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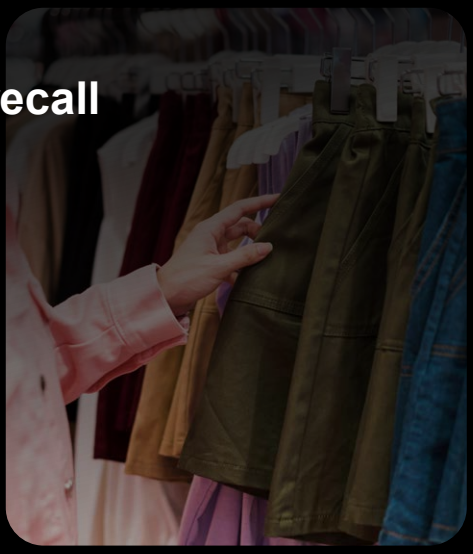
Recall Index

2026 edition 3

Product safety and recall

United States edition



















DATA, TRENDS & PREDICTIONS FOR U.S. INDUSTRIES

Introduction

Understanding the forces shaping product safety is fundamental to managing risk, protecting consumers and maintaining business resilience. Sedgwick's Product Safety and Recall Index provides an independent, data-led perspective on the developments reshaping the global product safety landscape, examining recall activity, emerging risk patterns and regulatory change to help business leaders understand not only where the market stands, but where it is heading.

Each edition covers five key product categories: automotive, consumer products, food and drink, pharmaceutical, and medical device.

Drawing on recall data from the U.S. National Highway Traffic Safety Administration (NHTSA), the U.S. Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA), the report delivers exclusive insights to help businesses protect their brands against operational risk and reputational damage.

This edition reviews recall data through the first three quarters of 2026, covering January 1 through September 30, with a preview of October data. Across all five industries there were 2,546 recalls compared with 2,418 over the same period in 2025, a 5.3% increase. This represents a continued rise in recall activity, although the underlying trends vary considerably across sectors.

Consumer products accounted for the largest increase in recall activity. The CPSC recorded 448 recalls, up 54.5% from 290 a year earlier. This marks the highest three-quarter event total for the sector in nearly 30 years, and it already exceeds the 414 recalls recorded across the entirety of 2025. Medical device events also rose, to 766 from 726. Automotive, pharmaceutical, and both FDA and USDA food recalls were down year-over-year, with USDA food recalls reaching their lowest three-quarter event total in more than 14 years.

The scale of product exposure, however, presents a markedly different picture. The volume of recalled products reached 1.72 billion units across all five industries. This is up 266.6% from 470.22 million in the first three quarters of 2025 and is more than double the 857.92 million recorded for all of 2025. In just nine months, the cumulative volume has surpassed the previous record of 1.48 billion units, set in 2022, placing 2026 on course to become the first year in which more than 2 billion units are recalled.

The medical device, automotive, and pharmaceutical industries have already exceeded their full-year recall volumes for 2025. Medical devices accounted for the largest share of recalled units, with 997.25 million, 526.6% above the first three quarters of last year and more than double the total for all of 2025. This is the highest three-quarter total in more than 21 years.

Pharmaceutical units rose 487.8% to 535.33 million, the third-highest three-quarter total in 22 years. Automotive units reached 32.77 million, a 61.3% increase compared to the corresponding period in 2025. Consumer product units were up 37.7% to 41.25 million. Food was the only sector to record a decline in recalled product volumes, with both FDA and USDA totals falling year-over-year.





Beyond the numbers, the Index looks at what is next for companies, from new compliance requirements to shifting priorities among regulators and legislators. Commentary from strategic partners at global law firms, insurers, and regulatory and safety organizations is included to help businesses anticipate emerging risks and make more informed decisions to protect their consumers and brands.

Oversight was a common regulatory thread throughout the third quarter. After several botulism outbreaks tied to powdered formula over the last four years, the FDA told infant formula makers to treat suppliers as part of the manufacturing process. A nearly $385 million settlement against an infant formula manufacturer underscored the cost of weak quality and safety controls.

The pharmaceutical sector faced similar risks. The FDA sent letters to telehealth companies and a compounding pharmacy over improper claims and practices around compounded weight-loss drugs.

The CPSC went further still, asking a federal court to order a recall for the first time since 1987. The agency also moved closer to mandatory safety standards for certain lithium-ion batteries.

Foreign suppliers found the U.S. market harder to enter. When trade talks with Canada collapsed, the U.S. added 50% tariffs on specified goods and then barred certain Canadian alcohol, dairy, and vehicles from importation. In the automotive sector, dealers, manufacturers, and labor groups asked Congress to finalize a ban on Chinese passenger vehicles and connected-vehicle technology after the administration suggested allowing Chinese automotive companies to build vehicles in the U.S.

A third theme was the line between what is regulated and what is not. The FDA asked for a review of software now excluded from the definition of a medical device to ensure there had not been a drift in functions. The agency also agreed to share nonpublic information with the Securities and Exchange Commission for filing reviews and enforcement, giving another agency a window into FDA-regulated companies.

This quarter regulators showed the cost of weak supplier controls, stretched enforcement beyond voluntary recalls, and made it harder for some foreign products to reach U.S. shelves. This report can help businesses assess what is next and plan even in a dynamic environment. We invite you to read the entire report cover to cover or just focus on the sections that matter most to your organization.

One final note: This edition of the Product Safety and Recall Index focuses on U.S. recall data and regulatory developments. For businesses operating across multiple markets, or managing supply chains exposed to international product safety risks, understanding developments beyond the U.S. is equally important. We therefore encourage you to explore our other regional publications.

Our European edition examines recall activity, regulatory developments and emerging product safety trends, providing independent analysis through the lens of companies and regulators operating in the UK and the European Union.

Our biannual Australian Product Safety and Recall Index report provides insights on recall activity, regulatory developments and evolving product safety priorities across the Australian market.

Q3 2026 European edition: click here

H1 2026 Australian edition: click here

Q2 2026 U.S. Recall Index: click here

Q1 2026 U.S. Recall Index: click here

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Automotive

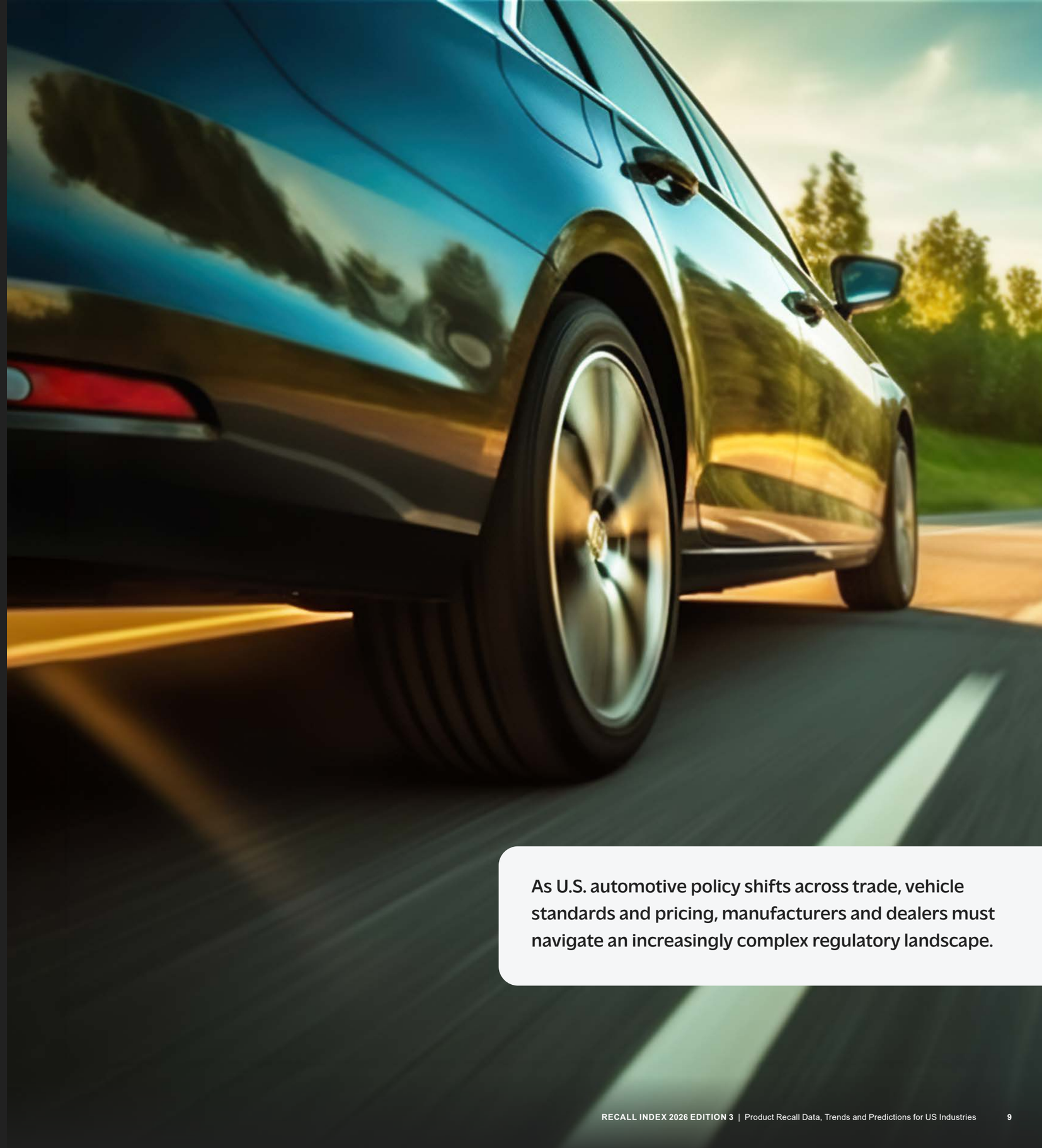
Ongoing trade tensions between the U.S. and Canada impacted the automotive supply chain in the third quarter. After talks stalled in August, the U.S. imposed additional 50% tariffs on specified Canadian goods, including steel, aluminum, automobiles, trucks, and truck parts. Canada responded with matching retaliatory duties on iron and steel, among a range of other products. A full ban on certain Canadian products, including motorcycles, took effect on September 29.

In Congress, automakers, suppliers, dealers, and labor groups worked to finalize a permanent ban on Chinese passenger vehicles and related connected-vehicle technology. If passed, the Connected Vehicle Security Act of 2026 would create formal legislation to replace a 2025 Commerce Department rule. Stakeholders were concerned after the administration signaled it might allow Chinese companies to build cars in the United States.

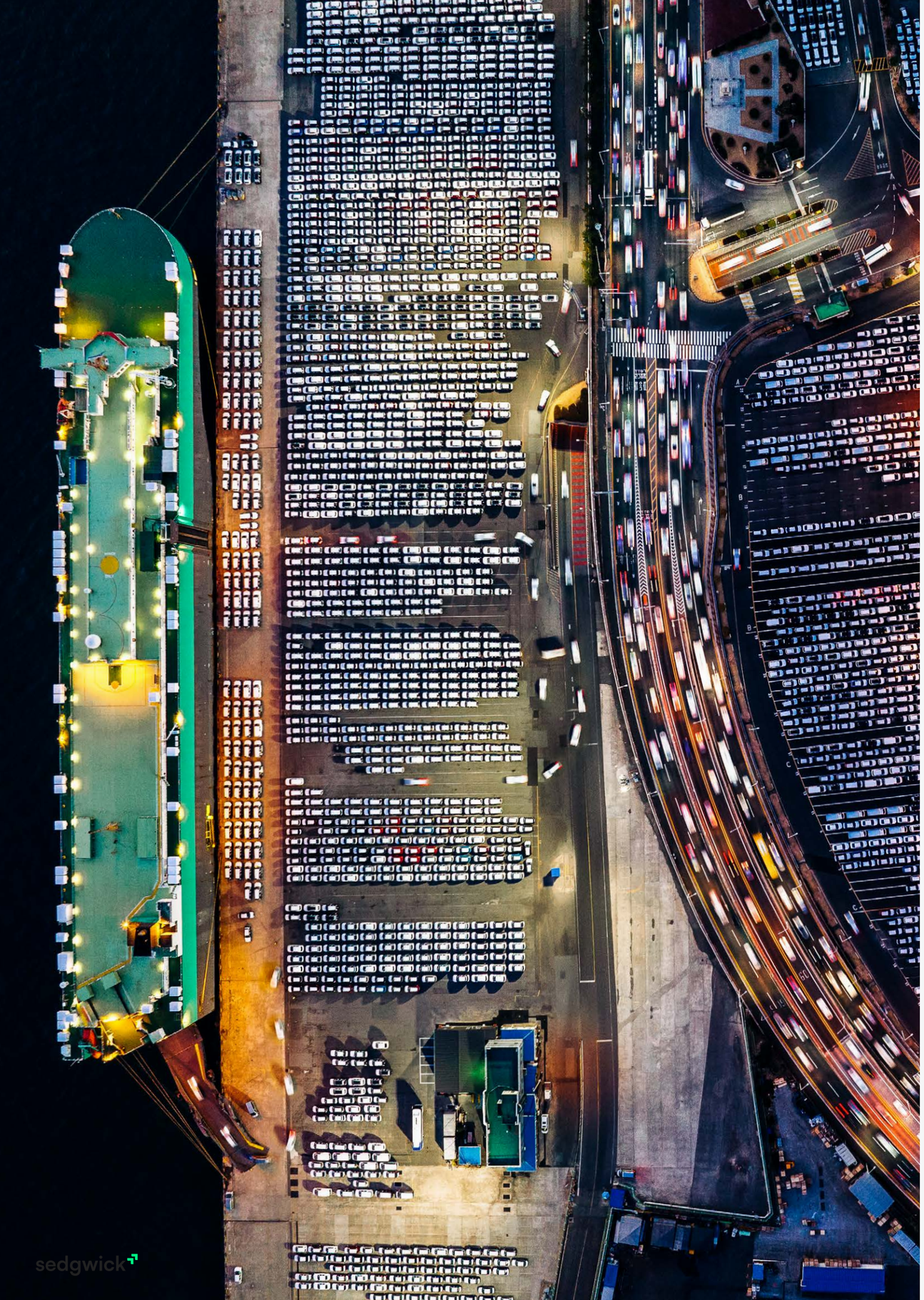
The National Highway Traffic Safety Administration (NHTSA) finalized plans to ease vehicle mileage rules for 2031 to well below levels that had been set in 2024 for the same time period.

The Federal Trade Commission (FTC) published price-transparency FAQs reminding dealers that the advertised price of a vehicle must be the price any consumer can walk in and pay, excluding only government-required charges. This follows a crackdown in March, when the agency sent warning letters to nearly 100 automotive groups.

Automakers and dealers now simultaneously face pressure on three fronts: who may sell and build vehicles in the U.S., how efficient those vehicles must be, and how they are priced to consumers.



As U.S. automotive policy shifts across trade, vehicle standards and pricing, manufacturers and dealers must navigate an increasingly complex regulatory landscape.



