RECALL INDEX
2022 EDITION 2

PRODUCT RECALL
UNITED STATES EDITION

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

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The Sedgwick brand protection recall index is a vital resource for manufacturers, suppliers and retailers who need an unbiased and educated perspective on past, present and future recall data and product safety trends. It reviews five product categories: Automotive, Consumer Products, Food and Drink, Pharmaceutical and Medical Devices.

The report collects and analyzes data from the U.S. Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), the U.S. National Highway Traffic Safety Administration (NHTSA) and the U.S. Department of Agriculture (USDA) to provide businesses with exclusive insights and guidance valuable to their operations.

This edition brings you recall data from the second quarter of 2022, April through June, as well as an early look at July data. The sneak peek into July shows the total number of impacted units recalled for the year has now surpassed the one billion mark. For context, only two years on record (2018 and 2022) have ever achieved this feat. As things stand, it is expected that 2022 will be a record-breaking year for recalled products in the U.S.

In addition, this report offers expert analysis and guidance regarding what lies on the horizon for business leaders and regulators. Insights from some of our strategic partners at leading law firms will also help your organization plan for new regulatory developments within your sector.

We are seeing regulators and consumer groups increasingly push for companies to be more proactive in their recall and risk planning. The FDA published documents encouraging both pharmaceutical and medical device companies to have risk management plans in place.

Agencies and lawmakers are also taking steps to learn from past mistakes. In April the Senate passed a bill to help strengthen the nation's medical and public health preparedness and response framework for future pandemics. Congress along with multiple state and federal agencies are examining last quarter's infant formula recall and resulting shortages to determine what changes may need to be made both in terms of the FDA's response and adding resiliency to the supply chain.

Whether you select the sections most relevant to your industry or read the recall index cover-to-cover, we promise you will gain a new perspective about current trends and what is around the corner that could affect your business or your industry.

One final note, this edition of the recall index focuses on U.S. recall data and regulatory developments. If your business also includes operations outside the United States, we encourage you to read our European Edition. Like this report, we share recall data from regulatory agencies and offer expert analysis on product safety and regulatory changes, but from the perspective of companies operating in the UK and the European Union.

European edition available here: click here

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

Q1 2022 U.S. Recall Index: click here
Q4 2021 U.S. Recall Index: click here
Q3 2021 U.S. Recall Index: click here
Q2 2021 U.S. Recall Index: click here

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2022 U.S. edition 2

AUTOMOTIVE

After a six-year debate, the National Highway Traffic Safety Administration (NHTSA) finalized Corporate Average Fuel Economy (CAFE) standards for fuel efficiency and increased the civil penalties dramatically. Automakers will be potentially liable for millions of dollars in fines.

NHTSA also took a big step forward in acknowledging the growth of the autonomous vehicle (AV) market by updating crashworthiness standards to reflect the realities for AVs. The changes will help protect occupants in AVs and account for differences in safety features and passenger seating between AVs and traditional vehicles.

NHTSA is not the only agency that has been busy. More agencies are cracking down on false advertising and unscrupulous business practices related to auto purchases. The Federal Trade Commission (FTC) and the Consumer Financial Protection Bureau (CFPB) have issued new rules and advisories.

> *"In March, NHTSA finalized the CAFE standards requiring passenger cars and light trucks to have a fleet average of 49 mpg by 2026. While improving fuel efficiency, these changes are set to increase civil penalties for CAFÉ violations."*

NHTSA establishes new fuel economy standards

In March, NHTSA finalized the Corporate Average Fuel Economy (CAFE) standards to increase fuel efficiency by 8% annually for model years 2024-25, and 10% annually for model year 2026. The new standard will require passenger cars and light trucks to have a fleet average of 49 miles per gallon by 2026.

This change is expected to increase the estimated fleetwide average by nearly 10 miles per gallon for model year 2026, relative to model year 2021. NHTSA predicts that these changes will reduce greenhouse gas emissions, air pollution, and the nation's dependence on oil.

However, these changes come with risks for automakers as NHTSA issued a final rule that increased the civil penalty for CAFE violations from $5.50 to $14. The rule has been in discussion since 2016 and sets fees for each 0.1 mile per gallon (mpg) that a manufacturer's performance falls short of the CAFE standard. That amount is multiplied by the number of vehicles in the manufacturer's fleet to determine the full civil penalty amount.

That means that if an automaker has a vehicle that, per CAFE requirements must average 40 mpg, but only averages 39 mpg, the manufacturer will be fined $140 for each vehicle it sold (at the new new $14.00 rate). This compares to $55 per vehicle at the old $5.50 rate.

If that same manufacturer sold 200,000 substandard vehicles, this would equate to$28 million in fines being levied at the new $14.00 rate, versus $11 million at the old $5.50 rate.

The final rule applies to vehicles from model year 2019, a move that frustrated some automakers who felt it should only apply to new vehicles. The rate is scheduled to increase to $15 per 0.1 mpg for model year 2022 vehicles to account for inflation. NHTSA argues that the automotive industry has known about this bill for six years, so the agency is unlikely to be lenient with its enforcement.

Crash testing standards updated for autonomous vehicles

Also in March, NHTSA issued a first-of-its-kind final rule for crashworthiness to ensure it included autonomous vehicles (AVs) which lack traditional manual controls in the occupant safety standard requirements. It is one way that the agency is working to make sure regulations reflect the technological advances in the industry.

The rule updates traditional terminology to be inclusive of AVs, such as changing "steering wheel" to "steering control" and adding new definitions for "driver air bag" and "driver dummy."

The new rule also makes amendments to account for the new terminology so that occupants in AVs have the same level of safety as those in traditional vehicles. AV manufacturers will be required to use "front row" instead of "driver's seat" as a spatial reference as well as other adjustments related to the treatment of air bags, seat belts, and describing the placement of test dummies during crashworthiness testing.

The rule is focused on crashworthiness and not on driving or performance requirements for AVs. However, it is a significant acknowledgement that regulators know these types of vehicles are growing in popularity. That's why NHTSA is working to make sure safety is still top-of-mind.

> *"NHTSA argues that the automotive industry has known about this (CAFÉ) bill for six years, so the agency is unlikely to be lenient with its enforcement."*

Electric vehicles continue to gain ground

Most industry insiders believe the writing is on the wall for electric vehicles (EVs) to replace cars powered by internal combustion engines. Auto industry lawyers with Foley & Lardner predict that with the current progress of increasing mass production in new EV factories, the shift to EVs could happen within a decade. Still, it won't be a seamless transition. There is a critical need for more efficient EV manufacturing processes and techniques including the potential for wireless EV charging, according to the legal experts.

In another sign of growth for EVs, the Biden Administration is working to create a national network of 500,000 electric vehicle charging stations by 2030. The Federal Highway Administration announced a Notice of Proposed Rulemaking in June to set minimum standards and requirements for projects under the National Electric Vehicle Infrastructure (NEVI) Formula Program.

The proposed rule would lay the groundwork for states to build federally funded charging stations across a national EV charging network. It would also establish workforce requirements for installation, maintenance, and operations to increase the safety and reliability of charging station function and use, and support workforce development and on-the-job training in helping to create highly skilled jobs around the nation.

One of the biggest obstacles to the growth of the EV market is the global supply chain. There has been a surge in battery metal prices combined with the ongoing shortage of semiconductor chips. Lithium, cobalt, and nickel prices have soared impacting production of EVs. It is certain however that even if the change is slower than manufacturers and consumers would like, the shift to EVs is coming.

> *"One of the biggest obstacles to the growth of the EV market is the global supply chain. It is certain however that even if the change is slower than manufacturers and consumers would like, the shift to EVs is coming."*

Regulators focusing on automotive sales and servicing

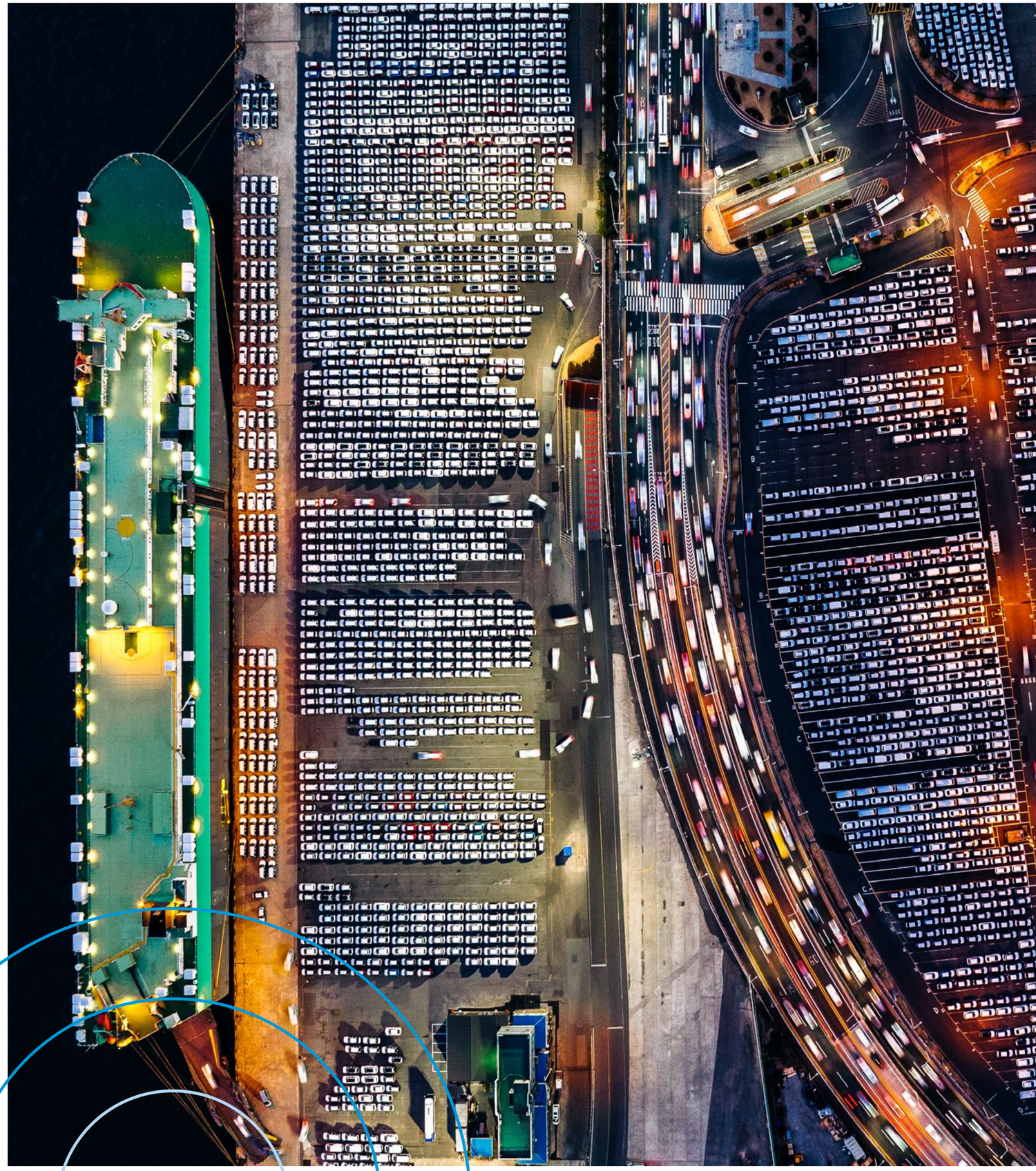
In June, the Federal Trade Commission (FTC) issued a notice of proposed rulemaking (NPR) for regulations that would protect consumers from junk fees and bait-and-switch advertising tactics during the car-buying process. The Commission wants to ensure consumers have the ability to comparison shop and are not hit with thousands of dollars of unwanted junk charges. Their approach is designed to make the car-buying process clearer and more competitive. There is also a provision that would allow the Commission to recover money when consumers are misled or charged without their consent.

According to the Commission, it has brought more than 50 law enforcement actions related to automobiles, and helped lead two nationwide law enforcement sweeps that included 181 state-level enforcement actions in these areas in the last 10 years alone. Despite that, automotive issues are still among the top ten types of complaints the FTC receives, with more than 100,000 consumer complaints annually over the past three years.

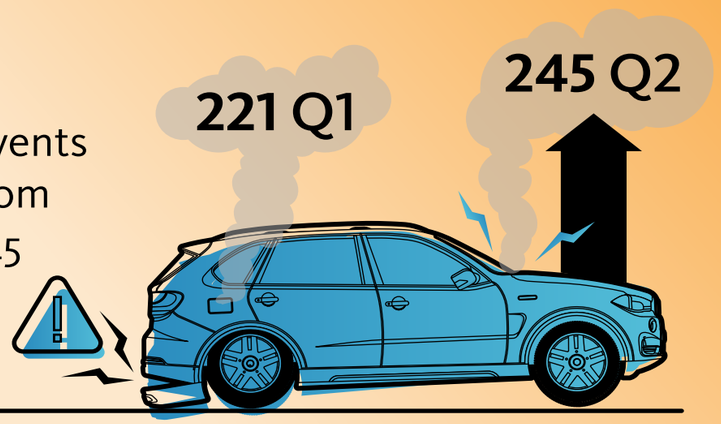
The proposed measures would ban bait-and-switch claims and deceptive advertising, fraudulent junk fees for add-on products, services that provide no benefit to the consumer, and surprise junk fees. They would also require dealers to provide full upfront disclosure of costs and conditions, excluding only taxes and government fees.

The FTC is not the only regulatory agency looking to protect car buyers. The Consumer Financial Protection Bureau's (CFPB's) Spring 2022 edition of its Supervisory Highlights devoted part of its report to several violations of the prohibition on unfair, deceptive, or abusive acts or practices (UDAAPs) related to auto loan servicing. Included in the CFPB's discussion were wrongful repossessions at auto servicers. Earlier this year the CFPB released a bulletin advising auto lenders, loan holders and servicers that the Bureau would hold them accountable if they carried out UDAAPs during the repossession of vehicles.

