FOCUS ON PROTECTING THE MOST VULNERABLE OF POPULATIONS

Regulatory scrutiny is always highest when it comes to toys. European regulators are particularly concerned with this vulnerable population – so much so that toy market surveillance activities and recalls are often initiated in a very different manner than other consumer products. Given it's a tangible enforcement practice, rather than part of written mandates, it is a risk that not even toy manufacturers fully appreciate.

The primary difference in the recall process is how it is initiated. As compared to other product categories, regulators more often look for and find issue with a children's product or toy before they even enter the country. There are many examples of Customs identifying shipments of toys and children's products, putting them on hold, and testing the products for compliance with technical standards before releasing them into the market. Notwithstanding the existence of well-worn debate within the toy industry regarding interpretation of some of even the most fundamental technical standards and their applicability, if the product fails the inspection and the testing the individual regulator believes should be applicable based on their practices, the products simply cannot enter the market. In extreme cases, a recall will be required to withdraw product already in market.

Whilst this process of stopping particularly toys and children's products (sometimes even internal EU borders) is informal, the risks are real. With more borders in close proximity in the Europe, particularly in the context of Brexit, the risk of a product stopped and held is greater than passing through a single US port.

In addition to a focus on products that cross borders, regulators have several priorities when it comes to oversight and enforcement in this area. Entrapment risks, choking hazards, chemical risks (including, in particular, lead) and products with foldable components are always high on the radar, as well as products not intended for children, but that pose risks to children who are present when such products are used. Regulators also consider the age and vulnerability of the population for which the product is intended – the younger the child, the higher the scrutiny.

There are also jurisdictional priorities. For example, the Netherlands regulators are particularly astute to and active in respect of connected device issues in toys, given the prevalence of high-end children's products and innovative products produced in that market. In Germany, aligning with a general focus on privacy, including at a product safety level, there is significant concern about surveillance-related products from children's smartwatches to any device with an ability to record or listen.

The increasing convergence of product safety and privacy issues in particular has created significant tension among regulators. Although a recall for a children's smartwatch in 2019 was phrased as a privacy concern in an original iteration of the RAPEX (as it then was) notice, the text was subsequently revised citing violation of product safety law specifically, the RED directive, which does have inbuilt privacy and security requirements.

Nonetheless, we can expect these concerns regarding the delineation between privacy and product safety to perhaps be tackled directly by regulators in the future, particularly since these risks are becoming increasingly common and more threatening.

CONSUMER PRODUCTS

CLOTHING

The global fashion industry, from “affordable” brands to fashion houses and high street retailers, will continue to face challenges in the coming months. The good news is there are a few signs that recovery is coming. Among them, the EU Business Confidence indicator in March 2021 documented upward trends in the textile industry, clothing industry and their employment expectations.

But the European Apparel and Textile Confederation (EURATEX) warned that these positive signals are under threat by supply chain challenges created by the COVID-19 pandemic. “Raising prices of raw materials (textile fibers, dyestuffs,...) and transport costs, negative impact of CO2 prices and political turmoil in some important sourcing countries (China, Myanmar) create uncertainty.”

In response to this turbulent environment, EURATEX noted that a progressive EU textiles strategy is needed to support companies as they focus on essential pillars for future success, including innovation, digitalization, competition, sustainability and circularity.

> *“A progressive EU textiles strategy is needed to support companies as they focus on essential pillars for future success, including innovation, digitalization, competition, sustainability and circularity.”*
>
> Source: EURATEX

Innovative clothing

Acknowledged by EURATEX as a pillar for future success, the clothing and textile industry is facing its own innovation-driven revolution. Take, for example, how the clothing industries have started diversifying into the medical device realm. While textile face masks need not follow the same strict standards as an N95 respirator, the COVID-19 inspired product line will not be immune from scrutiny by advertising authorities and public health regulators.

The clothing and textile industry would be wise to plan now for the new and evolving risks accompanying these priorities. After all, the same scrutiny could easily be passed to other products that exist on the fringes of the clothing industry, serving to blur the lines between industries. Consider athleticwear that contains biocides or claims to offer SPF protection.

