# RECALL INDEX
## 2021 EDITION 2

**PRODUCT RECALL**
EUROPEAN EDITION

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

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

This edition brings you data from the first half of the year, as well as expert analysis and predictions for what to expect for the remainder of 2021 as business leaders and regulators prepare to emerge from a global pandemic that changed the regulatory landscape, political climate, market drivers and consumer behaviour.

As we all know, the current global pandemic will have a continued impact on all industries. The magnitude of that impact remains unknown, however, some companies – 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 events, and the information in this report can serve as your guide to ensure you are prepared.

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

As a reminder, this latest edition of the 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:

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**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:

**Q1 2021 European recall index: LINK**

**Q4 2020 European recall index: LINK**

**Q3 2020 European recall index: LINK**

**Q2 2020 European recall index: LINK**

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## 2021 edition 2

# AUTOMOTIVE

The challenges facing the global automotive market are unprecedented. Vehicle manufacturers and Original Equipment Manufacturers (OEMs) around the world are navigating changes in consumer demand, a desired global shift to electrified vehicles, the testing and launch of new in-vehicle technologies, and global supply chain disruptions. And amid all of this, second quarter automotive recalls continue to rise.

"With vehicles staying on the road longer, companies should ask whether they are sufficiently prepared to effectively manage customer satisfaction campaigns and safety recalls in this environment."

> **"** *In the months and years to come, automakers may see increased recall related risks linking back to the global semiconductor shortage.* **"**

## Semiconductor shortage

Companies should be thinking as much about the longstanding automotive safety risks as the potential impact of emerging safety risks, ongoing business challenges, and upcoming regulatory developments on future recall activity.

For example, recall history tells us that in the months and years to come, automakers may see increased recall-related risks linking back to the global semiconductor shortage. There are two major reasons. First, when component manufacturers (across industries) are under pressure to produce more, quality slips. Second, when companies look to alternate sources for a component or ingredient, the supply does not always meet specifications. Unfortunately, when these issues are missed, recalls are often the result. And since the chips are used in a wide variety of electronics systems, the ways a product recall could play out are numerous.

But the risks and challenges do not stop there.

## Shift to electric

Political and economic pressures remain high for the world to shift to vehicles that operate with a smaller carbon footprint.

The European Union in July proposed an effective ban on the sale of new petrol and diesel cars starting in 2035. The proposed regulation aims to hasten the transition to EVs as part of a far-reaching strategy to combat global warming.

Meanwhile, automakers are increasing their electric vehicle investments. According to Reuters, "Germany's BASF has been chosen as the exclusive partner to develop high-performing lithium ion batteries for electric vehicles with Cellforce Group, a joint venture between Porsche and Customcells." Around the same time, Daimler announced it would launch three new electric platforms and build eight battery plants throughout the EU and the United States. Volkswagen Group also seeks to capitalize on the battery cell production trend through a partnership with China's Gotion High-Tech.

We will be watching to see whether these investments will pay off, not just financially but in terms of battery safety. We examined in the first quarter index recent recalls of the lithium-ion batteries powering hybrid and electric vehicles. These far-reaching events remind us there is work to be done to ensure EVs and all the new technology they use are safe alternatives to traditional combustion vehicles. Perhaps bringing the manufacture of this critical equipment in-house will improve quality control and ensure that the battery is suited to perform for the vehicles manufactured.

## Self-driving technology

The UK became the first country in the world to announce regulated guidelines for self-driving cars on motorways, paving the way for cars with Automated Lane Keeping Systems (ALKS) to be on British roads as early as the end of 2021.

While many cars have versions of Advanced Driver-Assistance Systems (ADAS), ALKS represents a significant step forward in the journey to fully autonomous vehicles. For that reason, it's likely the UK's guidelines will encourage automakers to compete for the first-mover advantage. But it is not without risk.

As automation and interconnectedness increases, more technology, devices, and software will be required, creating new failure points that may lead to recalls. Pre-production testing will help but many issues may not arise until technology is subject to continuous real-life road use. While over-the-air (OTA) updates may be enough to rectify software glitches, they are unlikely to suffice in the event of full-on failure of onboard devices.

Given these risks, some OEMs now demand component suppliers cover costs and liabilities associated with a faulty part. Against this background, there will need to be closer, more strategic co-operation between insurance companies, car manufacturers, and automotive suppliers. Not to mention dealers and car distributors who may lack the expertise to handle complex issues around electronics, telematic, and sensors.
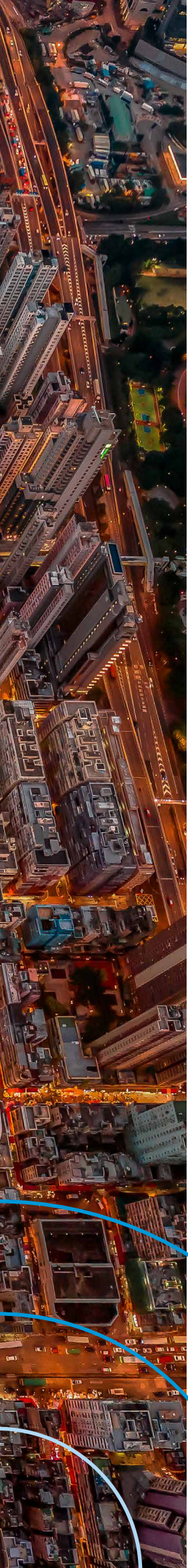
## Automotive black boxes

One year from now, in July 2022, "Event Data Recorders" will be required in all new light vehicles across the European Union. The device, which has been compared to "black boxes" on aircrafts, is designed to record data and input parameters from on-board safety and accident-avoidance systems before, during and after a crash.

A brief on the regulation by Jones Day automotive attorneys explains that the Event Data Recorders will log information including "the speed of the vehicle, the activation of the brakes, the position and inclination of the vehicle on the road, the state and rate of activation of all its security devices, and other relevant parameters of on-board active safety and accident-avoidance systems."

Automakers should expect regulators around the world to leverage this information to better understand the risk profile of new driver assistance, autonomous driving, and in-vehicle technologies as they are introduced in the market. The information gleaned could change the way fault and liability is assessed after an accident, inspire new regulations, and even lead to safety recalls. Companies should consider the potential business and reputational impacts of black boxes now, before the regulation goes into effect.

## Risk mitigation and brand protection

The demand for pre-owned vehicles continues to increase as a result of the financial impact of the COVID-19 pandemic on consumers as well as the global semiconductor chip shortage that has slowed production of new vehicles around the world. While this is a financial boom for automakers that can capitalise from sales of pre-owned and used vehicles, it has the potential to bring significant challenges in the future.

We know that as vehicles age, automakers and authorised repairers face greater challenges in engaging with the owners. It can be even more difficult when a vehicle changes ownership.

With vehicles staying on the road longer, companies should ask whether they are sufficiently prepared to effectively manage customer satisfaction campaigns and safety recalls in this environment. One potential solution to ensuring customers stay engaged, and necessary repairs are completed in a timely fashion, is by enhancing warranty programmes through strategic customer engagement campaigns, touchless concierge services, mobile repair solutions, and similar innovative solutions. The result will not only deliver improved repair rates, but also increased consumer satisfaction and loyalty.

> " *Automakers should consider the potential business and reputational impacts of black boxes now, before the regulation goes into effect.*"
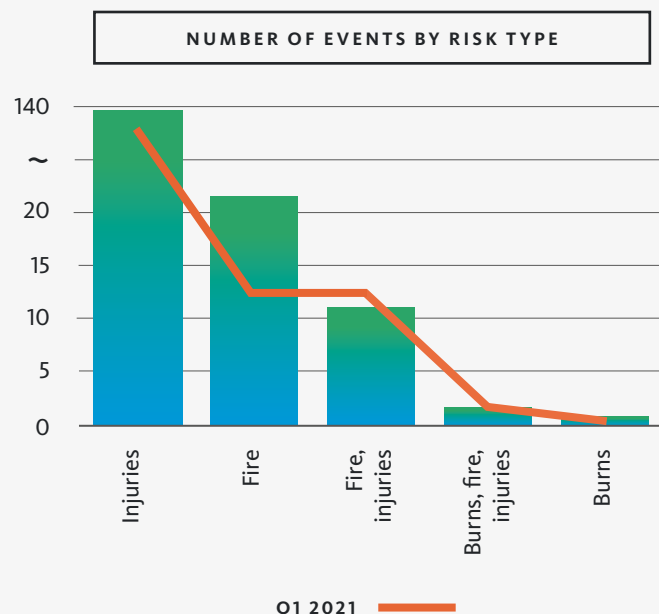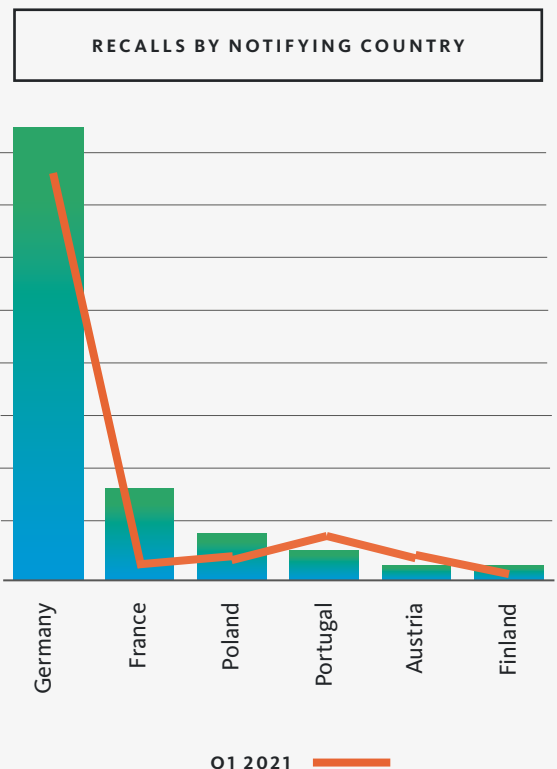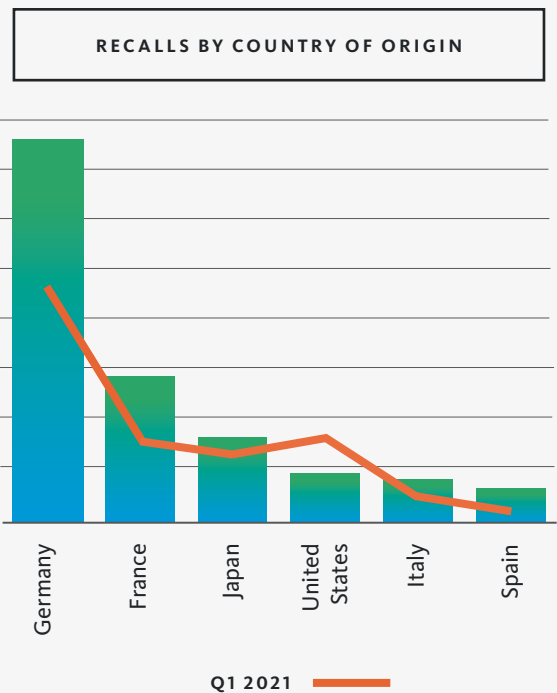
# SECOND QUARTER OVERVIEW

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Automotive recalls rose in the second quarter, up 15.8 percent from 152 recalls in quarter one to 176 recalls. As a reminder, the last pre-pandemic quarter (Q1 2020) saw just 133 recall events, demonstrating recall events are on the rise despite ongoing operational supply chain and pandemic-related challenges experienced by global automakers and original equipment manufacturers.

Germany once again dominated in terms of notifications, submitting 129 recall alerts or 73.3 percent of all recalls. France was responsible for the second most notifications (20), followed by Poland (10) and Portugal (7).

Germany was also the leading country of origin for second quarter recalls with 76 recalls or 43.2 percent of events. France was the second most frequent country of origin at 29 recalls, followed by Japan (16), the United States (9) and Italy (8).

Consistent with previous quarters, Injuries remained the leading risk associated with automotive recalls, accounting for 138 recalls or 78.4 percent of notifications. The next most common risk types were Fire, and Fire and injuries, cited in 22 and 11 recalls respectively. This follows the trends identified over the last 18 months.

Of all second quarter recalls, 58.5 percent (103 recalls) impacted passenger cars. Passenger vans were the second most-impacted category with 25 recalls, followed by lorries with 7 recalls.
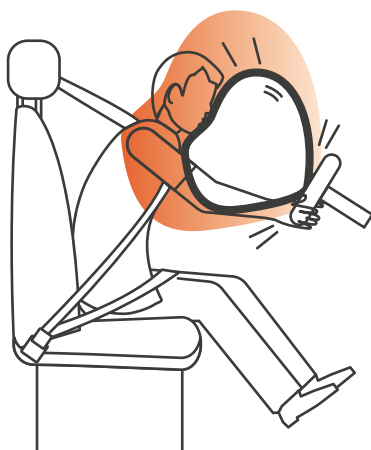
## RECALLS BY COUNTRY OF ORIGIN

Q1 2021 ▬▬▬

## NUMBER OF EVENTS BY RISK TYPE

Q1 2021 ▬▬▬

## RECALLS BY NOTIFYING COUNTRY

Q1 2021 ▬▬▬

At 176 events, **Q2 recalls increased 15.8%** from Q1, which continues to grow from pre-pandemic averages.

Q2 176
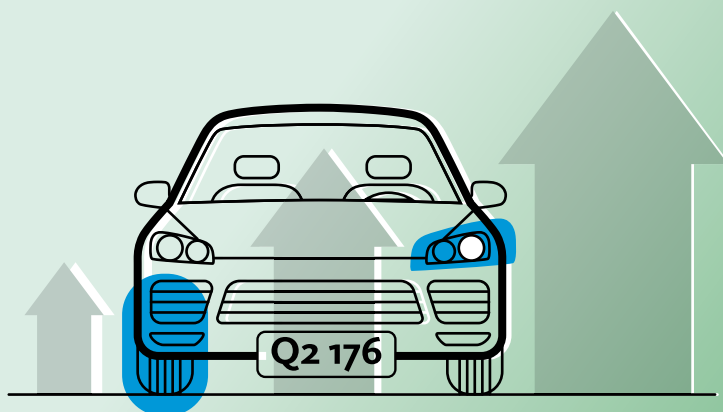
For comparison, the last pre-pandemic quarter (Q1 2020) saw just 133 recall events, with quarterly averages in 2019 of 128.

**138**

Accounting for 138 events (78.4%), **Injuries** remained the top cause of automotive recalls.

This was followed by Fire, and Fire and Injuries, cited in 22 and 11 events respectively.

Owing to the financial impact of COVID-19, European pre-owned vehicle **sales rose 11%** in the first half of 2021.*

PRE-OWNED

This trend has also been fueled by the global semiconductor chip shortage that has slowed production of new vehicles.
*source: indicata

**DANIEL CARTER,** MANAGER, **FORD OF EUROPE RECALLS AND SERVICE PROGRAMMES**

# A RECALL MANAGER'S PERSPECTIVE ON INNOVATING TO IMPROVE RECALL EFFECTIVENESS

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The motor industry has undergone enormous change in recent years. In addition to consumer-facing innovations, automakers are increasingly able to remotely monitor, and even converse with vehicles on the road. This connected technology brings with it significant benefits for drivers and passengers, including the ability to remotely diagnose and fix issues on customers' vehicles.

With most vehicles now digitally connected to the manufacturer, automakers have the ability to fix certain software related issues without vehicle owners scheduling a visit to an authorised repairer.

As a result, there will be an inevitable shift in the authorised repair model. With fewer updates requiring the involvement of authorised repairers, dealer intervention and customer vehicle downtime will be reserved almost solely for the more physical repair types. This will improve customer satisfaction, or at least reduce customer dissatisfaction.

## Innovation's impact on recalls

These developments will undoubtedly change the recall landscape in a dramatic way, increasing the penetration and speed of the recalls. But it can also bring unexpected complications in consumer communication.

While automakers may be able to streamline the repair process via over-the-air updates, a strong, positive strategy for customer mailing will remain critical to customer satisfaction.

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Specifically, the timing of any notification and corrective action can become quite challenging. Consider an automaker that takes swift action to fix vehicles by utilising an over-the-air update while simultaneously sending mail notification to the customer. There is then the possibility that, by the time the manufacturer received owner details from the authorities, and the customer subsequently received the mail notification, the vehicle is already fixed. While well-intentioned, this could lead to obvious confusion and some frustration among both the customer and the authorised repairer.

Preventing confusion by linking digital messaging timing and content to customers' vehicles and apps, alongside physical mails will be key to customer satisfaction success.

## Working together to improve recall effectiveness

In addition to the attention vehicle manufacturers are placing on recall effectiveness, regulators and third parties have an undeniable impact on consumer response.

From a regulatory perspective, vehicle manufacturers expect more regulators around the world to adopt Germany's latest approach to improving recall effectiveness. The Kraftfahrt-Bundesamt (KBA) has the authority to prevent re-registration of a vehicle with an outstanding safety recall. The UK could potentially take a similar approach, allowing regulatory authorities to prevent owners from receiving a successful Ministry of Transport (MOT) test for a vehicle with an outstanding recall. Similar approaches could be adopted in each jurisdiction, which would help vehicle manufacturers connect with current and new owners of used vehicles who can be difficult to engage.

An additional policy that regulatory authorities could implement to help ensure effective recalls is the ability to supply vehicle manufacturers with not just a name and address for a registered vehicle owner, but also an email address and phone number. This would allow manufacturers to leverage multiple communication channels to make contact with vehicle owners in the event of a safety recall or customer satisfaction campaign.

Industry organisations and third parties can also influence consumer response. For issues that affect multiple manufacturers, more engagement and support from industry bodies like the Society of Motor Manufacturers and Traders (SMMT) could be beneficial in educating consumers about recalls and vehicle safety.

For example, we know from our experience with the Takata air bag recall that customers are too often apathetic when receiving a recall notice about their relatively old vehicle. Not only is the message about the safety of the vehicle owner or their passengers somehow less impactful with an old vehicle, but we know they are less likely to have a relationship with a dealer who can help with the communication and repair.

Vehicle manufacturers stock tens of thousands of airbags in anticipation of repairing recalled vehicles, but few customers respond to our notices. But a national and vehicle manufacturer-agnostic awareness campaign about Takata airbags, sponsored by an industry body or neutral third-party, could help reach consumers and increase response rates.