Chinese vehicles face more resistance

In the third quarter of 2026, industry groups urged the administration to keep Chinese automakers out of the U.S. market. Six organizations representing manufacturers, suppliers, and dealers asked the White House to maintain policies that block Chinese companies from selling, importing, or manufacturing vehicles in the U.S. They argue that Chinese investment would not create new American jobs and would shift work away from companies that have already made long-term investments in U.S. plants.

A January 2025 Commerce Department rule already limits connected-vehicle hardware and software with significant links to China or Russia and restricts the sale of completed connected vehicles by entities tied to those countries. The U.S. also maintains 100% tariffs on Chinese electric vehicles.

The industry letter followed public comments from officials that the administration might accept Chinese car companies building vehicles in the U.S. Manufacturers say such a shift would pose a serious threat to domestic production by already established brands.

Bipartisan sponsors in the Senate sought fast-track approval of the Connected Vehicle Security Act of 2026 as U.S. and Chinese leaders prepared to meet on trade in late September. The bill would make the existing restrictions permanent, prevent White House waivers for Chinese vehicles, and bar the import, manufacture, and sale of connected vehicles, software, and hardware linked to China and other foreign adversaries. Vehicle and software limits would begin in 2027. Hardware limits would follow in 2030.

The measure has support from major automakers, labor unions, and supplier groups. An attempt to advance the bill by unanimous consent in late September fell short. Sponsors said they would continue gathering support, while a House companion bill still needs to advance. The two chambers would then have to reconcile any differences before a final bill could reach the president.

Automakers and suppliers should continue mapping software, hardware, and connectivity components against both the 2025 rule and the legislation. The third-quarter debate shows that the policy decision is not final. Congress is trying to harden the ban, while the administration seems open to the idea of Chinese automobile manufacturing in the U.S.

Administration cuts 2031 fuel economy targets

In September, NHTSA issued a final rule recalibrating Corporate Average Fuel Economy (CAFE) standards for passenger cars and light trucks. The agency projects that the revised requirements would set the combined industry fleetwide average to 34.9 mpg in model year 2031. Under the standards set in 2024, the goal was to raise the average for 2031 to 50.4 mpg, with passenger-car targets rising 2% annually through 2031 and light-truck targets rising 2% annually for model years 2029 through 2031.

The new framework covers model years 2022 through 2031 and takes effect on November 30, 2026. NHTSA notes that 34.9 mpg is a projection. The actual standards are footprint-based target curves. The fleetwide result will depend on the mix of vehicles manufacturers sell. Consistent with a June 2025 rule, the standards apply to gasoline and diesel vehicles and do not include electric vehicles.

The administration has argued that less stringent requirements could lower production costs and give manufacturers more flexibility across cars, SUVs, and pickups. Automakers still have to manage overall fleet fuel economy and meet other federal and state vehicle rules. In addition, consumer demand, technology costs, and fuel prices will impact the mix of gasoline, hybrid, and electric models.

In August, NHTSA also published an interpretive rule concluding that it has statutory authority to set fuel economy standards only for vehicles, not engines, in the commercial medium- and heavy-duty program. The agency plans to develop rules to revise that program. Together with the light-duty CAFE reset, the moves clarify the government's expectations for manufacturers around fuel efficiency for the next five years.

Vehicle makers should review product plans, footprint mix, and compliance credits against the new goals. The lower 2031 target eases near-term pressure to electrify the fleet to hit CAFE, but it does not remove other emissions, safety, or state-level requirements that still influence what gets built. It also does not factor in consumer desire for more fuel-efficient vehicles.

FTC releases price transparency guidelines for auto dealers

In September, the FTC published FAQs on price transparency to help the automobile industry comply with the FTC Act's restrictions on unfair competition and deceptive trade practices. The agency emphasized that the advertised price of a vehicle must be the actual price any consumer can walk in and pay to purchase it, excluding only charges that the government requires the consumer to pay.

The FAQs cover advertising across media, how mandatory fees must be disclosed, how discounts and rebates may be presented, and the shared responsibility of dealers, advertisers, and manufacturers regarding third-party ads. They follow warning letters the FTC sent to dealership groups nationwide in March. The agency is focusing on dealers that add document fees, "certification" charges, or other extras at the desk after advertising a lower price.

In August, the FTC and the State of Connecticut secured a $4 million settlement with a Connecticut auto dealer over alleged deceptive fees. The complaint said customers were charged thousands of dollars they had not authorized, including fees to "certify" used cars that had already been advertised as certified pre-owned, and add-on products inserted into financing agreements without consent. Under the order, the dealer must prominently disclose the maximum total price a consumer must pay, excluding only required government charges, and obtain express, informed consent for every charge.

Dealers, advertisers, and manufacturers that fund third-party listings should audit advertised prices against out-the-door numbers, including online and marketplace ads. The FAQs do not create a new statute, but they make it clear that this is a priority for the FTC—and the Connecticut settlement shows the cost of not complying.



By the numbers

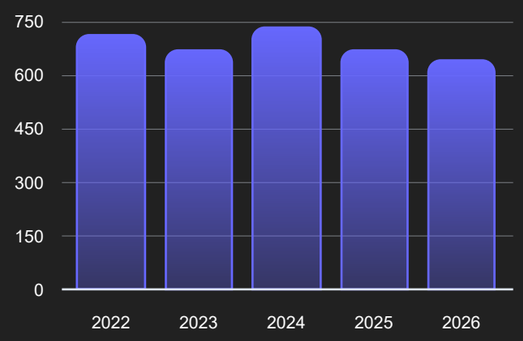
Across the first three quarters of 2026, there were 648 automotive recalls involving 32.77 million units. That compares with 676 recalls impacting 20.32 million units over the same period in 2025: 4.1% fewer events, but a 61.3% increase in volume year-over-year. The divergence between these figures highlights a significant shift in the scale of automotive recall exposure, with fewer events affecting substantially greater numbers of vehicles. The 32.77 million units recalled through September already exceed the 27.42 million recorded for all of 2025.

Electrical systems were the leading cause of U.S. automotive recalls by event through the first three quarters of 2026. They were linked to 124 recalls. Equipment was second with 100 events. Structure was third with 46 recalls.

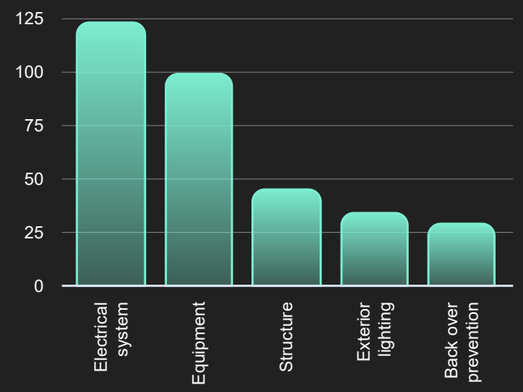
Electrical systems were also the top cause by volume, affecting 8.03 million units. Back over prevention ranked second with 5.02 million units impacted across 30 recalls. Power trains were third by volume with 2.47 million units affected across 28 recalls. Five recalls through September involved more than 1 million units, including one event impacting 4.38 million pickup trucks with an electrical-system defect.

Vehicles accounted for 577 of the 648 recalls through the first three quarters of 2026 and 32.16 million of the units affected. There were 56 equipment recalls involving 291,777 units, six child seat recalls affecting 293,449 units, and nine tire recalls covering 19,056 units.

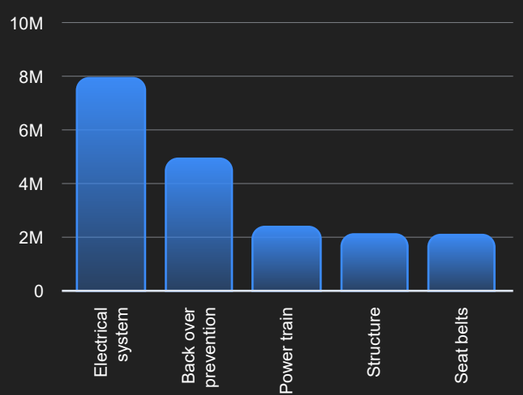
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recalled units by category (top 5)







Shifting gears: the changing landscape of U.S. vehicle regulation

ALLETTA BRENNER, **LINDSAY CARLSON** AND **TALINE GETTAS**,
ASHURST PERKINS COIE

U.S. vehicle regulation is currently being rewritten on several fronts. In the past few months, the National Highway Traffic Safety Administration (NHTSA) has finalized a contested reset of the Corporate Average Fuel Economy (CAFE) program, launched the first major overhaul of its tire safety standards in more than 20 years, and advanced a series of proposals to adapt the Federal Motor Vehicle Safety Standards (FMVSS) to automated vehicles.

Beyond NHTSA, the Commerce Department's Connected Vehicle Rule is reaching its first hard deadline with Model Year 2027. For manufacturers and suppliers, the result is a rulebook in flux, with much of it still open to legal and political challenge.

Fuel economy reset: Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule III

On September 30, 2026, NHTSA published the "SAFE Vehicles Rule III." The measure resets CAFE standards for passenger cars and light trucks, establishing the minimum average fuel economy that carmakers' fleets of new passenger cars and light trucks must meet.

The final rule lowers the fuel economy standards for passenger cars and light trucks for Model Years 2022 to 2031, applying retroactively from Model Year 2022 to the present. It also tightens which vehicles count as light trucks from Model Year 2030, ends trading of credits earned from Model Year 2028, and builds the $0 civil penalty that Congress set in July 2025 into the regulations. The new rule takes effect on November 30, 2026.

NHTSA's decision to weaken fuel economy requirements is being challenged in two parallel lawsuits, both filed October 2, 2026 in the U.S. Court of Appeals for the First Circuit. The first was brought by a coalition of environmental and consumer protection organizations. In the other, a coalition of 26 states, counties, and cities argues that NHTSA wrongly left the millions of electric vehicles already on the road out of its analysis. As a result, its targets for the next five years fall below what the U.S. fleet actually achieved in 2021. Moreover, the plaintiffs claim that drivers would lose nearly $220 billion in fuel savings, and ending credit trading is projected to harm the electric vehicle industry.

Tire safety back on the agenda

On October 26, 2026, NHTSA announced the first major overhaul of tire safety standards in more than 20 years in order to enhance driver safety and lower automotive costs. As part of this revision, NHTSA will update test methods for rim resistance and endurance and tire strength, set safety rules for new designs such as airless tires, modernize sidewall markings, and review weight-limit guidelines for trucks and SUVs.

To accelerate the process, NHTSA will use negotiated rulemaking. The Secretary of Transportation will appoint up to 18 stakeholders from tire manufacturers, vehicle manufacturers, safety organizations, research institutions, and engineering associations.

Rewriting the FMVSS for automated vehicles

Historically, safety rules have been developed with the assumption that a human driver would operate the vehicle. As part of the Automated Vehicle Framework announced in April 2025, NHTSA is rewriting a number of FMVSS so that they cover vehicles driven entirely by an automated driving system (ADS) with no steering wheel, pedals, or other manual driving controls. The updated rules may allow manufacturers to sell ADS vehicles without a special exemption.

At present, a manufacturer of vehicles that do not comply with the applicable standards has to apply for an exemption under 49 Code of Federal Regulations Part 555. This exemption allows manufacturers to temporarily sell a limited number of non-compliant vehicles. On July 30, 2026, NHTSA announced a temporary two-year exemption from sections of eight different vehicle safety standards for up to 2,500 robotaxis annually from a specific manufacturer.

So far this year, the agency has published modernization proposals related to transmission shifting, windshield defrosting/wiping, vehicle lighting, tire placards, and braking systems. One of the proposed modifications would exempt ADS-equipped vehicles without manual driving controls from the windshield defrosting/wiping standards, as these systems help a human driver see. These FMVSS serve no equivalent safety purpose without a human driver. The proposal relating to vehicle lighting includes an optional cyan marker lamp for ADS-equipped vehicles to indicate to other roadway users that the vehicle is not being operated by a human driver.

In addition, NHTSA announced its intention to update the standards for controls and displays, mirrors and rearview display, electronic stability control systems, and sun visors and warning labels.

However, the current rules still apply in full. In September 2026, NHTSA opened an Audit Query into one AV company's self-certification that its new robotaxi complies with all applicable FMVSS, stressing that "existing standards remain in force" until the rewrites are complete. Until the new rules are finalized, developers of vehicles without manual controls must either comply with the existing standards or obtain an exemption. They should also keep their self-certification records ready to withstand scrutiny.

Beyond NHTSA: the Connected Vehicle Rule

On January 14, 2025, the Bureau of Industry and Security (BIS) issued a rule restricting the import and sale of certain connected vehicles and related hardware and software linked to China and Russia. The measure was in response to concerns that connected vehicles collect sensitive data and may permit remote access by entities linked to a foreign adversary. It took effect on March 17, 2025 and applies to vehicles under 10,001 pounds.

The prohibitions are phased. Two of them start with Model Year 2027. First, vehicles may not be sold if they use connectivity or automated driving software from companies owned by, controlled by, or subject to the jurisdiction or

direction of China or Russia. Second, manufacturers linked to China or Russia may not sell connected vehicles in the U.S., even if the vehicles are built in the U.S.

From Model Year 2030—or January 1, 2029 for non-model-year components—imports of Vehicle Connectivity System hardware with a China or Russia nexus are also prohibited. Software developed before March 17, 2026—provided it is not later modified or maintained by an entity linked to a foreign adversary—falls outside the definition of covered software.

As of June 18, 2026, suppliers can apply to have their hardware or software listed on the Approved Supplier Registry of the BIS. The Registry itself has not been published yet.

The Connected Vehicle Rule might be put into statute by the Connected Vehicle Security Act of 2026. The federal bill is still pending, but the most recent draft would extend the framework, including adding Iran and North Korea to the list of covered countries.