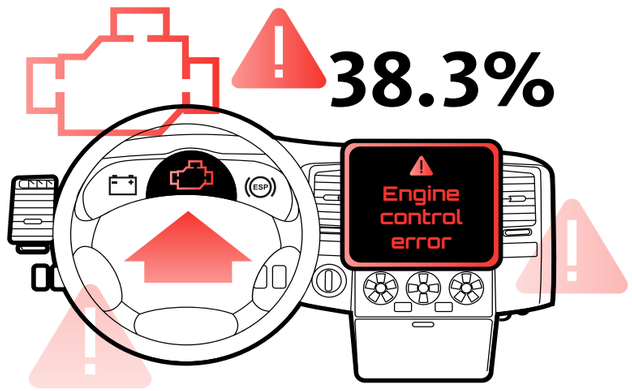
Auto dealers, especially those with a financial arm for servicing loans, should be aware that more attention is being paid to advertising, servicing and fees, and there are greater penalties for companies that ignore the rules.



Automotive recall events **increased 10.9%**, from 221 in Q1 2022, to 245 in Q2 2022.



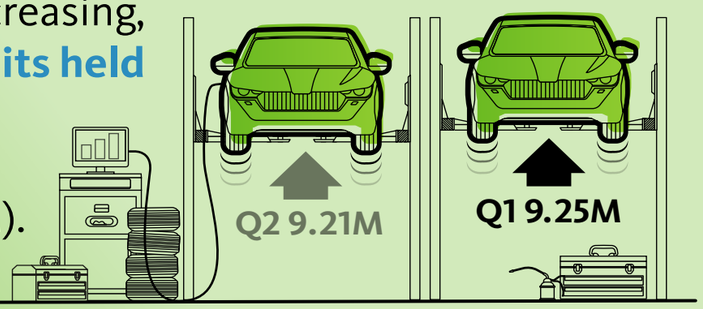
Despite this increase, total events remain in-line with the quarterly average of the last 5 years (243).



At 3.5M impacted units, **Power trains** were the leading cause of recall in Q2 (38.3%).

Power trains have not featured as a leading cause of U.S. automotive recall in over 10 years.

Despite events increasing, total **impacted units held constant** with the previous quarter (at 9.21M vs 9.25M).



This figure sits 15.7% below the quarterly average recorded for the last 5 years (10.9M).

JULY insight

There were 78 U.S. automotive recalls in July 2022, slightly more than the monthly average for Q2 2022 of 72. Despite the increase in the number of events, the number of units recalled dropped by 90.5 percent. There were only 878,763 units recalled in July, compared to a Q2 2022 monthly average of 3 million.

SECOND QUARTER BY THE NUMBERS

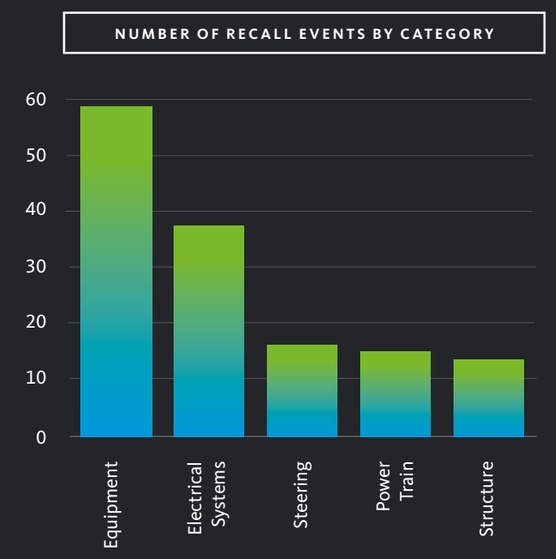
After decreasing for two consecutive quarters, the number of automotive recalls increased in Q2 to 245, up 10.9 percent on Q1's total of 221. There were 9.21 million units involved in the Q2 2022 recalls, a number that is virtually stagnant from the 9.25 million units recalled in the previous quarter.

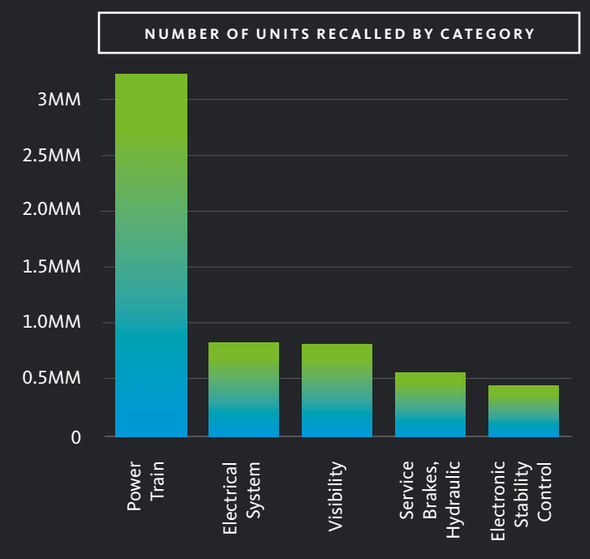
For the seventh-consecutive quarter – and the 10th time out of the last 11 quarters – equipment was the leading cause of NHTSA recalls. In total, equipment accounted for 58 recall events (up from 46 in Q1, and 37 in Q4 of 2021). Power train issues affected 3.53M vehicles, accounting for 38.3% of all units recalled during this quarter.

The largest category of NHTSA recalls was again automobiles with 223 events, up from the 192 in Q1 2022. There were 8.7 million automobiles recalled this quarter, which is down from the 9.1 million in Q1 2022.

There have been 22 recalls in the electric vehicle category this year, affecting 2.2 million units. The most common reason for EV recalls is electrical system issues, which were responsible for seven of the 22 recalls and involved 2.1 million vehicles.

The number of tire recalls stayed the same compared to Q1 at just three. However, in terms of units recalled, tires were the second largest category with 249,000. That's the most since Q1 2021. The number is significantly higher than the 16,418 units affected in Q1 2022.





VANESSA MILLER, PARTNER,
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THE IMPACT OF SUPPLY CHAIN DISRUPTIONS ON RECALL RISK AND WHAT'S AHEAD

The idea of producing products as needed to meet consumer demand as opposed to stockpiling inventory in anticipation of what the market might want has been a principle in automotive manufacturing for 100 years. Henry Ford wrote about "just-in-time" (JIT) manufacturing, or lean manufacturing, in the 1920's.

The model is incredibly efficient when it works well. It is a great way to drive profits to one sole supplier and manufacturers only need to negotiate contracts and manage processes and compliance issues with a single supplier. There is no inventory or warehousing, which is also a big cost saving.

However, the same things that make this model so efficient are what make it so vulnerable. This system of manufacturing is why the automotive industry was the first sector to be significantly impacted by the global shortage of semiconductor chips.

The real fallout from the scarcity of products started to appear at the start of 2021 for car makers – particularly with microchips or semiconductors chips. The industry did not have advance orders and did not maintain a backlog of supplies. The industry also was reacting to the whiplash effect of a production fall off and then drastic increase in orders after the 2020 shutdowns and followed by another sharp uptick in volumes driven by original equipment manufacturers (OEMs) and consumer demand for automobiles.

Other industries, such as computer companies, were increasing their own demand for semiconductor chips as more and more people were working from home and needed technology products to facilitate that switch. Chip makers focused on creating the types of more complex and sophisticated chips used in consumer electronics products and not the older, less profitable chips used in vehicles.

As the pandemic continued to wear on and semiconductor chip factories were shut down, the supply shortage became more acute. For auto makers there was a scramble to get replacement parts. However, the automotive industry is highly regulated and there is a very lengthy approval process that any parts must go through, all the way down to the subcomponent level.

The testing, validation and approval processes for any part being newly introduced to a vehicle from a new supplier can take three months to a year. It is impossible for manufacturers to just swap out parts or suppliers in a complicated assembly. There must be approvals on multiple levels including from the OEMs.

Entire production lines of popular cars were being shut down because of part shortages. Moreover, as the pandemic continued, lines also went down because of mandatory shutdowns and worker shortages under government-mandated public health restrictions.

Automotive companies had to get creative. Some looked to replacement parts, short-term "band-aid" fixes and other alternatives. That meant that while parts still had to go through a validation and testing process, they may not have been screened as rigorously as the original assembly parts. Sometimes their usage was a one-off approval of small supplies of chips because that was all that was available.

OEMs and their suppliers had to do a risk assessment for using parts from new suppliers with less testing and validation so that they could keep assembly lines running and get vehicles to market. In some cases, if components weren't available, vehicles would be manufactured without those parts and put on a lot to wait for the missing components. Assembling vehicles this way in a different order and plugging in parts later also created some risk since it was outside the normal process.

Higher risk of recalls

Automobile manufacturers did continue to follow review and validation processes even in these challenging circumstances. But we can still expect some product liability issues and recalls because a lot of protections and hurdles built into the very onerous process of getting qualification and validation for use in the field had to be relaxed.

The question moving forward is who will bear the risk for the decision to change out parts, even when both sides agreed to and approved the change. In order to accommodate the replacement parts and maintain continuity of supply, some suppliers have asked for an indemnity agreement from their customers with respect to the replacement parts. Although it will not absolve the supplier of all liability to the extent that there is a failure in the supplier's product, it can serve to mitigate risk associated with the customer-driven change or request to utilize a replacement part in the supplier's assembly. As issues arise in the field, there may be other commercial and legal negotiations over which party should bear the risk or how the risk for warranty and recall issues should be shared.

These band-aid fixes that were used because parts were unavailable through normal supply chain processes are just one factor that will create more recall risk due to the pandemic and the associated changes in normal production. Another issue that will impact product quality and recall risk is the shut down and then cold re-start of many manufacturing and assembly lines. Production lines were stopped and re-started multiple times during the pandemic. It is normal to have issues and quality spills at the start of production (SOP). Multiply that across every vehicle line, every assembly line, every OEM, across the entire global industry.

In addition, the industry lost skilled employees or had to work with fewer people. Some employees may have had less training than normal because of workforce changes under public health emergency regulations.

In addition to the semiconductor shortages, there were shortages of raw materials across the industry. Some replacement parts were in short supply. Because of global transportation disruptions, parts sat in place more often than usual, sometimes on ships or in hot warehouses.

The industry certainly did its best to mitigate risk and government regulations required certain processes be followed to protect public safety. Transparency is not just expected in the auto industry, it is required for any changes to materials or processes. There are stringent approval processes, and it will come to light quickly if rules aren't followed. Yet even with these protections, we can expect some issues to arise.

VANESSA MILLER, PARTNER,
FOLEY & LARDNER

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The next battle

The semiconductor chip supply is predicted to improve next year, though it may be a lingering challenge for a while. In the meantime, the automotive industry should be looking to the next big supply challenge – batteries for electric vehicles (EVs).

There is a big push by regulators in the U.S. and globally to switch all new car sales to EVs over the next 10-20 years. The UK's ban on sales of new combustion engine cars and vans is scheduled to come into effect in 2030. The infrastructure, pipeline and raw materials are not in place to supply all the batteries that are needed.

Some companies are rushing to find a solution. Any time people are rushing, mistakes are more likely to be made. Mistakes with batteries can be particularly harmful. Batteries have a lot of potential safety issues. They are very sensitive and inherently flammable.

There will be a tipping point where the demand for traditional vehicles will drop and there will be greater demand for EVs than there is for traditional vehicles. Government regulations, like bans on new combustion-engine vehicles, will push this demand. For a while, suppliers will have a foot in both camps – EVs and traditional vehicles. At some point they will have to decide where to put the most resources and devote more time, energy and research and development to switch to EVs. It is a gamble. There are rarely assurances about volume or order guarantees in the automotive industry.

There are some lessons manufacturers can take away from the semiconductor chip shortage that could apply to batteries. First, have dual sourcing options and qualify alternate suppliers at the outset. It is more expensive compared to planning to use one strategic supplier. However, at this point there is too much uncertainty around battery suppliers and manufacturers. It is not clear who will be viable, who will have highest quality of parts and who can meet the volumes needed since the technology is changing rapidly and there will be a need to ramp up quickly.

Companies should also conduct supply chain mapping for the battery supplier. Know where each subcomponent comes from and make sure the battery supplier has done the same due diligence. There should be sub-suppliers identified so there is a safety net in place.

The semiconductor chip shortage has tested the resiliency of the automotive industry. We can expect some processes to change, especially as we move into the era of more EV production. However, the attention to safety will stay rigorous, as will government oversight.

> *“According to the Sleep Foundation, inclined sleepers and crib bumpers have been linked to nearly 200 infant deaths in recent decades.”*

CONSUMER PRODUCTS

Child safety is a constant priority for U.S. regulators and lawmakers. The new Safe Sleep for Babies Act is one of the latest examples of their efforts to protect infants, but definitions within the law could cause some confusion for manufacturers of certain infant products.

The Federal Trade Commission (FTC) is aggressively enforcing its Made in the USA Rule, pursuing civil penalties of three times the manufacturer’s profits in one case. Companies should be aware of any marketing claims that may be in violation.

Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) chemicals have been attracting the attention of regulators for years. They are also creating more risk for litigation. Inconsistent regulation among states and the federal government creates vulnerabilities for companies and opportunities for plaintiffs’ lawyers.

> *“Even for companies working to phase PFAS out of their products, it is important to assess where their vulnerabilities may be in terms of potential litigation and start preparing now.”*

Safe sleep for babies act now law

In May, President Biden signed into law the Safe Sleep for Babies Act, which bans inclined sleepers and crib bumpers. The law also prohibits the manufacturing, selling or distributing of crib bumpers, the padded materials that are inserted around the inside of a crib to prevent children from being trapped in the crib’s opening. Inclined sleepers and crib bumpers have been linked to nearly 200 infant deaths in recent decades, according to the Sleep Foundation.

Normally a law offers clarity to manufacturers, however experts at Crowell & Moring predict infant sleep product manufacturers may have a difficult time interpreting parts of the new law. The main concern is around the age of children referenced in the definition of “inclined sleepers.” The new act states these are products, “with an inclined sleep surface greater than ten degrees” for “an infant up to 1 year old.” This may be in conflict with another rule.

In June 2021, the Consumer Product Safety Commission (CPSC) issued a final rule for “all infant sleep products” that weren’t already under another CPSC mandatory safety standard. This would include inclined sleepers. According to the CPSC rule, the age for these products are “infants up to five months old.”