Further into the future, it will be interesting to see whether we observe more effective recalls resulting from the increasing ability to conduct over air updates to vehicles via the latest connected technology. Similarly, vehicle manufacturers are watching to see if we experience improved response rate from millennials and the newest drivers and vehicle owners. Consumers, and millennials in particular, are used to updating software for consumer products, appliances and even medical devices on a regular basis and without pause or question. We may eventually see this willingness to embrace over-the-air updates and repairs via connected devices and even remote physical repairs become standard in the motor industry.

> " *It is important to re-emphasise the basics as contamination risks and undeclared allergens continue to drive recalls in the second quarter.* "

# FOOD AND BEVERAGE

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There is a renewed regulatory focus on the safety of our food supply – from the food we eat to the packaging it comes in. Where regulators had been focused on urgent and immediate needs in response to the global pandemic, we have been seeing a shift back to a forward-looking and proactive approach to food safety.

The latest science, consumer safety concerns, and a broadened definition of food safety are culminating in new regulatory guidance and stricter regimes. While food businesses must keep a close eye on these new and upcoming changes, it is important to re-emphasise the basics as contamination risks and undeclared allergens continue to drive recalls in the second quarter.

# Packaging and labelling

Food safety is increasingly about more than just ensuring a particular food – fresh or processed – is safe to consume. Increasingly, it's also about the type of packaging used and the information included on the label.

Product packaging safety often draws the attention of regulators. In one recent example, the European Union updated its food packaging rules in accordance with its Single Use Plastics directive to limit packaging waste, promote recycling, and establish traceability requirements. France also placed a ban on the use of non-compostable PLU stickers, which the Produce Marketing Association argues are an essential tool for reducing waste, promoting operational efficiencies, enabling traceability, and even enhancing the consumer shopping experience.

The second recent action in the EU pertained to labelling and risk communication.

The European Food Safety Authority (EFSA) recently issued guidance to help food suppliers determine what information to give consumers about food storage and time limits for consumption.

As scientific research continues into the safety of product packaging and the way products are labelled, expect to see additional guidance, rules, and subsequently recalls.

# Contamination risks

The leading cause of food and beverage recalls in the second quarter was contamination. While this category covers a wide range of substances, the most common contaminant was Aflatoxins.

Many countries have implemented strict regulations for aflatoxin levels in imported food and feed. The European Commission in recent months tightened up safety measures for specific products entering from non-EU countries, increasing official border checks in some cases from 10% to 50%.

During the month of April 2021 alone, EU border checks resulted in 25 RASFF (Rapid Alert System for Food and Feed) alerts for aflatoxins. These included hazelnuts from Turkey, pistachios from Iran, groundnuts from India, and peanuts from Argentina — illustrating the global scale and rising prevalence of aflatoxins on imported goods.

With heightened vigilance, we expect even more alerts and potential recalls in the months ahead. Food producers must remain alert and undertake the changes required to ensure they are meeting all food safety measures at all times.

# Food fraud

Consider the case of extra virgin olive oil (EVOO). Premium pricing and high consumer demand has long made EVOO a target for criminals seeking to profit by passing off inferior or fake products. In fact, the category is now considered one of the world's most adulterated food products with fraudulent practices amounting to €30 billion per year globally.

But that could come to an end soon. In May 2021, independent researchers in Italy announced the development of a new, simple, and fast analysis technique that can identify 45 different chemical elements found in EVOO. Evidence so far suggests that a quicker and more accurate determination of provenance is likely to find everything from undeclared allergens to dangerous chemical contaminants. Companies should be aware that these discoveries can lead to reputation-damaging recalls and even criminal sanctions.

# Risk communication

Overarching all food safety issues is the critical importance of effective risk management and risk communication – a current priority for the European Commission.

In leading the EU's implementation of the "General Plan for Risk Communication" for the food industry, the European Commission enlisted guidance from EFSA. According to Barbara Gallani, Head of Communication, Engagement and Cooperation at EFSA, "The General Plan will help food safety authorities in Europe to better coordinate their respective risk communication tasks, and provide more consistent advice and information for the benefit of EU consumers and food safety stakeholders."

In response, EFSA in April published four reports that provide insight into social research, existing risk communication structures, and best practices currently being used by food safety authorities across the EU. For your ease of reference, these reports include:

- Scientific report of EFSA on Technical assistance in the field of risk communication
- Mapping the coordination and cooperation mechanisms of risk communication on feed/food safety in the EU
- Catalogue of Communication Tools and Dissemination Guidelines: Benchmarking current practice in EU and Members State bodies
- Engagement Toolkit: Methods, tips and best practices to design effective participatory processes

EFSA will also leverage these findings to enhance its existing best practice Risk Communication Handbook, related materials, and training programmes. Companies should continue to watch this space and begin adopting the latest risk communication best practices as part of overall crisis and recall planning efforts.

> " The leading cause of food and beverage recalls in the second quarter was contamination. While this category covers a wide range of substances, the most common contaminant was Aflatoxins."

# SECOND QUARTER OVERVIEW

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EU data collected from the Rapid Alert System for Food and Feed (RASFF) in the food & beverage category revealed that recalls continued to slowly return to pre-pandemic levels. The second quarter saw 1,120 recalls, up 7.9 percent from 1,038 recalls in the first quarter.

While this volume remains down from 1,448 recalls in Q4 2020, we'll see recalls reach a three-year high if this level of activity continues.

The leading cause of food and beverage recalls is Contamination (other than bacterial), representing 402 events or 35.9 percent. This includes a variety of contaminants, the most common of which were Aflatoxins (90), Chlorpyrifos (63), and Ethylene Oxide (43).

Consistent with the first quarter, Bacterial contamination was the second-leading cause with 232 recalls. Of these recalls, Salmonella was the leading cause (185) followed by Listeria (28), E. coli (18) and Bacillus cereus (1).

Unauthorised substances – the third most common cause of recalls – accounted for 186 recalls.

Fruits and vegetables were the most impacted product category with 280 recalls (25.0 percent). The most common reasons for these recalls were Contamination other than bacterial (163) and Unauthorised substances (62).

Chlorpyrifos was the leading contaminant (55) followed by Acetamiprid (27) and Pyridaben (16). The leading unauthorised substances impacting fruit and vegetables were Additives (35).

Nuts, nut products and seeds were the second-most impacted product category at 106 recalls, followed by Poultry meat and poultry meat products (97), Dietetic foods, food supplements and fortified foods (85) and Herbs and spices (80).
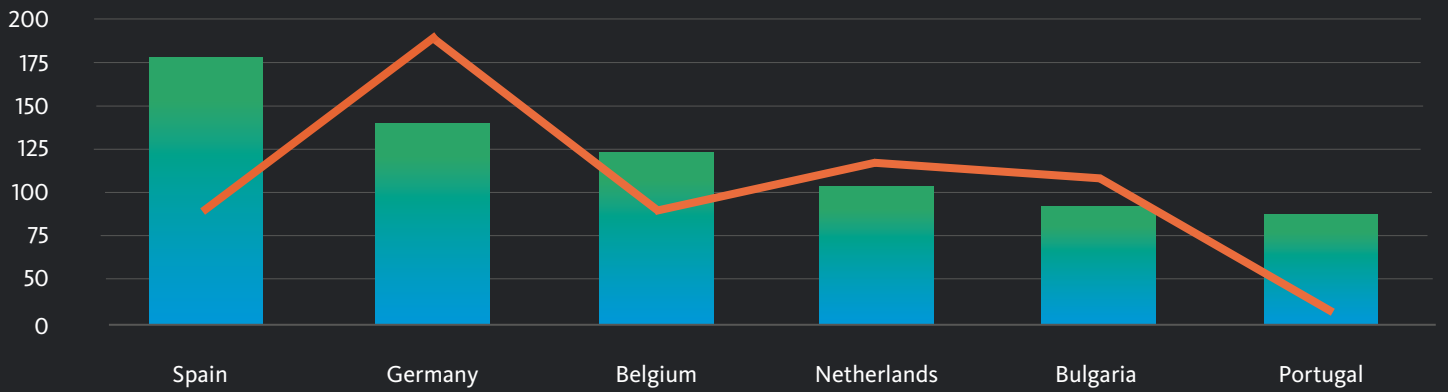
Spain was the top notifying country in the second quarter (179), followed by Germany (139), Belgium (123) and the Netherlands (106).

Undeclared allergens, while not a leading cause, resulted in 32 recall events in the second quarter, in line with first quarter activity. Three of these recalls impacted prepared foods. As we approach October 2021, when Natasha's Law will go into full effect, businesses in England, Wales and Northern Ireland will need to be prepared to provide full ingredient lists and allergen labelling on all pre-packaged food available for direct sale.
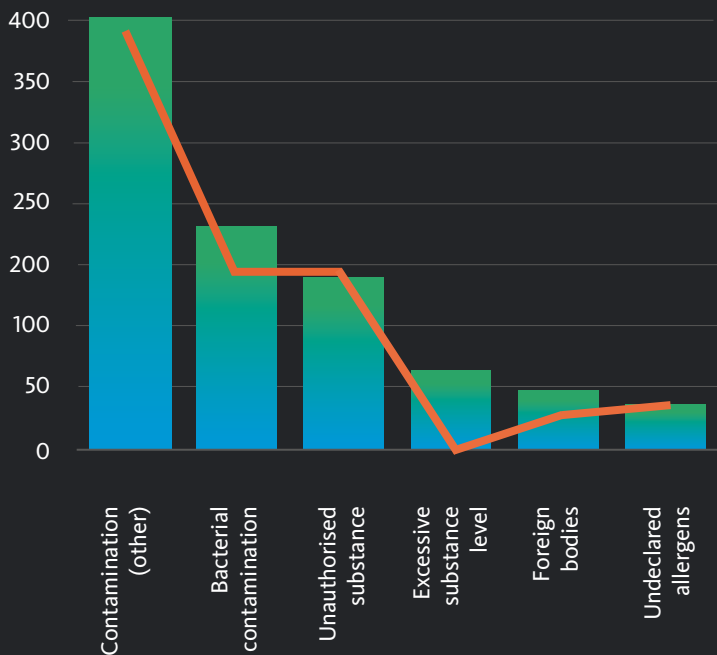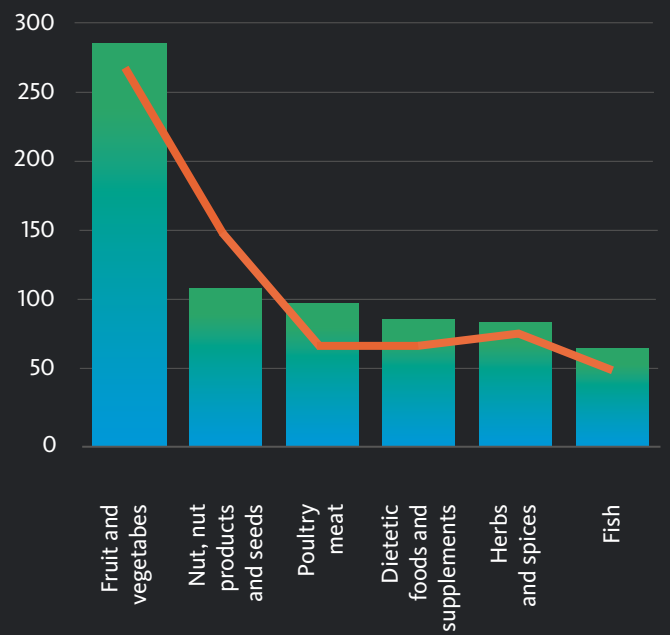
**Q1 2021** ———

## RECALLS BY NOTIFYING COUNTRY



| | |
|---|---|
| 200 | |
| 175 | |
| 150 | |
| 125 | |
| 100 | |
| 75 | |
| 50 | |
| 0 | |

Spain    Germany    Belgium    Netherlands    Bulgaria    Portugal

## RECALL EVENTS BY CATEGORY



400
350
300
250
200
100
50
0

Contamination (other)
Bacterial contamination
Unauthorised substance
Excessive substance level
Foreign bodies
Undeclared allergens

**Q1 2021** ———

## RECALL EVENTS BY PRODUCT TYPE



300
250
200
150
100
50
0

Fruit and vegetabes
Nut, nut products and seeds
Poultry meat
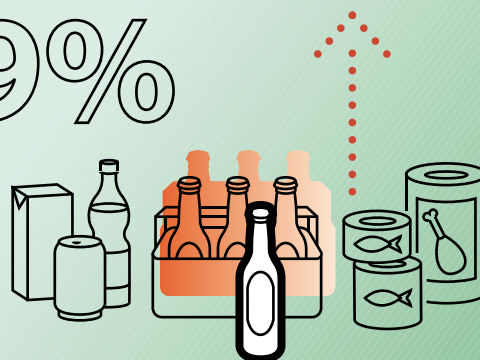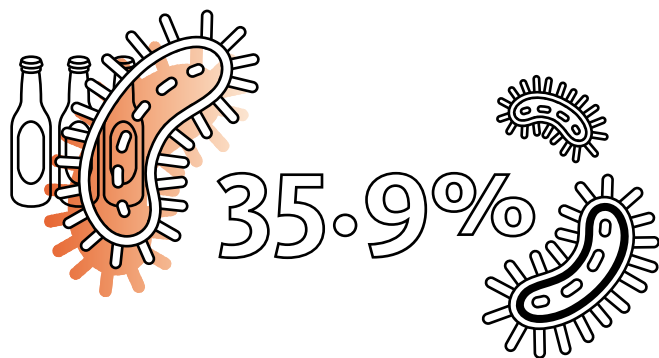Dietetic foods and supplements
Herbs and spices
Fish

**Q1 2021** ———

At 1,120 events, **Q2 recalls increased 7.9%** from 1,038 in Q1.
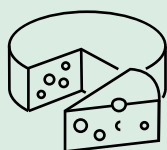
**7.9%**

While this remains down from Q4 2020 (1,448), recalls will reach a 3-year high if this level of activity continues.

**35.9%**

Accounting for 402 events (35.9%), **Contamination** (other than bacterial) was the top category impacting Q2 recalls.

Bacterial contamination was the second-leading cause with 232 recalls, followed by unauthorized substances (186).

**Fruits and vegetables** were the most impacted product category with 280 recalls (25.0%).
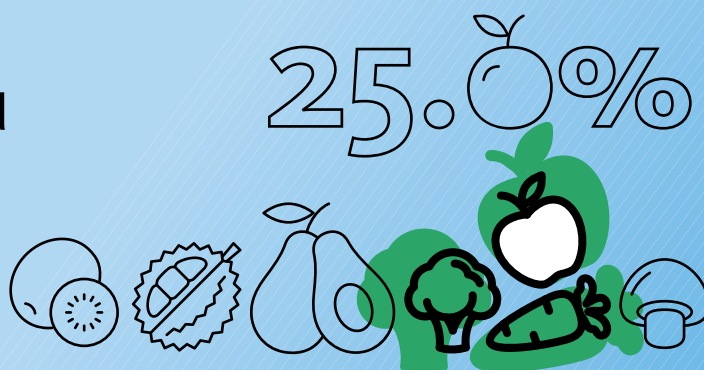
**25.0%**

Nuts, nut products and seeds were the second-most impacted category at 106 recalls, followed by poultry meat and poultry meat products (97).

**ALISON NEWSTEAD,** PARTNER/SOLICITOR,
**SHOOK, HARDY & BACON INTERNATIONAL L.L.P.**

# WHEN EVEN A TRACE IS TOO MUCH: HOW TO MITIGATE ALLERGENS AND OTHER FOOD SAFETY RISKS

Consumers have high expectations when it comes to food safety. They want to be confident that the food that they eat is safe and expect there to be a robust regulatory regime in place to ensure that any potential safety issues are addressed quickly and effectively.

In July 2021, the Food Standards Agency (FSA) published the results of their biannual "Food and You" survey which provides information on behaviours, attitudes and knowledge relating to food safety in England, Wales and Northern Ireland. The survey reported that 93% of respondents were confident that the food that they buy is safe and 89% of respondents indicated that they were confident that the information on food labels is accurate.

These results demonstrate that consumer expectations of manufacturers and regulators are largely being met. But that does not mean food safety risks are nonexistent.

## Undeclared allergens in the supply chain

The growing prevalence of food allergies, intolerance and other hypersensitivities – and the serious consequences that can ensue if products contain undeclared allergens – has impacted heavily on the food industry. Shortcomings in food labelling have triggered both a change in the law and an increasing number of recalls. The second quarter

of 2021 saw a number of recalls due to food products containing inter alia undeclared nuts, soya, milk and crustaceans. We can expect this recall trend to continue.

Every food business needs to ensure their suppliers do not lead them to fall foul of producing food products with undeclared allergens. Food supply chains can often be very long, and tracing products can prove challenging.

Consider a 2017 recall in the United States and Canada involving cumin found to be contaminated with peanuts and almonds. The contaminant of this single ingredient forced recalls of countless products across several product categories. The cumin was traced to two suppliers in Turkey, but the specific origin of the nut contamination remained unclear – the supply chain from the farm where the cumin was grown was lengthy. This example is illustrative of the global impact of such issues and the difficulties in tracing their origin through the supply chain.

However, keep in mind that allergen risks are not unique to foodstuffs on most grocery store shelves.

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## Allergens and the food service industry

The picture presented in the FSA's Food and You survey suggests that allergens remain a significant concern, particularly in the food service industry. Although confidence is high in relation to information provided by restaurants (82%), cafes, coffee and sandwich shops (79%) and pubs (75%), ordering from takeaways and ordering through online delivery services commanded much less confidence (63% and 50% respectively).

Looking forward, 1 October 2021 will see the coming into force of "Natasha's Law" which introduces new requirements in England, Wales and Northern Ireland for the labelling of food prepacked for direct sale (PPDS). The changes arise as a result of the death of a teenager who suffered an allergic reaction to an undeclared ingredient in prepacked food. Following the death, the UK government confirmed that it would introduce more robust laws to give those with food allergies greater confidence in the food that they buy.

Food businesses that produce PPDS food will be required to label items with the name of the food and a full ingredients list. Any of 14 specific allergenic ingredients must be emphasised on this list – for example, in bold, italics or in a different colour. Businesses need to make sure that they are prepared for these changes and that labelling complies with the new requirements. Regulatory action may ensue for those who do not label their products in accordance with the new requirements and civil claims could, of course, follow in respect of those who suffer adverse health effects as a result of non-compliance.