End-of-life textile management

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

The resolution is part of the EU's Circular Economy Action Plan and includes policies to address clothing design, consumer communication and the clothing and textile product lifecycle. Among the measures is a framework of Extended Producer Responsibility (EPR) that holds producers and fashion brands responsible for financial costs associated with end-of-life product management.

While these requirements aren't exclusively focused on recalls, the concepts certainly intersect. A product safety recall will need to be handled with Circular Economy Action Plan obligations in mind. But arguably the same reverse logistics requirements can be deployed to manage the product throughout its lifecycle, ensuring regulatory compliance and environmentally safe practices.

> *"While textile face masks need not follow the same strict standards as an N95 respirator, the COVID-19 inspired product line will not be immune from scrutiny by advertising authorities and public health regulators."*

FIRST QUARTER OVERVIEW

Clothing recalls in the first quarter of 2021 remained steady with average quarterly volume in 2020, but also signified a 43.8 percent drop compared with Q4 2020. At 32 recalls, the types of items recalled remained consistent with the previous quarter, focusing on children's items.

As we mentioned in our 2021 state of the nation recall index, we know there was a lag in reporting in 2020, possibly the result of regulatory and business challenges resulting from the global pandemic.

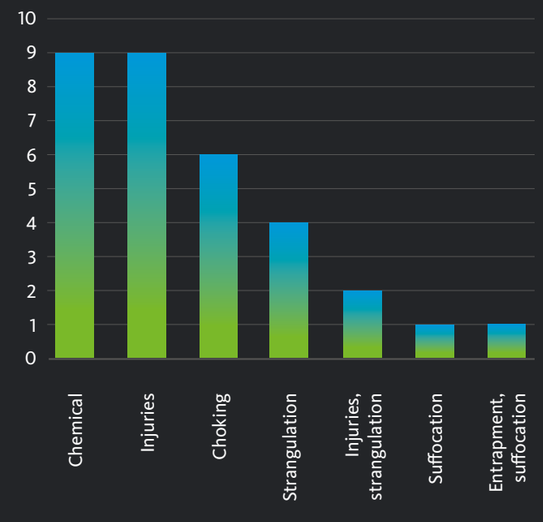
No one specific category had a significant lead in recall notifications. However, if you combine children's products from baby bodysuits to children's swimwear the broadened category experienced 21 notifications. Of these recalls, 9 were due to injury risk, 6 were the result of choking hazards, 4 resulted from strangulation hazards and 2 from injury and strangulation.

It is also worth noting that there were five recalls of leather products due to chemical risks.

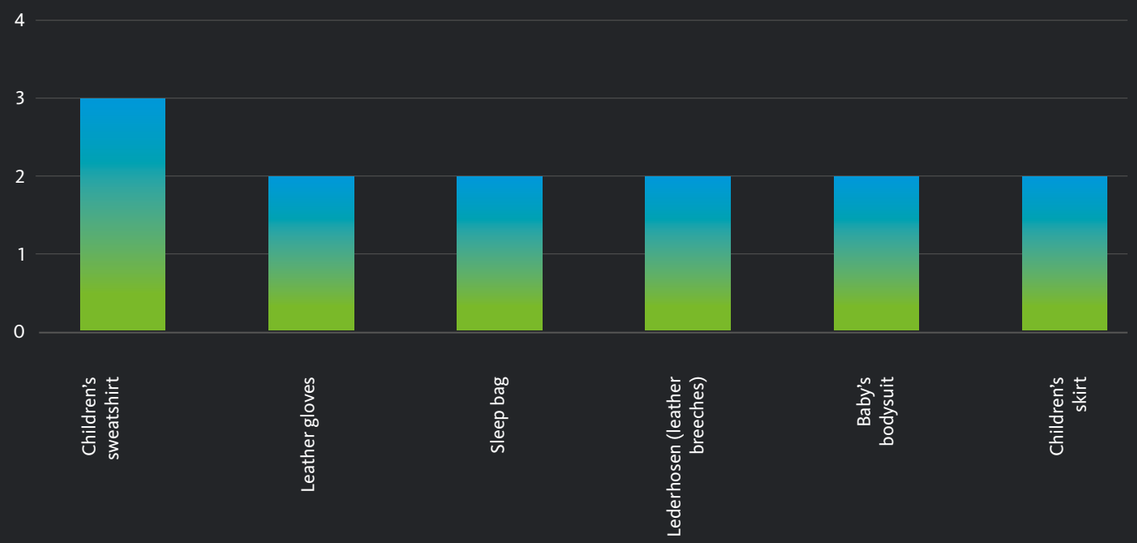
Belgium and Romania notified most (7) in the first quarter, each representing 22 percent of total recalls. For both countries, all recall notifications impacted children's clothing items. Germany was close behind with six notifications, five of which were leather products.