That discrepancy between the CPSC rule and the new federal law could in effect repeal the Commission’s definition and force manufacturers to conduct their own risk assessment on which definition to follow in marketing and designing their products. It is expected the CPSC will correct this discrepancy, but until that is done, manufacturers should remain cautious.

Other infant products have also caught the attention of the CPSC, which is working with major manufacturers to issue warnings that rockers targeted for infants and toddlers should never be used for sleep. This is a slight change for the Commission, who has in the past pressured companies to recall infant products such as infant loungers that had been used for sleeping in some instances, despite being clearly labeled that they are not sleep products.

Risk of PFAS litigation rises

Virtually every category of consumer products has some connection to PFAS. Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are a class of more than 3,000 synthetic chemicals used in a wide range of consumer, commercial, and industrial products. Nonstick pans, waterproof clothing, cosmetic packaging, stain-resistant furniture, umbrellas, and dirt-resistant rugs have all likely been treated with at least one of the thousands of PFAS.

Regulation of PFAS is complicated and constantly changing, especially as more and more states move to ban certain uses of PFAS. Even at the federal level, both the Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA) have different rules around the chemicals.

But compliance with the “whack-a-mole” environment of new regulations with different timelines and restrictions across multiple states and at the federal level is not the only risk companies face. Lately the industry is seeing a pronounced increase in litigation. In recent months, dozens of PFAS class action complaints have been filed against fast food chains, cosmetic manufacturers, and apparel companies.

Some suits are claiming that companies didn’t disclose the presence of PFAS in a product or its packaging. Other suits allege false claims or false advertising if a company says its products are safe or environmentally friendly, but then are found to contain PFAS.

If PFAS are added to California’s Proposition 65 (Prop 65) List, this will open up another category of vulnerability for companies. California Prop 65 is a chemicals management regulation that requires businesses to provide warnings about significant exposures to chemicals that cause cancer, birth defects, or other reproductive harm. These chemicals can be in the products that Californians purchase, in their homes or workplaces, or released into the environment. Currently there are more than 950 substances on the list including three PFAS chemicals. Prop 65 has a citizen suit provision often used by plaintiffs’ firms and non-government organizations (NGOs) that allows anyone to bring a claim on behalf of the state. This could trigger a flood of lawsuits if more PFAS are put on the list.

Even states are getting on the PFAS litigation bandwagon. In May, Massachusetts joined a multi-district lawsuit in South Carolina against a number of companies alleged to have manufactured PFAS and/or aqueous film-forming foam, a firefighting foam that contains PFAS. The focus of the claim is product liability, according to attorneys at Foley Hoag. However, the relief the plaintiffs are seeking is typical for a state superfund law complaint, which could open up yet another risk for companies.

Even for companies working to phase PFAS out of their products, it is important to assess where their vulnerabilities may be in terms of potential litigation and start preparing now.

FTC taking hard line on made in the USA rule

The Federal Trade Commission (FTC) brought its first action under the new Made in USA Labeling Rule against a lithium-ion battery company that falsely advertised its products as being USA-made. The company and its owner were ordered to pay civil penalties of more than $100,000, equal to three times the manufacturer's profits attributable to the illegal activity. It was also instructed to stop claiming that products are made in the United States unless they can verify the products meet the criteria for final assembly and processing, as well as ingredient and component sourcing and production.

The agency's second Made in the USA enforcement action was directed at a clothing company that falsely claimed its apparel is Made in USA when it is actually imported. That company went so far as to post a video bragging about how it added phony Made in USA labels to its products. That company was ordered to pay $211,335, stop making bogus claims, and be honest about where its products are made.

Manufacturers should not think the rule only applies to product labeling. The scope is much broader and includes any mail order catalog or mail order promotional material including a seal, mark, tag, or stamp. It also extends to claims made with online product listings, social media posts, and company websites.

Legal experts caution that the size of the civil penalties – three times the company's profits – are significant and shows the FTC's intention to aggressively enforce the rule and punish violators. Since the FTC has clearly made enforcing this rule a high priority, manufacturers should expect increased surveillance and more cases. If they have not yet reviewed the new standards and updated their own claims, they need to take steps immediately.

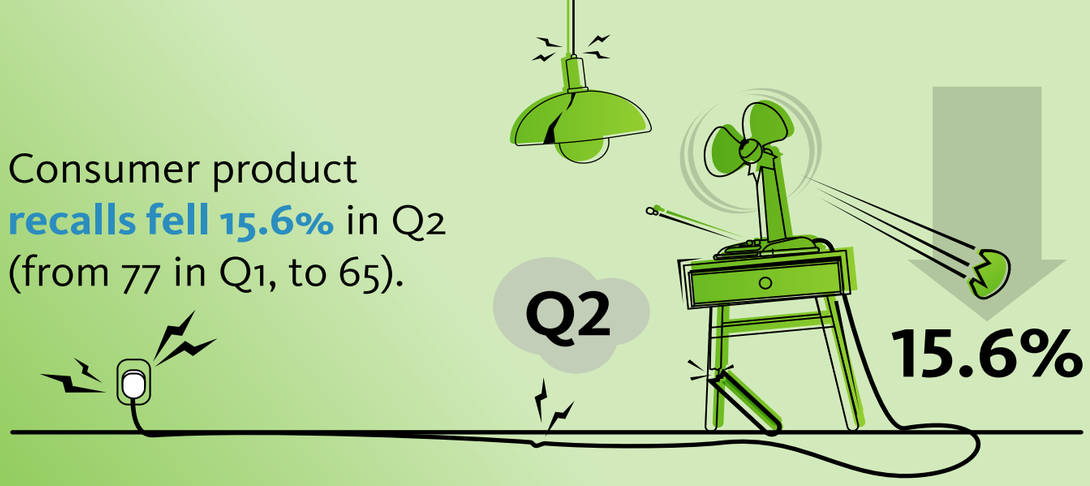
New EPA labeling for disinfectants and sanitizers

Consumers' desire for sanitizers and antimicrobial products has risen sharply since the start of the pandemic. In May, the EPA launched a new Design for the Environment (DfE) logo that will appear on antimicrobial products like disinfectants and sanitizers within the next year that have met new EPA criteria. The goal is to help consumers and commercial buyers identify products that meet a rigorous set of chemical and toxicological standards.

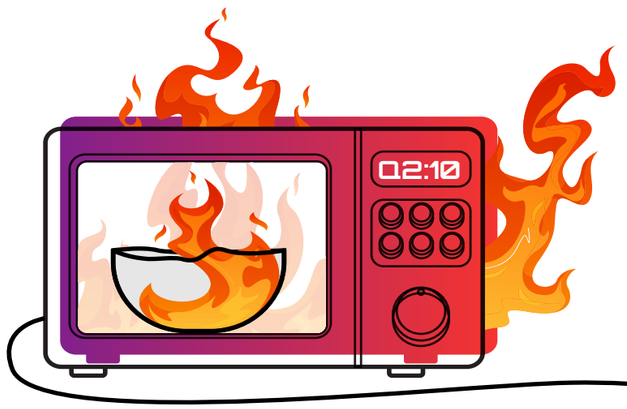
In its announcement for the new logo, the EPA recognized that manufacturers need to make a heavy investment in research and reformulation to ensure that their products meet the DfE certification requirements. The criteria will assess human health and environmental effects, product performance, packaging, and ingredients. The intent of these requirements includes minimizing possible risks to human health and protecting fish and other aquatic life.

The agency is careful to note that the logo is not an endorsement, but simply verifies the product has met the DfE standards. However, some manufacturers may consider the mark a competitive advantage and may want to start reviewing the certification process.

Consumer product **recalls fell 15.6%** in Q2 (from 77 in Q1, to 65).



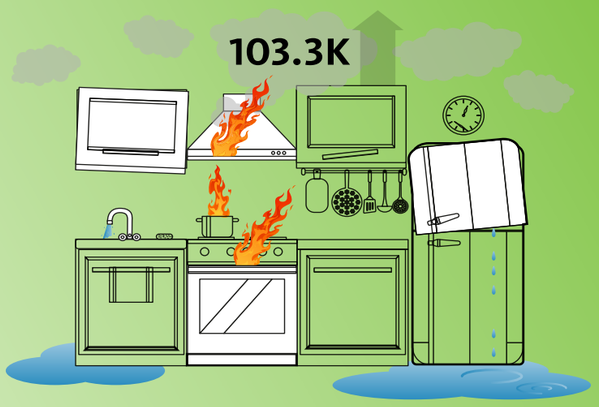
Despite this decline, events remain 4.4% above the quarterly average of the last 5 years.



Fire risks accounted for the greatest number of recall events in Q2 (with 10).

Fire risks also accounted for the greatest number of impacted units (2.7M).

While total impacted units fell 3.5% (to 6.7M) in Q2, the **average recall size increased 14.3%** (to 103.3K).



Home appliances accounted for exactly one third of all impacted units in Q2 (at 2.2M).

SECOND QUARTER BY THE NUMBERS

Compared to Q1 2022, the number of consumer product recalls dropped 15.6% in Q2 2022. The number of units recalled also dropped slightly to 6.7 million, a 3.5% decline from the previous quarter.

In contrast, the number of reported incidents increased for the third consecutive quarter, rising 37.9% to 1,178 in Q2. The number of injures rose slightly from 146 to 148. Unfortunately, there was a single death reported in Q2, increasing from zero deaths last quarter.

Fire risks accounted for the top recall hazard for the seventh consecutive quarter, though the number fell 16.6% from Q1 to 10 recalls this quarter. Fire was also the leading reason for recalls by number of units, impacting 2.7 million units or 40.5% of recalled units in Q2.

Sports & Recreation and Apparel tied with the most recalls by product category with 11 events each in Q2 2022. This represented a 50% decline in the number of Sports & Recreation recalls, while Apparel showed no change from the previous quarter, holding at 11 events. Home Furnishings, Toys, and Personal Care products tied for third place with seven recalls each.

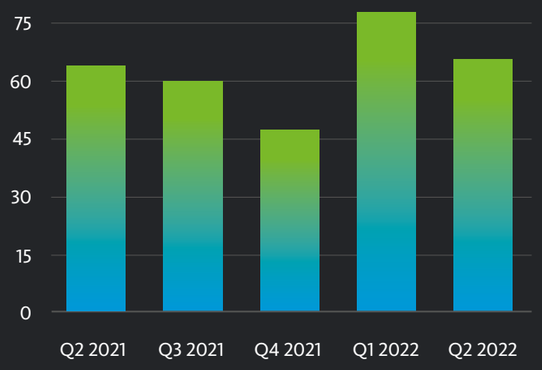
In terms of units, Home Appliances was the leading product category with 2.2 million units recalled, or 33.3% of all units in Q2. A recall that affected 1 million glue guns and another that involved 635,000 air fryers helped drive up the number of units in this category. Power Supplies was second with 1.4 million units linked to a single recall of breaker boxes and electrical panels.

JULY insight

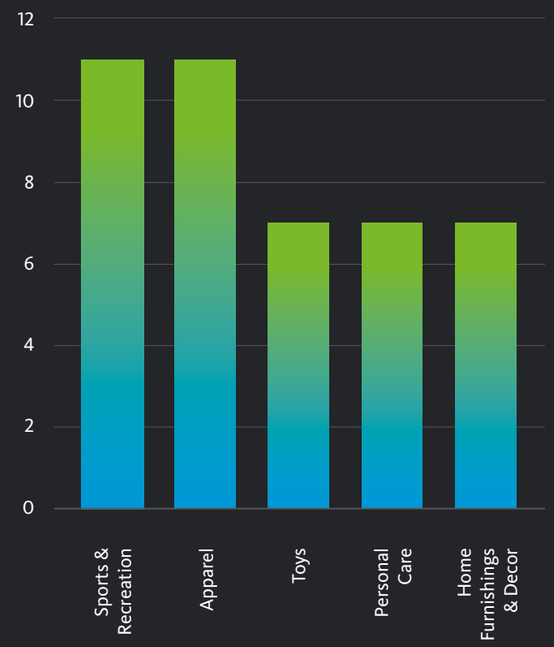
The 21 consumer product recalls in July 2022 were exactly the same as the monthly average from Q2 2022. However, the number of units dropped by nearly 43.9 percent to 1.3 million in July 2022 compared to the Q2 2022 monthly average of 2.2 million units.

As a category, Sports & Recreation had the most recalls, with 10 events. Toys had four recalls and Yard & Garden and had three. In terms of risk, there were four recalls linked to vehicle crash concerns for products such as lawn tractors and motorcycles. Fire and injury hazards were cited as risks in three recalls each.

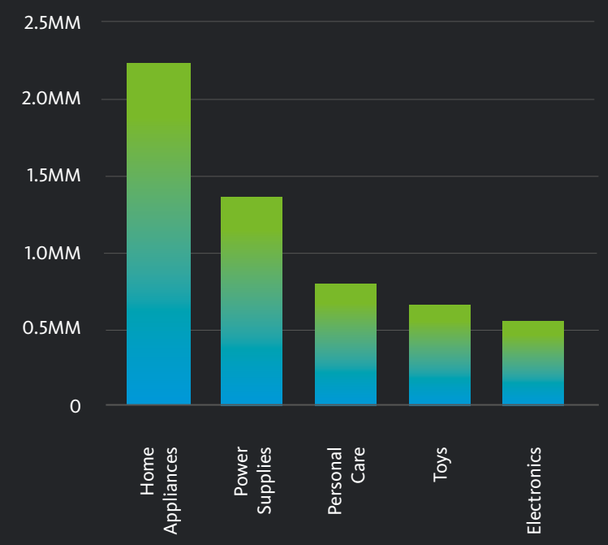
NUMBER OF RECALLS BY QUARTER



NUMBER OF RECALLS BY RISK TYPE



NUMBER OF UNITS RECALLED BY CATEGORY



WILLIAM TROUTMAN, PARTNER,
NORTON ROSE FULBRIGHT

ONSLAUGHT OF NEW PFAS REGULATIONS AHEAD

Perfluoroalkyl and polyfluoroalkyl substances, or PFAS, are a class of more than 3,000 synthetic chemicals found in a wide range of consumer, commercial and industrial products. They are used in everything from food packaging and high-performance outdoor clothing to household cleaners, carpeting and corrosion-resistant pipes and wires.