## Contamination risks

Although recalls concerning undeclared allergens continue to dominate, there still remain a considerable number of recalls relating to listeria, salmonella and foreign bodies being detected in food products. These recalls demonstrate that manufacturers have robust procedures for identifying such contamination and ensuring that affected products are recalled quickly. However, when such issues arise, processes and procedures will need to be reevaluated to determine how shortcomings arose and how they can be more efficiently detected and prevented in future.

## Packaging safety

Product packaging issues – such as exploding glass bottles, defective cans and choking hazards – have featured in recent 2021 recall statistics. Of course, food producers must also ensure that their packaging complies with the requirements of the regulations concerning materials and articles that come into contact with food. This is an area that has attracted the attention of regulators in the past: in 2018 the EU saw the introduction of a specific migration limit for Bisphenol A in varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes, milk-based drinks and similar products specifically intended for young children (Commission Regulation (EU) 2018/213). As scientific research continues into the safety of substances that come into contact with food, we may well see an increase in the scope of such regulations and potential for recalls.

As more is learned about food safety risks, ranging from allergens and foodborne illness to packaging-related hazards, expect regulators to increase and expand oversight to ensure consumers are not only protected, but do not lose trust in the safety of their food supply.

# PHARMACEUTICAL

The global pharmaceutical industry has had its work cut out for it amid the global pandemic. But the road is likely going to remain tough long after the pandemic passes as the EU and UK both look to overhaul their regulatory systems.

> " *The Medicines and Healthcare products Regulatory Agency (MHRA) issued yet another recall for certain impure batches of commonly prescribed sartan medicines.*"

## Overhaul of EU rules

In late 2020, the European Commission launched an effort to overhaul EU rules for the pharmaceutical industry. The initial results of the process, which began with the publication of a policy document, are beginning to be apparent. The ultimate goal for the Commission is the publication of reform plans for pharmaceutical legislation which is expected to be unveiled next year.

As POLITICO Europe notes, "The decision to open up the hood of the EU's medicines regulatory system couldn't come at a more fateful time, as Europe tries to move out from under the pandemic's grip. Given the stakes, the EU, capitals, industry and activists all want to leave their stamp on a package that will have to balance their often-competing goals." Among the biggest battle grounds will be the use of incentives, reshoring manufacturing, how to address antimicrobial resistance, and striking a balance between regulation and competition.

More recently, in late April, European Federation of Pharmaceutical Industries and Associations (EFPIA) cast the review as "an opportunity to implement learnings from COVID-19 and ensure a competitive, world-class regulatory system in Europe supporting a globally competitive research-based industry at a critical time." In sharing proposals to address weaknesses in the existing regulatory framework, Pink Sheet noted that the organisation had its own four priorities:

- Reinforcing expertise-driven assessment and enabling a more agile centralised authorisation framework by removing "unnecessary interfaces" between the commission, the European Medicines Agency (EMA) and its committees.
- Improving the expedited pathways framework.
- Expanding the EMA's role in assessing drug-device/ diagnostic combination products.
- Replacing paper patient information leaflets with electronic versions.

While the industry will have more questions than answers for quite some time, it is prudent for companies to prepare now for how various proposals would impact future operations.

## Drug-device products

The EMA adopted a guideline on the quality of information manufacturers of drug-device combination products must submit as part of marketing authorisation applications (MAA). According to Regulatory Focus, the guideline covers three types of products:

- drug-device combination products where the medical device is integral to the product;
- medical devices co-packaged with medicinal products; and
- medical devices that are obtained separately by the user for use with medicinal products.

Similar information will be required for medicinal products with co-packaged or reference devices. Companies should track these changes closely, including how this guideline will translate to go-to-market marketing and product documentation. This is particularly important since violative labelling and informational materials are a frequent cause of drug recalls.
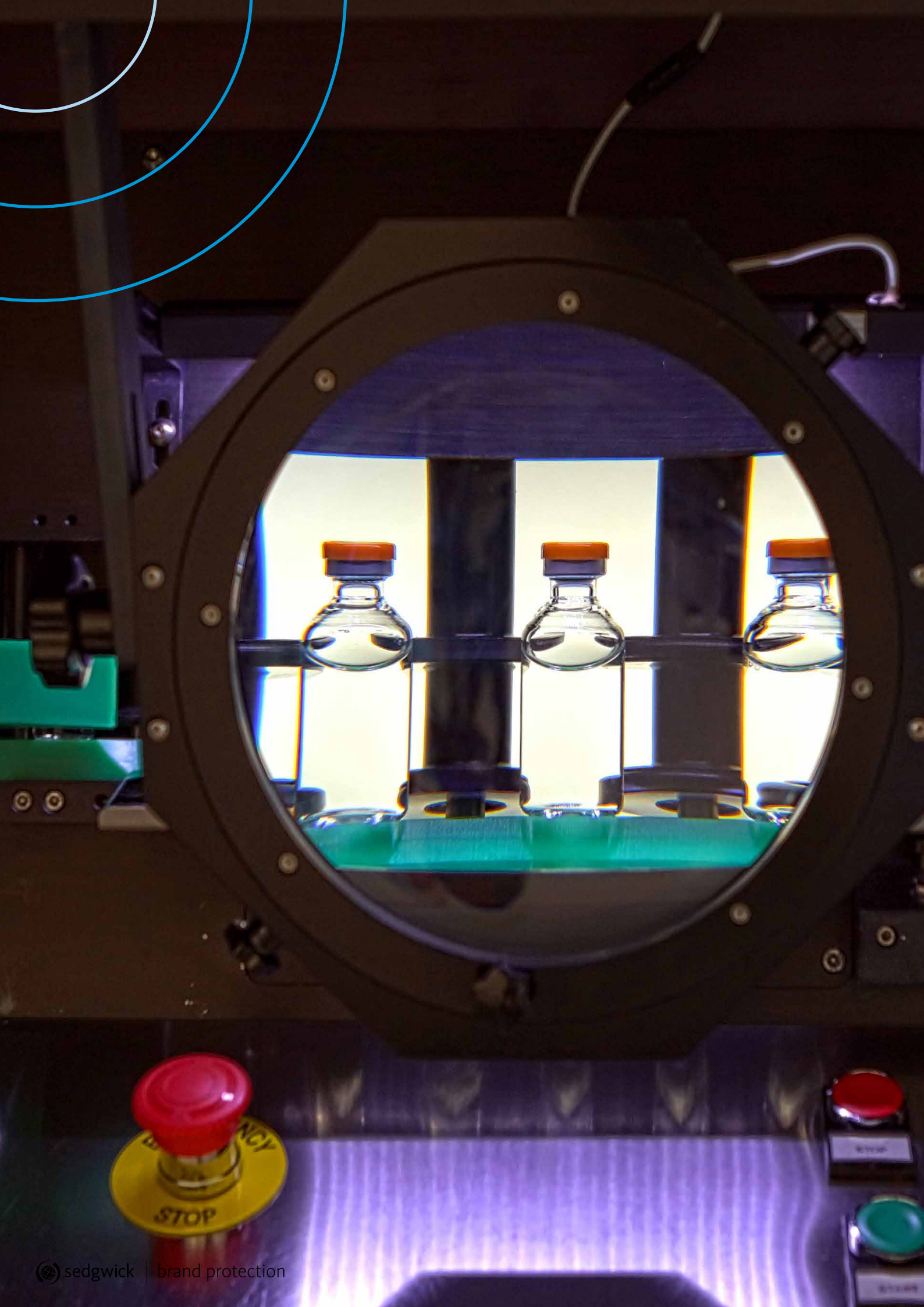
## Ongoing investigations leading to recalls

The Medicines and Healthcare products Regulatory Agency (MHRA) issued yet another recall for certain impure batches of commonly prescribed sartan medicines. The notifications follow previous recalls of the class of antihypertensives in 2018 and 2019 and continue to inform ongoing investigations.

The recall to pharmacies and wholesalers impacted certain irbesartan-containing medicinal products and losartan-containing medicinal products that were contaminated with a potentially cancer-causing substance.

These recalls are evidence of the continued regulatory focus on cancer-causing chemicals in pharmaceutical products. Companies would be wise to spend the same amount of energy monitoring and investigating their own supply chain to prevent or identify issues before the regulators do.

## Nutraceuticals, probiotics, and supplements

There is general consensus that there are significant regulatory complexities and challenges for nutraceuticals. In response, this category is a focus of MHRA expansion in the post-Brexit era. The UK government task force focused on post-Brexit regulatory reform acknowledged that the products challenge the "traditional silos" of regulatory classification, establishing a cross-departmental organisation to manage borderline products like probiotics and supplements.

"It points towards an exciting future for the nutraceutical industry in which innovation and expansion are better supported, without in any way weakening consumer protection standards, as the report itself stresses," said Michelle Riddalls, CEO of the UK's consumer healthcare industry association, the PAGB.

Pharmaceutical and food companies that produce these borderline products should engage in this process as appropriate, as it will dictate future oversight and enforcement.
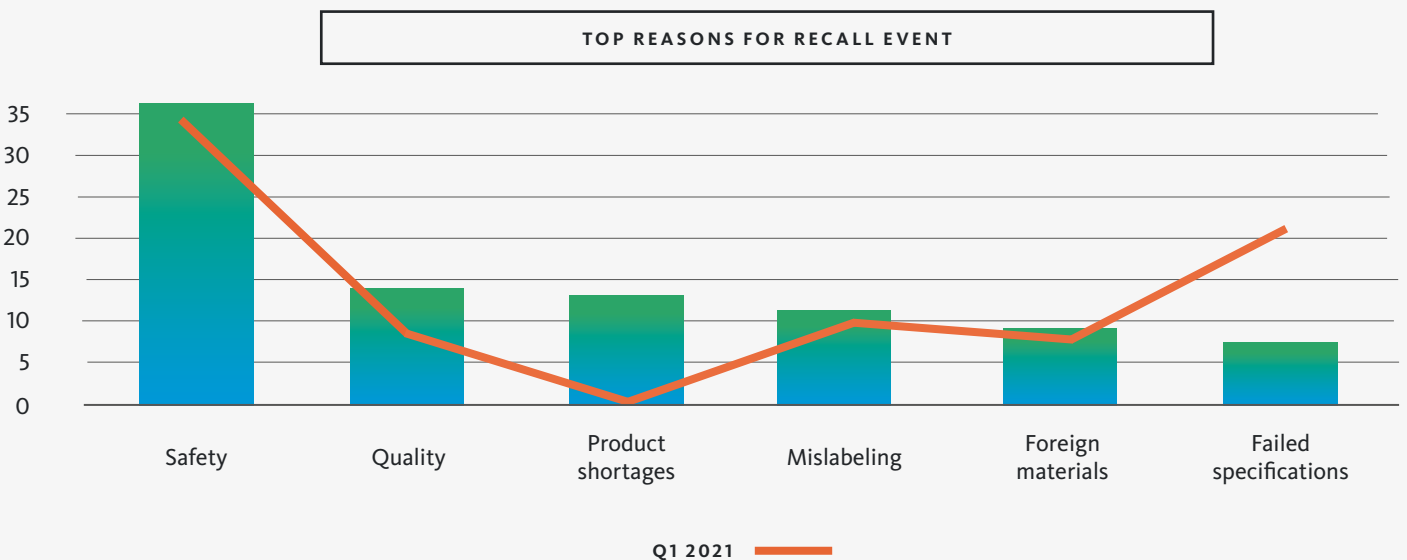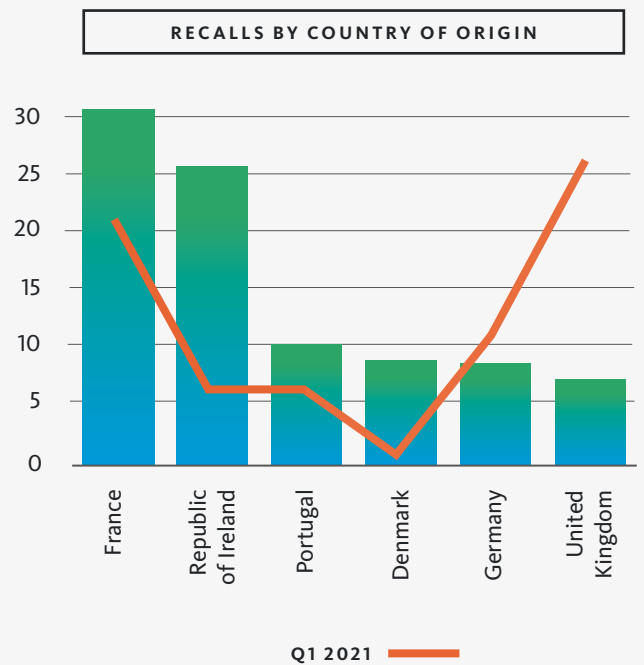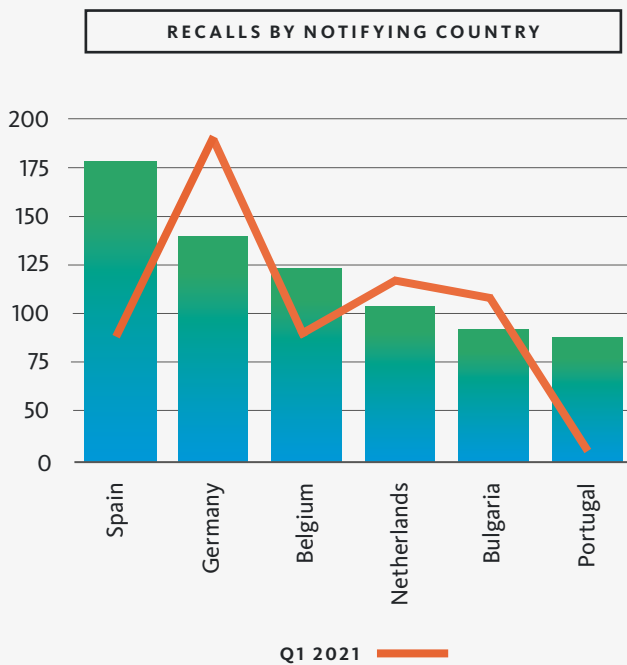
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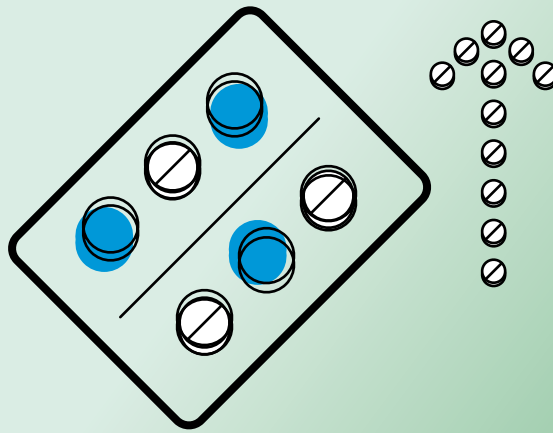
# SECOND QUARTER OVERVIEW

Pharmaceutical recall activity continued to increase in the second quarter, signalling a return to pre-pandemic levels. Pharmaceutical recalls increased 8.2 percent to 106 recalls in the second quarter, from 98 in the first quarter.

The most common reason for recall was cited as Safety (38). This was followed by Failed quality (14), Product shortages (13) and Mislabelling (11). Foreign materials and contamination recall activity remained low in the second quarter with just 9 recalls. As global regulators collaborate and find innovative ways to audit and inspect manufacturers, these recalls may continue to increase.

According to the data, pharmaceuticals produced in France continued to be the most likely to be recalled, accounting for nearly one-third (31) of pharmaceutical recalls in the second quarter. This was driven by Quality (6), Safety (6) and Mislabelling (6) concerns. Pharmaceuticals produced in the Republic of Ireland were the second most likely to be recalled (26) followed by Portugal (10).

## RECALLS BY NOTIFYING COUNTRY



Q1 2021

## RECALLS BY COUNTRY OF ORIGIN



Q1 2021

## TOP REASONS FOR RECALL EVENT



Q1 2021

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Signalling a return to pre-pandemic levels, Q2 recalls **increased 24.7%** to 106 events.

As European regulators return to more traditional approaches of oversight, we may expect to see these levels increase further.
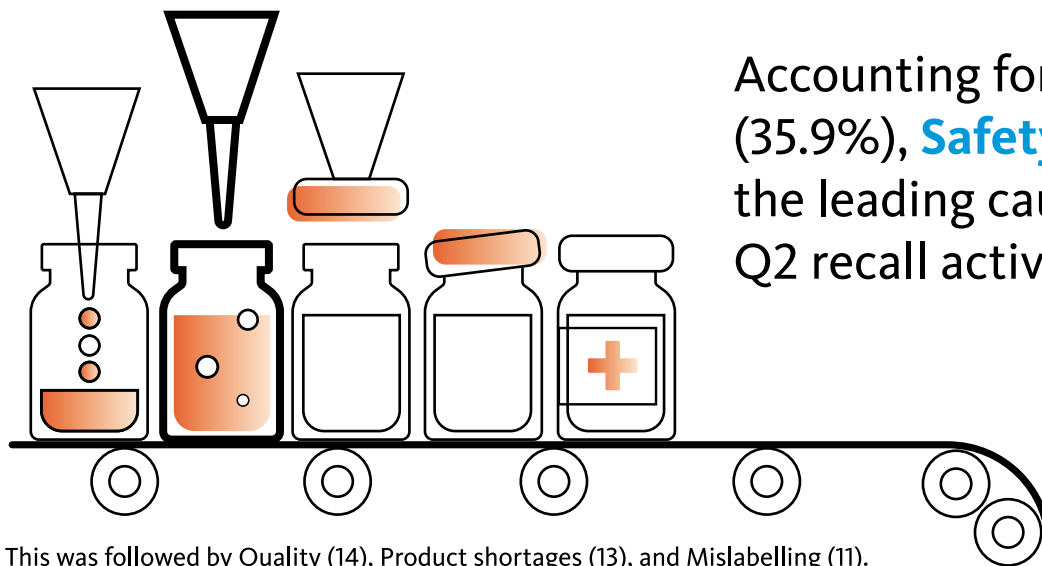
Accounting for 38 events (35.9%), **Safety** was the leading cause of Q2 recall activity.

This was followed by Quality (14), Product shortages (13), and Mislabelling (11).