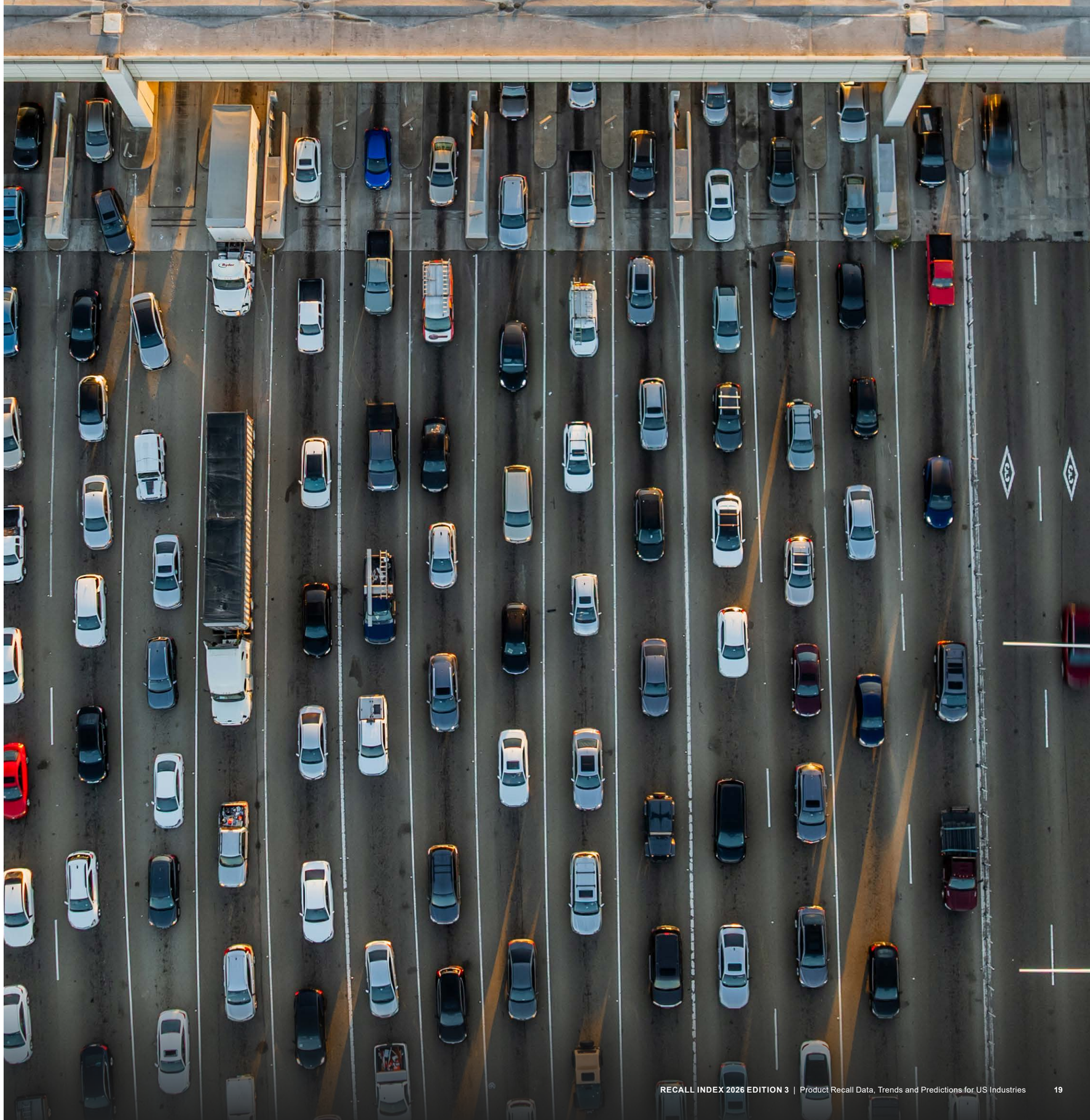
Staying ahead of a moving rulebook

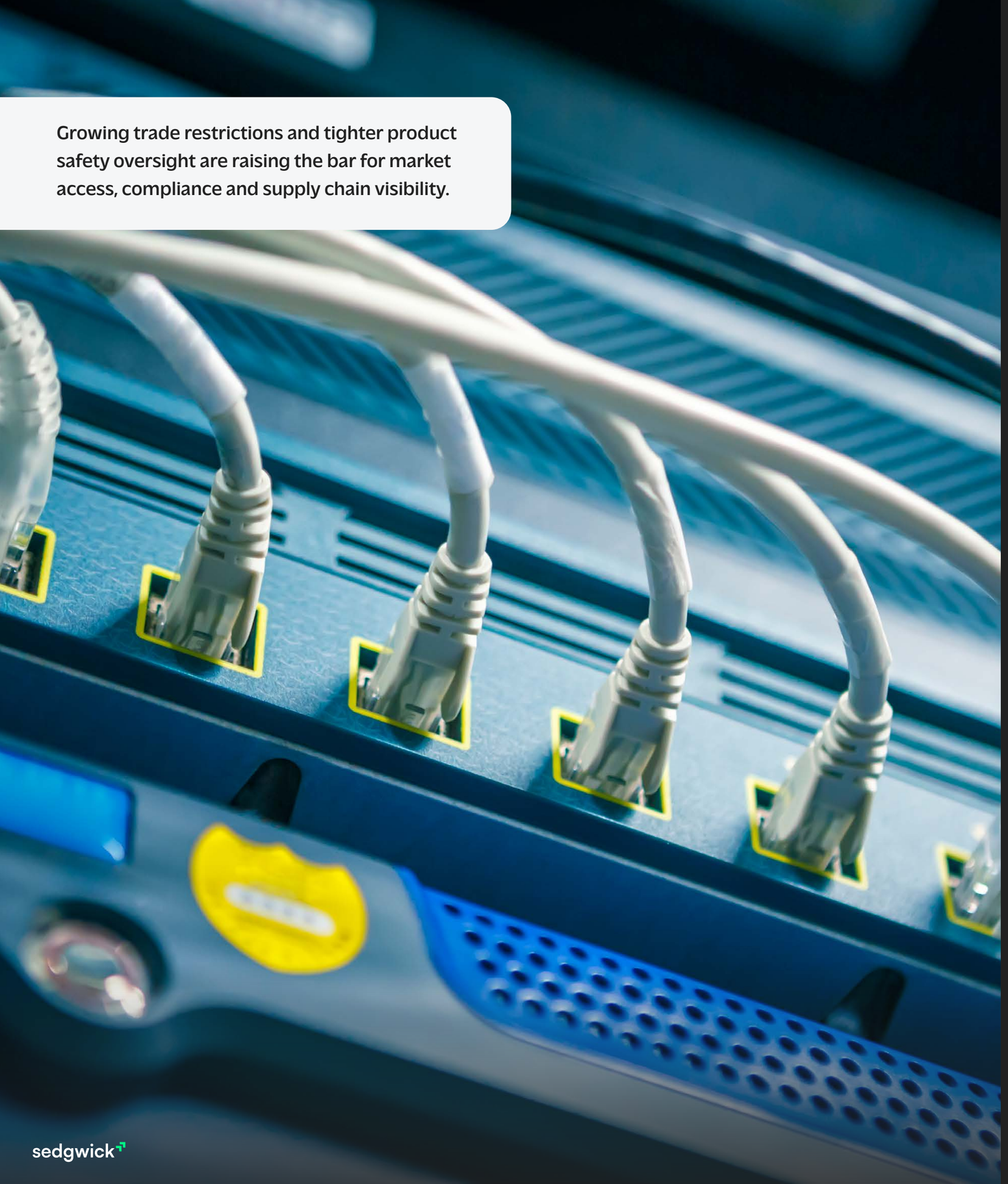
Many aspects of the existing U.S. vehicle rulebook are being rewritten all at once. The next few months will test how far the Trump Administration's priorities can be locked in before the political or legal climate changes. Rules made by executive action can be undone just as quickly by the courts, Congress, or a future administration. Carmakers would be wise not to abandon compliance strategies built for the previous rules too quickly.

For automated vehicles, the pace depends on how fast proposals become final rules; for example, comments on the vehicle lighting proposal are open until November 25, 2026. Until then, exemptions and well-documented self-certification remain the practical route to market.

More broadly, vehicle regulation is no longer only about safety and emissions. It increasingly involves data, national security, and industrial policy and is influenced by agencies well beyond NHTSA. As a result, compliance can no longer be handled one standard at a time. Manufacturers and suppliers with a flexible compliance program that spans these areas, and that take part early in rulemaking, will be best placed to help shape the rules rather than simply react to them.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.





Growing trade restrictions and tighter product safety oversight are raising the bar for market access, compliance and supply chain visibility.

Consumer products

The Senate confirmed two new Republican Commissioners to the U.S. Consumer Product Safety Commission (CPSC). This brings the agency to three members—all Republicans—which is the number needed to officially transact business. The CPSC had operated with a single sitting Commissioner since August 2025 after three Democratic Commissioners were removed earlier that year.

After trade negotiations with Canada collapsed on August 21, the U.S. set additional 50% tariffs on specified Canadian products. Canada announced matching countermeasures on roughly C$27.6 billion of U.S. goods, effective September 8. In response, the U.S. banned the import of specific Canadian alcoholic beverages, dairy products, and motor vehicle products completely as of September 29.

Canadian goods aren't the only prohibited products. In August, the Federal Communications Commission (FCC) added foreign-produced power inverters, drones, routers, and advanced robotic devices to its Covered List. This essentially bans new models of certain devices because they will not be eligible for the equipment authorization most electronics need before they can be imported or sold in the U.S.

In July, the Department of Justice (DOJ) announced that its Trade Fraud Task Force had generated more than $1 billion from civil and criminal recoveries, penalties, forfeitures, and publicly charged losses in less than a year. The DOJ and Department of Homeland Security are prioritizing efforts to combat trade fraud—including country-of-origin, classification accuracy, and duty evasion—through criminal prosecutions and civil enforcement actions.

The comment period for the first mandatory federal safety standard for lithium-ion batteries in micromobility products closed in August as the CPSC works to finalize new legislation. In addition, the agency announced in July that it is modernizing the National Electronic Injury Surveillance System (NEISS), which uses hospital-based data to spot emerging product safety hazards. The new system will use secure, standardized electronic data exchanged through a federally designated health information network to collect injury information from emergency rooms in all 50 states. This could help regulators identify dangerous products sooner.

The CPSC continued its aggressive enforcement stance, using a legal statute to mandate a product recall through the federal court system for the first time since 1987. However, some of its tactics are being questioned.

Companies across the consumer products sector face a widening set of market-entry obstacles. Tariffs, import exclusions, and equipment authorization requirements now sit alongside traditional product safety compliance. A restored quorum means the CPSC can once again vote on mandatory standards and civil penalties, while the agency's strict oversight shows no signs of slowing down.

Regulations for lithium-ion batteries move forward

The CPSC has been discussing mandatory rules for lithium-ion batteries for several years due to reports of fires involving e-bikes, e-scooters, and similar products. In June, the CPSC published a proposed mandatory safety standard for lithium-ion batteries that would apply to e-bikes, e-scooters, hoverboards, electric skateboards, electric unicycles, and similar products, as well as replacement battery packs, aftermarket chargers, and e-bike conversion kits.

Commercially owned micromobility products used by consumers, including rental fleets, are also in scope. This means shared mobility operators would be subject to the same federal battery safety requirements.

The agency based the proposal on 227 unique incidents involving 357 victims between January 1, 2019 and December 31, 2023. Those incidents were linked to 39 fatalities and 181 injuries. The CPSC estimates the rule would mitigate roughly 90% of the deaths and injuries within its scope.

Under the proposed rule, manufacturers would need to incorporate specific UL safety standards by reference depending on whether the product is an e-bike, personal e-mobility device, or replaceable battery pack.

The measure also adds several new requirements such as tamper-resistant battery enclosures, new testing to prevent batteries from being charged while cells remain too hot after use, and reverse-polarity protection to address incompatible chargers. Device makers would also need to expand warning labels and enhance consumer instructions related to charging, battery replacement, homemade batteries, and water exposure. Where applicable, the final regulation would also be added to the CPSC's list of children's product safety rules requiring third-party testing and certification.

The comment period closed in August. Attorneys with Beveridge & Diamond PC encourage companies that manufacture, import, distribute, or sell micromobility products, replacement batteries, aftermarket chargers, or e-bike conversion kits to evaluate the proposal and identify any gaps between current product designs and the proposed federal requirements, particularly if products are certified to existing UL standards.

The legal experts also recommend reviewing product testing, labeling, and certification programs and assessing the proposal's potential preemption of state and local battery safety requirements.





FCC bans certain electronic imports

On July 28, 2026, the FCC's Public Safety and Homeland Security Bureau announced the addition of foreign-produced power inverters, drones, routers, and advanced robotic devices to the Covered List maintained under the Secure and Trusted Communications Networks Act of 2019.

Products on the Covered List cannot receive FCC equipment authorization. Most electronic devices need that authorization before they can be imported, marketed, or sold in the U.S. Therefore, the listing effectively closes the market to new models.

The FCC defines "foreign-produced" by place of production rather than by company nationality. To be considered a U.S. domestic product, a device must be manufactured in the U.S. and contain more than 65% of U.S. components.

The restriction applies only to new device models seeking authorization. Previously authorized models may continue to be imported, marketed, and sold, and consumers may keep using devices they already own. Sales to the federal government are exempt, as are small quantities imported solely for product development, testing, or re-export.

The agency significantly narrowed the list on August 20, 2026. Several definitions were updated and exclusions were added for a range of products. In addition, connected vehicles, rail vehicles, uncrewed aircraft, underwater vehicles, FDA-regulated medical devices, including wheelchairs and walkers, and fixed industrial robot arms are all excluded.

Importers and manufacturers of connected hardware should determine whether any product line now requires a conditional approval before new models can be certified. They should also factor this review time into product launch schedules.

Attorneys with Steptoe LLP also suggest that companies consider onshoring manufacturing for certain products if the new restrictions are overly prohibitive.

CPSC continues aggressive enforcement

In July, the CPSC and DOJ filed an imminent hazard lawsuit in a U.S. District Court against a foreign manufacturer and a retailer of immersion water heaters. It is the first time in nearly 40 years that this tactic has been used.

The complaint alleges that the heaters can overheat and catch fire within minutes when energized while partially or completely out of water, and that they lack a cutoff to shut the unit off when the heating element is not in contact with water or reaches a dangerous temperature. The CPSC identified at least 235 fire-related incidents since December 2022. The lawsuit claims more than 98,000 units were sold in the U.S. through an online platform. The agency issued a unilateral safety warning alongside the filing.

Normally, the CPSC uses voluntary recalls to take unsafe products off the market. Under Section 12 of the Consumer Product Safety Act, the government can file suit if a product presents an imminent and unreasonable risk of death, serious illness, or severe personal injury. The court may declare the product imminently hazardous and order relief that includes notice to purchasers, public notice, recall, repair, replacement, or refunds.

Acting Chairman Peter Feldman said the agency had formed a Section 12 Task Force and would continue to use this process, particularly for "dangerous foreign imports" from overseas manufacturers.

The agency also faced a setback in its enforcement efforts. In September, a U.S. District Court challenged the agency for publishing a statement warning against the use of weighted blankets and weighted swaddles for infants. The court said that the agency did not provide a "satisfactory explanation" to support its warning and had not conducted its own investigation to determine if statements made about the products' safety by a third party were accurate.

Taken together, these developments point in two directions. Companies—especially foreign manufacturers—should expect to see more court-ordered recalls and should ensure their own surveillance of incident data keeps pace. At the same time, manufacturers should keep clear, comprehensive records on product safety in the event that they need to defend themselves against claims they feel are unfounded.

By the numbers

Across the first three quarters of 2026 there were 448 CPSC recalls compared with 290 recalls over the same period in 2025. That is a 54.5% increase and the highest three-quarter event total in nearly 30 years on record. The 448 recalls through September 2026 already exceed the 414 recorded for all of 2025.

In terms of volume, there were 41.25 million units recalled from January 1 through September 30, 2026. This is up 37.7% compared to the first three quarters of 2025. Nine recalls through September involved more than 1 million units.

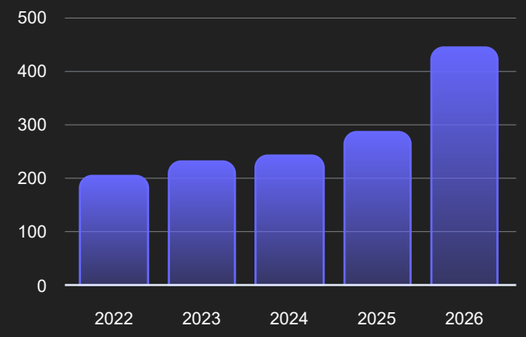
Yard & Garden accounted for the most recalls by category through the first three quarters of 2026, linked to 70 events. Toys was second with 68 recalls, followed by Home Furnishings & Décor with 54.