While PFAS have been used since the 1940s, in recent years, state and federal regulators, encouraged by advocacy groups, are targeting the substances for their potential risks to human health and the environment. In June the Environmental Protection Agency (EPA) announced new drinking water health advisories for PFAS chemicals and more than 15 states have enacted or proposed new regulations, some that go into effect as soon as December 2022.

Patchwork of PFAS regulations

For the companies who use PFAS chemicals in their products, navigating the patchwork of state and federal regulations is challenging at best. On the federal level, the EPA has adopted a "strategic roadmap" that outlines expected efforts through 2024. As part of this process, EPA issued a regulation for PFAS use in products that effectively divides the chemicals into three different classes: one class that is essentially banned, a second class whose use may be permitted subject to EPA's review of health and environmental impact data and a third class that is not yet regulated in most products but may be regulated in the future.

The agency also looks at PFAS from two different perspectives. One is the frequency of the chemical compounds showing up in the environment, such as community water supplies. PFAS chemicals break down very slowly and persist in the environment and in organisms for a long time, earning them the name "forever chemicals." The other perspective is the potential risk to human health from exposure through use in products treated with PFAS, such as nonstick pans, waterproof clothing and stain-resistant furniture.

State regulations regarding PFAS tend to be less nuanced. Generally, states lump all 3,000 chemicals into the same category and treat them equally. And every state has its own approach to what products can use PFAS and whether the chemicals are banned outright or simply require that their presence is disclosed. The difference between EPA and state regulation is due, at least in part, to EPA's functioning within existing statutory authority under the Toxic Substances Control Act, while state legislators are enacting new laws without the same constraints.

Target on essential use

Often times in product chemical compliance, the issue is contaminants, defined as chemicals found in products that are not part of the standard product formulation. This frequently results from contaminants getting past the quality assurance process. But PFAS compounds typically have been intentionally used in products to provide non-stick surfaces, stain resistance, water resistance and other performance attributes. While some of these uses provide nice-to-have benefits, like unstuck fried eggs, PFAS treatments are used in high-performance gear for skiers, professional sailors, park rangers, firefighters, military personnel and others for whom protective gear is an essential health and safety requirement. Some PFAS chemicals offer other safety benefits, such as those used by firefighters and the military in aqueous film-forming foam (AFFF) to extinguish hydrocarbon fuel fires.

Early-stage regulation of PFAS substances in products largely seemed to separate these nice-to-have applications from essential uses. They also typically focused on products and uses that have viable alternatives to using PFAS. But advocacy groups and some regulators are now increasingly pushing for PFAS regulations targeting even these essential uses.

Recently the Assembly in California passed a bill that would ban PFAS in all textiles for use in households and businesses, with only a narrow exception for personal protective equipment (PPE) and equipment exclusively for military use. It is now being discussed in the Senate and is expected to pass into law. Recent amendments slightly expand the narrow exception to include "outdoor apparel for severe wet conditions." It's yet unclear what companies that make performance clothing will do in response to the California law, or whether the California Senate will recognize that weekend warriors also need protective gear. In fact, due to their more casual activity, this group of consumers may need it more than extreme users who train for these extreme conditions and are well aware of the risks.

Consumer product companies that currently use PFAS chemicals must start figuring out the timelines for the new regulations in all the jurisdictions they produce and sell their merchandise. They also need to evaluate if there any product lines they need to discontinue because they don't have an alternative to PFAS that may be essential to their products—whether because the technology is not widely available or the customers in the market segments they serve cannot afford these new technologies.

The need for RSLs

This rise in an inconsistent and rapidly changing regulatory landscape for such a big category of chemicals may be the tipping point that forces more companies to implement a comprehensive approach to chemicals compliance.

The solution may lie in adopting a restricted substances list (RSL). Five or 10 years ago, companies might have thought an RSL was unnecessary. Many organizations have a piecemeal approach to chemicals compliance, relying on upstream partners to provide compliant products and addressing significant issues one-by-one. But given how widely-used PFAS have been for decades, and how many states are now imposing new regulations, there is a compelling business case for adopting an RSL to reduce the risk of violating state laws.

An RSL is a protocol for retailers and manufacturers to list all the substances that are limited or not permitted in the products they make or sell. That list is shared with suppliers instead of having individual conversations about each substance and each product. Some companies generate and maintain the list internally. There are also third-party advisors and associations that have well-respected, and routinely updated, global RSLs, particularly for the apparel and footwear sector. Using a respected third-party RSL can simplify things for the internal compliance and manufacturing teams.

Questions around product disposal

Another change in PFAS regulations has to do with the supply chain. Historically, many chemical regulations have applied to the manufacture or import of new products, but existing inventory could be sold through. However, most new PFAS laws and regulations do not include sell through provisions. Instead, they prohibit the manufacture, distribution, sale and offer for sale of covered products starting on a specific date. While many of these laws provide lead time, this is often not reflective of supply chain realities or the time it takes to sell existing inventory. This is particularly true for performance gear that does not benefit from the same churn as everyday apparel. The end result is that product will need to be pulled from store shelves, warehouses and distribution centers.

When this occurs, there will be questions around whether the retailer, the supplier, the manufacturer or some combination of the three pays for the disposal, and about how retailers will be compensated for their financial loss. To complicate the issue further, special handling may be required due to concerns over PFAS in the environment.

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If PFAS substances are toxic, as some regulations allege they are, can a jacket treated with PFAS be thrown in the dumpster? Or is it considered hazardous waste? Does it matter if it is one jacket being thrown out at 100 stores, or 100 jackets thrown into one store compactor? What method of disposal will be required? And who pays for it?

These are all issues that the regulations don't address head on, but the consumer products industry will have to answer. Even if regulations don't clearly state the products need to be handled as hazardous waste, from a brand protection standpoint, companies may decide to mitigate reputational exposure by treating them as such, so that the products don't end up in a landfill and create more reputational, regulatory and litigation risk for the company.

Companies need to understand their risk

Consumer product companies need to start assessing their use of PFAS now and understand the timeframe for new regulations in all the states in which they operate. They also need to start thinking about what their options are for alternatives to PFAS or if they will need to phase out certain products or adjust performance claims.

In addition, they must consider questions around what products are in the market, what their inventory is and what the sell-through time with their retailers is. Products that typically stay on the shelves longer may need a different strategy from those that sell quickly.

It is also a good time to review contracts with supply chain partners. Companies will need to determine who will be responsible for taking products out of circulation when new regulations go into effect, how disposal will be done and who will pay for it.

State and federal regulators are moving fast. Companies that are not concentrating on these changes and gathering as much knowledge as possible are going to be caught off guard. That can create a lot of serious – and expensive – business issues if suddenly their products can't be sold in most of the country and they are left holding the bag or facing hefty fines or expensive lawsuits for non-compliance.

FOOD AND DRINK

The massively disruptive recall of infant formula in February continues to have a ripple effect for both parents and retailers. Multiple agencies including the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) are looking into the causes, the FDA's poor response time, and preventative measures. State and federal lawmakers are also monitoring for price-gouging that may still affect consumers.

A voluntary recall of peanut butter products due to potential Salmonella contamination occurred in May. By June, two class-action lawsuits had been filed against the manufacturer for negligence and breach of warranties, among other claims. By the end of the second quarter nearly 12.3 million units had been recalled.

The FDA is halting a temporary policy that allowed food importers in its Foreign Supplier Verification Programs (FSVP) to register as "unknown" instead of supplying a commonly used "unique facility identifier" (UFI). This move may increase security and transparency in the food supply.

Ten companies were hit with warning letters from the FDA for selling adulterated dietary supplements that contain either new dietary ingredients (NDIs) that lack specific documentation with the FDA or unsafe food additives. Supplements were also the focus of a new bill introduced by the U.S. Senate in May that aims to increase transparency in the industry.

> *"Data from the week of July 3 reported that the out-of-stock rate for powder infant formula was more than 30%. While improving, the numbers are still not back to their normal rate of 10%."*

As infant formula shortage eases, focus shifts to the cause

Parents were left searching empty shelves for infant formula after a major manufacturer issued a voluntary recall in February and closed its primary production facility. During the week of May 28, national out-of-stock rates for infant formula were more than 70%. Data from the week of July 3 reported that the out-of-stock rate for powder infant formula was more than 30%, so numbers are improving but still not back to the normal rate of 10%.

The FDA Commissioner Dr. Robert Califf has admitted the agency didn't respond quickly enough to conditions at the plant, despite a history of concerns noted in FDA Form 483 documents as far back as 2019.

In May, the agency issued a guidance document discussing steps it would take to increase the supply of infant formula and the enforcement discretion it would use to allow certain infant formulas to be sold even if they didn't comply with some of the established statutory and regulatory requirements.

Other agencies are getting involved as well. In May, the FTC opened a public comment period to help the agency address any anticompetitive, unfair, or deceptive acts or practices that have contributed to the infant formula shortage or made the problem worse. It also said it would look at the infant formula industry to understand how the closure of a single plant could jeopardize the entire supply chain so dramatically.

In the wake of shortages, price gouging has also become a major concern. Several states including California, Oregon, Colorado, New Jersey, and Kentucky announced set limits on price increases on infant formula. Two federal bills were also introduced in Congress in May to protect consumers against price gouging.

While the situation with infant formula seems to be improving, it will likely be some time before public trust in the FDA and the industry are restored.

False advertising lawsuits may target bioengineered food

Lawyers at K&L Gates anticipate plaintiffs' lawyers will be watching companies closely to make sure they comply with the U.S. Department of Agriculture's (USDA's) National Bioengineered Food Disclosure Standard (NBFDS). The standard, which went into effect in January, requires that certain retailers, manufacturers, and importers disclose food and drink that contains bioengineered ingredients for products labeled for U.S. retail sale.

The USDA maintains a list of bioengineered foods subject to the standard to help manufacturers comply. However, it can also be a tool for attorneys. Manufacturers must disclose all foods and ingredients included on the list, as well as ingredients not included, but that the company knows to contain bioengineered materials.

The risk for companies, according to the legal experts, is that if manufacturers claim their foods are "non-bioengineered," and in fact they contain any ingredient on the NBFDS list, it would be false advertising.

According to K&L Gates attorneys, competitors may also try to discredit their rivals by filing suits under the Lanham Act or other state unfair competition laws claiming that the company has misrepresented the nature and quality of the product in its advertising if its bioengineered ingredients are not disclosed.

Meanwhile, the USDA itself is involved in legal action around the new rule. In February, the agency filed its opposition to a summary judgement as it tried to defend the rule against claims by the Center for Food Safety (CFS). In its lawsuit to try to get the NBFDS overturned, the CFS alleges that the regulations don't label the majority of foods derived from genetically modified organisms (GMOs), among other claims.

As the CFS lawsuit works its way through the system, food producers should consider what adjustments they would need to make, if any, should the regulations be overturned.

FDA to start enforcement for foreign supplier verification

The FDA's Foreign Supplier Verification Programs (FSVP), requires food importers to take steps to verify that food produced by foreign suppliers meets U.S. food safety standards. As part of the FSVP, importers must provide certain information to the FDA in order to be declared entry.

When the program first went into effect, the FDA offered some leeway if the importer did not have a Dun & Bradstreet Data Universal Numbering System (DUNS) number to use as a "unique facility identifier" (UFI). These nine-digit identification numbers can be used to identify and access information about a business, similar to how a social security number works for individuals. They are free for businesses to acquire. Importers were temporarily permitted to input "UNK" (unknown) as their UFI in lieu of a DUNS number.

Effective July 24, 2022, that policy is no longer in place and food imports covered by FSVP must provide a DUNS number for the importer. Customs and Border Protection (CBP) will have the authority to reject entry of food subject to FSVP if the importer's DUNS number is not provided.

While the FDA has not specifically stated this, this step can be viewed as another way to protect the safety of the U.S. food supply by holding importers more accountable. Importers who are active in the FSVP will need to update their processes to ensure they have a DUNS number and they are using it in all the relevant FDA communications.

New dietary ingredients are a focus for FDA and lawmakers

The FDA issued warning letters in May to 10 companies for selling adulterated dietary supplements that contain either unsafe food additives or new dietary ingredients (NDIs) that lack specific documentation with the FDA. The agency stated that some of the identified dietary supplements could harm consumers because they are intended for use in the cure, mitigation, treatment, or prevention of disease, but lack proper approval as drugs.

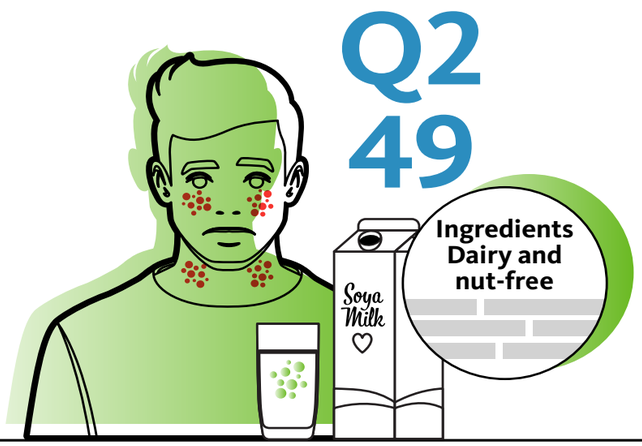
This action comes as the U.S. Senate moves toward more transparency in the U.S. dietary supplement industry. Senators Dick Durbin (D-Ill.) and Mike Braun (R-IN) introduced the Dietary Supplement Listing Act of 2022 in May. The bill requires dietary supplements manufacturers, packers, and/or distributors to submit product information to the FDA to be included in a public database.

The mandatory information includes an ingredient list, warnings and precautions, allergen statements, and any claims related to health and/or structure and function. The rule would apply both to new supplements and those currently on the market. The penalty for not providing the information to the database could include FDA enforcement for misbranding under the Food, Drug & Cosmetic Act.

> *"Importers who are active in the FSVP will need to update their processes to ensure they have a DUNS number and they are using it in all the relevant FDA communications."*

The number of FDA **recalls increased 9.1%** in Q2 (from 110 events in Q1 to 120).