Accounting for nearly a third of Q2 events (29.3%), Pharmaceuticals produced in **France** remain the most likely to be recalled.
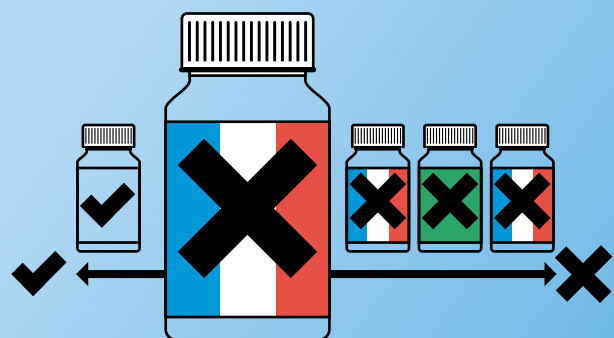
This was driven by Quality (6), followed by Safety (6), and Mislabelling (6).

**SARAH-JANE DOBSON,** PARTNER AND
**LEWIS MCAULEY-JONES,** ASSOCIATE, **KENNEDYS LAW**

# THE POST-COVID-19 PANDEMIC PHARMACEUTICAL INDUSTRY: NEW AND REVISITED REGULATORY AND LEGAL RISKS

Three primary drivers are changing the way the pharmaceutical industry is thinking about safety as we emerge from the COVID-19 pandemic. Each will undoubtedly make a lasting impact on how companies interact with consumers, supply chain partners and regulators. A close examination of these challenges will, therefore, be beneficial in helping companies identify and mitigate reputational risks through careful planning.

## Supply chain challenges

First among the changes impacting the pharmaceutical industry are those related to the pharmaceutical supply chain. Companies are seeking to localise their pharmaceutical operations in response to varying lockdown restrictions due to COVID-19. While the vast majority of major pharmaceutical suppliers are currently located in China and India, companies across the EU and UK are looking at re-shoring manufacturing and distribution lines in order to minimise supply risk. Localisation of pharmaceutical suppliers will also provide benefits to manufacturers when seeking to ensure regulatory consistency across product supply chains.

The catalysts changing supply chains are not limited to the COVID-19 pandemic. Post-Brexit, the UK has seen large shipments of a multitude of products experiencing significant delays and challenges at the ports. What was previously a theoretical risk is now a real and tangible supply issue. As companies work through the practicalities of regulations, they are considering localising those supply chains and bringing all entities within the supply chain into the same jurisdiction. In doing so, companies that operate internationally may need to have discrete operations in various markets across the EU and UK and this may result in a very sophisticated market with its own benefits.

## Counterfeit drug risks

While counterfeit drugs are not a new concept, there has been a significant increase in the level of criminal activity over the course of the COVID-19 pandemic. Not only are there more offenders but there is also an increase in the range of pharmaceutical products that are being counterfeited, including those marketed as COVID-19 preventatives or treatments without proper authorisation. While issues concerning counterfeit products traditionally had a greater impact in developing nations, these issues and risks are now affecting the UK and EU in an unprecedented way as evidenced by INTERPOL's latest 'Operation Pangea' effort.

In May 2021, countries across the EU combined forces to seize noncompliant medicines, including routine counterfeit product categories such as anabolic steroids and pain killers. The latest Operation Pangea effort also targets online marketplaces that were rife with fraudulent products like those advertised to treat COVID-19. The effort was deemed an immense success, resulting in the seizure of approximately four million counterfeit medicines and devices worth around USD 13 million.

While counterfeit issues do not often lead directly to product recalls, they can create uncomfortable situations

both up and down the supply chain and companies should be prepared for the regulatory, legal as well as reputational risks that flow from these issues.

Counterfeiting concerns could trigger questions from healthcare partners prescribing or dispensing a drug. While supplying a counterfeit drug by accident may expose the physician or pharmacy to liability rather than the manufacturer, such an event could create the potential for difficult situations to arise between those involved in the supply chain. With that in mind, pharmaceutical manufacturers may decide to 'over-communicate' on occasion to share information about potential counterfeit products.

Companies may also benefit from monitoring online sales of products within their product categories so as to report any suspicious products to the relevant regulators within the UK or EU. Taking the initiative in this way helps to build rapport with regulators which can be beneficial for companies impacted by counterfeiting issues.

Manufacturers should expect regulators to continue using their powers to bring criminal prosecutions against counterfeiters, but those actions may not take the traditional intellectual property or fraud approach. Instead, product safety regulators are typically viewing these issues as pure safety risk – which is a seismic shift in conceptualisation of these issues.

The legal and regulatory risk isn't only to the counterfeiter, however. When a customer or patient genuinely believes an adverse event was caused by a product manufactured by the original pharmaceutical company, the individual may bring a claim even if the drug or treatment was produced by a counterfeiter.

In these cases, the onus will initially fall to the pharmaceutical company. The closer the counterfeit is to the genuine product or medicine, the tougher it is to shift liability to the counterfeiter. To do so, the pharmaceutical company must supply sufficient documentation to prove that the product was not manufactured or supplied by them in this counterfeit format.

Manufacturers should take any and all steps to differentiate their products from counterfeits in order help prove their origin and authenticity. They also need to know definitively what markers deem their product genuine. One option may be antigen chemical testing that confirms authenticity. Additional specific steps can be tailored based on the type of product in question.

**SARAH-JANE DOBSON,** PARTNER AND
**LEWIS MCAULEY-JONES,** ASSOCIATE, **KENNEDYS LAW**
*CONTINUED FROM PREVIOUS PAGE*

## Evolution of recalls

With increased adoption of digital and social media, including a growing consumer population with access to smartphones, there are new ways that companies can communicate with customers and patients about recalls. Arguably, these communication channels will prove more effective than traditional means, particularly for non-prescription products.

Take for example the Yellow Card scheme in the UK, the government platform for patients and providers to report pharmaceutical side effects or adverse events, which benefited from a significant increase in awareness during the pandemic. The online application collects reports of 'suspected problems or incidents' related to COVID-19 vaccines and other medicines (including falsified medicines) and medical devices. With this awareness may come increased adoption by healthcare professionals and patients, thus resulting in more reports of adverse events, side effects or even fraudulent medicines. News updates from the MHRA can be accessed by healthcare professionals and consumers and side effects can be reported via the Yellow Card app on a smartphone. It is worth noting that the use of the Yellow Card application also comes with data privacy issues that must be considered when communicating with consumers.

The industry is changing. So is the regulatory environment as well as customer expectations. Whether it be established risks such as counterfeiting or new innovations like the Yellow Card scheme, risks to reputation are high as we emerge from the pandemic. Pharmaceutical companies should conduct regular case-by-case risk assessments and crisis planning reviews that include an evaluation of supply chain vulnerabilities, product liability exposure, insurance coverage and regulatory risks.

> **"** *Class II device manufacturers should learn from the challenges Class III companies faced in preparing to comply, and start acting now if they haven't already.*"

# MEDICAL DEVICE

—

With continuous innovation comes regulatory uncertainty in the medical device industry. But now global regulators, including those in the EU and UK, are seeking ways to increase oversight by providing clearer guidance and regulations.

## Wearables and health apps

The Medicines and Healthcare products Regulatory Agency (MHRA) may soon have a further expanded scope post-Brexit. Among about 100 suggestions recently issued by the taskforce on Innovation, Growth and Regulatory Reform was the recommendation that MHRA create new regulations for consumer health apps and wearables.

The taskforce recognises this segment as an "unregulated grey zone."

"The regulatory rules covering this relatively new and emerging area, including wellness apps, which do not claim to diagnose, treat or monitor a specific illness, are not yet clearly established," the taskforce noted in its report. "This is providing a barrier to integrating them into the health system."

"Recent market studies have shown that some fitness apps and wearable technology are wildly inaccurate," the report claimed. "There is also very limited regulation in apps which are advocating potentially unproven health benefits."

The report added, "By creating a new Digital Health Unit, the MHRA can standardise assessment and certification of health apps and wearable technology to the benefit of the consumer, and provide a central point for business-to-consumer use of personal health data, by providing a clear regulatory standard."

Medical device and even consumer products with exposure to wearable technology and digital health products must be vigilant in following these developments, while ensuring that they fully understand the scope, use, and impact of their products. While the rules that result from this effort will provide clarity, in all likelihood they will also remain broad enough to be applied to future innovations.

## Drug-device products

On July 22, 2021, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted guidelines on quality documentation for medicinal products used with a medical device. This guidance is applicable to medicinal products when the medical device and/or part of a medical device is single use and is integral, co-packaged, or referenced.

Mark Durivage, Quality Systems Compliance LLC, explained, "This guideline focuses on product-specific quality aspects of a medical device and/or part of a medical device that may have an impact on the quality, safety, and/or efficacy of a medicinal product. It describes the information that should be presented in the quality part of a marketing authorization dossier for a medicinal product when it is used with a medical device and/or as part of a medical device."

> **Global regulators, including those in the EU and UK, are seeking ways to increase oversight by providing clearer guidance and regulations."**

## EU medical device regulation

Implementation of the European Union Medical Device Regulation (Regulation [EU] 2017/745, EU MDR) is well underway. While Class III medical device manufacturers must already comply with new unique device identifier (UDI) labelling requirements, Class II businesses are working toward an implementation deadline of 2023.

Class II device manufacturers should learn from the challenges Class III companies faced in preparing to comply, and start acting now if they haven't already. With other regulatory deadlines and changes forthcoming – such as the implementation of MDR, which is set to be followed by requirements such as UKCA (UK Conformity Assessed) marks for products intended for sale in the UK – compliance challenges can quickly pile up and be insurmountable.

Failure to comply could result in a company being barred from selling in the EU or, at a minimum, face increased regulatory scrutiny in the form of detailed inspections and audits. And as with any operational disruption, significant reputational damage can follow.

# SECOND QUARTER BY THE NUMBERS

After appearing to return to pre-pandemic levels in the first quarter, medical device recall activity dropped 7.1 percent in the second quarter to 670 recalls. This quarterly activity remains higher than the quarterly average 515 recalls logged in 2020, but falls below 2019's quarterly average recall volume of 710 notifications. Looking more closely, we saw monthly recall activity climb slowly upward from April through June (2021).
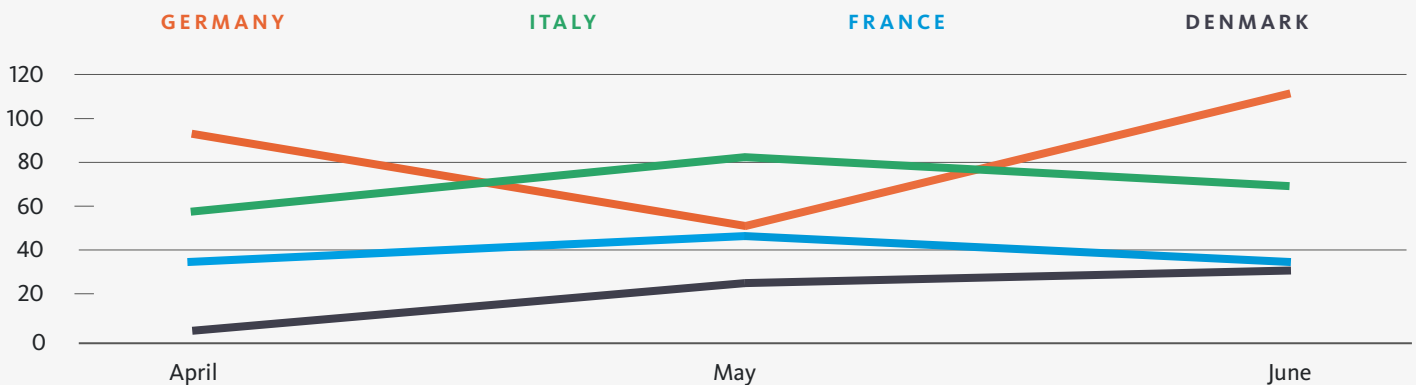
Quality issues remained the most common listed reason for medical device recalls at 194 events, followed by Sterility (169) and Software (85).

Germany was the top country for notifications and recalled products in the second quarter with 251 events, followed by Italy (208) and France (116). Quality concerns were the leading cause of recalls notifications from Germany (83), followed by Sterility (56) and Software (36).

Breaking down the data even further, however, Italy dominated recalls in May with 83 events, followed by Germany (47) and France (42).

Of all second quarter medical device recalls, there was only one event in which the notifying country announced a recall of a product originating from a separate jurisdiction.
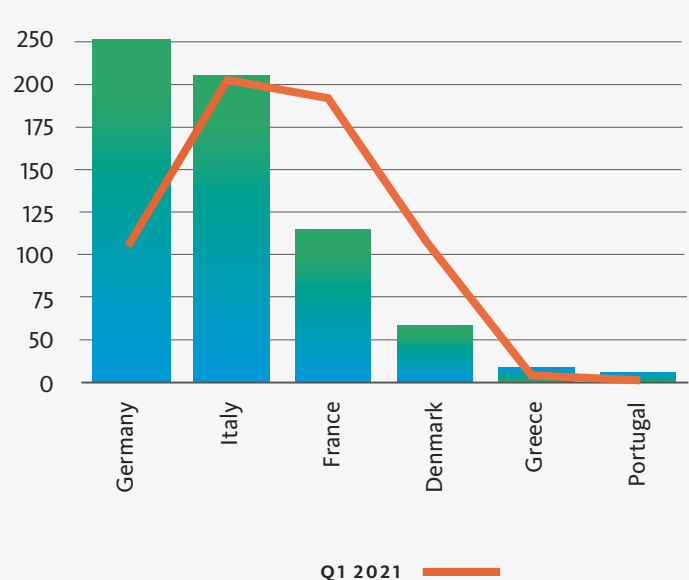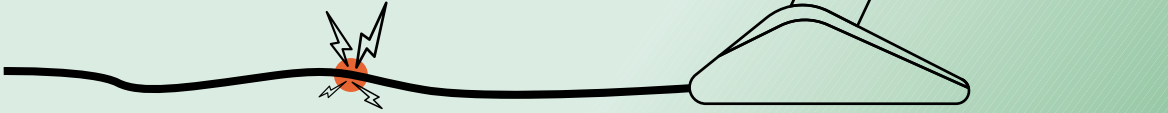


Q2 RECALLS BY COUNTRY OF ORIGIN

GERMANY    ITALY    FRANCE    DENMARK

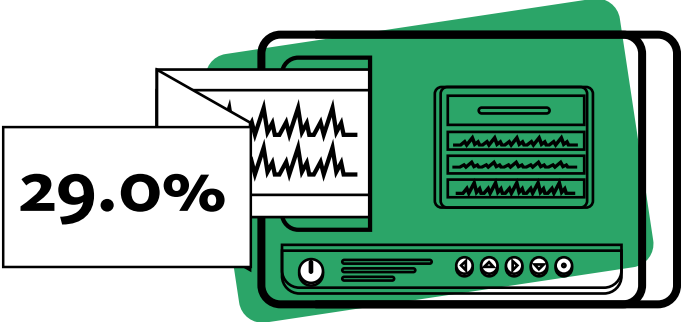

TOP REASONS FOR RECALL EVENT

Q1 2021



RECALLS BY NOTIFYING COUNTRY

Q1 2021
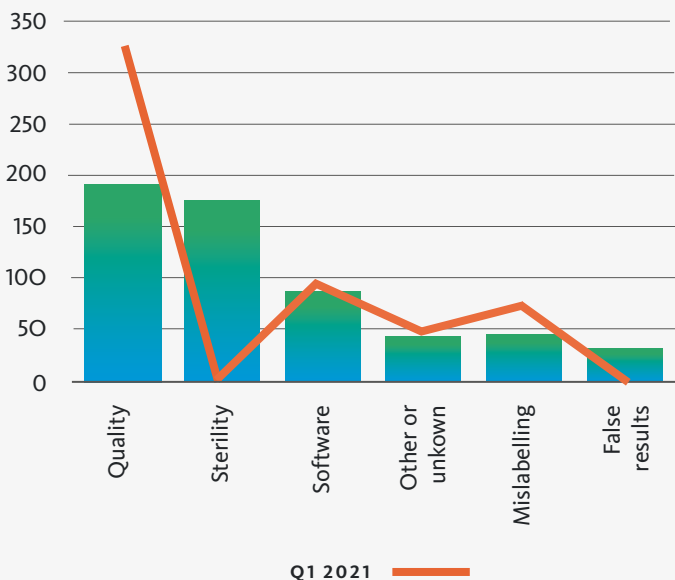
At 670 events,
Q2 recalls **declined 7.1%** from 721 in Q1.



Despite this drop, average quarterly recall events in 2021 (696) sit just 2.0% below 2019's pre-pandemic quarterly average of 710 events.



Accounting for **194 events (29.0%)**, Quality was the leading cause of recall activity in Q2 2021.

This was followed by Sterility (169), Software (85), Other (45), and Mislabelling (44).

**Germany** was the top notifier in Q2 with 251 events (37.5%).
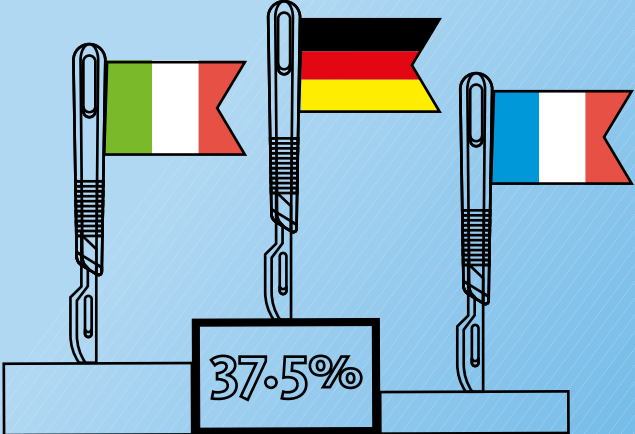


This was followed by Italy (208), France (116), Denmark (61), and Greece (16).

**LEO FIELDING,** SENIOR ASSOCIATE,
**SHOOK, HARDY & BACON INTERNATIONAL L.L.P.**

# MEDICAL DEVICES AND THE EVOLVING RISK LANDSCAPE

The medical device industry has faced several significant product safety challenges already in 2021 – from a high number of safety issues with cardiology devices to sterilisation issues across a broad spectrum of devices. But the risks don't stop there. As new devices are introduced, the regulatory environment evolves, and patients and healthcare professionals embrace telehealth services, companies should consider how to mitigate current and new safety risks in a way that protects the company's operations and reputation.