In terms of recalled units, Yard & Garden was also the top product category, with 18.51 million units impacted: including 15.31 million grill brushes across three separate recalls. Home Appliances was second by volume with 4.26 million units, driven by four steam cleaner recalls involving 3.44 million units. Electronics was the third highest category with 3.49 million units impacted.

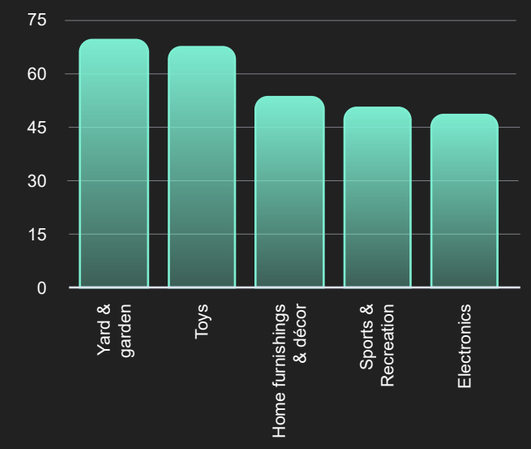
Ingestion was the top consumer products hazard by event. It was linked to 71 recalls through the first three quarters of 2026. Entrapment was second with 47 events, followed by the combination of burns and fire with 41.

Ingestion also led by volume, impacting 19.13 million units: driven largely by the grill brush recalls. Burns were second with 4.34 million units. The combination of burns and fire ranked third with 4.13 million units.

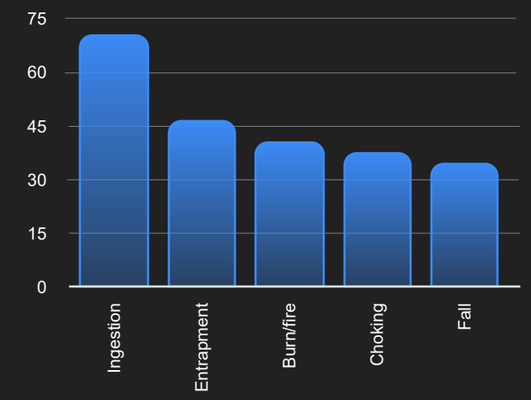
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)







Consumer product safety and cyber risks

DR. SUMMER CRAZE FOWLER AND **DR. JASON L. HERTZBERG,** *EXPONENT, INC.*

Consumer product safety analyses have traditionally involved the investigation of physical failure modes such as battery thermal runaway, mechanical or electrical hazards, or products that do not meet a particular safety standard. Cybersecurity is an emerging risk category, and not all corporate risk managers and attorneys are equipped to spot it. The trigger for a cyber recall may follow a different logic than the trigger for a traditional recall. The discussion below focuses on that logic and what it means for those who assess risk within an organization and legal counsel.

The biggest cybersecurity challenges and risks for consumer products

A central cybersecurity risk in 2026 is that product connectivity is converting software defects into product safety events like unintended door unlocking, heating, and charging. Take for example the very recent October 2026 report of hackers raising the temperature of connected refrigerators and freezers at hundreds of French supermarkets reportedly as a result of a software vulnerability, causing fires and spoiling food.

Cyber-triggered recalls cluster around incidents meeting at least one of two conditions: a regulator has clear recall authority over the sector, or an incident is large and visible enough that a recall becomes unavoidable regardless of jurisdiction. It is reasonable to conclude that Consumer Product Safety Commission (CPSC) recall statistics understate the industry's cyber exposure because most cyber incidents meet neither condition.

The first condition, which is regulator-driven recalls, is the one most risk managers and attorneys will recognize. Cybersecurity risks are not limited to consumer products. After researchers demonstrated in 2015 that they could use a cellular connection to remotely control the steering, brakes, and transmission of a specific vehicle model, the manufacturer recalled 1.4 million vehicles at the direction of the National Highway Traffic Safety Administration (NHTSA). NHTSA had jurisdiction because it regulates vehicles generally, not because a cybersecurity-specific rule existed.

The 2017 recall of 465,000 implantable pacemakers followed the same logic. The Food and Drug Administration (FDA) ordered a firmware update after researchers showed the devices' radio-frequency authentication could be bypassed by a nearby attacker. The agency already had recall authority because it regulates medical devices.

The second condition appears where no dedicated regulator exists and mass visibility substitutes for regulatory authority. In 2016, Chinese-made webcams were conscripted into a widespread malware attack and used in a denial-of-service attack that knocked several leading e-commerce and social media sites offline, among others.

The manufacturer recalled the affected cameras in the U.S. market not because a CPSC-style mandate required it, but because the incident was too visible to ignore. Compare that to a situation in 2024 in which a smart-lock application was found to store hardcoded credentials that could let an attacker remotely control locks used across an estimated 50,000 households. The Cybersecurity and Infrastructure Security Agency (CISA) issued a public advisory. There was no recall because ordinary smart-home devices have no dedicated regulator with clear recall authority. Also, the incident, while serious, produced no mass, publicly visible event.

For corporate risk managers and legal counsel, the lesson is that the absence of a recall does not mean the absence of exposure. A vulnerability in a connected lock, camera, appliance, or wearable device can generate liability, notification duties, and reputational harm long before, and often instead of, a formal recall.

How companies can prepare

Three measures matter most, and they are cyber-specific rather than general compliance housekeeping. First, build a documented vulnerability-intake and triage process with a defined threshold for when the organization is on notice of a defect. Because most connected consumer products fall outside a sector-specific regulator's recall authority, that internal threshold, not a regulatory trigger, is often what a court will examine later in assessing whether the response was reasonable.

Second, have a software update channel and treat it as a security-critical asset. Without an update channel, all vulnerabilities are permanent. A compromised or unreliable update mechanism turns every device in the field into a single point of failure, and it is frequently the first thing a plaintiff or cybersecurity expert will scrutinize.

Third, maintain a software bill of materials that traces firmware and third-party libraries to their source. A defect introduced upstream, such as in a compromised chip, camera module, or lock controller supplied by a third party, is a recurring fact pattern in the incidents above. Knowing precisely which products and components are affected determines whether a response can be narrowly targeted (i.e. putting a fence around a problem) or must be broad and potentially costly. Traceability is an important part of a company's product safety compliance program which is expected to be implemented and effective.

Changes ahead for the recall landscape

Expect the volume of cyber-driven recalls to rise, but unevenly, tracking the two conditions above rather than rising uniformly across the industry. The clearest driver is the EU's Cyber Resilience Act (CRA), whose vulnerability and severe-incident reporting duties took effect in September 2026. Several security-by-design obligations follow in December 2027. The CRA effectively manufactures the first condition of a regulator with clear recall-adjacent authority for a huge swath of connected consumer products that have never had one.

Manufacturers should expect a meaningfully higher rate of cyber recalls in the EU once the regime is fully in force. In the United States, no comparably comprehensive framework is likely in the near term, and even if one eventually emerges, it is unlikely to reach the CRA's scope.

What is more likely is continued sector-by-sector expansion. Motor vehicles and medical devices already have it, and other

categories, such as home routers, are more likely to gain oversight through national-security or critical-infrastructure authority than through a CPSC-style product safety mandate. It is also possible that increasing AI cyber capabilities will also increase the number of impossible-to-ignore incidents.

Looking ahead

Four developments are worth tracking. First, the CRA will likely become an informal global baseline for security-by-design practices for products that are not already regulated by a specific approach. Manufacturers rarely maintain separate designs for separate markets, so products sold in the U.S. will likely meet the higher EU standards, even without an equivalent U.S. mandate.

Second, expect the U.S. government to keep addressing consumer-product cyber risk through channels other than product-safety regulation. A U.S. Department of Commerce rule restricts Chinese- and Russian-linked connected-vehicle hardware and software, phasing in for model years 2027 through 2030.

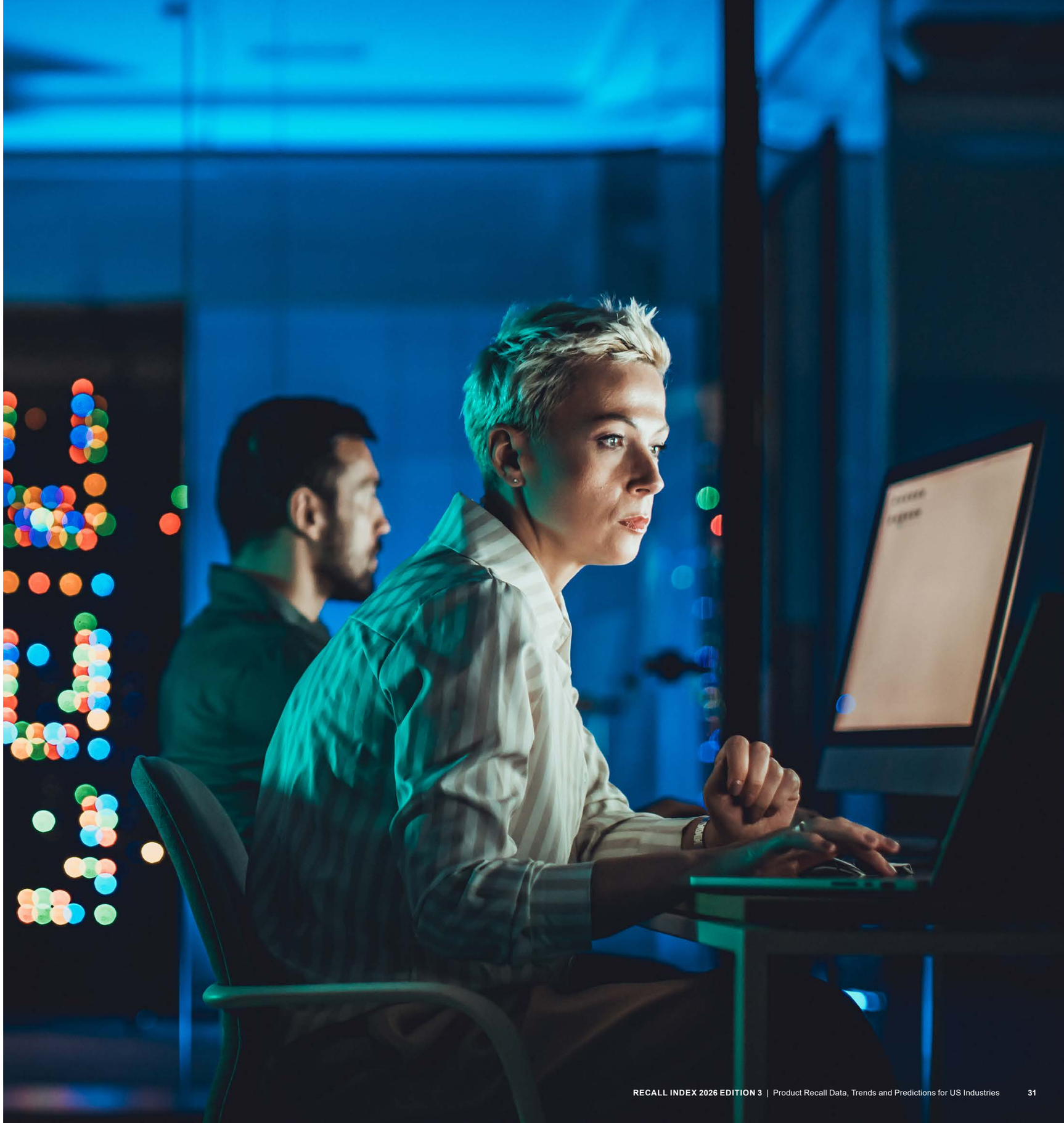
The Federal Communications Commission (FCC) announced a March 2026 decision adding all foreign-produced consumer-grade routers to its Covered List after intelligence agencies tied compromised routers to state-sponsored attacks on U.S. networks. Both measures show that the government is treating consumer-product cybersecurity as a national-security concern even without a domestic cyber-recall statute.

Third, expect new product-liability theories arguing that a failure to patch a known vulnerability or to define and honor a support period qualify as a design or warning defect. This adds more post-market responsibilities for manufacturers and follows regulators' trend to want more management of the full product life cycle.

Fourth, expect insurers to underwrite cyber and product recall risk together by pricing coverage against a company's demonstrated vulnerability management practices rather than waiting for a recall history to develop. This emphasizes the importance of having—and continually testing and updating—a robust recall plan.

The organizing idea is that cyber recalls remain rare not because cyber risk is low, but because the legal machinery to force one is still developing. Companies that manage cyber risk as though a recall were always possible will be better positioned as that machinery catches up.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.



Food and drink

In September, the Food and Drug Administration (FDA) released the 2026 Food Code. It is a model of best practices for state, local, tribal, and territorial regulators of retail and food service, though not binding federal law. New provisions include written employee illness policies, an alternative cooling process, and food safety management system requirements during plan review.

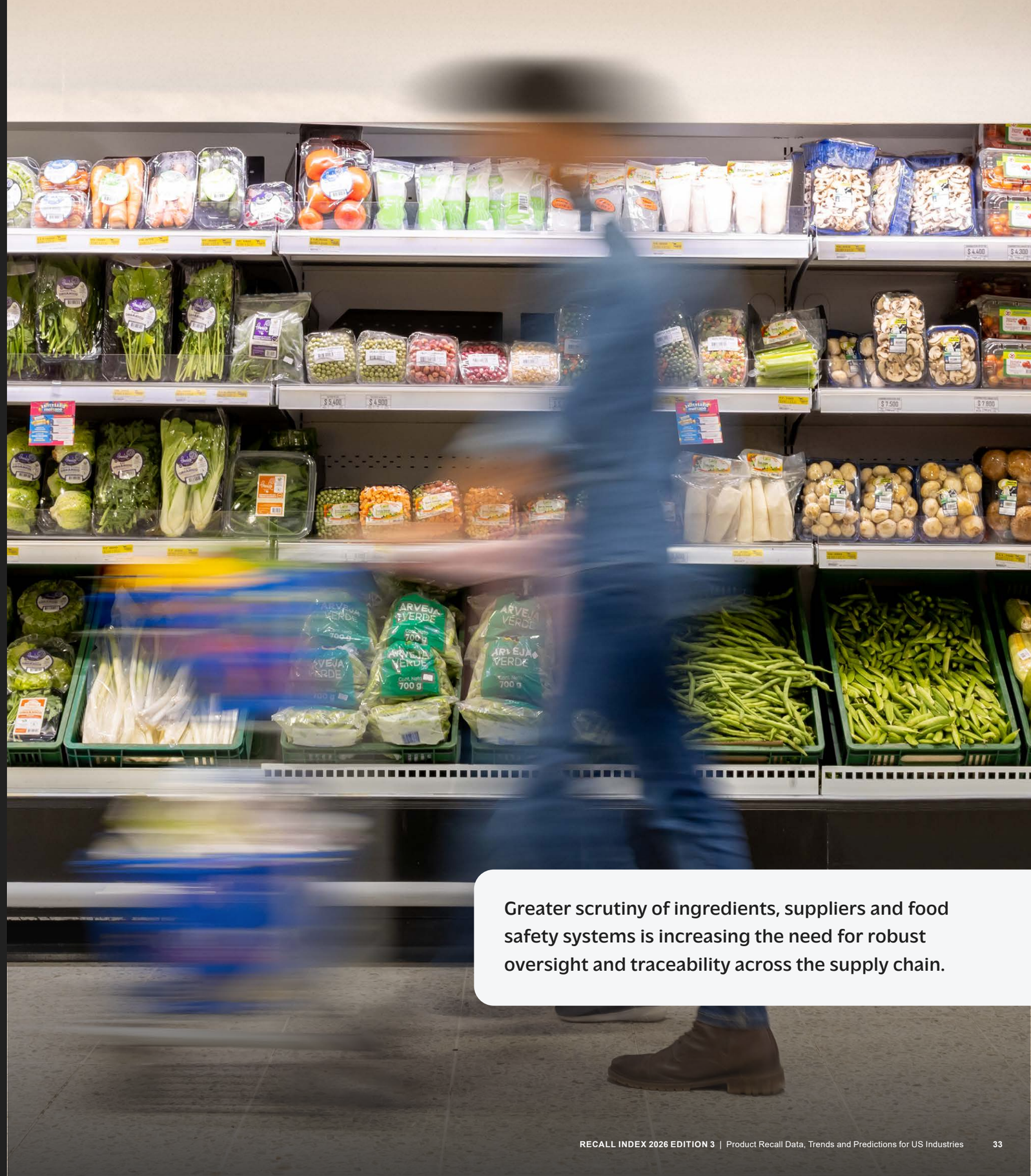
The same month, the agency also released its report on the Occurrence of Foodborne Illness Risk Factors in Retail Food Store Delis. Having a well-developed food safety management system was the strongest predictor that risk factors would be minimized. Improper holding time and temperature and poor personal hygiene were the most often cited factors across the more than 430 facilities in the report.