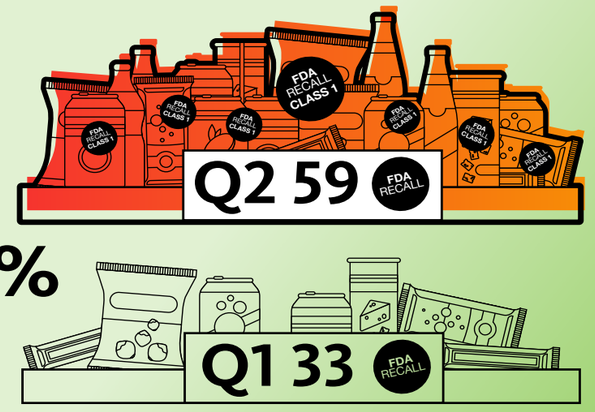
Despite this increase, events remain 4.1% below the quarterly average of the last 5 years.



At 49 events, **Undeclared allergens** were the largest cause of recalls in Q2.

Despite this, recalls caused by Bacterial contamination more than doubled (from 18 in Q1, to 37).

Class I designations surged 78.8% in Q2, from 33 events (in Q1), to 59.



This rise led to the highest volume of Class I recalls recorded in a single quarter for 5 years.

SECOND QUARTER BY THE NUMBERS

FDA

After dropping last quarter, U.S. food recalls were up 9.1% to 120 in Q2 2022. However, the number of units affected dropped 81.3% to 27.5 million. A major recall for peanut butter products that impacted 20 different food items was responsible for 12.2 million units, or 44.0% of all products. There were no additional units of infant formula recalled in Q2.

Undeclared allergen was the top reason for U.S. food recalls for the sixth straight quarter with 49 recalls in Q2 2022. It has been the leading cause in 19 of the past 20 quarters. Bacterial contamination was second with 37 events and foreign materials were third with 16 recalls.

In terms of units, bacterial contamination impacted the most units, with 12.3 million units affected, primarily peanut butter products. Foreign material recalls were linked to the second largest number of units, with 11.6 million, mostly tied to a single recall of candies that had a risk of metal. Undeclared allergens were responsible for the third highest number of units, with 3.1 units recalled, nearly 75% of which came from a single recall for undeclared egg in fried fish products.

For the fourth consecutive quarter, produce had the most recall events with 31, or 25.8% of all recalls. Prepared foods had fewer recalls (26), but the most units recalled at 12.1 million, were from the peanut butter recall. The large foreign materials recall pushed the total number of units recalled in the candies category to 11.7 million, the second highest category. Seafood was third in terms of units with 2.4 million.

The number of Class I recalls rose to 59 events involving 15.1 million units. While there were 78.8% more Class I recall events than in Q1, the number of units of this classification fell by 68.7%. Class II recalls dropped in Q2 2022, from 71 to 55. The number of units involved dropped even more significantly from 98.9 million in Q1 to 12.3 million for Q2. The number of Class III recalls remained stable at six.

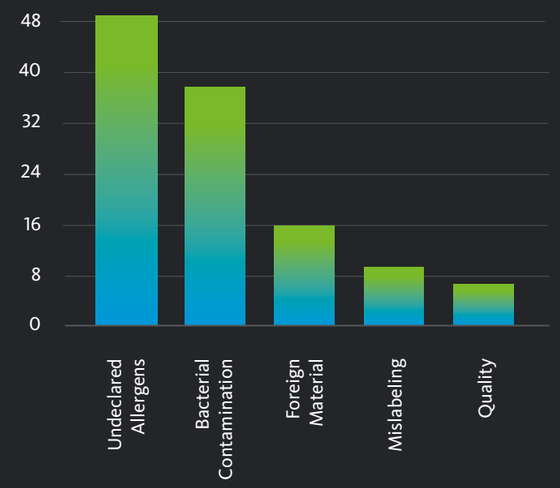
JULY insight

In July 2022, the FDA issued 33 food recalls. That is a 17.5 percent decline compared to the monthly average in Q2 2022. The number of units dropped even more dramatically from an average of 9.2 million in Q2 to 851,522 units in July, a decrease of 90.7 percent. Half (47.6%) of the units recalled in July were from a single event of a potential norovirus contamination in raspberries.

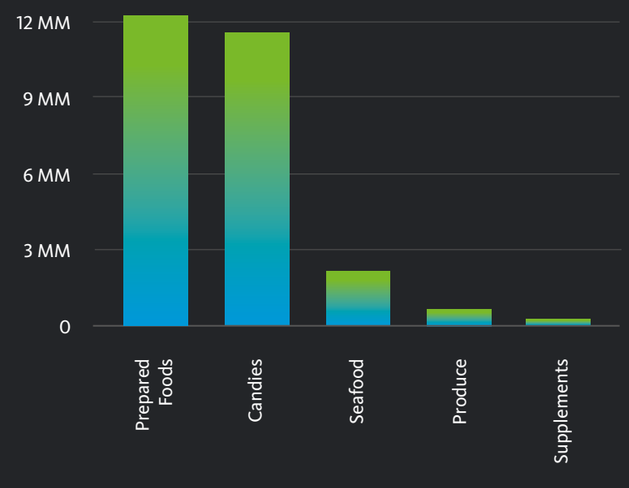
Undeclared allergens were responsible for the most food recalls in July at 14 events, or 42.4 percent. Bacterial contamination was the second leading cause of recalls, with nine (or 27.3 percent), and foreign material was third with five events (or 15.2 percent).

In terms of the product category, dairy and baked goods tied for the most recalls with six events each. Prepared foods had five recalls and produce had four.

NUMBER OF FDA RECALLS BY REASON



FDA UNITS IMPACTED BY PRODUCT TYPE



USDA

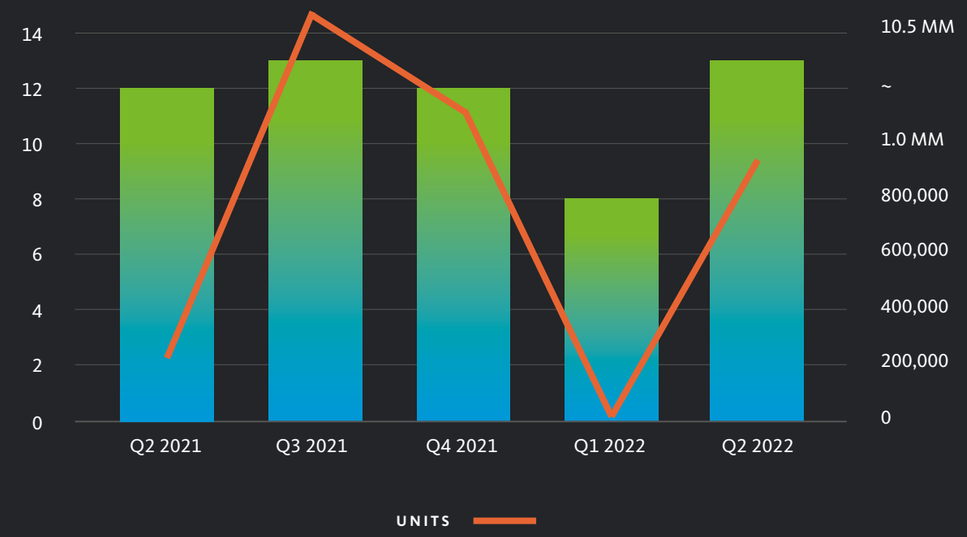
Total recalls were up 62.5% in Q2 2022, from eight in the last quarter to 13. The number of units affected rose sharply to 973,374 pounds, a 1,391.3% increase.

In terms of events, the most recalls were linked to no inspection with three recalls. Bacterial contamination, foreign materials, undercooking, and undeclared allergens were all responsible for two recalls each. Failure to comply with FSIS import and misbranding were each cited in one recall.

Undercooking was the leading cause of units being recalled with 615,315 pounds linked to two recalls of ready-to-eat chicken breast from the same manufacturer. These recalls made poultry the category tied to the largest number of units in Q2 recalls.

Pork was tied to five recalls, a big increase from no pork recalls last quarter. Beef and poultry were cited in three recalls each, with seafood and multiple meats responsible for one recall apiece. All of the USDA recalls were designated Class I.

NUMBER OF USDA RECALLS AND IMPACTED UNITS BY QUARTER



JULY

insight

The USDA published five recalls in July 2022, almost the same as the quarterly average of 4.3. The 165,618 pounds that were recalled in July represent a decrease of nearly half (48.9 percent) compared to the monthly average for Q2 2022. Nearly three quarters of those units (72.2 percent) were tied to a single recall for undeclared eggs. That recall made undeclared allergens the top reason for recalls by units. In terms of events, pork was the top category with two recalls while poultry, beef, and multiple meats had one each.

JENNIFER M. THARP, ASSOCIATE, **NICOLE E. BOTHWELL,** ASSOCIATE AND **JENNIFER SATTERFIELD,** ASSOCIATE, **SQUIRE PATTON BOGGS**

WITH INNOVATION COMES RISKS FOR THE U.S. FOOD AND BEVERAGE INDUSTRY

Food and beverage companies are constantly finding ways to innovate and offer new products to consumers. But those innovations can carry added risk if product claims and regulatory requirements are not carefully vetted. And regulators are always alert for additives, supplements and novel foods that could potentially pose a threat to the health and well-being of consumers.

Risks from novel foods and health claims

The U.S. Food and Drug Administration (FDA) continues to issue warning letters for food additives such as cannabidiol (CBD), an active ingredient in cannabis. Any substance added to food must either be submitted to the FDA for premarket review and approval or be categorized as "generally recognized as safe" (GRAS) by food safety experts. Because CBD doesn't fit into either group, FDA prohibits food to which CBD has been added from entering interstate commerce.

Some companies that add CBD in their food products also claim the product will treat or mitigate a disease or affect the structure or function of the body. If a food has these qualities, it qualifies as a new drug or a dietary supplement and must be approved by the FDA before it can be marketed.

Manufacturers seeking to market a human or animal food product with CBD should carefully assess the risks and consult with legal counsel to review the products and claims being used. In March, the FDA and the Federal Trade Commission (FTC) jointly issued seven warning letters to companies marketing CBD products with claims they cure, mitigate, treat or prevent COVID-19.

Another market to which food and beverage companies are catering is health-conscious consumers. More and more, products promise to be "gluten-free", "dairy-free" or have "no artificial flavors." These claims may be subject to FDA regulation. For example, the FDA is expected to soon release guidance on the Labeling of Plant-based Milk Alternatives: Draft Guidance for the Industry. The question of whether plant-based products, such as almond and oat milk, can be classified as a "milk" as part of their statement of identity remains a hotly contested issue.

Supply chain risks brought to light

The infant formula shortage in the United States highlighted risks in the food supply chain when a market relies on a few manufacturers – especially for specialty products for individuals with allergies or food sensitivities.

The shortage also indicates the risks associated with delayed regulatory safety inspections during the COVID-19 pandemic. In February 2022, the FDA inspected a major infant formula maker's production facility in Michigan and found potential contamination with ***chronobacter sakazakki***, among other violations. The company initiated a voluntary recall of the suspected products on February 17, 2022. When the factory shutdown, the market was not able to keep up with consumer demand. The FDA finally issued guidance on May 16, 2022 permitting importation of formula from other countries. Even though the manufacturer entered into a Consent Decree reopening the facility in May 2022, the formula shortage has continued more than six months after the initial recall.

Online food sales

E-commerce is booming in the U.S. but it comes with its own set of liabilities and safety concerns. From the "pink sauce" homemade condiment that went viral on TikTok to cybersecurity concerns, entities seeking to sell their products online need to know the relevant regulations and risks. Some states have "cottage food" laws for intrastate sale of certain products, often shelf-stable foods such as jams and jellies. However, the FDA regulates the interstate sale of food. Start-up food and beverage companies should be familiar with both state and federal laws before selling their products, especially if they anticipate having customers across state lines. Businesses seeking to sell food and beverage products online should also strongly vet any platform they use for security purposes. This ensures both business and customer information is protected. Businesses should also implement cybersecurity policies, including implementation of strong passwords and phishing training. Otherwise, they may risk significant data breaches that could result in enforcement by the FTC and civil litigation by the affected parties.

Recall readiness

The FDA is likely to focus on company policies regarding internal audits and recalls in the wake of the infant formula shortage. The agency finalized guidance in March 2022 entitled Initiation of Voluntary Recalls under 21 CFR Part 7, Subpart C, encouraging companies to be "recall ready." Companies should have policies and procedures in place for recalls, including a recall communications plan that quickly and efficiently alerts retailers and consumers of possible food safety threats.

New employees should be trained in product safety, compliance and recall procedures as part of their onboarding process and all employees should receive periodic updates. Trying to learn about required state and federal procedures and documentation rules in the midst of an internal investigation may cause unnecessary delays, penalties and even risks to consumer safety.

Section 204 of the Food Safety and Modernization Act provides for the tracking and tracing of food. In September 2020, FDA issued a proposed rule requiring additional recordkeeping for certain high-risk foods such as cheeses, shell eggs, leafy greens and finfish that were included on a new Food Traceability List (FTL). The final rule is expected by November 7, 2022. Entities subject to the regulation will be required to maintain records to support accurate and timely traceability of food for reasons such as potential contamination.

The proposal includes developing a traceability program that will require companies to track key data elements, critical tracking events and a traceability lot code that follows the product through the supply chain. The traceability lot code would be established and assigned when an entity originates, transforms or creates a food listed on the FTL. Food growers would need to include records of the growing area coordinates. Businesses will likely need to convert any old systems into electronic records to ensure this information is available upon agency request.

Food packaging rules

Legislation to address safety and sustainability relating to food packaging continues to advance at both the state and federal level. There is a particular focus on Extended Producer Responsibility laws, which make manufacturers of packaging materials responsible for the entire lifecycle of their products, including making sure their products are recycled or otherwise disposed of appropriately. Manufacturers may be required to update their materials in order to comply.

The safety of food packaging materials is another area of focus for lawmakers. The FDA regulates substances that make up the materials used in manufacturing, packing, packaging, transporting or holding food, also called food contact substances. The agency has been updating guidance for food packaging made of recycled materials in recognition of the potential for contaminants that remain after recycling.