## Cardiology devices in the spotlight

Cardiology devices have been the subject of more field safety notices (FSNs) than any other type of medical device in the UK so far this year. Those affected have included ventilators, vascular access devices and infusion devices. Identified safety concerns have covered issues such as degradation of materials, leakages from devices and sterilisation issues.

The high number of safety issues with cardiology devices in the UK may be a sign of increased demand for them from National Health Service (NHS) trusts potentially because of greater numbers of patients being diagnosed with cardiology issues. At the same time, there remain enduring challenges associated with commercialising high-tech innovative devices that generate regulatory concerns.

## Sterilisation shortcomings

Shortcomings in sterilisation equipment has been an issue for several device manufacturers this year. Following reports of non-compliance by an Italian sterilisation plant, 28 manufacturers informed the Medicines and Healthcare products Regulatory Agency (MHRA) of field safety corrective actions (FSCAs) relating to this sterilisation issue. The large-scale impact of this incident

provides a timely reminder for device manufacturers of the importance of rigorously vetting proposed third parties within the supply chain before contracting.

This incident also provides insight into how some regulators are taking an increasingly proactive approach in response to large-scale, cross-border safety incidents. In this case, the MHRA identified affected manufacturers known to have significant supply into the UK and proactively contacted them to request that they undertake a risk assessment. The agency also shared risk assessments to inform clinical decision-making, negotiated with manufacturers to ensure the feasibility of actions in FSNs, developed supporting guidance for healthcare professionals and patients, and shared resulting best practice on recalls with international medical device regulators. The high level of engagement shown by the MHRA in this case may well be something that we will see more of in the future.

## Development of diagnostic devices for detection of SARS-COV-2

Devices designed to detect markers of SARS-COV-2 (i.e., the virus that causes COVID-19) seem likely to continue generating significant interest. As a new ecosystem of diagnostic products emerges, it seems likely that such

products will increasingly capture the attention of regulators, legislators and other stakeholders responsible for oversight of such products. Indeed, regulators are already sitting up and paying attention: in May 2021, the EU's Medical Device Coordination Group issued guidance to manufacturers of such devices that underlined their responsibilities to continually assess the impact of newly identified genetic variants of SARS-COV-2 on the ability of those devices to meet their safety claims.

## In vitro diagnostic medical devices (IVDs) concerns

The implementation date for the InVitro Diagnostic Medical Device Regulation (IVDR) in Member States is 26 May 2022. One concern the EC has flagged recently is the potential future risk of shortages in the supply of IVDs in Europe due to lack of certification capacity. It seems likely that there will be greater demand for the services of notified bodies under the IVDR: it has been estimated that, under the current regime, around 10% of all IVDs placed on the market need notified body involvement, whereas under the IVDR this will rise to 80-90%. Manufacturers will therefore need to think carefully about developing a contingency plan to ensure they can bring their IVD products to market in a timely way, taking into account the possibility of delay and/or disruption at the certification stage.

## Wider adoption of telehealth

While early adopters of telehealth have typically been patients in remote communities with inadequate access to traditional health services, adoption rates increased steadily during the COVID-19 pandemic because of a broader need to treat patients remotely, when possible, to adhere to social distancing requirements. Continued attention on this topic is likely to have implications across a range of issues, such as the consideration of the types of patient inquiries suitable for telehealth services, data security issues and confidentiality concerns related to video or audio recording of services.

Just as data and privacy risks know no borders, there is a growing prevalence of safety incidents that involve a cross-border element. Combined with the long-term trend towards globalisation of supply chains for medical devices, companies should expect safety regulators to collaborate when responding to potential safety incidents. The UK's MHRA has already shown a willingness to coordinate a global response. There will be plenty more opportunities in the future for regulators of medical devices to work together, and companies should prepare accordingly.

# CONSUMER PRODUCTS

—

We will examine three leading consumer product categories in the pages that follow, but we first need to set the stage for the future of consumer product regulations.

The European Commission on 30 June 2021 published proposed revisions of the 20-year old General Product Safety Directive 2001/95/EC (GPSD) that outlines general safety requirements for consumer products.

Wim Vandenberghe with Reed Smith LLP writes that the proposed framework, which would apply in all Member States, "aims at adapting product safety to the digital economy and at the same time imposes strict measures to protect consumers from dangerous and deceptive products. These measures not only impact product manufacturers but also supply chain actors and online marketplaces."

While many changes are afoot in the way consumer products are regulated, companies must prepare for the way the recall process is set to evolve. In its brief on the proposed revision of the Directive, the Cooley LLP product compliance & product liability practice outlined some of the "eye-catching provisions," some of which are included below:

- There are specific provisions for the content of product recall notices – with a prohibition on using certain terms, e.g. "voluntary", "precautionary", "rare", "no reported accidents" and in addition, recall notices must include an instruction to immediately stop use.
- There are also provisions relating to the conduct of product recalls, notifying consumers, and the remedies offered including proposals on the mandatory use of social media for recalls and requiring companies to use customer information to directly contact them.
- There are specific provisions for the sharing of information internationally between the European Commission and other regulatory agencies around the world.
- And as a final point, that commitment to ensuring the proposed regulation has teeth is seen with the proposal that businesses which fail to undertake these obligations are likely to incur heavy fines for non-compliance, namely penalties of up to 4% annual turnover.

There is significant support for this proposal compared to previous recommended revisions of the Directive. Companies should keep this in mind as they consider the potential business and reputational impacts of these changes. And to the extent that recall obligations and expectations are being refined, companies would be wise to pay close attention and adjust recall policies accordingly.

> " *While many changes are afoot in the way consumer products are regulated, companies must prepare for the way the recall process is set to evolve.*"
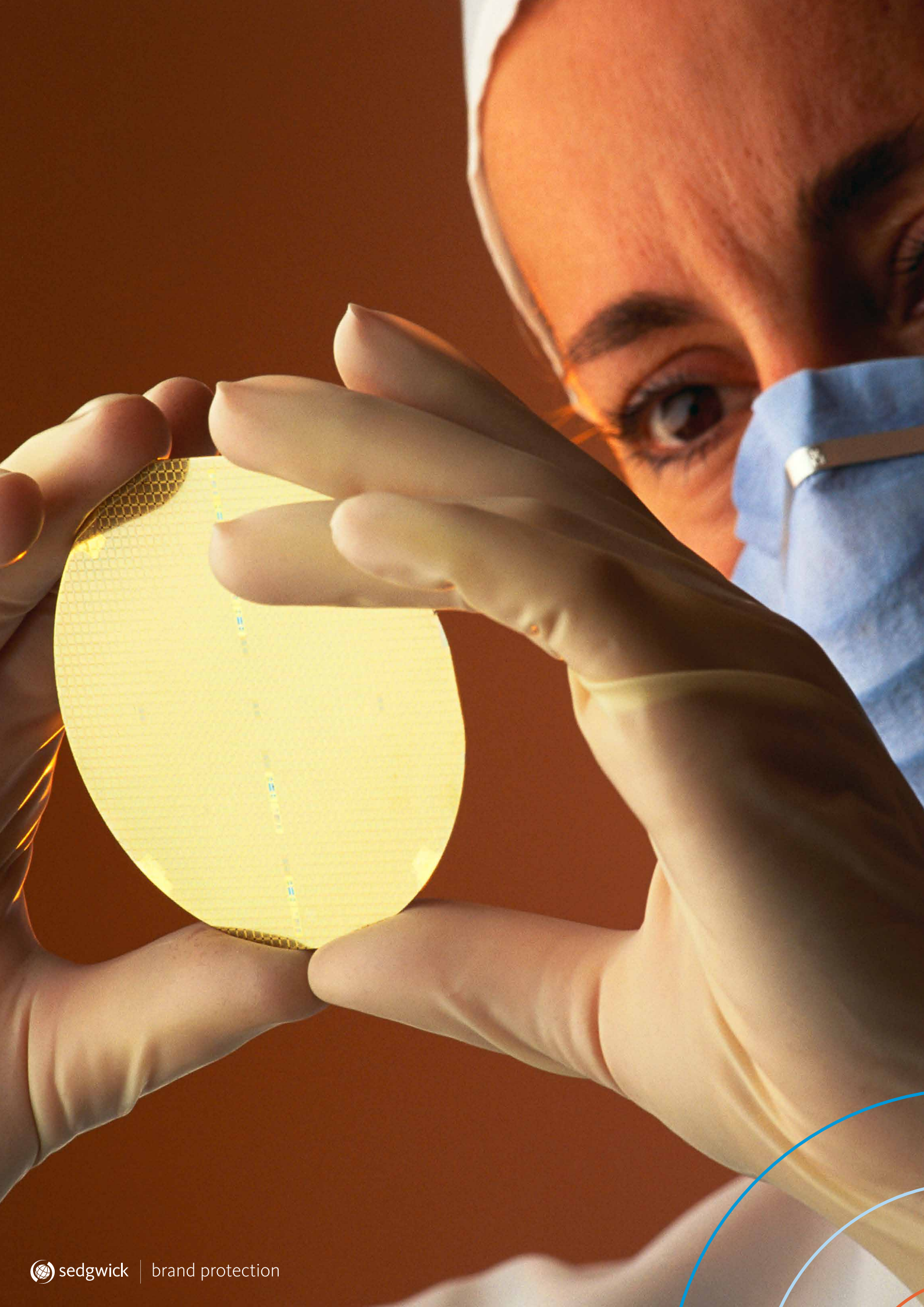
**CONSUMER PRODUCTS**

# ELECTRONICS

—

The electronics industry is experiencing a strong rebound in world consumer markets, as the US, China, and Western Europe drive growth in demand for electronics, according to the latest IHS Markit Global Electronics Purchasing Managers' Index (PMI). As predicted, the global pandemic accelerated the pace of digital transformation as workers around the world worked at home rather than from a corporate office.

That said, the category does face challenges ahead, including supply chain challenges and regulatory pressures.

*With the rollout of new technologies, like 5G, new telecommunications, electric vehicles, and more, the demand for new semiconductors will only rise."*

## Supply chain challenges

We are seeing the impact of raw material shortages play out around the world and across industries, but most notably within the automotive and smart phone sectors. This has been further exacerbated by recent COVID-19 waves impacting electronics manufacturing hubs across east Asia.

With the rollout of new technologies, like 5G, new telecommunications, electric vehicles, and more, the demand for new semiconductors will only rise. While component manufacturing is slowly catching up, supply is unlikely to meet demand until well into 2022.

## Environmental sustainability

The Circular Economy Action Plan for the EU aims to prevent environmentally harmful products from entering the EU market by "prioritizing the reduction and reuse of materials before recycling them, and by fostering new business models with innovative products / services," notes Judith Bussé, a partner with Crowell & Moring. One sector of focus for the Circular Economy Action Plan is the electronics industry.

Given the European Commission's ongoing focus on climate and environment-related challenges, electronics companies must embrace the notion that they are "sustainable products." That means all products will need to consider the common methodology and principles laid out by the in the Circular Economy Action Plan. Perhaps most notably this includes a "right to repair."

Electronics are often seen as disposable goods to be discarded at the end for the lifecycle, in many cases because technology upgrades and innovations render old versions out-of-date if not extinct. But that notion will be challenged under a right to repair. Companies will need to develop and manufacture products, and replacement parts, that can be repaired and maintained throughout an extended lifecycle. If companies cannot meet these new demands, they may ultimately face enforcement action down the road.

# SECOND QUARTER OVERVIEW

Quarterly recall activity dipped slightly from 76 events in the second quarter, compared to 86 events in the first quarter of 2021. This represents an 11.6 percent decline, but a 35.7 percent increase compared to 2020'S quarterly average of 56 recalls. This heightened level of recall activity suggests a continued focus on the safety of electronic products, caused in part by 'on-again, off-again' stay-at-home restrictions forcing non-essential employees across Europe to work remotely.

Electric shock was the most cited single risk, accounting for 36 recalls. Consistent with previous quarters, Electric shock was also listed as one of two or more reasons cited in additional recalls. 'Burns, electric shock and fire' was the second-most cited recall risks with 15 second quarter recalls, followed by 'Electric shock and fire' at 3 events, 'Burns and electric shock' (2), and 'Burns, electric shock and injuries' (1).
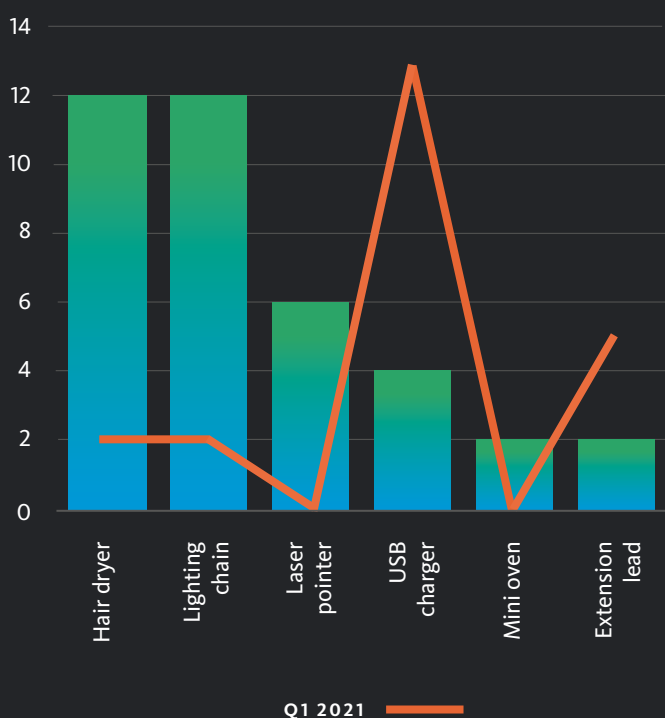
In sum, Electric shock contributed to 57 recalls, or 75 percent of second quarter events. These recalls commonly impacted products such as electric cables (including USB chargers and adapters), lighting chains, hair styling tools, and appliances.

In terms of notifications, Hungary was the top notifying country with 37 events, followed by Finland (7), and The Netherlands (7).
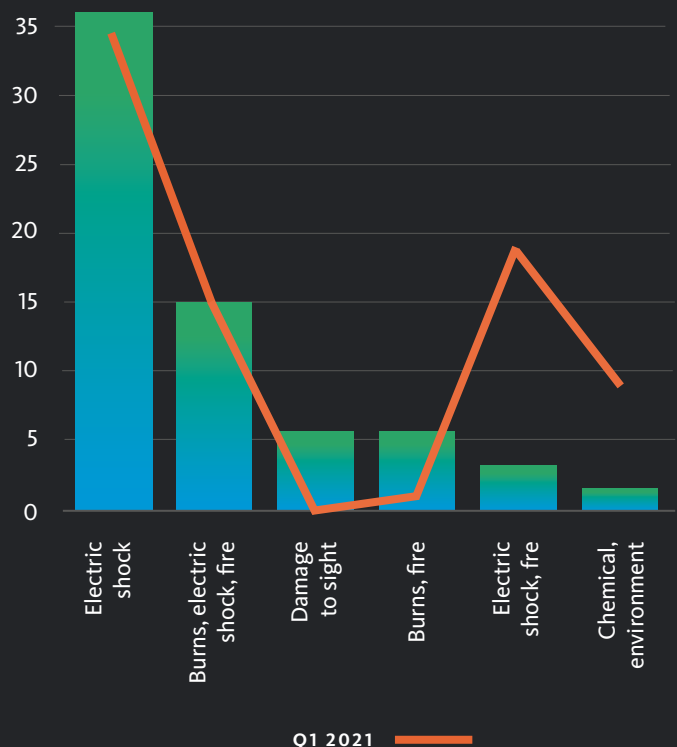
Consistent with the first quarter, the majority of recalled products originated from China, accounting for 63 recalls or 82.9 percent of second quarter recalls. Following China, seven recalls came from an unknown country.