Infant formula remained under close watch. After two infant botulism outbreaks and a separate global contamination event, the FDA told manufacturers and suppliers to tighten oversight of ingredients. In September, the Department of Justice announced a nearly $385 million settlement with a major U.S. manufacturer of powdered infant formula over alleged manufacturing failures at two plants.

In August, the Department of Health and Human Services (HHS) announced a long-awaited proposed rule to close the loophole around substances that are Generally Recognized as Safe (GRAS). This has been a priority for the current administration. The proposal would create a mandatory reporting process instead of allowing manufacturers to self-declare food ingredients as GRAS.

The U.S. Department of Agriculture (USDA) launched a new program in September offering up to $50 million to help states start or expand their own meat inspection programs. The move followed a September 4 executive order on market access for American meat producers.

Food companies now face a tighter GRAS process, heavier infant formula supply-chain expectations, and a shift in how some meat plants may be inspected. Together, these developments add another layer to an already complex compliance landscape for the industry.



Greater scrutiny of ingredients, suppliers and food safety systems is increasing the need for robust oversight and traceability across the supply chain.

New responsibilities in infant formula safety

In July, the FDA sent a letter to manufacturers, packagers, distributors, exporters, importers, and retailers of infant formula and infant formula ingredients asking them to strengthen their oversight of suppliers. This includes knowing where ingredients come from, how they are produced, and whether supplier controls actually work. The companies were also asked to act quickly when a contaminated ingredient or a supplier problem is identified.

The letter follows a major infant formula recall in 2022, a 2025 multistate botulism outbreak from powdered formula, and a major recall in June 2026. The FDA tied the same supplier to both the 2025 and 2026 outbreaks, though the formulas were from different manufacturers. A separate global recall from late 2025 through early 2026 involved nearly 150 suspected and confirmed cereulide intoxications across 10 countries, traced to contaminated arachidonic acid oil from a supplier in China.

The letter highlights existing preventive-controls and infant-formula production rules, including supplier approval, onsite audits where a supply-chain control is identified, and redundancy risk-management plans required after the 2022 formula shortage.

In September, the Reagan-Udall Foundation published recommendations drawn from a July roundtable on Clostridium botulinum in infant formula. The report lists 22 recommendations, including better spore monitoring across farms and supply chains, validated preventive controls such as bacteria-removal separators and ultrafiltration, and FDA guidance on fit-for-purpose tests and thresholds. A central technical finding was that trace C. botulinum spores can occur at levels too low for traditional plating methods to detect, while still being enough to make an infant ill.

The same month, the federal government and a coalition of 40 states announced a settlement of nearly $385 million with a major U.S. manufacturer of powdered infant formula and nutritional therapy products for failing to meet state and federal safety standards for preventing contamination when manufacturing products sold to government health programs. The allegations cover 2018 through 2022 at plants in Michigan and Arizona and include roof leaks over equipment, cracked spray dryers, longer intervals between cleaning cycles, and failures to test for bacterial growth or to share contamination results with the FDA.

Attorneys with Covington & Burling LLP note that the FDA expects manufacturers to know their suppliers, understand how ingredients are produced, and confirm that supplier controls actually work. Lawyers with Keller and Heckman LLP highlight the agency's call for supplier audits and verification activities, as well as monitoring of recalls, outbreak investigations, and Import Alerts.

Infant formula manufacturers and ingredient suppliers should treat supplier verification as an active control, not a paper file, and review whether current testing can detect low-level spore contamination. The July letter, the two botulism outbreaks, and the September settlement all point at the same weak spot: what happens upstream of the final product. The safety of products intended for infants will continue to be a key focus of regulators.

GRAS regulations take another step forward

In August, the FDA published its proposed rule that would amend the GRAS regulations for human and animal food. Under the current system, companies may conclude on their own that a substance is GRAS and go to market without FDA approval. The agency has filed more than 1,200 GRAS notices since 1998, but it estimates that 1,000 or more additional substances are used in human food on self-determined GRAS conclusions with no notice.

The draft regulation would require companies to notify the FDA about why they made their GRAS declaration, unless an exception applies. The notice must include signed statements and a certification of completeness/truthfulness, as well as the identity, method of manufacture, specifications, and physical or technical effect of the substance. It must also provide dietary exposure data, a narrative providing the basis for the GRAS conclusion, and a list of supporting data and information. The proposed rule expands GRAS from just direct ingredients to include substances added indirectly, such as from food packaging.

The updated process does not provide premarket approval for a substance, and companies may continue to market an ingredient before submitting a GRAS notice or while a notice is pending with the FDA. Companies will continue to make the GRAS determination, but they must inform the FDA about this decision.

Failure to notify would not, by itself, make a food adulterated. The FDA plans to treat noncompliance as a factor in deciding which substances to review after they are on the market.

The FDA's own 2016 GRAS rule said the agency lacked express statutory authority to require these notices. The 2026 proposal relies on food-additive and enforcement provisions of the Federal Food, Drug, and Cosmetic Act. HHS has said it is acting within its legal power and will working with Congress on additional tools. That authority question is likely to be a central theme in the comments.

Comments on the proposed rule are due by December 9, 2026. Attorneys with Holland & Knight LLP recommend that food and beverage companies and ingredient suppliers that have relied on independent GRAS conclusions begin assessing their portfolios now. That includes inventorying direct ingredients and food-contact substances marketed under GRAS, mapping which uses may qualify for an exception, and deciding whether legacy substances already in commerce should use the proposed one-year streamlined pathway.

The legal experts also suggest that companies evaluate the competitive exposure that comes with public disclosure of GRAS notice information and use the comment period to address the scope of the exceptions, processing timelines, and the practical mechanics of the streamlined submission.



States to conduct more meat inspections

The USDA announced the Stand-Up Program in September. The initiative offers up to $50 million to help states start or expand their own meat and poultry inspection programs in partnership with the USDA's Food Safety and Inspection Service (FSIS). The funding is meant to lower the start-up costs that have kept some states from launching a program, allowing more small and very small processors to gain access to inspection services closer to livestock producers.

The announcement implements Executive Order 14424, signed September 4, which directs the USDA to increase state participation in cooperative inspection programs, cut unnecessary reporting, and expand Packers and Stockyards Act enforcement. Food safety standards under the new funding do not change. How the $50 million will be allocated, who applies, and on what timeline have not been published.

The existing framework has two main tracks. First, the state Meat and Poultry Inspection program mandates that states enforce requirements "at least equal to" federal law. Generally, the products stay in intrastate commerce. FSIS already funds up to half of those operating costs.

Under the Cooperative Interstate Shipment program—the second track—selected small processing plants in participating states may operate to the same standard as federal plants and ship interstate under the USDA mark. Those plants are limited to 25 or fewer employees.

As of late September 2026, 31 states ran their own inspection programs and 11 of them also participated in interstate shipment. The practical effect is a new on ramp. Small processors in states that stand up or expand a program would have an alternative to a federal grant of inspection.

Plants in states that later join interstate shipment could sell across state lines. Livestock producers could see more local slaughter options. However, industry groups have warned that funding alone may not be enough if regulatory costs and labor shortages remain high and cattle supplies remain tight.

State departments of agriculture and small processors should watch for the application details. Companies that already operate under federal inspection should not assume their status or requirements change, though they may gain some additional options.

By the numbers

Across the first three quarters of 2026 there were 389 FDA food recalls involving 79.81 million units. That compares with 415 recalls affecting 109.74 million units over the same period in 2025: 6.3% fewer events and 27.3% fewer units.

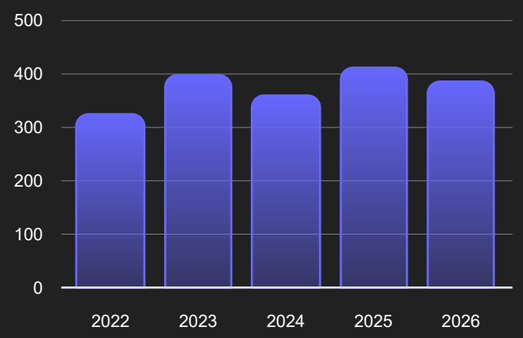
Undeclared allergens were the leading cause of FDA food recalls with 152 events. The most common allergens cited were nuts, which were linked to 25 recalls, colors with 24, and milk with 23. Bacterial contamination was the second most common cause with 99 recalls, including 65 linked to Salmonella. Foreign materials had the third-highest number of recalls with 51.

Foreign materials impacted 29.90 million units, the most of any hazard through the first three quarters of 2026, including 19.67 million units linked to glass in prepared foods. Undeclared allergens were second by volume with 26.67 million units recalled, driven largely by undeclared colors, including large recalls for ramen and lemonade. Bacterial contamination was third and impacted 18.57 million units, including 11.46 million linked to Salmonella.

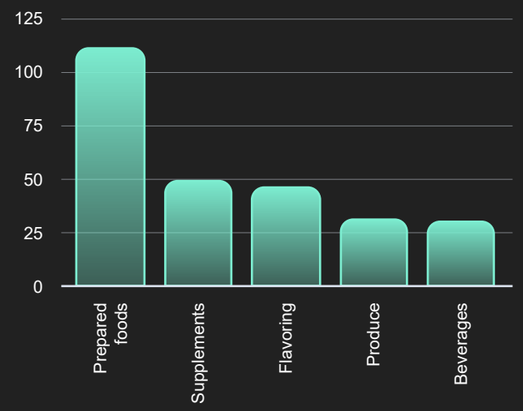
By category, prepared foods led by events with 112 recalls. Supplements were second with 50 events, followed by flavoring with 47. By volume, prepared foods were also the leading category, with 50.81 million units impacted. Supplements were second with 11.43 million units affected. Beverages were third with 8.39 million units recalled.

There were 366 unique companies involved in FDA food recalls through the first three quarters of 2026. Twenty-one companies had between two and four events. The remaining companies had only one incident each.

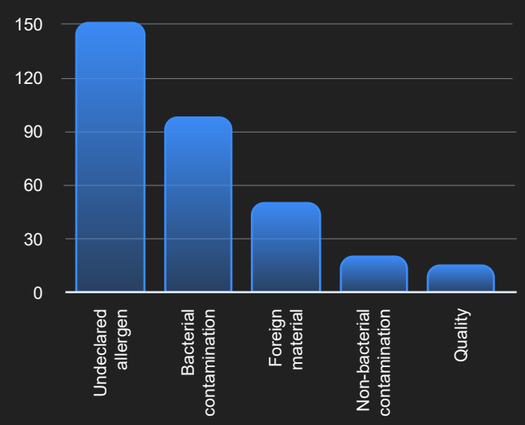
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)





By the numbers

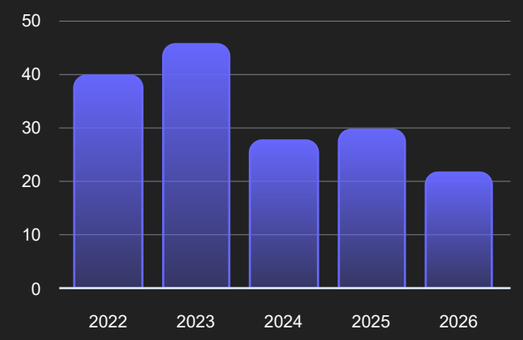
Across the first three quarters of 2026 there were 22 USDA recalls, 26.7% fewer than the same period in 2025 and the lowest three-quarter event total in more than 14 years. Year-over-year, volume was down 37.6%, falling from 59.99 million pounds in the first nine months of 2025 to 37.45 million pounds for the same timeframe in 2026. Despite the decrease, it is still the third-highest three-quarter volume in more than 14 years, behind only 2025 and 2016. A single poultry recall of 36.99 million pounds accounted for 98.8% of year-to-date volume. Twenty-one of the 22 events were Class I.

Product produced without inspection was the leading cause for recalls with eight events, accounting for 292,468 pounds. Four recalls were linked to foreign materials, four to bacterial contamination, and three to product ineligible for export. Foreign materials were responsible for 37.02 million pounds, nearly all of the year-to-date volume.

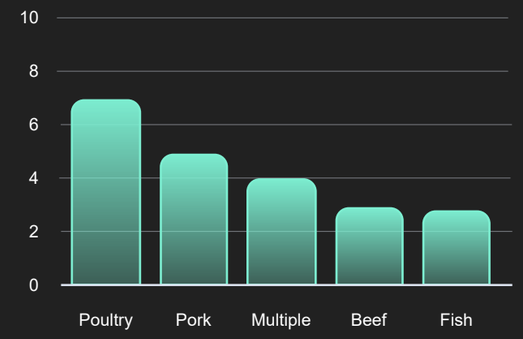
Poultry accounted for the most events by category with seven recalls and the highest volume, with 37.06 million pounds affected. Pork was second with five events. Multiple-meat products ranked second by volume, with 246,663 pounds affected across four events.

Each of the 22 recalls involved a different company. No manufacturer had more than one event through the first three quarters of 2026.