At the state level, chemicals of particular concern include perfluoroalkyl and polyfluoroalkyl substances, or PFAS, a class of more than 3,000 synthetic chemicals found in a wide range of products. California has passed a law banning the use of PFAS chemicals in paper-based food packaging effective as of January 1, 2023, and it is expected other states will pass similar laws. Earlier this year two of the largest fast-food chains in the United States were hit with class action lawsuits in Illinois and California over the alleged presence of PFAS in their packaging. Companies will need to evaluate risk not only from regulators but also from plaintiffs' attorneys.

JENNIFER M. THARP, ASSOCIATE, **NICOLE E. BOTHWELL,** ASSOCIATE AND **JENNIFER SATTERFIELD,** ASSOCIATE, **SQUIRE PATTON BOGGS**

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How companies can prepare

Companies should review and assess their standard operating procedure (SOPs) for compliance with FDA regulations and guidance, including the Food Safety Modernization Act. In addition, now is the time to assess entities up and down the supply chain, including requirements under the Foreign Supplier Verification Program.

Other measures food companies can take to mitigate risk include remote and on-site audits for new suppliers, conducting mock recalls, reviewing supplier SOPs, engaging third-party experts and the legal team to review product labeling and periodically assessing product claims against updated FDA guidance.

> *“The FDA’s draft guidance, “Cybersecurity in Medical Devices” outlines the growing vulnerabilities the healthcare sector faces from cybersecurity threats, rapid advances in technology and the increased use of personal and interconnected medical devices.”*

MEDICAL DEVICE

As medical devices become more digitally connected, the U.S. Food and Drug Administration (FDA) is providing detailed guidance to manufacturers on steps they should take to reduce cybersecurity threats. The recommendations update a 2018 document and illustrate how quickly technology is advancing.

Congress is also taking action to improve the country’s preparedness for public health emergencies, though some of the recommendations are also applicable in the absence of a crisis. The proposed legislation includes device-specific reforms as well as broader changes.

With new variants of COVID-19 on the rise, the FDA has launched a resource on its website to help consumers avoid fraudulent or unapproved COVID tests. The agency also continues its enforcement actions, conducting recalls for 9 different rapid tests in the second quarter.

FDA provides comprehensive guidance on cybersecurity

In April, the FDA issued its draft guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," which updates a 2018 guidance. The document outlines the growing vulnerabilities that the healthcare sector faces from cybersecurity threats, rapid advances in technology, and the increased use of personal and interconnected medical devices.

The detailed recommendations include types of information device makers should include in premarket submissions. They also examine how companies can incorporate cybersecurity considerations into their quality management systems and the idea that cybersecurity controls should be a standard part of a company's operations, rather than considered as an afterthought. The idea of taking proactive steps to reduce risk is a theme appearing more and more in FDA guidance documents.

Some notable updates to the 2018 publication include eliminating the need to separate medical devices into tiers based on their cybersecurity risk, and the recommendation that companies develop a software bill of materials, which would give device makers insights into potential cybersecurity risks throughout the supply chain.

Legal experts at DLA Piper note that despite the attention paid to data breaches and other risks, the FDA has issued only a few warning letters specifically about cybersecurity. They suggest the reason for this is because the Federal Food, Drug & Cosmetic Act (FD&C Act) lacks express federal statutory requirements for medical device manufacturers regarding cybersecurity. While the FDA has issued guidance to encourage companies to pay attention to these types of issues, there is no clear mandate that they must do so.

That may be changing. Both the U.S. Senate and the House of Representatives recently introduced bipartisan bills that would amend the FD&C Act. The proposed changes would mandate manufacturers of 'cyber devices', defined as devices that include software or are intended to connect to the internet, to implement certain cybersecurity requirements.

Even without a specific law, medical device companies have a vested interest in making sure they address cybersecurity proactively and as part of their standard operations. Not only are they at risk financially and legally, but there is also a large reputational risk if an incident occurs.

> *"Both the U.S. Senate and the House of Representatives recently introduced bipartisan bills that would amend the FD&C Act. The proposed changes would mandate manufacturers of 'cyber devices' to implement certain cybersecurity requirements."*

Congress takes steps to improve public health preparedness and response

In April, the Senate Health, Education, Labor and Pensions (HELP) Committee overwhelmingly voted to advance the bipartisan Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act (S.3799) (PREVENT Pandemics Act). The act is designed to help strengthen the nation's medical and public health preparedness and response framework. It includes reforms related to the FDA that would apply beyond pandemic response and management.

The bill outlines FDA reforms in several areas, including ways to modernize and improve clinical trial design through the use of digital health, decentralized trials, and seamless methods to improve the FDA's guidance practices (and communications) with external stakeholders.

The bill also contains device-specific reforms such as ways to combat counterfeit devices, and a mandate that manufacturers of medical devices (that are "critical to public health") develop, maintain, and implement a redundancy risk management plan to increase the resiliency of the supply chain.

There is also a section of the bill that examines FDA and medical countermeasure provisions and clarifies that the FDA may consult with or contract with third parties to evaluate in vitro diagnostic tests if an emergency use authorization (EUA) has been requested. It also increases transparency around products that are granted EUAs.

We can expect many bills and regulations that apply lessons learned during the COVID-19 pandemic to future public health events. However, the policies in this act will add a layer of protection to the U.S. drug supply even when there is not an ongoing health emergency. Medical device companies should be reviewing the bill to see if there are changes they will need to make should the proposal become law.

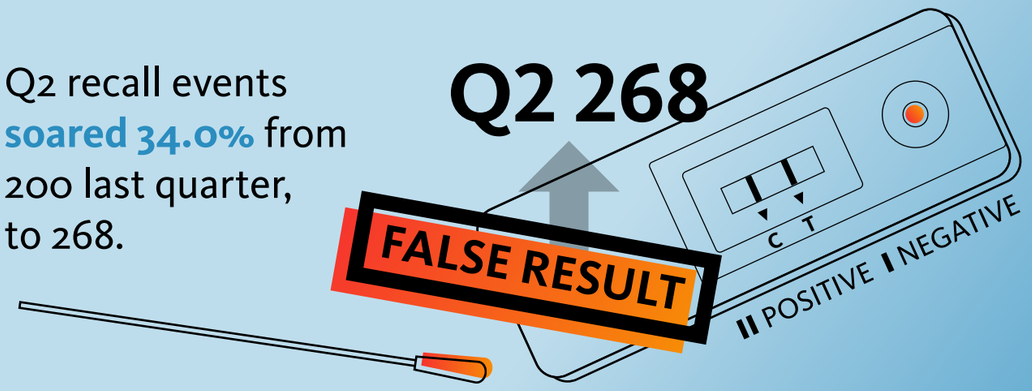
FDA continues to monitor COVID-19 tests

With another highly contagious variant of COVID-19 spreading around the world, at-home COVID tests remain in demand. That means some companies will try to cut corners to get their products on the market quickly, sometimes without FDA approval.

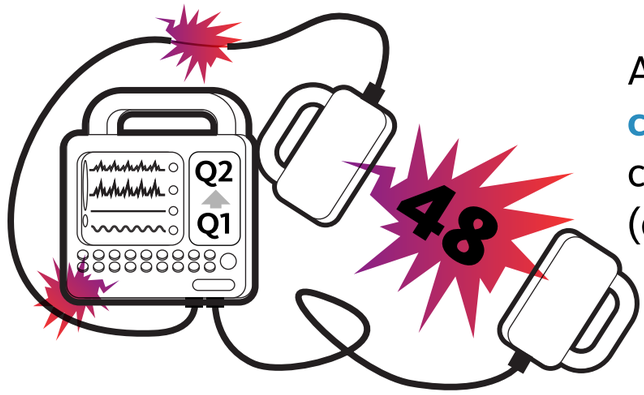
There were 9 recalls of unapproved or unsafe COVD-19 rapid tests issued in the second quarter, involving approximately 982,483 units. This is a 12.5% increase from the eight recalls in the first quarter. In addition to the threat of FDA enforcement actions, the industry continues to see false claims class action lawsuits filed against manufacturers for the marketing of unauthorized tests.

In April, the FDA launched a new tool to help consumers avoid unscrupulous test manufacturers. The Counterfeit At-Home OTC COVID-19 Diagnostic Tests provides information for identifying unauthorized or counterfeit tests and includes a list of all COVID-19 tests the agency has identified as counterfeit.

Q2 recall events **soared 34.0%** from 200 last quarter, to 268.



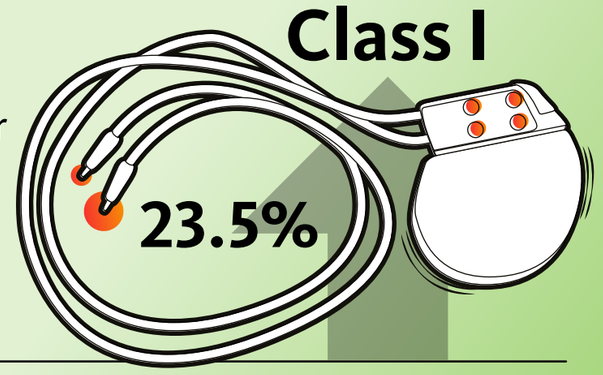
This figure sits 10.2% above the quarterly average recorded for the last 5 years.



At 48 events, **Safety concerns** were leading cause of recalls (doubling from Q1).

Only one quarter in the last 6 years (Q2 2020) has seen more recall events issued due to Safety.

Class I designations increased by a quarter (**23.5%**) in Q2.



This is the highest number of Class I recalls issued in over 15 years.

SECOND QUARTER BY THE NUMBERS

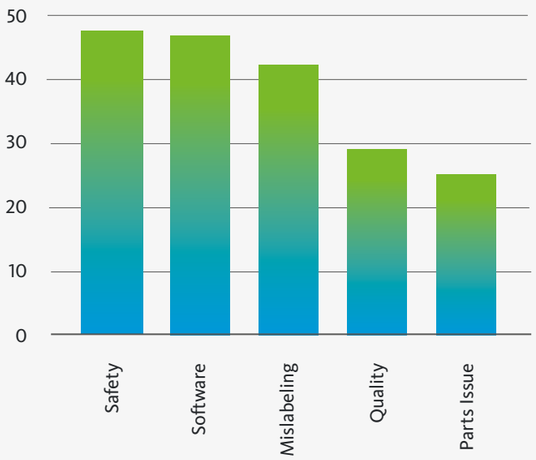
The number of medical device recalls hit a two-year high in Q2 2022 with 268 events, a 34.0% increase from the 200 recalls in Q1 2022. However, the number of affected units dropped by 96.8% to 10.1 million units. This marks the lowest quarter in terms of units recalled since Q1 2017.

For the first time since Q2 2020, safety concerns was the leading reason for recalls, accounting for 48 events, or 17.9% of all recalls. Software issues were the second most common reason for recalls and were linked to 47 events. Mislabeling was third with 42 events.

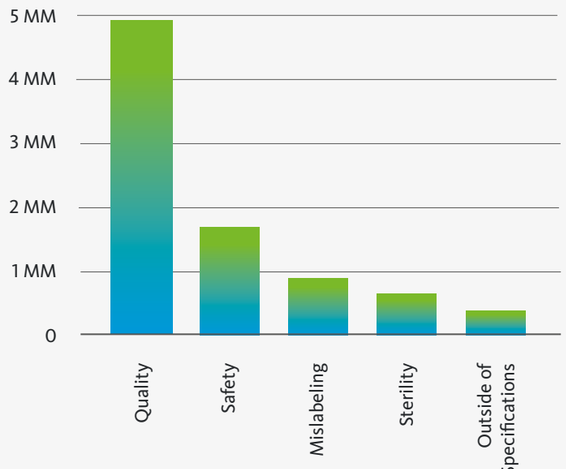
In terms of units, the top cause of medical device recalls was quality issues, with 5.0 million units recalled. That represents 49.5% of all medical device units recalled in Q2. Among the recalls conducted for quality concerns, two events were responsible for 79.2% of the recalled units (totaling 4.0 million). One incident for DNA collection kits involved more than 2.17 million units and another for defibrillator pads was linked to more than 1.8 million units.

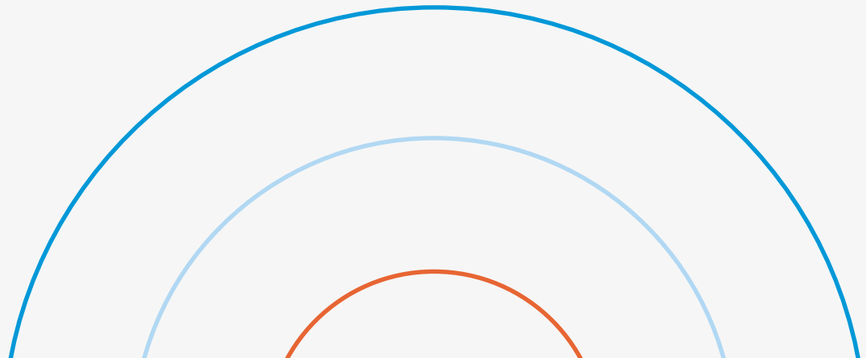
While Class I recall events increased to 21, the number of units in this designation fell 26.6% to 1.5 million (from 2 million in Q1 2022). Class II recalls followed a similar trend with events increasing 37.6% (from 170 in Q1 to 234 in Q2 2022) and impacted units falling 65.7% (from 24.6 million in Q1, to 8.4 million in Q2). The number of Class III recalls remained constant at 13, but the number of recalled units fell from 288.2 million in Q1, to just 167,897 in Q2.

NUMBER OF RECALLS BY REASON



NUMBER OF UNITS IMPACTED BY REASON





JULY insight

There were 96 FDA recalls for medical devices in July 2022, a 7.9 percent increase on the second quarter monthly average of 89. The number of units recalled increased more than three-fold from Q2's monthly average of 3.4 million, to 10.8 million in July. The vast majority of those impacted units (83.3 percent) were due to leakage, with 9.0 million units recalled.

Software was the most common reason cited by the FDA for medical device events in July 2022 (tied to 22 recalls, or 22.9 percent). Quality was second with 21 recalls (21.9 percent), and mislabeling was third with 17 recalls (17.7 percent).