Whilst there were no recorded instances of counterfeit products in Q2, there were 13 events with a classified status of 'Unknown', 10 of these originated from China. The remaining recalls in Q2 (63) were all identified as non-counterfeit.
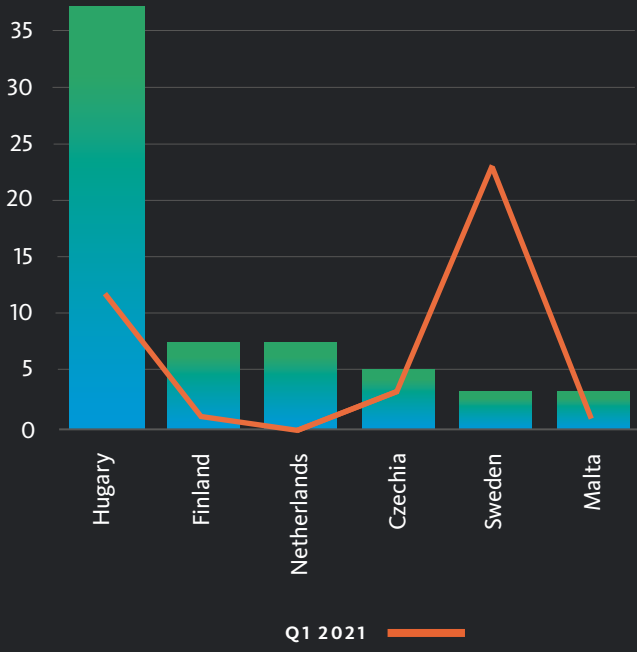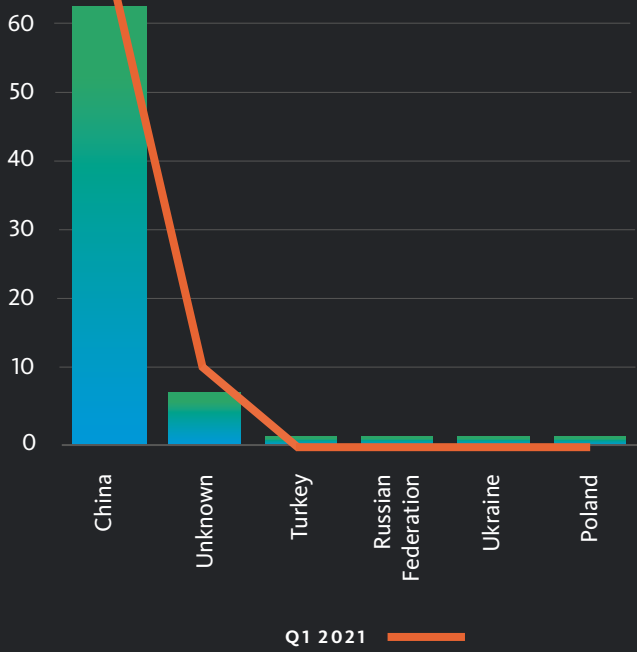
### TOP ELECTRONIC PRODUCTS RECALLED



Q1 2021

### TOP CAUSE OF RECALLS



Q1 2021

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## RECALLS BY NOTIFYING COUNTRY
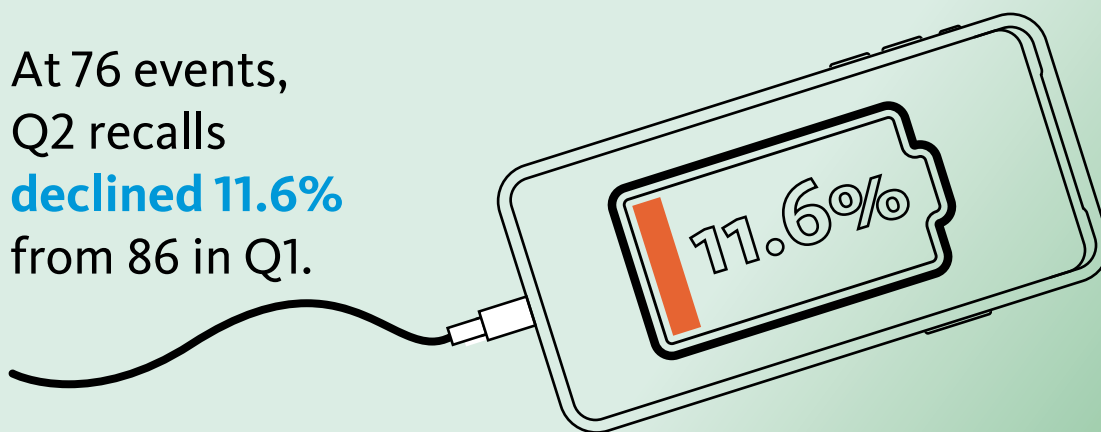


Q1 2021 ────

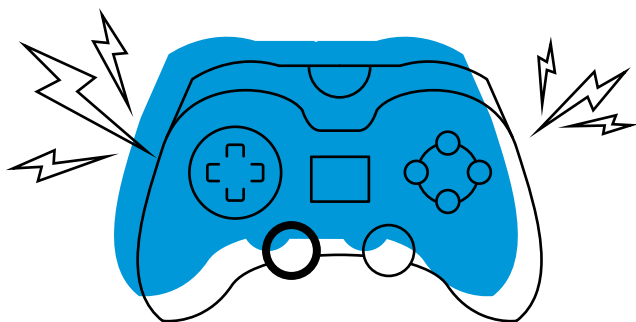## RECALLS BY COUNTRY OF ORIGIN



Q1 2021 ────

At 76 events,
Q2 recalls
**declined 11.6%**
from 86 in Q1.

Despite this decline, this represents a 35.7% increase on 2020's
quarterly average of 56 recalls.

Accounting for 36 events
(47.4%), **Electric shock**
was the leading cause
of recall activity in
Q2 2021.

Electric shock also featured in an additional 21 events, including: Burns & Fire (15),
Fire (3), Burns (2), and Burns & Injuries (1).

**Hair dryers** were
the most impacted
electrical appliance
with 12 recalls (15.8%).
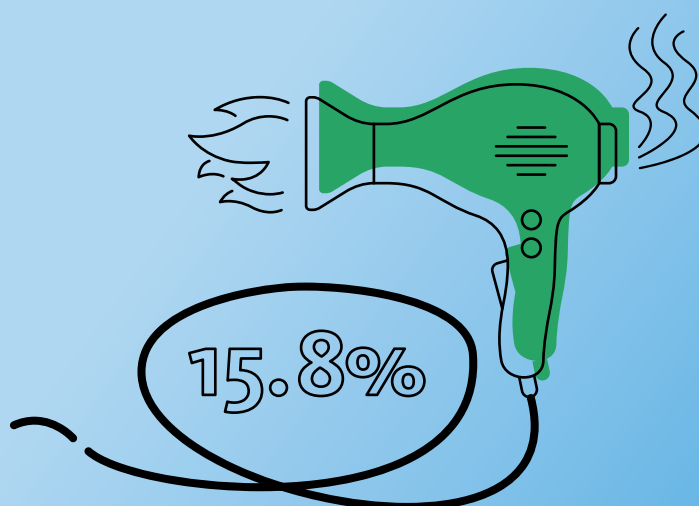
USB chargers (the most impacted appliance of last quarter)
experienced a 71.4% decline, totalling just 4 events.

**MARISA PEARCE,** ASSOCIATE,
**SHOOK, HARDY & BACON INTERNATIONAL L.L.P.**

# ELECTRONICS SURGE MAY PROVE PROBLEMATIC

In June 2021, the UK's National Audit Office published a report on protecting consumers from unsafe products. It found that 90% of UK internet-using adults have used online marketplaces. This is not surprising in the current climate where consumers are less keen to browse aisles and retail tourism has taken a downturn.

According to a 2019 survey referenced in the report, worryingly, only 17% of consumers were reported to have considered product safety in a recent purchase. The main factor considered on purchase was price. This was followed closely by quality and then by brand name, ease of purchase and style/fashion. However, product safety was more of a factor than the speed of delivery, online reviews and running costs.

While this data precedes the global pandemic, it is likely that COVID-19 has made product safety even less of a factor in consumer decisions. It is cause for concern for electronics companies as overseas manufacturing and e-commerce make an array of previously inaccessible consumer electronics available to the masses – introducing a range of new and sometimes unforeseen risks to consumers.

## The online marketplace

As consumer confidence grows, there is likely to be an increased demand for consumer electronics. Consumers are likely to face higher exposure to safety issues online than they would through traditional purchases. With the increase in online sales and consumers hunting for deals, often seemingly without a good engagement with product safety considerations, disputes are likely to arise.

In the United States, the Consumer Product Safety Commission filed a complaint against a major online marketplace platform pursuant to consumer product safety legislation. The complaint seeks "public notification and remedial action to protect the public from the substantial product hazards presented by certain consumer products" sold on the online marketplace and distributed through its fulfilment program. This action represents a shift for the regulator, which now wants to force companies up and down the supply chain to be responsible for recalls.

It has not yet been established under which conditions an online marketplace might be found liable for unsafe or defective products on its platform in the UK. Certain major marketplaces have signed up to the Product Safety Pledge, committing to act expeditiously in response to notifications of unsafe products. There are, however, calls from consumer organisations for the UK to take a more proactive approach.

The Consumers' Association's *Which?* is active in this conversation, calling for:

- online marketplaces to be required to ensure that consumer products offered for sale on their platforms are safe;
- enforcement powers, resources, skills and intelligence for the policing of online marketplaces; and
- greater seller transparency obligations.

Until there is clarification through regulatory guidance, legislation or case law as to when platforms may face liability, consumers and regulators are bound to confront serious challenges in ensuring safety standards have been met and in taking action and enforcing any order or judgment against companies and individuals overseas.

# Data, security and privacy

Given the prevalence of smart devices which collect, analyse, hold and upload consumer data, manufacturers also need to understand data privacy obligations in all jurisdictions where products are sold. Similarly, manufacturers should have effective and efficient systems in place to prevent, detect and respond to cyber security issues.

We expect an increasing number of recalls to directly reference data, security and privacy issues. Healthcare-related electronics in particular will be under the magnifying glass given their increased significance during the pandemic. As we see increased adoption of remote health monitoring, manufacturers must be quick off the mark on notice of device issues, and in particular those which could put consumers at risk or which allow for the release of sensitive personal information.

# Home working brings new liability risks

With consumers having worked from home for so many months due to the COVID-19 pandemic, and many set to continue to do so on a permanent basis, home electronics are seeing unprecedented, regular usage. Some of these goods may not have been produced with this scope of usage in mind, be that daily and light, heavy and intense, or simply more frequent.

Consider that goods which were traditionally used on a limited basis may now be used for longer, extended periods for business-related purposes. This could lead to a range of potential product safety, insurance and liability disputes. Manufacturers should examine the potential for change in frequency of use of their products and take steps to assure themselves that their products can tolerate, and ideally shine, under different usage frequencies and schedules. Both quality issues, such as early end-of life and safety issues, such as overheating, should be considered.

# Ecodesign considerations

On 1 July 2021, new rules came into force in England, Wales and Scotland requiring manufacturers to make spare parts available to purchasers of electrical appliances. These rules are part of a package of measures relating to electrical goods which are found in the Ecodesign for Energy-Related Products and Energy Information Regulations 2021 (the Regulations). By way of this legislation, the Government is striving for energy and carbon savings as part of its efforts to reach net zero by 2050.

Among its objectives, the legislation aims to tackle premature (also known as planned or built-in) obsolescence where products are allegedly made with intentionally short lifespans with a view to obtaining repeat business. Among these products are electronics that are simply not manufactured to last for such long periods of time.
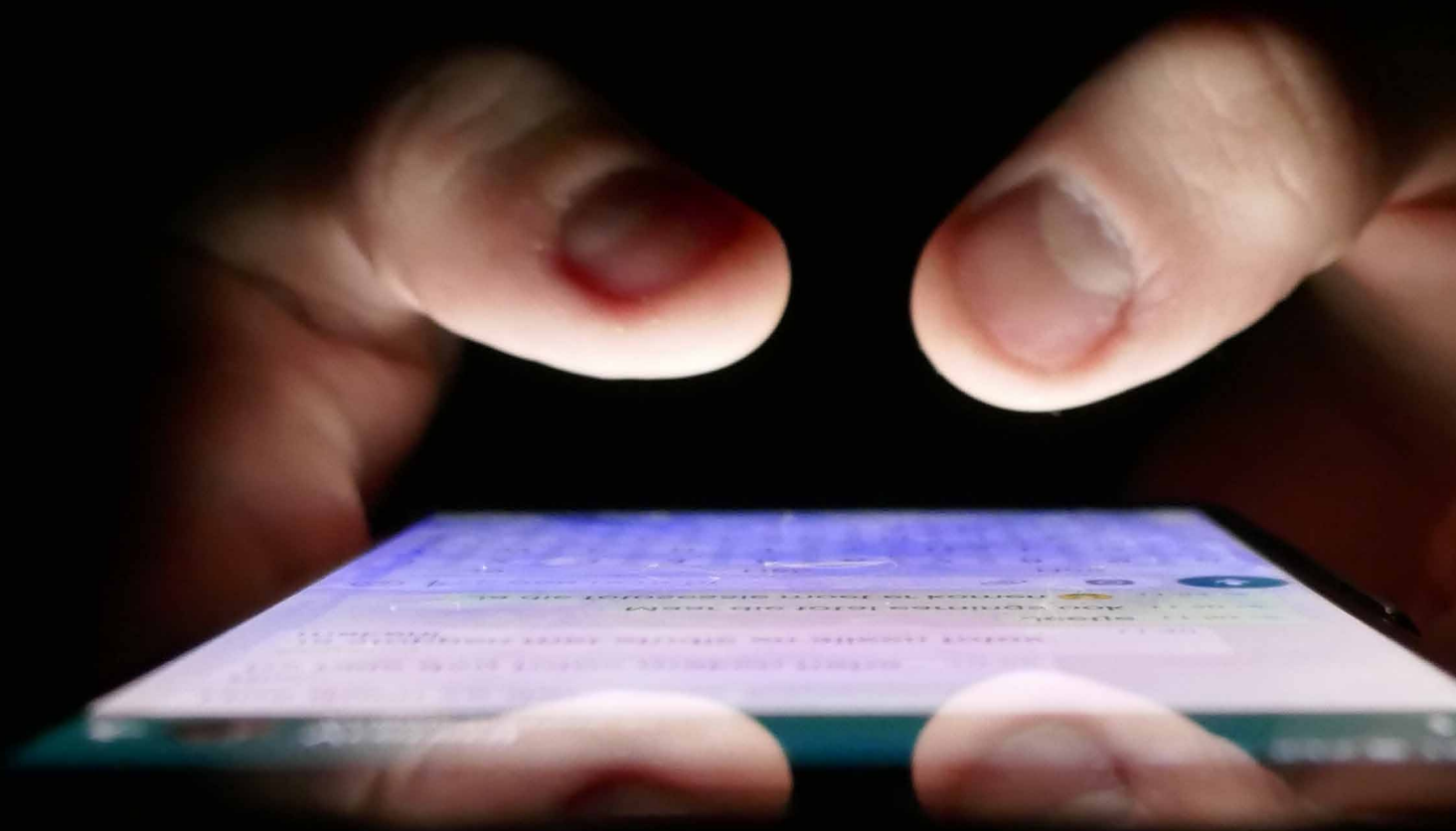
**MARISA PEARCE,** ASSOCIATE,
**SHOOK, HARDY & BACON INTERNATIONAL L.L.P.**
*CONTINUED FROM PREVIOUS PAGE*

Depending on a manufacturer's business model, the rules could cause a serious setback to profitability in light of foreseeable reduced sales and the cost of creating spare parts for goods even if they are no longer produced. More concerning, however, is the potential increase in product liability and safety issues arising from the continued use of these electronics past what might otherwise have been their end of life.

In civil matters, the 10 year "long stop" provision under the UK's Consumer Protection Act/the EU Product Liability Directive, which extinguishes the right to bring a strict liability claim 10 years after a product is placed on the market, is likely to see increased use. Expert evidence will certainly be required to demonstrate the level of safety persons are entitled to expect in "old" products and, as is so often the case with products claims, there may well be conflicting views as to where liability lies as between manufacturers and repairers.

Consumer purchase and use of electronics changed dramatically during the pandemic. The regulatory environment is poised to catch up to protect consumers. Companies should take steps now to not only comply with new regulations, but position themselves as safety-first businesses.

## CONSUMER PRODUCTS
# TOYS

—

The global educational toys market is expected to reach revenues of USD 31.62 Billion by 2026, according to a report by Arizton. Product categories expected to benefit from the highest growth are augmented reality (AR) educational toys, sustainable, and STEM toys.

Growth for the cognitive thinking educational toy type in particular is expected to be highest at a CAGR of 9.23 percent in response to the focus on building logic and thinking skills. Toys that help develop motor skills are also likely to see increases.

From an age perspective, toys for 3-8 year-olds are expected to lead the global educational toy market, growing at a CAGR of 8.35 percent.

While this is all great news for the industry as a whole, keep in mind that regulators in the EU, UK, and around the world always have a close eye on products intended for use by children, particularly as we head into a potentially challenging holiday shopping season.
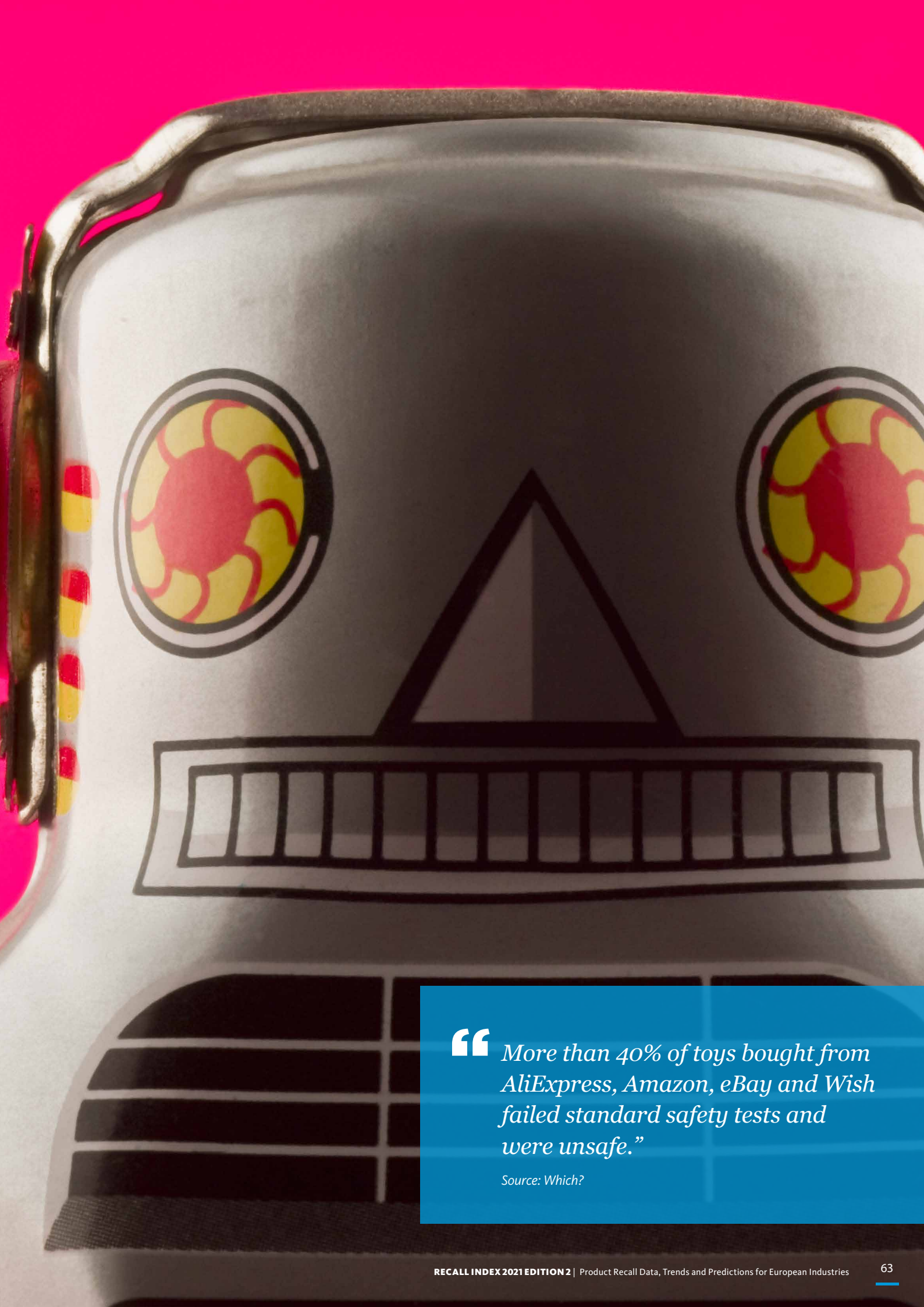
> **"** *More than 40% of toys bought from AliExpress, Amazon, eBay and Wish failed standard safety tests and were unsafe."*
>
> *Source: Which?*

## Holiday shopping

According to [Retail Week](#), online sales are expected to remain high in the third quarter as we approach the holiday season. Unfortunately, the industry faces continued operational, fulfillment, and shipping challenges – not only as a result of the ongoing pandemic but also in preparation for the first post-Brexit Christmas.