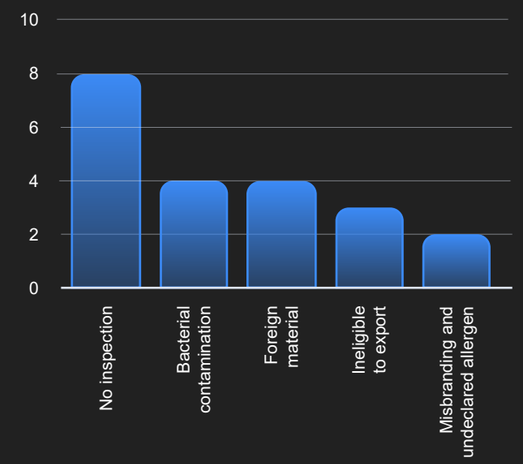
Number of recall events (Q1-Q3)



Number of recall events by category (top 5)



Number of recall events by risk (top 5)







Managing produce recalls in the midst of uncertainty

BY **MARK HUTTON** AND **CRYSTAL COLLISON**, *TOKIO MARINE HCC*

On July 17, 2026, a large fruit and vegetable producer recalled all iceberg lettuce sourced from central Mexico. The recalled product had gone to retailers and foodservice customers across more than 30 states, in multiple pack formats, under more than one brand name. The lettuce had been linked to a growing number of illnesses caused by the parasite Cyclospora.

By the time the Centers for Disease Control and Prevention (CDC) declared the outbreak over on September 11, 2026, it had linked 12,883 illnesses across 21 states to that lettuce, along with at least 570 hospitalizations and two deaths. That makes it the largest Cyclospora outbreak ever recorded in the United States, by a wide margin. The previous record set in 1996 involved roughly 1,465 cases traced to Guatemalan raspberries.

Cyclospora is a microscopic, single-celled parasite that causes an intestinal illness called cyclosporiasis. Infections are most common in tropical and subtropical regions. In the U.S., cases are less frequent and largely seasonal, with most occurring between May and August.

The parasite spreads when human waste reaches food or water, typically through contaminated irrigation or wash water. In the U.S., outbreaks are mostly linked to imported fresh produce. The illness can last from a few days to a month or longer and can return after seeming to clear. Four characteristics of the parasite help explain why the 2026 recall took the shape that it did.

First, it is not contagious in the usual sense. Cyclospora does not spread from person to person through everyday contact. The parasite spends one to two weeks maturing outside a host before it infects anyone. Illness clusters therefore tend to point upstream, to a field or a water source, rather than to a kitchen or a store.

Second, it survives washing. The parasite is shed as an oocyst: a tough egg-like capsule that is unusually sticky and clings to the surface of leaves. As a result, washing has limited effect. In one laboratory study, a minute under running water removed only around 39% of Cyclospora from raspberries and, more concerningly, no washing method tested removed all of it. Even chlorine, the standard sanitizer in produce processing, is ineffective against it, according to the U.S. Food and Drug Administration (FDA). Cooking can kill the parasite, but a fresh-cut lettuce line has no equivalent kill step.

Third, it cannot be grown in a lab the way bacteria can. With Salmonella or E. coli, a lab can let a small sample multiply until it is easy to detect. Cyclospora cannot be grown this way, so testers must find the few parasites that are already there. They do this by rinsing the produce and testing the rinse water for the parasite's DNA.

Contaminated produce typically carries only small numbers of the parasite, and the method struggles at those levels. In a Canadian validation of the FDA method, leafy greens spiked with 200 oocysts tested positive 93% of the time, but those spiked with 10 oocysts tested positive only 30% of the time. A clean test result, in other words, doesn't rule out a dirty field.

Fourth, it is harder to trace genetically. Whole genome sequencing is routinely used to match bacteria to their suspected source, but genetic tracing for Cyclospora is less established. The CDC can use genetic markers to group related patient samples, but because the parasite is so rarely found in the food itself, there is usually nothing to match those samples against. Linking illnesses to a particular product still depends largely on patient interviews and supply chain tracing.

This year's outbreak shows each of these characteristics in practice. On July 18, the FDA announced a positive lettuce sample, then withdrew it the following day as a false positive. No contaminated product sample was ever confirmed.

When the FDA closed its investigation on October 2, it reported finding Cyclospora in wastewater at the processing facility and in a drainage ditch at an implicated grower but said there was not enough evidence to determine exactly

how the lettuce became contaminated. So, standard processing could not be relied upon to remove the parasite, testing could not reliably find it, and sequencing could not tie it to a source. A company facing a Cyclospora event, it seems, cannot test its way to blame or exoneration.

Symptoms usually appear around a week after infection, and the CDC estimates a further six weeks between a person falling ill and the case reaching federal surveillance, so timing compounds the problem. Illnesses in this particular outbreak began more than a month before the recall was announced, and the count rose from 1,644 reported cases on July 17 to 12,883 by the time the outbreak was declared over.

For a brand, this could mean customer notifications, managing media, legal claims, and crisis costs that continue months after the product has left the shelves. A well-developed recall plan can help limit the impact, but it cannot prevent those costs from continuing. Insurance and crisis support provide an additional layer of protection.

A single processor supplied a national restaurant chain and the retail market at the same time. When its lettuce was recalled, the cost spread far beyond that one business. It hit franchisees, distributors, and retailers further down the supply chain.

Supply chain concentration is an exposure companies may underestimate, because it does not necessarily show up on their own sites. A business can hold an excellent audit record and still absorb the full cost of a problem that started in someone else's field.

For insurers, Cyclospora also raises a question of proof. Product contamination policies respond to defined insured events, which can include accidental contamination where consumption of the affected product has resulted, or would result, in bodily injury. Yet in this outbreak, Cyclospora was never confirmed in a lettuce sample, highlighting the potential difficulty of establishing contamination where positive product testing is absent.

The position is harder still for a business that cannot prove its own product was contaminated but is publicly linked to an outbreak regardless. Adverse publicity coverage can be important in that situation, because it can respond to media reporting of an alleged contamination, rather than requiring the underlying contamination to have already been proven.

When the FDA closed its investigation, it set out ten actions to complete before the 2027 growing season, including more surveillance of produce historically linked to Cyclospora. For U.S. businesses, one significant action is the FDA's closer scrutiny of importers. Additional inspections are planned under the Foreign Supplier Verification Program and importers are expected to account for Cyclospora when assessing hazards and checking suppliers. The FDA will also publish an Outbreak Investigation Report.

In addition, the outbreak has renewed pressure around Section 204(d) of the FDA's Food Safety Modernization Act (FSMA 204), which regulates food traceability. Enforcement is currently restricted until July 20, 2028, despite arguments that the traceability requirements could have sped up this investigation.

FSMA 204 will require businesses handling leafy greens and other listed foods to keep lot-level traceability records and provide them to the FDA within 24 hours of a request. Companies that can already name the field and the lot within a day—and link them to the water source that field relies on—will be far better placed during an event, whatever form the final requirements take.

The 2026 outbreak was a reminder that the most damaging contamination events are not always the ones a business can see, test for, or control. Knowing where products come from and having the right cover in place when the source can't be proven is what makes those events manageable.

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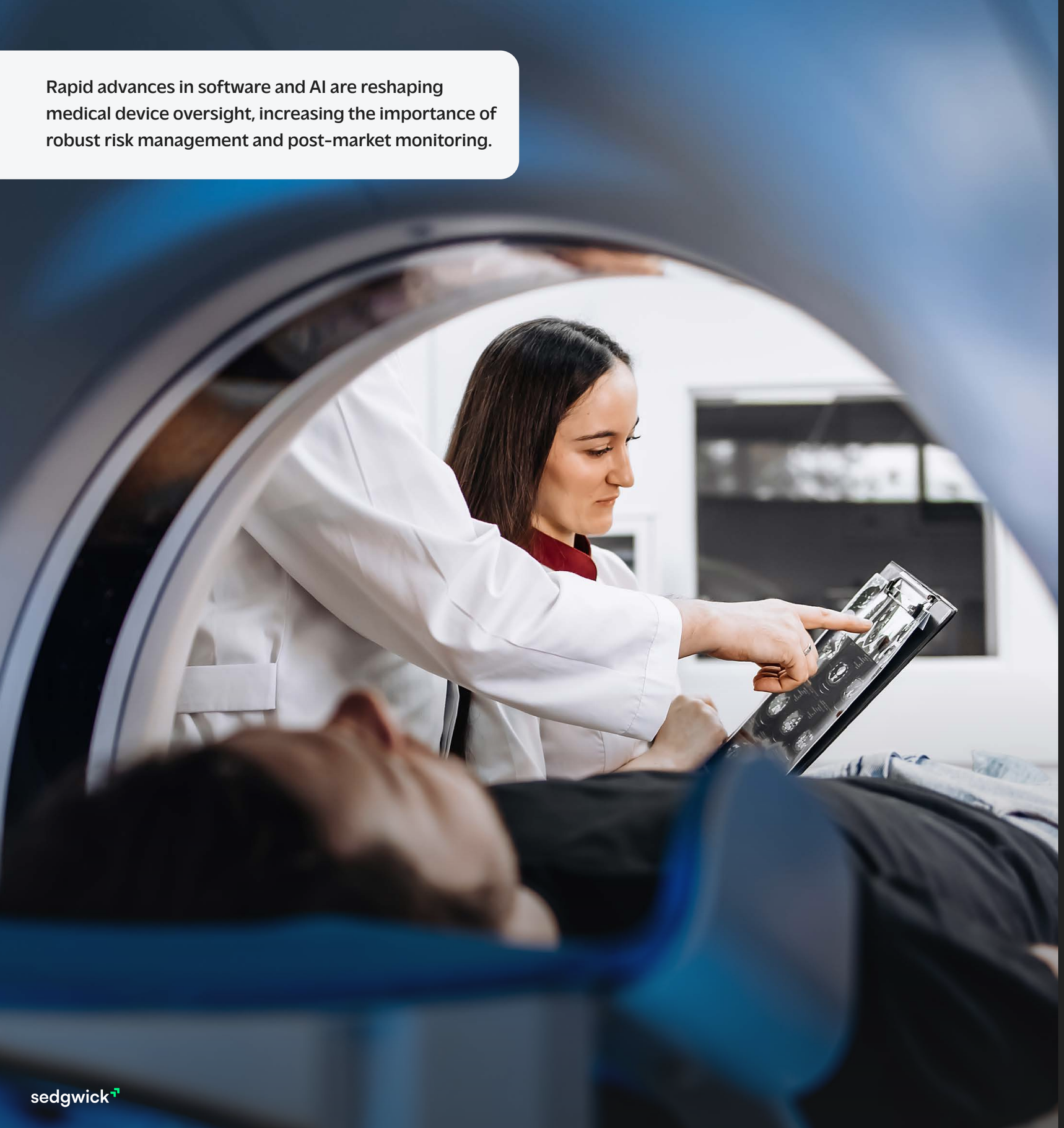
Rapid advances in software and AI are reshaping medical device oversight, increasing the importance of robust risk management and post-market monitoring.



Medical device

The Food and Drug Administration (FDA) issued a call for comments on several programs in the third quarter. These include the Medical Device User Fee Amendments to set fees and target timeframes for various premarket approval processes through fiscal year 2032.

The agency also opened comments on non-device software as part of a biennial report. It is important to gather postmarket data to ensure that usage and functionality haven't evolved to make the software fit the definition of a medical device and thus in the scope of different regulations.

In September, the Center for Devices and Radiological Health (CDRH) launched its regulatory reliance portal that collects already-public FDA device information for foreign regulators. The hope is that this data will help improve efforts to harmonize global standards and promote more international reliance pathways among countries to allow an approval in one country to expedite marketing authority in another.

The CDRH also opened the comment period on a discussion paper that examines generative AI-enabled (GenAI-enabled) medical devices. The publication looks at various ways to mitigate and oversee possible device risks.

Device makers and other stakeholders should treat the quarter as a comment-and-planning period since all of the proposals are still under consideration or are not binding policies. They should review their products and processes as they apply to the possible changes under consideration.

Changes under the latest Medical Device User Fee Amendments

In July, the FDA opened a comment period on draft commitments for the next Medical Device User Fee Amendments (MDUFA VI) for fiscal years 2028 through 2032. The current program expires on September 30, 2027.

Because the number of pre-submissions has steadily increased in recent years, the FDA has stated that its target timelines will only apply to the first 5,000 submissions for each fiscal year. Applicants not in that group may see processing delays.

Under the proposal, the biggest changes would be to the pre-submission process. The target goal to provide written feedback for pre-submissions would stay at 70 calendar days, or five days before a scheduled meeting. However, sponsors would also have the option of a “focused follow-up pre-submission” with a 45-day written response for narrow follow-up questions.

The latest proposal also adds a $2,000 fee for certain initial pre-submissions, credited against a later marketing submission. In addition, the FDA recommends decreasing domestic registration and marketing submission fees in fiscal year 2028 and raising fees for foreign firms.

Fee rates for fiscal year 2027—which runs from October 1, 2026 through September 30, 2027—were published in July. A standard premarket approval fee is $636,732, a De Novo request is $191,020, a 510(k) is $28,653, and the annual establishment registration fee is $13,785.

The timeframe for the agency to provide a decision on De Novo reviews would remain at 150 days. However, starting on October 1, 2027, there would be an “introduction meeting” between the FDA and the applicant within 30 days of the submission being received.

The FDA acknowledged some inconsistencies in its reviews across offices. The agency committed to addressing at least one high-impact topic each fiscal year to improve its review processes and reduce variability.

Device makers should treat the draft as a negotiating document until the agreement is confirmed. The final letter is due to Congress by January 15, 2027, and the statute must be enacted by September 30, 2027. Pre-submission planning, including the proposed fee and the focused follow-up type, is likely to have the biggest impact on day-to-day operations for most companies.

Sponsors should also note the 5,000 cap on performance standards for pre-submission reviews and avoid waiting until the end of the year to file their applications if they want to ensure a timely review process.

Agency reviewing impact of software functions on patient safety

In July, the FDA asked stakeholders for input on the risks and benefits of software functions that are excluded from the 21st Century Cures Act definition of a medical device. These include electronic patient records and software that provides administrative support of health care facilities; maintains or encourages a healthy lifestyle; transfers, stores, converts, or displays data; or offers limited clinical decision support.

The agency also encouraged respondents to offer suggestions for ways to mitigate patient safety risks while preserving the efficiencies and clinical benefits offered by non-device software. Other topics of interest in the call for comments included user training, escalation pathways, and oversight of software recommendations, among others.

The information will be used in a biennial report required by law. Attorneys with Bass, Berry & Sims state that software’s intended use and operation determine whether it meets the definition of a medical device. The





FDA has been assessing these interpretations and announced a new enforcement discretion policy for software products earlier this year.

The legal experts caution that small changes to the functionality and process of similar clinician recommendation features can shift a software product from an excluded product to one subject to regulation. How products are classified has major consequences for FDA oversight and often payor reimbursement. A software product's intended functionality can change as the product evolves, stressing the importance of the agency's regular review process.

While the comment period closed on August 13, 2026, software developers, healthcare providers, health systems, technology companies, and other stakeholders should be continuously evaluating how they are using software in medical settings. They don't have to wait two years until the next report to adjust their risk management and reporting processes.

FDA seeking input on regulating AI-enabled medical devices

In August, CDRH's Digital Health Center of Excellence published a discussion paper on generative AI-enabled (GenAI-enabled) medical devices and invited public comments through October 19, 2026. While the paper is not guidance or policy, it offers a way to think about premarket evaluation.