There were two recalls for rapid COVID-19 tests or testing components. One recall was for mislabeling. The other recall was for safety concerns because the test fell outside the scope of the Emergency Use Authorization (EUA) guidelines.

LYNN TYLER, PARTNER,
BARNES & THORNBURG

DELAYED CONGRESSIONAL ACTION RAISES CONCERNS FOR MEDICAL DEVICE COMPANIES

Medical device companies are particularly influenced by the lingering pandemic. At-home COVID-19 diagnostic tests, masks, respirators, personal protective equipment (PPE) and ventilators are all in higher demand and more companies want either to increase production or introduce new products.

But COVID is not the only uncertainty that medical device companies are trying to plan around. There are two pieces of legislation awaiting Congressional approval that are vital to the industry. The first is the reauthorization of the Medical Device User Fee Amendments (MDUFA).

The MDUFA was first established in 2002 and must be renewed by Congress every five years. Medical device companies must pay a fee to the FDA for nine different applications as well as an annual fee for periodic reporting on Class III devices. The actions covered by the MDUFA include companies' registration of their "establishments" and the listing of their devices with the agency when they submit an application or notification to market a new medical device.

The FDA's definition of "establishment" includes 11 categories of domestic companies and 13 categories of foreign companies, including manufacturer, contract sterilizer, foreign exporter, relabeler and specification developer. This means the fees impact multiple organizations beyond just the primary manufacturer.

The MDUFA fees vary by specific application. The 2022 fiscal year fees range in price from $5,061 for a 513(g) application, which is used to obtain information about how the FDA would classify a specific device, to $329,000 base amount for a premarket approval application for a Class III device. Reduced rates of up to 75% less are offered to for businesses certified by the Center for Devices and Radiological Health (CDRH) as a "small business."

These fees help the FDA increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market. They constitute a large part of the CDRH's budget. The current statutory authority for MDUFA expires on September 30, 2022, and new legislation will be required for the FDA to continue collecting user fees for the medical device program in future fiscal years. FDA Commissioner Robert Califf recently reached out to Congress, asking for assurance that the fees will not run out.

If lawmakers don't act before the September deadline, the FDA's authorization to collect user fees will go away, along with a significant amount of funding for the agency. There is no reason to believe that Congress won't pass the authorization, but it is timing that has some in the industry concerned because lawmakers are likely to be focused on regaining their seats and passing other legislation in a mid-term election year.

The Senate Health, Education, Labor and Pensions Committee passed its version of the legislation, S. 4348, the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act, in June. However, it needs to be passed by the full Senate, by the House and signed by President Biden. Medical device companies are pushing to get the Act passed quickly, but there are a limited number of actions they can take.

The other piece of legislation that some medical device companies are anxiously awaiting is re-authorization of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Many small medical device companies get funding through these programs. However, Congress has not yet approved a renewal of the $4-billion-a-year program, which is also set to expire on September 30, 2022.

According to AdvaMed, a leading medical device trade association, program funding is already part of the budgets for the 11 agencies that participate in the SBIR/STTR programs. Additional funding is not required. But Congress does need to re-authorize the programs. The group is calling on lawmakers to take this step quickly to assure the participating federal agencies, small businesses and academic institutions have a consistent source of funding to drive the research and development.

The programs are coordinated by the Small Business Administration but managed by each agency. They have been reauthorized several times by Congress but never made permanent. The most recent extension, for six years, came in 2016 as part of legislation providing annual guidance to the Department of Defense, which is the largest provider of SBIR grants. Recently there have been reports of a compromise for the bi-partisan bill to extend the program, but nothing has been finalized and the clock is ticking.

Not everything is a waiting game, though. There are signs that some parts of the FDA are working to get back to more normal, if not completely pre-pandemic, operations.

In June the agency announced it plans to withdraw the guidance that automatically extended hold times for additional information requests by 180 days and return to pre-pandemic policies for marketing submissions and applications placed on hold.

While some medical device companies may wish the longer periods for providing information would stay in place, the FDA stated that returning to the preexisting deadlines would facilitate more timely premarket review of innovative devices. It also noted being able to more quickly close out files that have been abandoned would allow for better management of the device review program.

In its statement, the agency acknowledged that the circumstances that created the public health emergency declaration for the pandemic still exist, but these specific policies are no longer needed. The FDA also said that it would end the policy that required all advisory committee meetings to be held virtually. As of July 7, 2022, these policies are no longer in place.

Key pieces of legislation are progressing slowly, but the FDA is managing to move its reviews forward in a more timely fashion. And observers remain hopeful Congress will prioritize the re-authorization for the MDUFA and the programs benefitting small businesses.

PHARMACEUTICAL

The U.S. Food and Drug Administration (FDA) released a draft guidance for creating a Race and Ethnicity Diversity Plan, complementing action Congress is taking on the issue. The agency is also working to prevent drug shortages by providing manufacturers with recommendations on creating a Risk Management Plan (RMP). An RMP has been required for certain categories of drugs since the Food, Drug & Cosmetics Act (FD&C Act) was amended at the start of the COVID-19 pandemic.

The FDA is also focused on enforcement for two specific substances – cannabis and nicotine. The agency issued its first warning letters for products containing delta-8 tetrahydrocannabinol (delta-8 THC). It also took aggressive action banning the sale of one e-cigarette manufacturer's products and proposing rules to ban non-tobacco flavors including menthol in cigars and cigarettes.

> *"The FDA recommends that a Race and Ethnicity Diversity Plan be submitted to the agency before beginning clinical trials. Companies should be incorporating recommendations from the FDA's guidance into their protocols."*

FDA encourages more diversity in clinical trials

In April, the FDA released its draft guidance, "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials." The agency acknowledged that inequities in healthcare access, racism and historical mistrust of the clinical research system have led to certain populations not being adequately represented in clinical trials.

The FDA recommends that a Race and Ethnicity Diversity Plan be submitted to the agency before beginning clinical trials. The guidance offers a framework for how to develop this type of plan and suggestions on what to include. Under the framework, trial sponsors should provide information on enrollment goals for minority participants, how they plan to explore the potential for differences in safety and/or effectiveness associated with race and ethnicity and a description of metrics used to ensure trial diversity.

The guidance also encourages companies to provide financial reimbursement for participants' expenses, language access to participants with limited English proficiency and partnering with community-based organizations.

The public comment period for the guidance ended on June 13, 2022. While the final draft of the guidance will be non-binding once it's promulgated, it is a sign that the FDA is looking more closely at the diversity of study populations. That means companies should also be examining their study participants and incorporating recommendations from the guidance into their protocols.

FDA issues warning letters for products with Delta-8 THC

Despite more and more states legalizing the use and sale of cannabis, and related products such as cannabidiol (CBD) and delta-8 THC, the FDA continues to enforce federal regulations regarding those substances.

In May, the agency issued its first warning letters to five companies for selling products with delta-8 THC, a psychoactive substance found in cannabis, for what it charged were violations of the Food, Drug and Cosmetic Act (FD&C Act). The companies were cited for illegally marketing unapproved delta-8 THC products as unapproved treatments for various medical conditions or for other therapeutic uses.

Additional violations included inadequate directions for use and the addition of delta-8 THC in foods, such as gummies, chocolate, caramels, chewing gum, and peanut brittle. CBD and delta-8 THC are not approved by the FDA as food additives for use in any human or animal food product. In addition, the FDA has not classified them as generally recognized as safe (GRAS) or otherwise exempt from food additive requirements.

In March, the FDA and the Federal Trade Commission (FTC) jointly issued seven warning letters to companies marketing CBD products with claims they cure, mitigate, treat, or prevent COVID-19. Since the products have not been approved by the FDA as drugs under the FD&C Act, those products were classified as unapproved and misbranded drugs. The FTC issued a cease-and-desist demand, prohibiting the companies from making such claims.

The FDA is paying increasing attention to products that make health claims, especially when they are in highly visible and popular categories such as cannabis products. Companies should review their marketing and ensure they're not making unproven claims that will draw enforcement action.

Sweeping changes for cigarette and e-cigarette industry

In June, the FDA issued marketing denial orders (MDOs) against one of the top-selling e-cigarette companies to force the manufacturer to stop selling and distributing its products. The orders also state that any products currently on the U.S. market must be removed or risk enforcement action. While a federal appeals court has temporarily blocked the ban and no similar actions were taken against other e-cigarette companies, it is clear that the FDA is taking aim against the cigarette and e-cigarette industry.

The reason the agency gave for its aggressive action was that the company's premarket tobacco product applications (PMTAs) lacked sufficient evidence regarding the "toxicological profile of the products" to demonstrate that marketing of the products would be appropriate for the protection of the public health.

In the same month, the sector suffered another blow when a bipartisan group of attorneys general (AGs) from 27 states, the District of Columbia, and three territories called on the FDA to halt marketing authorization for non-tobacco nicotine products, also known as electronic nicotine delivery systems (ENDS).

The letter expressed concerns that some manufacturers of ENDS, which include vaping products, have been marketing with minimal oversight, and that the health implications of those products have been insufficiently evaluated. The AGs also specifically raised concerns about the use of non-tobacco flavors in these products, enticing and endangering youth.

Further evidence of the agency's focus on reducing the appeal of tobacco products among youth and young adults are two proposed product standards that would ban all added flavors in cigars and menthol flavoring in cigarettes. The FDA believes the standards would decrease the likelihood of experimentation, the development of nicotine dependence, and the progression to regular use of cigars and cigarettes. The comment period for both rules closed in July. If passed, the new rules would apply to manufacturers, distributors, wholesalers, importers, and retailers. The regulations could be devastating for companies whose primary product category relies on these flavorings.

FDA encourages risk management plans for drug makers

In March of 2020, Congress added a provision to the Food, Drug & Cosmetics Act (FD&C Act) that requires manufacturers of certain drugs to develop Risk Management Plans (RMPs). These plans identify and evaluate risks to the supply of those drugs and support the industry's efforts to prevent shortages of critical medicines.

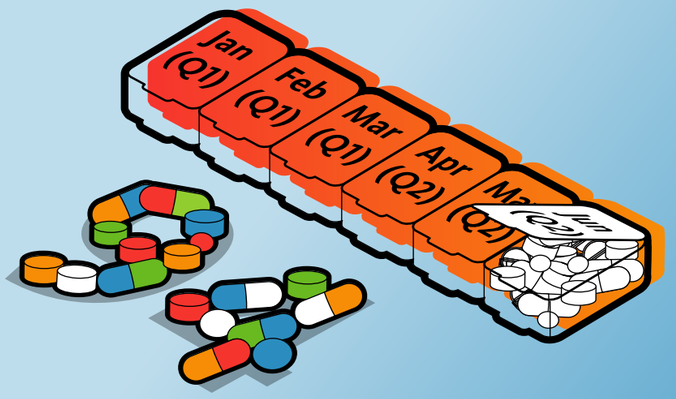
In May, the FDA issued a draft guidance to help manufacturers to develop these plans. Included in the amendment are products that are life-supporting, life-sustaining, or intended for the use in prevention of treatment of a debilitating disease or condition. Also included are any drugs that are critical to public health during a public health emergency, as well as any related active pharmaceutical ingredient or associated medical device. Not all manufacturers are required to have an RMP, though the agency recommends them even if they are not mandated.

Both "primary stakeholders," which includes the holder of the drug application or license, as well as the "secondary stakeholders," which extends to companies that manufacture or package the active pharmaceutical ingredient (API) necessary for the product should have RMPs in place.

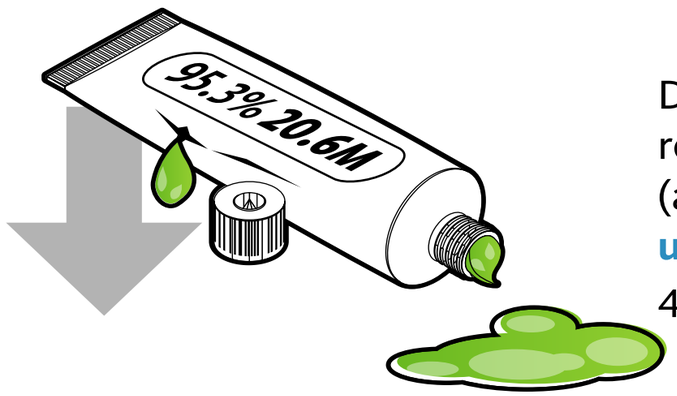
The FDA recommends companies follow a six-step framework when developing their RMPs. This includes proactively developing the document instead of waiting until there are disruptions, identifying potential hazards and their associated risk, and proactively communicating with regulators and external shareholders about their RMPs. The agency's focus on taking action ahead of a crisis illustrates that these types of plans should be part of every company's normal business planning process.

> *"The FDA is taking aim against the cigarette and e-cigarette industry. In June, it issued marketing denial orders against a top selling e-cigarette company, forcing it to stop selling and distributing its products."*

For the second consecutive quarter, the FDA recorded **94 recall** events.



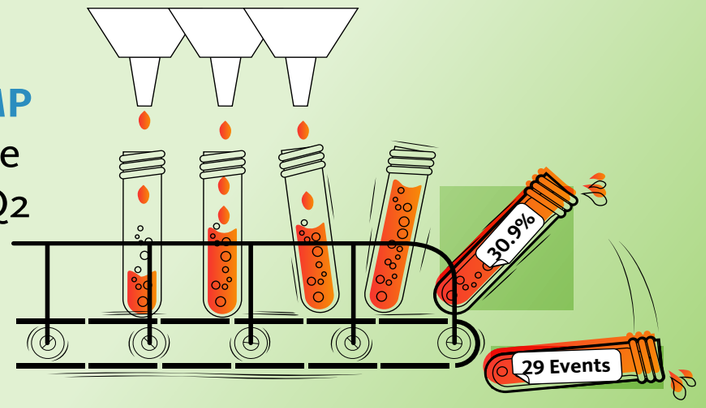
Only 1 quarter in the last 3 years has exceeded this figure.



Despite events remaining consistent (at 94), **impacted units fell** 95.3% (from 435.3M to just 20.6M).

For context, impacted units in Q1 were significantly inflated due to a single erroneous recall impacting 326.9M units.

At 29 events, **cGMP deviations** was the leading cause of Q2 recalls (30.9%).