There is a focus on children's products when it comes to clothing recalls. But we may see the focus shift to more innovative clothing or fabric products that are in high demand as a result of the pandemic. Consider products from the simple fabric face mask to athletic clothing containing biocides or making SPF claims. We may see regulators start to turn their attention to these products for compliance with environmental or chemical regulations. Even more dangerous, the industry should pay careful attention if they approach or cross the line into the world of medical devices.

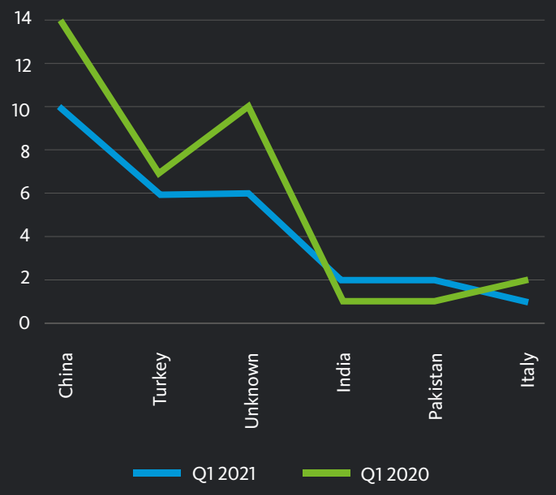
RECALLS BY RISK TYPE



RECALLS BY PRODUCT TYPE

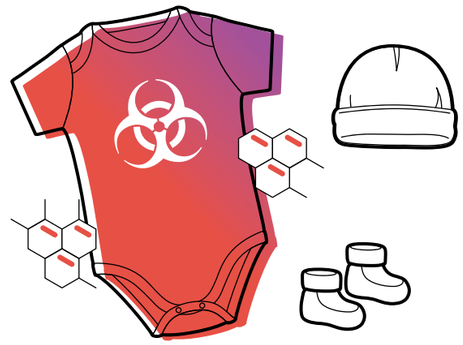


RECALLS BY COUNTRY OF ORIGIN



At 32 events, **Q1 recalls fell 10%** (compared to average quarterly activity in 2020)

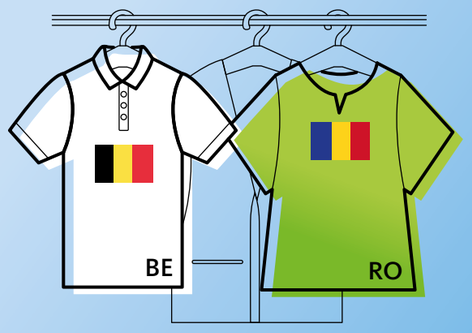
This figure also represents a fall of 44% from the 57 recalls experienced in Q4 2020.



Chemical and Injuries were the most common risk types in Q1 with 9 events each (combined they accounted for 56%)

These fell 16% and 3% respectively compared to average quarterly activity in 2020.

Belgium and **Romania** notified most (7) in the first quarter, each representing 22% of total recalls



For both countries, all recall notifications impacted children's clothing, with 64% of items originating from China.

SARAH-JANE DOBSON,
PARTNER, **KENNEDYS**

WHEN DOES A T-SHIRT BECOME MORE THAN A PIECE OF CLOTHING?

Modern clothing presents a unique challenge in respect of product regulatory compliance and recall matters. Our expectations for apparel are far different today than in years past. First, clothing is no longer simply a fashion statement or textile that we wear – with the introduction of electronic or chemical aspects, clothing can now deliver health and sport performance benefits, among a wide range of other helpful features. Second, given the nature of the production and historical issues of the industry, we hold clothing companies to some of the highest corporate social responsibility standards.