The publication recommends a two-axis framework to evaluate device risk, which could in turn influence the level of regulatory scrutiny applied to GenAI-enabled devices. While the paper does not specify the exact axes, it suggests that risk-based calibration would account for factors such as the clinical significance of the device's output or intended use and the level of autonomy of the GenAI system.

The document outlines a premarket evaluation based on a two-part competency assessment. The first part is non-clinical device benchmarking—testing the finished, user-facing device, not the underlying AI foundation model alone. The tests cover a range of factors, including safety-critical recognition and escalation, staying within intended scope, communicating uncertainty, clinical knowledge, information gathering, and how clearly the device talks to the user. There is also a user-comprehension piece that explores the risk that a fluent answer will be accepted without scrutiny.

The second part is clinical confirmation, which could include real-world or simulated evaluations. Among the suggested test options are a retrospective review of real patient inputs, shadow deployment, standardized patient interactions, and a clinical trial.

Attorneys with Katten Muchin Rosenman LLP note that because GenAI devices may be changed after they are deployed, postmarket monitoring will be increasingly important. The paper suggests monitoring not only the manufacturer's own GenAI model, but also the underlying foundation model for performance drift, hallucinations, or unexpected outputs, as well as calibrating postmarket requirements to the level of risk identified under the two-axis framework.

Other considerations include addressing the complexities introduced by continuous learning and adaptation in deployed devices and tracking adverse events and other safety signals unique to GenAI outputs.

The paper also proposes using confidential Foundation Model Device Master Files that a model developer could hold and a device sponsor could reference. This poses the question of whether the FDA could accept more uncertainty before placing a device on the market in exchange for stronger postmarket monitoring. A Predetermined Change Control Plan remains one possible tool for later modifications.

Lawyers with Cooley LLP recommend that companies developing, deploying, or investing in GenAI-enabled medical devices map existing and pipeline products against the proposed two-axis risk framework, review foundation model supply chain arrangements, and prepare for expanded postmarket obligations. Stakeholders should also consider how these proposals would affect their quality systems, postmarket surveillance capabilities, and operational costs.

By the numbers

Across the first three quarters of 2026 there were 766 medical device recalls involving 997.25 million units, compared with 726 recalls affecting 159.15 million units over the same period in 2025. Events were up 5.5% year-over-year. Units were up 526.6%: the highest three-quarter unit total in more than 21 years. The 997.25 million units recalled through September are more than double the 490.23 million recorded for all of 2025.

Six recalls year-to-date impacted more than 86 million units each. The three largest—327.10 million administration sets pulled for foreign materials, 154.00 million exam gloves for quality, and 94.23 million infusion sets—together made up 57.7% of all units recalled.

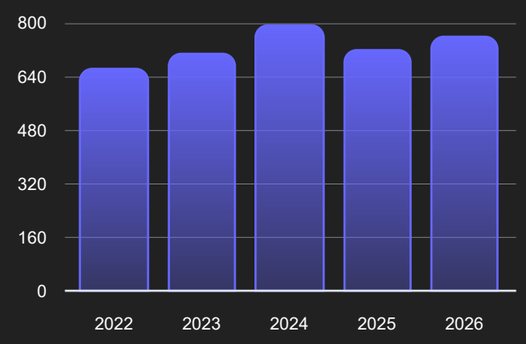
Software was the leading cause of medical device recalls through the first three quarters of 2026, accounting for 97 events. Device failure was second with 90 events. Mislabeling was third with 77.

Foreign materials were responsible for the most units recalled, with 330.68 million, almost entirely from the administration-set event. Sterility was second by volume, with 182.12 million units. Quality had the third-highest number of units recalled, with 155.95 million, driven by the exam glove recall.

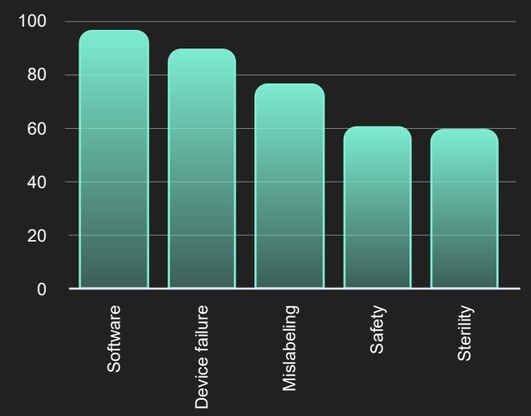
There were fewer Class I recalls than over the same period in 2025, with 83 events compared with 103, though 83 is still the third-highest three-quarter Class I total in 22 years. Class I volume rose from 55.25 million units to 150.90 million. Class II recalls increased from 612 events and 103.71 million units to 673 events and 846.26 million units: the highest three-quarter Class II volume on record. Class III recalls fell to 10 events, the lowest three-quarter Class III total in more than 22 years. Class III units fell to 87,532.

The medical device recalls through the first three quarters of 2026 were linked to 318 unique companies. While most had only one recall, there were 81 companies that had between two and four events, 13 companies with five to nine recalls, and 15 companies with 10 or more events, including one manufacturer with 53 recalls.

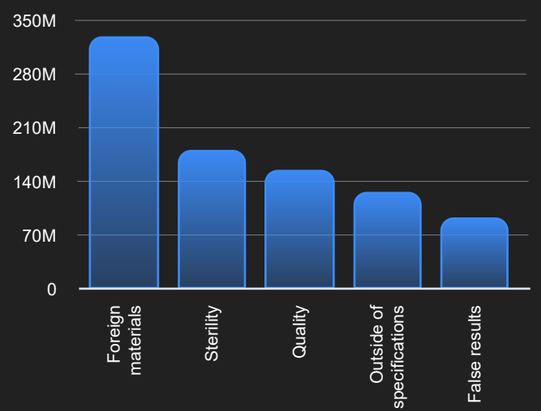
Number of recall events (Q1-Q3)



Number of recall events by risk (top 5)



Number of recalled units by risk (top 5)





Beyond the recall count: what FY2026 medical device trends mean for manufacturers

SONIA NATH, PARTNER, **SON NGUYEN,** SPECIAL COUNSEL, AND **KELLY MARCO,** SENIOR REGULATORY ANALYST, *COOLEY LLP*

Data for medical device recalls for fiscal year 2026 (FY2026), October 1, 2025, through September 30, 2026, tell a more nuanced story than rising recall counts suggest. Product records increased 23.8% compared to FY2025. In addition, distinct recall events rose 5.9%, while Class I events declined 9.4%.

The key signal is on average more products are impacted per action, not a proportionate increase in independent failures or evidence of greater patient harm. For manufacturers, the question is whether a single defect, supplier issue, or software problem can spread across a portfolio faster than the company can identify affected products, communicate with customers, and implement a remedy.

The FDA framework in brief

Most recalls combine voluntary industry action with Food and Drug Administration (FDA) oversight. Under 21 CFR Part 7, firms may initiate recalls without waiting for FDA to review their strategy or communications. FDA evaluates the health hazard, classifies the recall into Class I (most severe), II, or III, and oversees the response.

FDA also has mandatory medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 810. Where the statutory threshold for "serious harm" is met, FDA may order distribution to stop and require notification of health professionals and device-user facilities. After an opportunity for an informal hearing, FDA may require a recall if necessary, subject to statutory limitations.

More listed products do not mean proportionately more recall events

The FDA Data Dashboard provides information on device recalls at two levels. A product record is the listing for one recalled product, identified by its own recall number. Lot codes, serial numbers, and package sizes of that same product are all part of the product record.

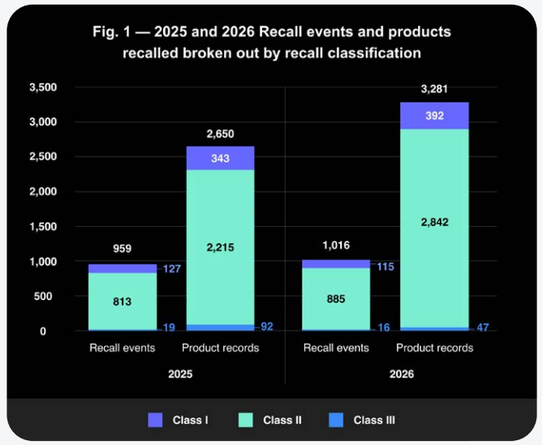
The dashboard also lists recall events, which are the action (or group of related actions) that the manufacturer takes. The same event ID covers one or more products recalled together.

Product records related to medical device recalls rose from 2,650 in FY2025 to 3,281 in FY2026, while distinct events rose from 959 to 1,016. Average records per event consequently rose approximately 17%, from 2.76 to 3.23. A few large, multi-product actions could account for much of that change. These averages do not establish that the typical event covered more products. Product records are not counts of units in the field; those are reported separately.

Severity does not move in a single direction

Class II recalls drove the net increase in events, rising from 813 to 885. Declines in Class I and III recalls partially offset that growth. Class I events fell from 127 to 115, while Class I product records increased from 343 to 392. (See Figure 1 below)

Average Class I records per event rose approximately 26%, from 2.70 to 3.41. Fewer high-hazard events coexisted with broader average product coverage within that category, underscoring why neither measure should be read alone.



Recall classification describes potential harm, not reported injuries. Under 21 CFR § 7.3(m), Class I recalls involve a reasonable probability of serious adverse health consequences or death. Class II events concern temporary or medically reversible consequences or a remote probability of serious consequences. Class III recalls concern situations unlikely to cause adverse health consequences. Changes in these counts alone do not establish whether patient harm increased or decreased.

Large events can reshape the headline

Two FY2026 Class II events illustrate how large actions affect product totals. One manufacturer's event accounted for 116 records involving potential medication backflow and inability to prime. Another device maker had 92 records involving distribution without premarket approval or clearance. Together, they represent approximately 6.3% of FY2026 product records but only two of 1,016 events.

FY2025 also contained large actions, so these examples do not explain the year-over-year increase. They do show why shared technical defects and portfolio-wide authorization issues require different preventive controls.

Shared components can extend the recall footprint

FDA's 2026 safety listings also show how a component issue can extend into finished products. Listings for one company's angiographic syringes were followed by listings for convenience kits containing the same model of syringes. These examples illustrate a supply-chain mechanism, not a quantified explanation for the annual increase.

Distinct firm-level events may share an upstream problem, so counting events does not necessarily identify independent root causes. Manufacturers and kit assemblers should maintain searchable component-to-finished-product maps and test supplier-notification processes.

Software and conventional quality problems coexist

The records describe both software failures and conventional quality problems. Examples include an analyzer startup failure that could delay patient results, an application issue for a CT scan that potentially exposes patients to additional radiation, and an application sensor-pairing problem preventing automated insulin-pump control. Other entries concern cracked breathing-circuit hoses, missing screwhead threads and incorrect labels.

Recall planning should test these different scenarios and whether each remedy reaches affected configurations. The examples do not establish which failure category predominates. The recall information contains narrative reasons, not a consistently validated cause taxonomy. Ranking causes would require equivalent coding across both years.

A recall need not mean a product return

Under 21 CFR Part 7 and FDA guidance, corrections can include repair, modification, relabeling, inspection, or patient monitoring without removing the product. Software updates and field corrections can therefore qualify. Routine servicing, qualifying market withdrawals, and stock recoveries are not necessarily recalls. The regulatory character of the problem and response controls the action, not the manufacturer's label.

Separately, 21 CFR Part 806 requires manufacturers and importers to report qualifying corrections or removals undertaken to reduce a health risk or remedy a violation that may present one, subject to exceptions. Reports are due within ten working days after initiation. FDA's Quality Management System Regulation, which took effect February 2, 2026, incorporates ISO 13485:2016 for medical devices, reinforcing the need to integrate recall readiness with quality processes.

Earlier public visibility changes the response timeline

On September 29, 2025, the Center for Devices and Radiological Health expanded Early Alert communications to potentially high-risk removals or corrections across all medical devices. Alerts can precede FDA's determination that a recall is needed.

Dashboard counts and early public communications therefore represent different information streams. More alerts do not necessarily mean more classified recalls, and an alert and subsequent recall notice should not be counted separately without checking the underlying action.

Manufacturers should prepare clear interim instructions and coordinated customer communications while investigation and classification remain pending, rather than wait for classification to begin response planning.

What manufacturers should do with these findings

Manufacturers should assess recall readiness across event frequency, product breadth, and affected-unit volume, distinguishing hazard class and the remedy required. The goal is to identify the complete scope, reach those affected, and verify that the remedy works.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.



Pharmaceutical

In the third quarter, the Food and Drug Administration's (FDA's) leadership remained in flux after the departure of Marty Makary in May. Kyle Diamantas continues as Acting Commissioner, and Dr. Heidi Overton has been nominated to officially fill that role.

On August 31, the FDA and the Securities and Exchange Commission signed a memorandum of understanding on sharing nonpublic information for filing reviews and enforcement. This could increase risk for manufacturers and distributors as regulators gain more access to company information. Regulators are using AI tools to quickly analyze large amounts of data to find possible violations. Third-party purchasing claims were behind a warning letter the FDA sent to a medical spa last quarter.

In July, the FDA's Pharmacy Compounding Advisory Committee voted to recommend six unapproved peptides for the list of bulk substances that certain pharmacies may use in compounding. It is only the first step toward officially adding them to the approved bulk substance list.

The FDA sent a warning letter to a large compounding pharmacy over compounded versions of two widely used weight-loss drugs, after concluding that a prescriber was not eligible for an exemption it was claiming. This follows 25 warning letters sent to telehealth companies over website claims about compounded products.

The agency continued efforts to get new drugs to market sooner, while tightening the rules for compounded versions of approved medications. In September, the FDA opened applications for an Expedited Investigational New Drug (IND) Pilot that pairs sponsors with outside research institutions.

Regulators want to get safe products to market as soon as possible. However, close oversight remains to ensure that manufacturers and distributors are not cutting corners.



Efforts to accelerate drug development are being matched by greater scrutiny of compounding, reinforcing the need for strong regulatory and compliance controls.



Peptides in the spotlight

On July 23 and 24, 2026, the FDA's Pharmacy Compounding Advisory Committee (PCAC) met to consider seven unapproved peptides for the Section 503A bulk drug substances list. A 503A pharmacy is permitted to use ingredients on the approved FDA 503A list. The substances were evaluated for uses including ulcerative colitis, wound healing, inflammatory conditions, obesity, osteoporosis, and migraines.

The FDA's scientific reviewers had previously opposed adding any of the seven ingredients to the list. They had raised concerns about a lack of clinical safety or effectiveness data, and about unknown immunogenic risk. However, the PCAC voted to recommend adding six of the seven to the list.

Attorneys with Mintz noted that some PCAC members felt that allowing the peptides to be included on the 503A list would provide more opportunities to study them and develop safety profiles. The legal experts state that if the substances can be sold commercially, there is less incentive for drug developers to conduct formal safety studies.

Some committee members also recommended authorizing the use of these peptides in compounding, but only under certain circumstances, such as an obligation for 503A compounders to report serious adverse events to the FDA. However, since 503A pharmacies are state regulated, the FDA does not have statutory authority to impose mandatory reporting requirements. It would take congressional action to give the FDA oversight over these types of pharmacies.