This perfect storm has manufacturers, retailers, and parents concerned about shopping in the lead up to the festive period. [Fortune](#) warns of a toy shortage, reporting that as manufacturers experience increased costs, "renegotiations are underway with retailers on prices, which are normally agreed on up to a year in advance." At the same time, retailers have the added challenge of having been unable to build inventory over the course of the year.

While there was a significant shift to online shopping during the 2020 Christmas period, the industry expects a shift back to brick-and-mortar establishments, at least in part, for 2021. But as consumers struggle to find and purchase gifts for friends and loved ones, they may increasingly turn to online marketplaces which cannot always be relied on for selling safe products.

## Online marketplaces

Online marketplaces are increasingly facing scrutiny when it comes to product safety. Consumer safety organization [*Which?* recently warned](#) that "more than 40% of toys bought from AliExpress, Amazon, eBay and Wish failed standard safety tests and were unsafe." Hazards included choking risks, strangulation risks, dangerous magnets, and button batteries. But the safety risks to consumers go beyond the products sold on these shopping platforms.

For example, the U.S. Consumer Product Safety Commission filed a lawsuit against one global e-commerce provider in an attempt to force the company to initiate its own recall of products sold by third-parties. According to The Washington Post, a senior agency official who spoke on the condition of anonymity stated that officials at the e-commerce provider refused to acknowledge that the CPSC has the authority to compel the company to remove unsafe products. While this legal action is a U.S. matter, e-commerce providers and the third-party sellers who use these platforms have a global reach.

That translates to increased global regulatory exposure and enforcement risk for manufacturers and distributors leading into a potentially tumultuous festive season.

# SECOND QUARTER OVERVIEW

After plummeting in the first quarter, toy recalls continued to decline, falling 19.1 percent to 85 events in the second quarter. For historical context, toys accounted for 105 events in Q1 2021 and 262 recalls in Q4 2020.
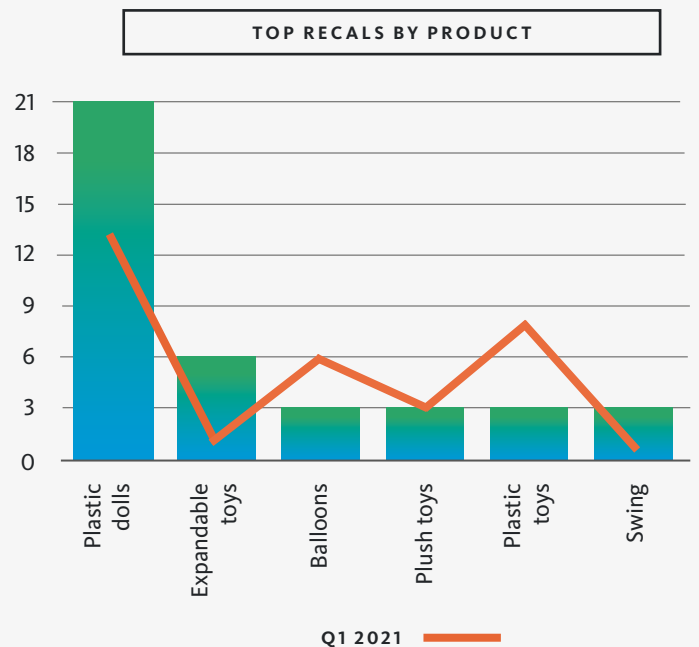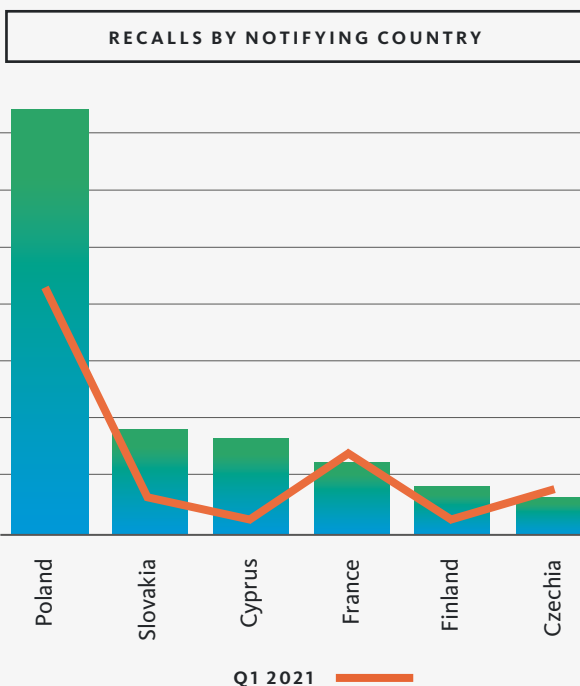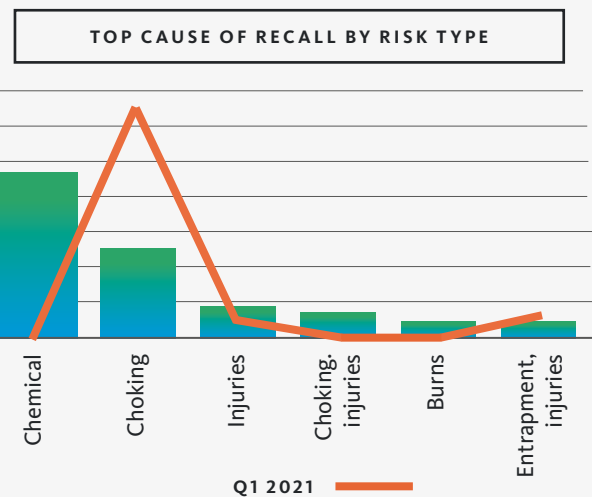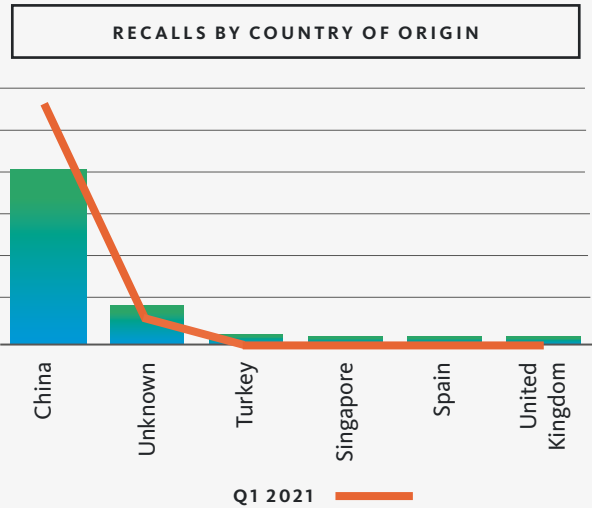
Chemical risk was the most common cause of second quarter recalls at 38 events, accounting for 44.1 percent of recalls. More than half these chemical related events impacted Plastic dolls. An additional five impacted Balloon products.

Choking concerns was the second most common cause of recalls, accounting for 20 events. Injury risk was a distant third at 7 recalls.
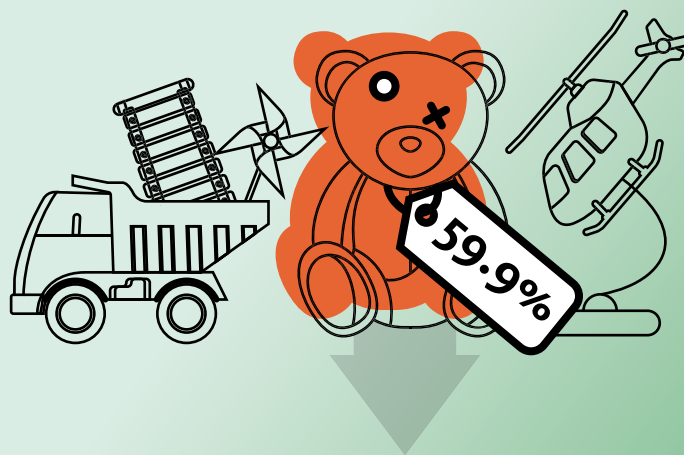
Plastic dolls were the most common recalled toy accounting for 21 notifications in the second quarter, a marked increase of 40% from Q1 (15).

Poland notified most with 38 events, followed by Slovakia (9), Cyprus (8), France (6) and Finland (4).

Of all second quarter recall events, 22 (25.9 percent) were identified as non-counterfeit. The remaining 63 events were classified as 'unknown'; of these, 46 originated from China, 12 from an unknown country, while Poland, Singapore, Turkey, and the UK, each registered single events.

## RECALLS BY COUNTRY OF ORIGIN

Q1 2021

## TOP CAUSE OF RECALL BY RISK TYPE

Q1 2021

## RECALLS BY NOTIFYING COUNTRY

Q1 2021

## TOP RECALS BY PRODUCT

Q1 2021

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After plummeting 59.9% in Q1, toy recalls **declined** a further 19.1% to 85 events in Q2.

This equates to just 56.3% of the 151 toy recalls averaged every quarter in 2020.

**24.7%**
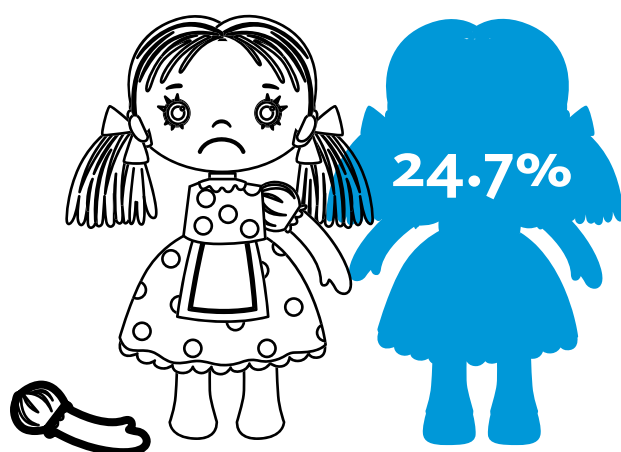
Accounting for 21 events (24.7%), **Plastic dolls** remain the most recalled toy in Q2 2021.

Expandable toys (6), Balloons (6), Plastic toys (5) and Soft toys (3) rounded out the top 5 categories impacted.

**Chemical risk** was the most common risk type in Q2 at 38 events, accounting for 44.1% of recalls.

**44.1%**
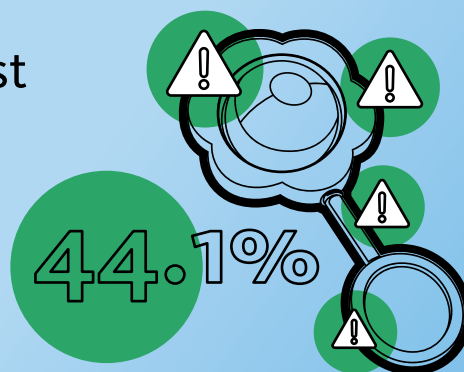
Choking concerns followed with 20 recalls. Of these, Plush toys accounted for 3 events, with both Wooden toys and Plastic toys accounting for 2 each.

**ALISON NEWSTEAD,** PARTNER/SOLICITOR,
**SHOOK, HARDY & BACON INTERNATIONAL L.L.P.**

# PROTECTING CHILDREN IN A WORLD WHERE A TOY IS SO MUCH MORE THAN A TOY

—

Toys repeatedly feature high in the rankings of recall statistics. They are also among the ones most likely to generate media headlines and social media conversation. There is good reason for this: toys are enjoyed by one of the most vulnerable sectors of society – children.

Toys come under heavy scrutiny from parents and regulators alike. Potential safety issues are extremely likely to be reported, and regulators are likely to sit up and take notice. The stakes are extremely high for manufacturers and the decision to recall potentially unsafe products is often taken quickly and without question.

Whilst the prevalence of corrective action regarding toys has not significantly altered over the last decade, the reason for recalls has changed dramatically. There are still common toy safety hazards at the origin of recall action: choking on small parts, toys containing prohibited chemicals and risks of entrapment. However, as products have become more complex and technology has advanced, risks emerge that toy manufacturers, regulators and caregivers would not have even contemplated a decade ago.

## Cybersecurity risks

Cybersecurity risks in children's toys is one such issue. Many industries have reported cybersecurity incidents and data breaches that present a wide variety of potential safety risks. Cars have been hacked, with changes being made to air conditioning, radio and transmission functions. Medical device manufacturers have reported security flaws that put patients at risk of suffering adverse effects from illicit alterations to implanted devices or modifications made to devices being used to treat them.

The toy industry is not immune to cyberattacks. In 2019, toys were recalled for the first time as a result of cybersecurity issues: the European Commission ordered the recall of a smartwatch after learning that the watch could allow hackers to communicate with a child wearing the watch and to locate them via GPS. Similar issues have been discovered with other toys that connect to the internet. Even dolls, soft toys and other connected toys that use microphone and camera technology are at risk of being hacked and allowing uninvited guests into homes – seeing, speaking and tracking the movements and location of children.

We can expect such issues to arise more frequently, particularly as toys are increasingly interconnected and utilise wireless connectivity.

To minimise risk, manufacturers need to consider security vulnerabilities throughout the lifecycle of the product - both at the design stage and as the product starts to become outdated. However, a question arises as to how long a manufacturer can be expected to make security patches available to customers to ensure optimum cybersecurity protection for its products. It is a question being asked across all industries as wireless technology becomes outdated and potentially less secure.

Consideration also needs to be given as to the warnings that accompany a product: for example, advising caregivers that the toy should only be paired with one or two specific devices with a specific password (to avoid unwelcome Bluetooth connections from others within a certain range of the toy) and recommending that security is updated regularly.

## Battery-related risks

Injuries arising out of the ingestion of batteries have been on the rise and no doubt will continue to concern

regulators. Children's toys have included batteries for many years. Historically, the most common risk posed by these batteries was a choking hazard. Child injuries have increased significantly as very small, button (or coin) batteries have become commonplace in toys. When ingested, the batteries mix with saliva and cause a chemical reaction that can burn through the esophagus, stomach and other internal organs, causing significant internal damage which can even be fatal.

In accordance with EN 62115 (which deals with electrical safety in toys), a button cell or coin cell should not be removable without the aid of a tool. This commonly means that the battery compartment in toys is secured by a screw. However, this requirement is not seen in household appliances and we are likely to see continuing injuries to children who access batteries in such products and associated recalls.

## Magnet risks

Magnets in children's toys also continue to pose risks to children and have been the cause of recalls throughout 2021. A recent surge in the sale of toys such as necklaces and bracelets made of magnetic ball bearings led to an increase in injuries and action taken by regulators. In March 2021 in the UK, the Office for Product Safety and Standards (the OPSS) launched a magnet safety campaign in response to a growing number of cases where children had suffered serious internal injuries after swallowing small, high-powered magnets which pull together within the digestive system and cause life-threatening damage. The OPSS issued a Safety Alert in May 2021, engaged with

businesses and, throughout 2021, has continued to oversee the withdrawal or recall of magnetic products. We expect this trend to continue.

## Previously unheard-of risks

While cybersecurity, privacy and ingestion risks are increasing in frequency and severity, the risk categories are not entirely surprising.

But an unusual issue that occurred in the United States should serve as a reminder that recalls and safety concerns can take many shapes and forms. In this case, items that are not toys – but look like toys – made headlines recently. Specifically, a gun manufacturer produced a gun that looked like a toy. A cease-and-desist letter from a toy manufacturer to the gunmaker led to the product being withdrawn from sale. While resolved with no regulatory action being required, one would expect that safety regulators were certainly poised to act should the issue not have been resolved voluntarily.

The toys children of today play with and learn from are incredibly different from the products parents and grandparents used when they were young. As the toy industry evolves and introduces children to new technology, features and ways to play, businesses should consider the new, sometimes unintended, risks that accompany the innovations. The stakes are extremely high for manufacturers when the safety of children is threatened.

> *Competition in the fashion and apparel industry is fierce. Without careful oversight, brands are at risks of counterfeiting."*

## CONSUMER PRODUCTS
# CLOTHING

—

While the apparel and textile industries may have been on the road to recovery, European Apparel and Textile Confederation (Euratex) in April warned it may be jeopardised by evolving challenges. Among them are rising raw material prices, increased transport costs, supply chain challenges, environmental concerns, and social and political affairs.

> **"** *We expect to see more recalls of innovative clothing or fabric products like fabric face masks and athletic clothing containing biocides or making SPF claims.*"

## Environmental concerns

In June, 25 European non-governmental organisations (NGOs) pushed back against the "fast fashion" industry, considered one of the largest global polluters. Calling for the EU to hold brands accountable for their contribution to pollution, the organisations launched a Wardrobe Change campaign calling for "minimum standards for how long clothes should last, a ban on the destruction of unsold and returned goods, rules to verify and substantiate green claims, and ambitious targets for an absolute reduction in the amount of natural resources used across the supply chain," Fibre2Fashion.com reports.

The groups also want to see rules on hazardous chemicals and action to end labour rights violations in the European Commission's new regulatory measures expected by year-end.

"The EU urgently needs to redesign the textile industry by tackling overproduction and overconsumption as well as unfair working conditions. To ensure longer-lasting and repairable products, priority must be given to waste prevention and preparing for re-use. In parallel, greater support and protection must be given to social economy enterprises active in the sector to help ensure an inclusive and fair textile value chain," said Mathieu Rama, senior policy officer at RREUSE.

In addition to any new regulations as ultimately written, textile and apparel companies will need to consider new rules within the context of the extremely broad definition of safety and consumer protection. Failure to do so risks additional enforcement, and potentially even recalls.