Complex, functional clothing as a leading recall risk

The first unique compliance challenge relates to the evolving role of clothing.

Today's clothing is made from many different types of materials, including, more and more chemicals. The type of chemicals being used in clothing has now broadened too. The garments of today, especially, sporting apparel, need to be hardworking and multi-functional. Often antimicrobials, such as antibacterial or antifungal substances, are used in such clothing to combat against sweat and body odors. Whilst the inclusion of these chemicals is intentional, the risks associated with this are perhaps unseen.

The most obvious risk relates to recalls. Chemical contaminants are increasingly the driving force for all recalls across all sectors, and clothing is no exception. Chemicals are one of the most highly regulated product categories in Europe, and successful navigation of the system requires a deep knowledge and understanding of the unique regulations applicable.

However, a less obvious, but perhaps more complex risk relates to the creation of borderline products through this use of chemicals in clothing, and/or the introduction of other features to increase the functionality of clothing and apparel.

If your favorite exercise t-shirt contains antimicrobial agents, are you actually wearing a biocidal product? Does the addition of electronics, such as self-lacing capabilities, make a pair of shares an electronic device? If your sweatband monitors your heartbeat, is it a medical device? As was played out quite publicly during the COVID-19 pandemic, even a fashion face mask can be considered not an article of clothing but personal protective equipment (PPE), or even, a medical device.

These borderline products increase a company's exposure to regulatory and reputational risks. The moment a product crosses the line into a more complex regulatory regime, such as from a piece of clothing to a biocidal product or medical device, laws are stricter and enforcement more severe.

The influence of corporate social responsibility on the definition of safety

A second unique feature of the clothing industry is the focus on corporate social responsibility (CSR), environment and sustainability. Most often the conversations in the clothing industry focus on labour-related concerns. Clothing companies in particular have faced a lot of success but also a lot challenges in addressing these issues as a part of a drive across Europe over the years, it is not inconceivable that a company's failure to deliver on CSR commitments could be a future driver of recalls as these obligations become more and more embedded in product compliance laws.

In the present day, regulators (admittedly often advertising rather than product safety regulators) throughout the EU and the UK are increasingly taking enforcement actions against companies making unsubstantiated green claims, requiring companies to pull product from the market – a recall by process even if not by name.

Then there is the safety risk. Europe has always been deliberately broad in its definition of safety and defective products. The concept of safety covers physical and psychological harm; and the definition of a defective product is anything that does not meet a person's reasonable expectations. So, the question becomes: will expectations eventually include an ethical supply chain, fair labour, and an environmentally friendly product. If so, when will we see a recall due to a non-ethical practice or environmental concern?

Practical tips for the way forward - evaluating your risk profile

As clothing producers become more innovative and continue to embrace a "fashion meets functionality" approach, it will be critical to dissect the product and evaluate what regulatory regimes, frameworks and guidance apply. At the same time, ensure you understand how core elements of your product impact its full lifecycle from a corporate social responsibility standpoint.

To date, Europe has not necessarily introduced any specific regulatory standards to assist with these unique challenges. Without harmonized standards, clothing companies face increasing regulatory, legal and reputational risk that can only be mitigated through thoughtful planning.