This represents the highest quarterly number of cGMP deviations in the last 5 years.

SECOND QUARTER BY THE NUMBERS

The number of pharmaceutical recalls stayed flat from Q1 to Q2 2022, holding at 94 events. However, the number of units impacted dropped sharply from 435.3 million units recalled in Q1 to 20.6 million in Q2. That is the lowest number of units in the past five quarters.

cGMP deviations were the leading cause of both recall events and units impacted in Q2 2022, accounting for 29 (30.9%) and 8.9 million (43.4%) respectively. Only three other quarters in the last six years have seen cGMP deviations dominate both events and units. On these occasion however the average number of impacted units was significantly higher at 27.1 million.

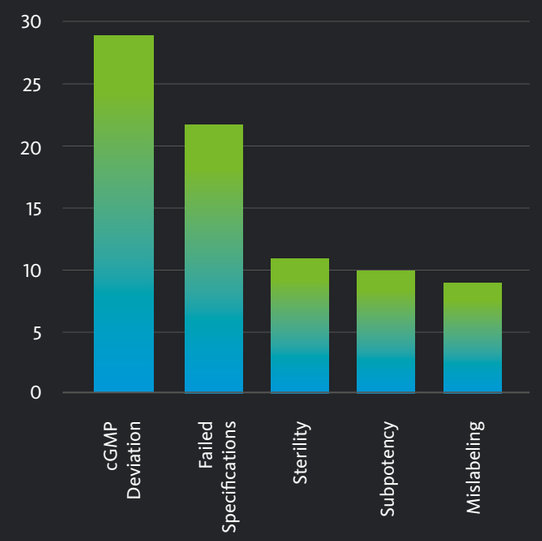
Nine of these cGMP deviations and 90.1% (8.0 million) of the units were associated with AZIDO impurity levels above acceptable limits in potassium tables.

Failed specifications were the second most common cause from both an event and unit standpoint. This reason was tied to 22 recalls and 3.2 million units. Sterility issues were third, with 11 events and 3.2 million units.

Among second-quarter recalls, 14 were classified as Class I, which pose the most serious health or injury threats. As expected, most recalls were deemed Class II. There were 59 events involving 15.3 million units listed as Class II. There were 21 Class III recalls.

NUMBER OF RECALLED UNITS BY QUARTER

NUMBER OF RECALLS BY REASON



JULY insight

The FDA issued 28 pharmaceutical recalls in July 2022. That is slightly below the 31.3 monthly average for Q2 2022 (or a 10.5% decline). The difference between the number of units recalled was similar. There were 5.9 million units recalled in July, a drop of 14.0 percent compared to the 6.9 million units per month averaged in the second quarter. A single recall of 3.4 million units of hydrogen peroxide topical solution (due to cross contamination) accounted for 57.9 percent of all the July units recalled. This was followed by a recall of 1.6 million amino acid injection bags (for sterility concerns) which accounted for a further 27.4 percent of pharmaceutical recalls by unit.

In terms of events, concerns about cGMP and quality were responsible for the most July recalls with six events each. Lack of assurance of sterility came in second with five events, followed by contamination with four recalls.

KELLY JONES HOWELL,
MEMBER, **HARRIS BEACH, PLLC**

NEW FDA SURVEILLANCE TOOLS MAY MEAN GREATER RECALL RISK

The COVID-19 pandemic has upended regulatory plans over the past couple of years. The Food and Drug Administration (FDA) had good intentions to finally shift its focus and resources away from COVID as the surge of cases tied to the Delta variant started to come down. But then Omicron hit and the agency was forced to put those plans on hold.

The virus is unpredictable, and more than once the FDA has had to adapt on the fly. The agency is still balancing a very challenging workload and is overburdened with COVID-related reviews of emergency-use authorizations for products such as vaccines, medical devices and diagnostic tests, along with the other demands of what used to be "normal" operations.

There is every indication that this dynamic environment will continue. It seems unlikely the public health emergency will end in 2022 since we have seen more new variants evolve. Despite the fact that FDA resources continue to be stretched thin, the need for surveillance and monitoring to protect public health and safety remain essential.

FDA looking to alternative tools

One way that the FDA is trying to make sure product safety remains uncompromised is through the use of alternative tools in lieu of on-site inspections and some of the traditional tools the agency employed prior to the pandemic.

One of the most popular new tools is remote regulatory assessments (RRAs), including electronic records requests. This is particularly true with over-the-counter (OTC) drug companies and compounding pharmacies. Given the distinct possibility that anticipated future COVID variants could thwart the agency's efforts to get into facilities, the use of electronic records audits will become more common. Therefore, we can expect to see more warning letters result from these types of audits.

A significant percentage of warning letters in the second quarter of 2022 went to OTC drug companies, compounding pharmacies and outsourcing facilities. It is expected that a focus on OTC manufacturers for these types of reviews will continue. The documents that are generated to manufacture OTC drugs are often maintained electronically which makes it easier for the FDA to access the necessary records to deploy such alternative tools.

Final rules around electronic records inspections remain to be codified, so the expectations for companies are not always clear. However, in a post-pandemic world it is expected this still will move forward and these audits will become a permanent tool for the FDA. Giving the agency more authority for electronic records inspections could cause the FDA to cast a wider net and perform more alternative inspections. It would be one way of potentially reducing some of the current backlog caused by the pandemic-related restrictions that apply to on-site inspections.

FDA's continued pressure on compound pharmacies

Another sector of the pharmaceutical industry attracting increased regulatory attention is compounding pharmacies. Compounding pharmacies combine, mix or alter two or more drugs, and potentially other ingredients, to create a medication tailored to the specific needs of an individual patient.

The FDA does not approve compounded drugs, but it does inspect the facilities that create these products. There has been a rise in enforcement against compound pharmacies for cross-contamination issues, particularly concerning clean rooms at these manufacturing sites. Clean rooms are the part of a manufacturing facility engineered to have no contamination or infiltration.

Sterility issues had not been mentioned very often in enforcement documents over the past few years, but now issues such as cleaning and maintenance are showing up more frequently. Several recent warning letters have cited facilities' maintenance protocols including cleanliness of air ducts and clean rooms.

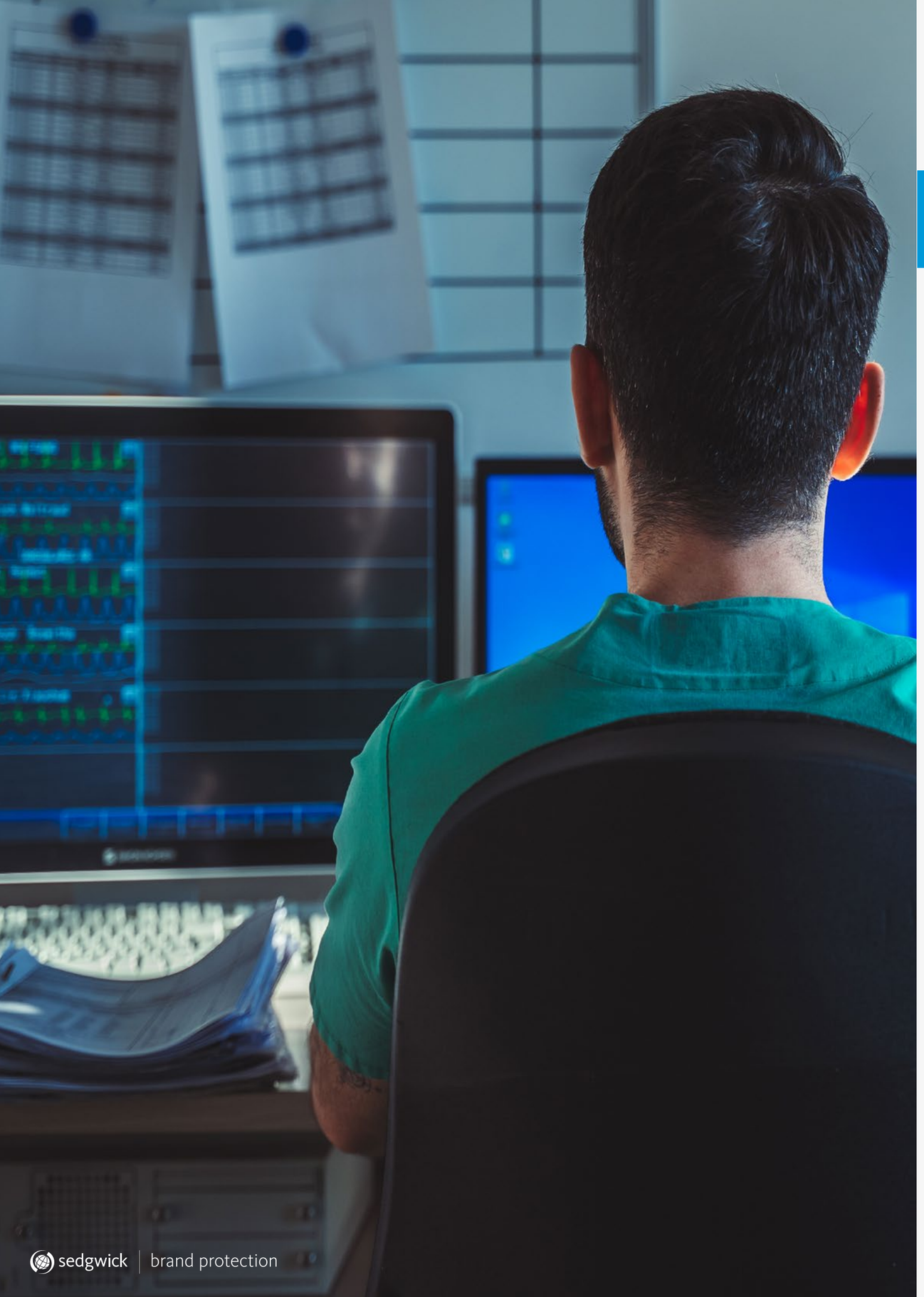
As would be expected, with increased FDA scrutiny, these facilities are seeing more enforcement actions.

Increased litigation risk

As FDA increases enforcement – either with remote inspections or other tools – the number of pharmaceutical recalls is likely to rise. And with more recalls, there is likely to be product liability litigation.

Plaintiffs' attorneys routinely follow recall activity and seek out people impacted by recalls in order to bring lawsuits against the companies involved. The move to e-records and more FDA transparency with tools such as the enhanced FDA Recall Data Dashboard are a gold mine for plaintiffs' lawyers. There is now much more access to information than ever before and more ways to capitalize on small violations that may not have led to a major recall but have generated concerns from the FDA.

As we see more lawsuits related to recalls, we also see an uptick in in such cases being consolidated in multi-district litigation (MDLs). Many plaintiffs' attorneys have been more aggressive in their requests for incredible amounts of data. This places a big burden on pharmaceutical companies to produce vast amounts of documents in these consolidated actions.



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How companies can prepare

There are several things companies can do to prepare for remote inspections and potential litigation. First, they should conduct internal audits, mock audits and general training. It is better to test out processes before the FDA comes calling. While things are calm, it is critical to revisit policies and procedures, especially around electronic documentation.

Companies should also have their internal risk and legal teams and their outside counsel meet to discuss perceived or potential issues that may be on the horizon. The earlier the internal risk and legal teams are involved in proactive planning for recalls, litigation and enforcement actions, the better. As part of that planning, identify key documents and the custodians of those documents. In today's business culture, people do not stay at one company for as long as they did in the past. Companies need to ensure they have the proper provisions for separation agreements in case former employees are called as witnesses in litigation or need to cooperate in an FDA inquiry.

Another area that should be reviewed and possibly updated is work-from-home policies. While the idea of people working from home was embraced because of the pandemic, people have come to demand that kind of flexibility. Once the public health emergency is over, it is expected many people will continue to work remotely. Companies need to ensure compliance is still in place for policies and procedures even if people are off-site.

Legal, risk and outside counsel should review how things are being done and how work-from-home policies interplay with other policies around compliance and risk and what the big picture looks like. For a quality function at any FDA-regulated company, companies need to have systems in place to ensure people can perform in the same way they would on-site in terms of complying with necessary protocols. There needs to be an integrated look at how that quality function is performed remotely.

Smaller and mid-sized companies should take the time to do a review with their insurance broker about their recall coverage. A surprising number of companies overlook this planning step. This is particularly important since there may be an increase in recall activity and more opportunity for the FDA to inspect a company by simply reviewing records and citing them for a violation. Companies need to make sure they have adequate and ample coverage. That includes knowing what is and isn't covered. Understanding the scope of coverage is key to mitigating a company's risk. If companies are underinsured, they may want to increase their coverage.

Looking ahead

While new COVID variants may keep the number of on-site inspections lower than the FDA had planned, enforcement through other digital and technological methods is on the rise. By assessing their vulnerabilities early and preparing for recalls and other regulatory actions, companies can mitigate the risk and hopefully reduce the length of time for and impact of any enforcement actions when they occur.

CONCLUSION

The U.S. and global business communities keep hoping for a return to "normal," but geopolitical and global health events continue to disrupt supply chains and operations. Companies are trying to gain ground lost during the worst of the COVID-19 pandemic, but new issues arise. In the U.S., political unrest is playing havoc on the markets, pulling focus away from core business operations and making consumer behavior less predictable.

This fall, all 435 of the U.S. House of Representatives seats and one-third of the U.S. Senate will face elections, which makes it hard to foresee what the legislative agendas will be, and if regulatory agencies will try to take the lead with enforcement if Congress is distracted.

Even though regulatory agencies have yet to return to pre-pandemic enforcement levels, 2022 is on track to set a new record for the total number of units recalled across all five industry sectors that we track. Only two other years on record have ever witnessed more than 1 billion units recalled, and in both instances, it was not until the fourth quarter that this figure was hit. This year, it took only until the close of July to surpass this milestone.

The one certainty is that companies need to plan for risks across a variety of areas, including the following:

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

Unfortunately, recalls in today's business environment are inevitable. But if recall and remediation plans are tested and updated in a routine manner (like other business processes), you can mitigate their impact and protect your brand when the inevitable occurs.

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

ABOUT SEDGWICK BRAND PROTECTION

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

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

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

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

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

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

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

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

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

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