## Competition leads to counterfeiting

Competition in the fashion and apparel industry is fierce. Without careful oversight, brands are at risks of counterfeiting. Manufacturers "will sometimes continue to produce and sell your products to other distribution channels during an engagement and after you switch to a new manufacturer. Even with property agreements and security measures, counterfeit products produced from the actual production line happens in the real world," notes Jeffrey Greene, a partner with Foley & Lardner LLP.

"To make business even more challenging, the ability for competitors to distribute knock-offs has become much more pervasive on Internet sales platforms," Greene adds.

To protect your brand and reputation, Greene recommends companies protect their intellectual property as early as possible in the lifecycle. Companies should also mark the final product with IP identifiers to help reduce counterfeiting, maximise damages and improve the ability to remove fraudulent products from the market.

These steps will be increasingly important for apparel that has been recalled. Companies should take appropriate measures to ensure they are not liable or responsible for the recall of counterfeit products on the market. Similarly, clothing that encroaches on medical devices for their purported health benefits pose unique risks. Shoring your supply chain and actively monitoring for and removing counterfeit products will be critical to protecting your brand.

# SECOND QUARTER OVERVIEW

Clothing recalls increased 78.1 percent, from 32 events in the first quarter of 2021 to 57 in the second.

Children's apparel dominated second quarter notifications with 41 events or 71.9 percent of recalls. Of these, 17 resulted from Strangulation hazards, 10 were due to Injury risk, 7 were the result of Choking hazards, and 7 from Injury and strangulation.
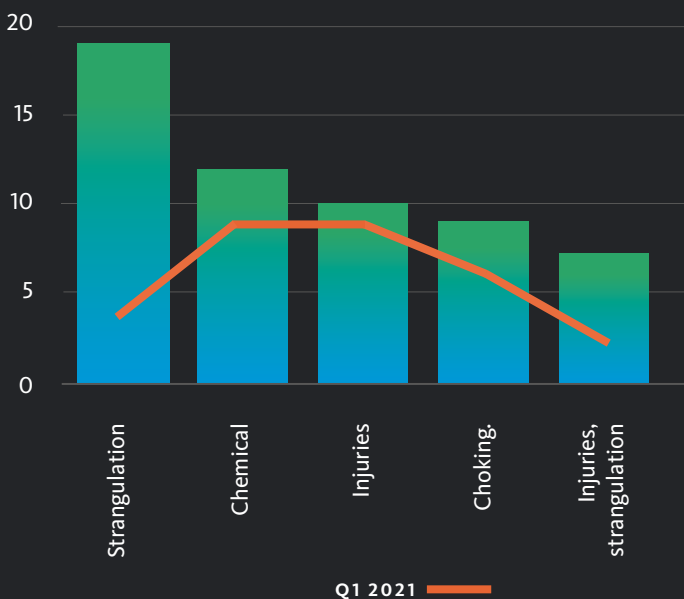
Romania issued recall alerts for seven false nail products. All these products originated from China.

Bulgaria notified most (28) in the second quarter, followed by Romania (13), Lithuania (5), and Belgium and Germany both notified 3 events.
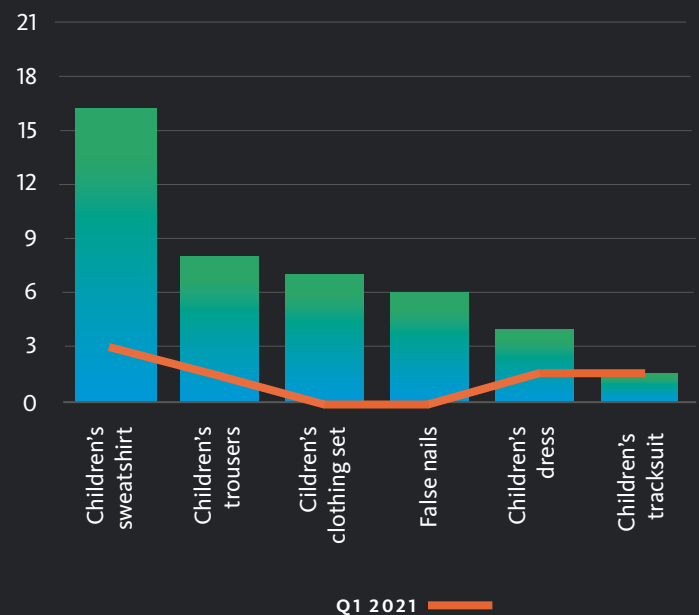
It is clear a focus remains on children's products when it comes to clothing recalls. But it is important we echo a prediction from the first quarter. We expect to see more recalls of innovative clothing or fabric products like fabric face masks and athletic clothing containing biocides or making SPF claims. These recalls may be due to environmental or chemical non-compliance, or the result of crossing the line into the world of medical devices.

Evidence of this becoming a reality can be found within the Q2 data, where one face mask recall was cited for non-compliance with both the Biocidal Products Regulation and General Product Safety Directive requirements.
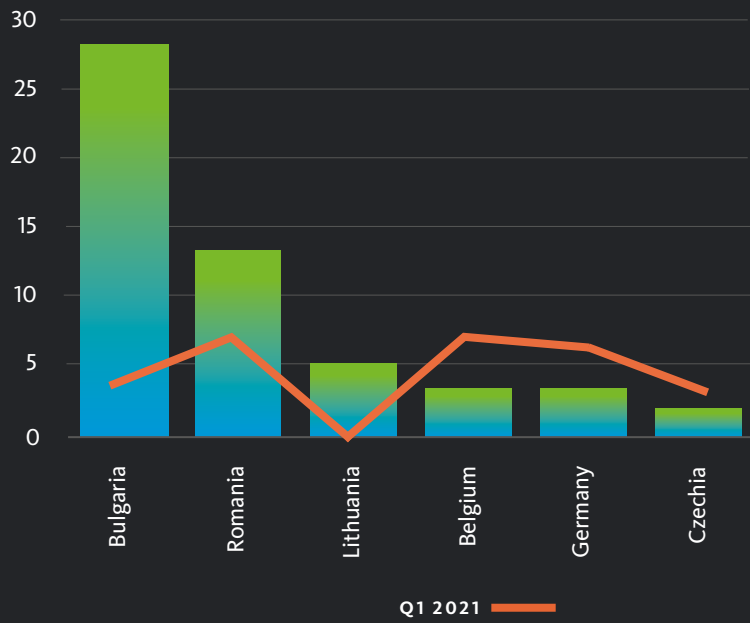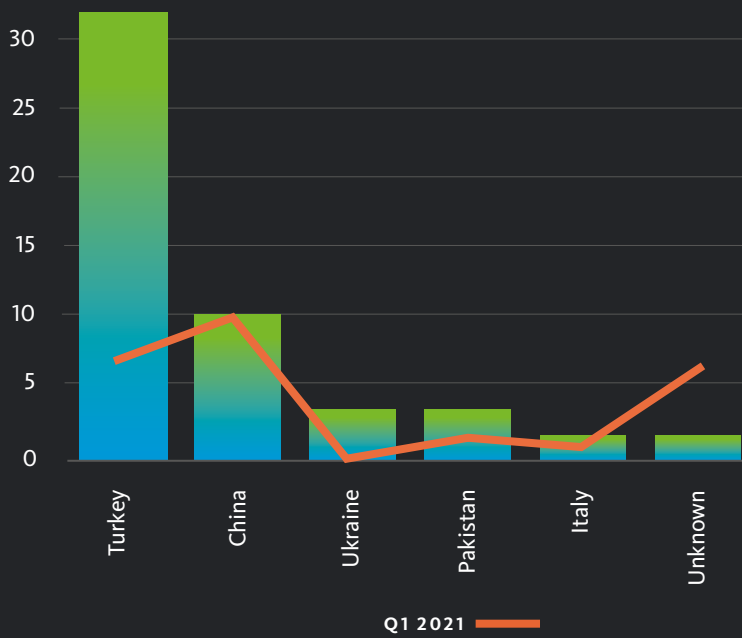
### TOP CAUSE OF RECALL BY RISK TYPE



Q1 2021

### TOP RECALS BY PRODUCT



Q1 2021

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## RECALLS BY NOTIFYING COUNTRY



Q1 2021

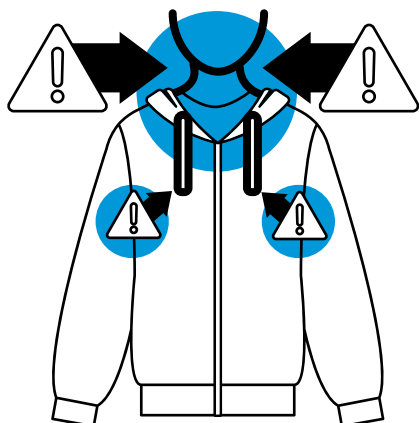## RECALLS BY COUNTRY OF ORIGIN



Q1 2021

At 57 events,
Q2 **recalls jumped**
78.1% from 32
in Q1.

This figure falls level with the 57 recalls recorded in Q4 2020,
and eclipses last year's quarterly average of 36.

**Strangulation** was
the most common risk
type, impacting a third
of Q2 recalls (19).

This was followed by Chemical (12), Injuries (10), Choking (9), and Injuries & strangulation (7).

**Children's** apparel
dominated Q2, with
41 events or 71.9%
of recalls.

71.9%
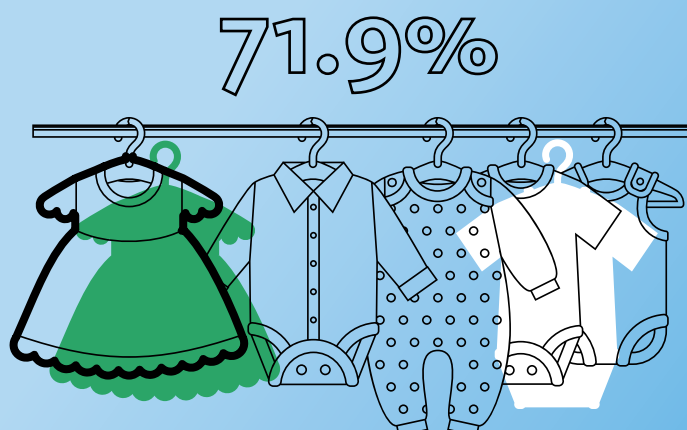
The most frequently recalled items included: Sweatshirts (14), Trousers (8)
Clothing sets (5), and Dresses (2).

**MARISA PEARCE,** ASSOCIATE,
**SHOOK, HARDY & BACON INTERNATIONAL L.L.P.**

# APPAREL RECALLS: WHERE FASHION, FUNCTION AND SAFETY INTERSECT

—

The pandemic changed the clothing and textile industry in both predictable and unexpected ways, many of which show no signs of reversing.

In particular, the clothing and textile industry's efforts to pivot its operations to produce Personal Protective Equipment (PPE) and face coverings for public use during the COVID-19 pandemic should be applauded. Even more impressive is the industry's ability to deliver these critical materials despite disrupted global supply chains.

A number of trends have arisen over the course of the pandemic. We have seen faster than anticipated growth of digital retail, which will no doubt continue. The fast fashion majors are seeing a corresponding boost. At the same time many consumers are seeking out sustainable brands.

Regulatory requirements and consumer expectations are rapidly evolving, and businesses would be wise to devote resources to ensuring compliance and mitigating risk before a product safety or reputational crisis hits.

## Pandemic-driven pivot

Although pandemic-driven restrictions are likely to be steadily lifted across Europe, demand is expected to remain whilst COVID-19 continues to circulate. As a result, PPE production by the clothing industry is here to stay for the foreseeable future.

As numerous businesses continue to produce items such as masks, aprons, surgical gowns and other protective clothing, it will be critical that they remain on the right side of regulators. Many of these products fall into different

regulatory categories, so care needs to be taken to ensure compliance with the requirements of the relevant regimes. For example, masks intended to protect patients are regulated under medical devices legislation as Class I medical devices. Masks intended as PPE, to protect the wearer, must comply with EU Regulation 2016/425 on PPE as implemented in the UK by the Personal Protective Equipment (Enforcement) Regulations 2018 and require verification by a EU or UK Notified Body. Masks used as face coverings by the general public, however, will not fall under the PPE or medical device requirements and must not be sold or donated as such. These must comply with the General Product Safety Regulations 2005. Failure to navigate, apply and comply with the correct regulatory requirements may result in a recall, as evidenced by second quarter recalls.

The EU's Safety Gate rapid alert system reported 55 serious recalls of masks for failure to comply with Personal Protective Equipment Regulations or the relevant European standard EN 149. Looking closer at enforcement actions in the UK provides insight into the risks for businesses and consumers.

In June 2020, the UK's Trading Standards disclosed that, since the start of the pandemic, more than 6.5 million face masks had been seized at Heathrow Airport for failing to meet the requisite requirements. Many of these masks were labelled with false claims or fake safety certificates. About 4.25 million required label amendments and were ultimately released, but 2.25 million were found to be in irreparable breach of safety standards.

These actions by UK regulators demonstrate the need for businesses to:

- have solid quality control systems in place;
- carry out due diligence on the supply chain;
- ensure chosen suppliers attach correct labelling (in the required languages); and
- ensure the product's features, components, cleaning requirements and capabilities are not misrepresented.

## A focus on supply chains

The COVID-19 pandemic resulted in unprecedented supply chain disruption, leading to increased costs, reputational damage and loss of business for many. In some cases, supply chains collapsed entirely and had to be rebuilt.

In response, the European Commission updated its industrial strategy for the EU as outlined in "A New Industrial Strategy for Europe" released March 2020. In May 2021, the Commission revised the strategy to place an emphasis on lessons learned from the COVID-19 crisis. Most notably, the pandemic exposed the interdependence of global value chains, issues arising from border restrictions, lack of availability of essential goods and disruption of demand. The updated strategy focusses on strengthening the Single Market's economic resilience and supporting its open strategic autonomy, for example, by monitoring strategic dependencies, diversifying international partnerships and launching industrial alliances.

The implementation of the revised New Industrial Strategy may result in fewer recalls, not only in the apparel industry, but generally across all industries. Businesses nonetheless need to be ready to recall. This is of critical importance for businesses that sell internationally, and particularly UK businesses post-Brexit. Businesses will need to have considered, planned and prepared as best as possible for any difficulties with border crossings.

## The ethical consumer

Out of what we hope are the ashes of the pandemic, a more discerning consumer is rising, with a nuanced and ethical approach to their purchasing decisions. There is increased scrutiny of the environmental impact of manufacturing as well as a focus on social justice issues including pay and working conditions. Businesses will be expected to meet both regulatory and consumer expectations.

Manufacturers and suppliers will need to ensure particularly stringent testing of, and carry out regular risk assessments on, newly created eco fabrics and materials that are not commonly used in the industry. Perceived greenwashing will be challenged, particularly in today's call-out culture. Litigation against large corporates in relation to social issues such as climate change and worker exploitation is on the rise across industries. Businesses at every level of the supply chain should proactively examine how regulatory obligations are being met, ensure due diligence is conducted with regard to supply chain partners, and review marketing and product materials to avoid inaccurate or misleading claims.

A proactive approach to risk mitigation before a crisis remains one of the best ways to protect your business and reputation.

# CONCLUSION

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

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

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

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

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

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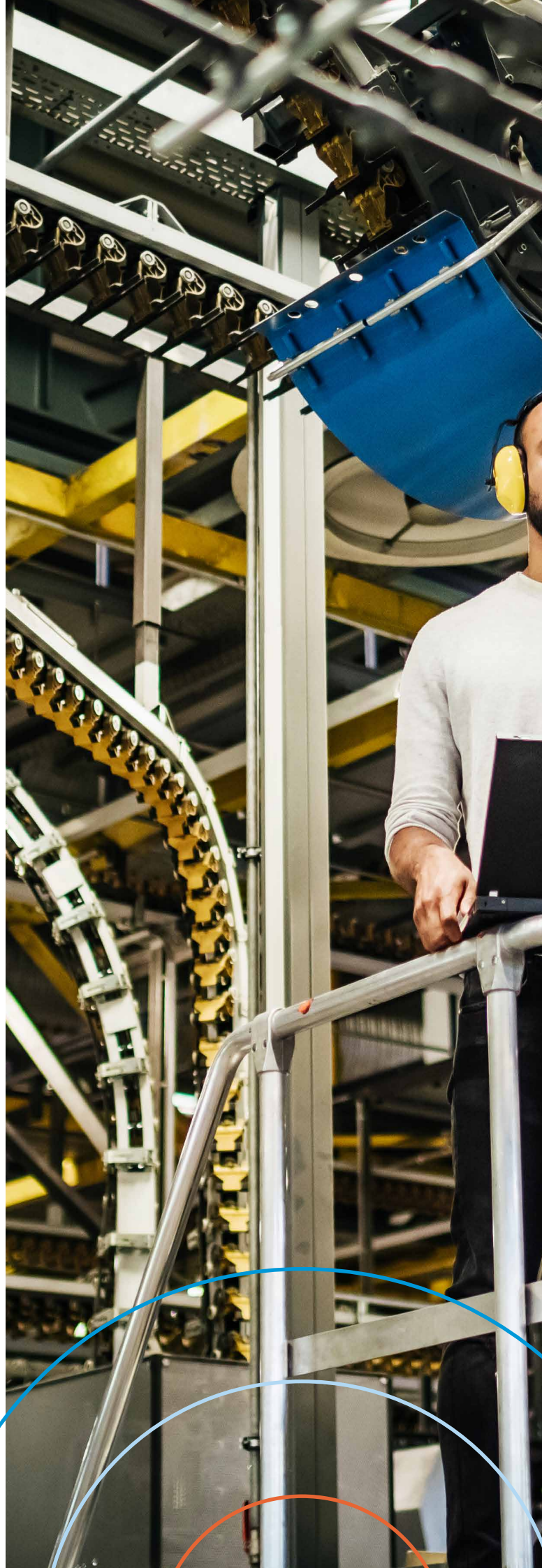
# ABOUT SEDGWICK BRAND PROTECTION

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

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

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

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

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

So, while we predict continued change in 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 events, give us a unique perspective on the risks, challenges, and often overlooked opportunities associated with the reputational threats you face every day.

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

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

For further reading, our previous index reports are available for you to download:

**Q1 2021 European edition: DOWNLOAD HERE**

**2021 State of the Nation European edition: DOWNLOAD HERE**

**Q3 2020 European edition: DOWNLOAD HERE**

**Q2 2020 European edition: DOWNLOAD HERE**

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**EUROPEAN INDUSTRIES**

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