CONCLUSION

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

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

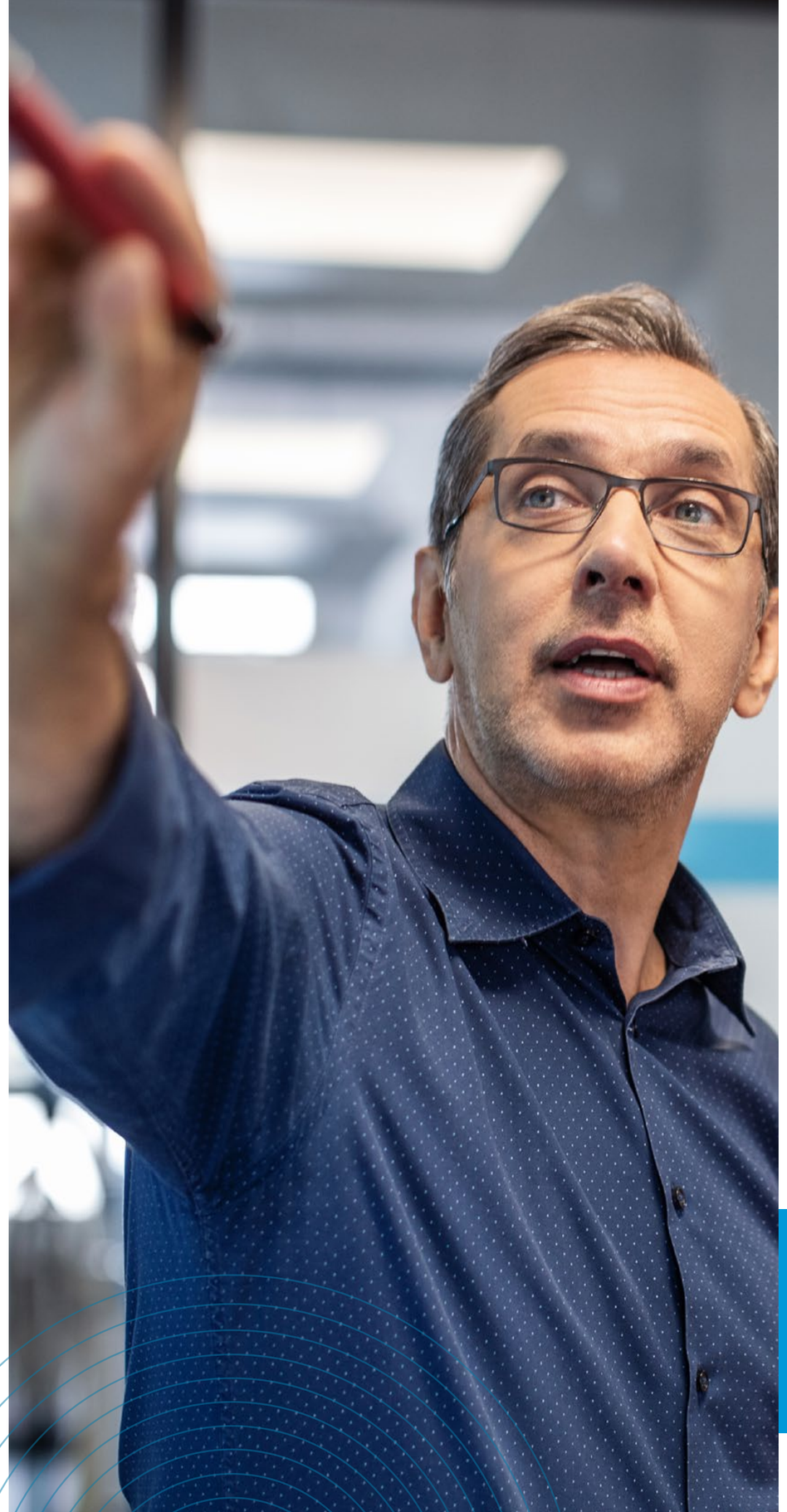
- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades and warranty work
- Product recalls and market withdrawals
- Data, privacy and cybersecurity issues
- Innovation and advancements in technology
- Constantly shifting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

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

Given how quickly our business and regulatory environments are evolving, expert partners help uphold your commitments to customers, supply chain partners, industry groups and regulators, while protecting your reputation among the stakeholders that matter most.

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

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



ABOUT SEDGWICK BRAND PROTECTION

We are in-market risk managers. We are problem solvers. We are crisis managers.

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

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

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

So, while we predict continued change in 2021 (and beyond), it’s nothing we haven’t seen or dealt with before. In fact, it’s often that these events, even what feels like a devastating product recall, offer opportunities to demonstrate trustworthiness and to build greater customer loyalty.

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

Sedgwick’s brand protection quarterly recall index reports guide businesses to make better decisions when it comes to recall, by providing detailed industry analysis underpinned by data. Previous reports are available for you to download:

2021 State of the Nation European edition: DOWNLOAD HERE

Q3 2020 European edition: DOWNLOAD HERE

Q2 2020 European edition: DOWNLOAD HERE

Q1 2020 European edition: DOWNLOAD HERE

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RECALL INDEX: EDITION 1, 2021

PRODUCT RECALL - EUROPEAN INDUSTRIES

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