The PCAC's recommendation is only the first step. Before the substances can be used under that pathway, the FDA must publish a proposed rule, take comments, and issue a final rule amending the Code of Federal Regulations. A second PCAC meeting to discuss an additional five peptides is expected to be scheduled in February 2027.

Meanwhile, the FDA is monitoring online peptide sellers. It sent warning letters in August to parties marketing certain products as "research use only" while still providing dosing or injection instructions. The agency treated those products as unapproved new drugs. Those letters targeted different substances, including unapproved metabolic drugs, and did not name the six peptides the committee had just recommended.

Compounders should not treat the support from the PCAC as permission to proceed. The legal status of these peptides has not changed, and it is clear that the FDA is watching.

Scrutiny over compounded drugs continues

Compounded versions of approved weight-loss drugs remained an enforcement priority for the FDA. In June, the agency posted 25 warning letters to telehealth companies over website claims about compounded products. The letters alleged that the claims made the drugs misbranded.

Examples included implying that a compounded drug is a generic, that it is FDA-approved, that it is "clinically proven" to match the approved product, or that it comes from an "FDA-approved" pharmacy. This was the third wave of warning letters in less than 12 months, following larger batches in September 2025 and March 2026.

On September 18, 2026, the FDA sent a warning letter to a large Texas-based 503A compounding pharmacy after a November 2025 inspection. The agency concluded that compounded semaglutide and tirzepatide products, including combinations with niacinamide or cyanocobalamin, appeared to be essentially copies of the FDA-approved drugs.

Under Section 503A, compounded drugs are typically exempt from current good manufacturing practice, adequate directions for use, and premarket approval. However, this is not the case if the pharmacy regularly compounds versions of a commercially available drug.

In that case, a compounded version can avoid the stricter requirements only if the drug is made for an identified patient and it produces a significant difference for that patient as determined by the prescriber. The September letter said some orders had no such determination, others repeated the same language across many records, and the volume of product suggested the differences were false. The agency also objected to third-party prescribing platforms that offer pre-selected menu options for the significant-difference statement.

The letter was not only a 503A case. It also alleged insanitary conditions and manufacturing-practice failures, including inadequate smoke studies and media fills. Those adulteration provisions apply whether or not the 503A exemption is met.

Lawyers with Buchanan Ingersoll & Rooney PC recommend that 503A pharmacies review a representative sample of GLP-1 prescriptions, corresponding formulations, and related prescriber communications. They should also observe aggregate production and dispensing patterns for sharp increases or prolonged high-volume patterns that could signal an issue.

The legal experts also suggest compounding pharmacies confirm that validation reports, investigations, and corrective actions are supported by complete and consistent underlying records and maintain oversight of any contract laboratories or other vendors. Based on activities over the past year, the FDA will continue to monitor these types of operations and take enforcement action.

FDA launches pilot program to expedite approval of new drugs

On September 15, 2026, the FDA began accepting applications for its Expedited Investigational New Drug (IND) Pilot. The agency hopes to shorten the time from identifying a drug candidate to starting a first-in-human trial by pairing a sponsor with a qualified research institution that can support the IND. Up to 10 sponsor–institution pairs are expected for the first cohort.

A qualified research institution can be an academic medical center, health network, contract research organization, regulatory advisor, or similar group. The FDA will prioritize legal U.S. entities with U.S.-based advisory staff that can cover nonclinical, clinical, and chemistry and manufacturing work. The organization must also be able to support a U.S. Phase 1 start through its own infrastructure or a formal partnership.

Under the new program, the sponsor and research institution apply together. The FDA will review individual application components as they are finished in the pre-IND phase, rather than waiting for a complete submission.

The pilot is aimed at commercial, first-in-human INDs for novel products with no existing clinical experience. The FDA discourages applications for new formulations, delivery systems, drug-device combinations, new routes of administration, or 505(b)(2) products.

The FDA is trying to bring U.S. drug development timelines more in line with other nations. Currently, first-in-human trials may take up to two years to complete in the U.S., versus an estimated 6–12 weeks in Australia and 60 days in China.

The program complements several other programs, including the PreCheck program and the Commissioner's National Priority Voucher program, which are intended to streamline other phases of the new drug approval process and increase U.S. manufacturing.

Applications were due October 30, 2026. The FDA expects to notify selected pairs on December 18. Sponsors who do not apply in the first wave should look for possible new cohorts in the future and determine if there are institutions with which they could partner.



By the numbers

Across the first three quarters of 2026 there were 273 pharmaceutical recalls involving 535.33 million units, compared with 281 recalls affecting 91.07 million units over the same period in 2025.

This is a 2.9% decrease in events year-over-year and a 487.8% increase in volume: the third-highest three-quarter unit total in the 22-year series beginning in 2005. The 535.33 million units recalled through September also exceed the 99.73 million recorded for all of 2025. Five recalls involved more than 10.9 million units each, accounting for 95.0% of all year-to-date volume.

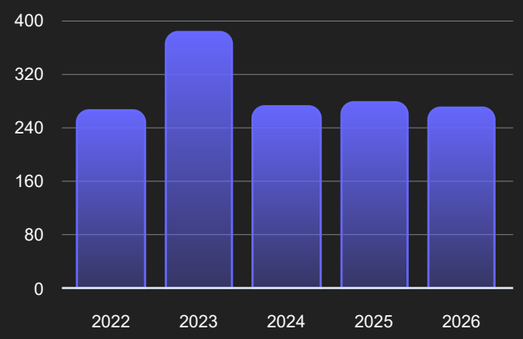
The leading cause of pharmaceutical recalls through the first three quarters of 2026 was failed specifications with 71 events. That was followed by sterility with 45 events. Foreign materials was third, linked to 38 recalls.

Current good manufacturing practice (cGMP) deviations impacted the most units by volume with 214.84 million, primarily due to a recall of more than 212 million antiseptic towelettes and wipes. Contamination was second by volume, affecting 178.50 million units, including a recall of 174.38 million alcohol prep pads. Sterility impacted 130.27 million units, the third-highest total of any pharmaceutical risk through September.

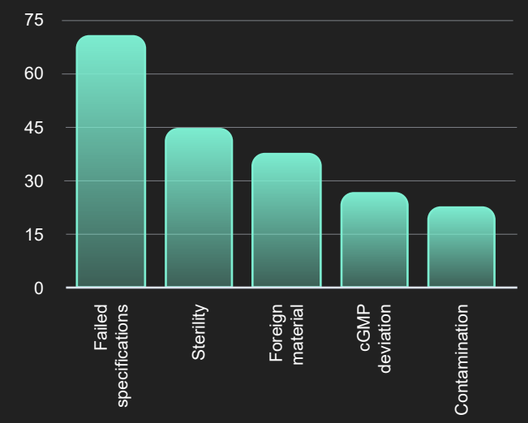
Class I pharmaceutical recalls rose slightly by event, from 27 over the same period in 2025 to 29, while Class I volume increased from 25.46 million units to 175.61 million: the highest three-quarter Class I total on record. Class II recalls decreased from 230 events to 204, though Class II units rose from 65.70 million to 357.20 million. Class III recalls increased by both events and volume, with 40 recalls involving 2.52 million units.

There were 167 unique companies involved in recalls through the first three quarters of 2026. Thirty-six companies had between two and four events, seven companies had between five and nine, and one company had 11. The remaining companies had only one incident each.

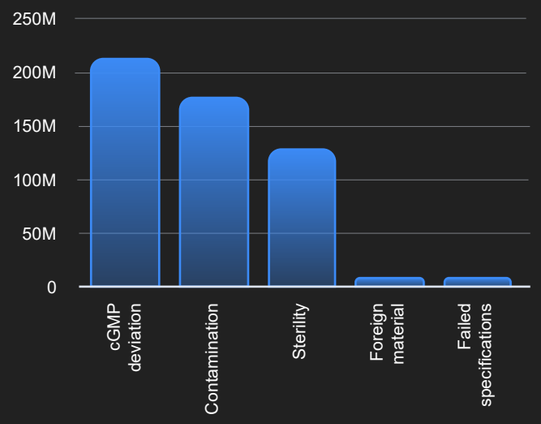
Number of recall events (Q1-Q3)



Number of recall events by risk (top 5)



Number of recalled units by risk (top 5)







Drug recalls and global supply chains: managing the heightened cross-border regulatory risk

SONIA NATH, PARTNER, **LAURA AKOWUAH,** SPECIAL COUNSEL, **LAURA WENZEL,** ASSOCIATE, **AND KELLY MARCO,** SENIOR REGULATORY ANALYST, *COOLEY LLP*

The U.S. Food and Drug Administration (FDA) has publicly signaled a heightened emphasis on monitoring and regulating foreign drug facilities and manufacturing operations. Reflecting this approach, the agency has expanded inspections of foreign facilities and the frequency of unannounced inspections abroad.

Alongside increased and more robust inspections, the agency is also utilizing additional tools to strengthen its oversight of overseas manufacturing and ingredient sourcing, including recalls, safety alerts, warning letters, import alerts, and the detention and refusal of product at the border. Unlike some of FDA's other compliance tools, its compliance actions at the border require few resources on the part of the agency and incredibly effective tools to keep products out of domestic commerce.

For companies whose products or ingredients are manufactured overseas and subject to a recall, the recall may be only the beginning of a company's regulatory and commercial disruption. Related import restrictions can interrupt supply long after the recall ends, significantly disrupting a company's commercial operations and business relationships.

We expect the agency to continue using its authority at the border to keep products out of the United States until it is satisfied that companies have addressed compliance gaps and implemented robust corrective actions for recalled products.

Heightened cross-border regulatory risk

For companies that manufacture drugs overseas or source ingredients abroad, related import restrictions can have a negative impact on supply, even after a recall action has been resolved. This risk is not limited to foreign companies. U.S.-based companies may face the same disruption when their products or ingredients are manufactured overseas.

FDA may pursue several compliance measures alongside a recall, including unannounced for-cause inspections, increased product sampling, safety alerts, regulatory meetings, warning letters, seizures, injunctions, and import restrictions. The agency's authority at the border is particularly consequential because FDA can quickly use this authority to prevent affected products and ingredients from entering the U.S.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may refuse products at the border that merely appear to violate the law. Additionally, the agency has the authority to go further and add companies and their products to import alerts. Import alerts identify products subject to detention without physical examination (DWPE). A company's products that are on an import alert may continue to be detained and refused admission until the company successfully petitions FDA to have itself and its products removed from the import alert.

To be removed from DWPE, a company must provide evidence that it has resolved the conditions that led to DWPE and that future shipments will be safe and compliant. Obtaining release of a particular shipment does not resolve the restrictions affecting future shipments.

Additionally, even when a company obtains the release of a detained shipment, delays can disrupt contractual performance, damage business relationships, and create uncertainty about future imports.

Based on data from FDA's website, 12% of pharmaceutical products recalled in fiscal year 2026 (October 1, 2025, through September 30, 2026) were recalled by companies located outside of the U.S. In comparison, in fiscal year 2025 (FY2025), only 6.3% of drug product recalls were initiated by overseas firms. Additionally, in FY2026, at least 10 foreign manufacturers involved in product recalls also had import alerts issued for their pharmaceutical products around the time of the recalls—approximately double the number in 2025.

The location of the recalling company does not tell the whole story. A U.S.-based company may initiate a recall of a pharmaceutical product manufactured abroad or made with an imported ingredient. In September 2026 alone, at least three domestic companies initiated recalls of products manufactured overseas. These recalls involving foreign manufactured products or foreign-sourced ingredients are easy targets for FDA action.

We expect scrutiny of foreign drug manufacturing and ingredient sourcing to continue for the foreseeable future. Not only has FDA made overseas facilities a focus of its enforcement efforts, but there is also bipartisan support on Capitol Hill for this heightened scrutiny.

In September 2026, two U.S. Senators sent a congressional letter to the Government Accountability Office (GAO) requesting a study to understand, among other things, the connection between country of manufacture and drug recall patterns.

The practical lesson for companies with a global supply chain is to plan for two related but distinct challenges: managing the recall and restoring reliable supply in light of the possible import consequences.

A recall response that does not also address potential import restrictions may leave the company exposed to continuing delays, contractual breaches, and uncertainty about future shipments.

Reducing recall and import risk across global supply chains

Pharmaceutical companies with global supply chains should prepare not only for a product recall, but also for potential import restrictions that may outlast the recall itself. Several proactive steps can help manage these overlapping risks.

First, companies should map their manufacturing and ingredient supply chains. This means identifying critical foreign manufacturing sites and suppliers, including single-source dependencies that could leave the company vulnerable to an import disruption.

Second, companies should strengthen oversight of critical foreign suppliers through risk-based audits and quality agreements. Agreements should require prompt notification of inspections, significant quality issues, and potential recalls. Manufacturers should also ensure that agreements provide for access to relevant supplier records and an opportunity to review supplier communications and proposed responses before they are submitted to FDA.

Third, companies should develop and test a coordinated recall and import-response plan that addresses how to manage a recall while sustaining operations through a potential import disruption. Planning should extend beyond the recall itself to include remediation, resolution of related import actions, and restoration of reliable supply. Ending a recall will not necessarily resolve the conditions that led to an import restriction.

Finally, companies should work closely with overseas business partners to identify and address compliance issues early. This includes conducting thorough due diligence before engaging and onboarding and ensuring that the partner has processes in place to conduct root cause investigations and implement comprehensive corrective and preventive actions.

The views expressed in this article are those of the authors and do not necessarily reflect the opinions of Sedgwick.



October insights

Automotive:

There were 83 U.S. automotive recalls in October 2026, up 15.3% compared to the monthly average of 72 events for the first three quarters of 2026. However, the number of units recalled by NHTSA fell 73.5% from a monthly average of 3.64 million units from January 1 through September 30 to 966,560 units in October.

There were 18 electrical systems recalls, making them the leading cause of events for the automotive sector in October 2026. That was followed by equipment with 13 recalls and diesel fuel systems with nine events.

Seats had the most units recalled in October with 335,199 across five events, boosted by a single recall of 228,367 units. Electrical systems were second in terms of volume with 209,268 units recalled. Gasoline fuel systems were third with 110,000 units impacted across two events, nearly all from a single recall of 105,794 units.

Consumer product:

There were 43 U.S. consumer products recalls in October 2026, down 13.6% from the monthly average of 49.78 events for the first three quarters of 2026. However, the number of units recalled increased from a monthly average of 4.58 million units in the first three quarters to 11.69 million in October 2026. There were two recalls that each had more than 4.44 million units impacted.

Yard & Garden was the top consumer product recall category for October 2026 with seven events. Electronics, Home Furnishings & Décor, Personal Care, Sports & Recreation, and Toys tied for second with five recalls each. Children's Products were third with four events.

Kitchen products had the most units recalled in October with a total of 5.91 million, almost entirely due to a single recall of 5.9 million French press coffee makers that posed a burn hazard. Yard & Garden was second in terms of volume with 5.02 million units, including 4.48 million metal wire bristle grill brushes recalled for an ingestion hazard. Electronics was third with 507,753 units impacted, including 360,500 electric balloon pumps.

Food and drink:

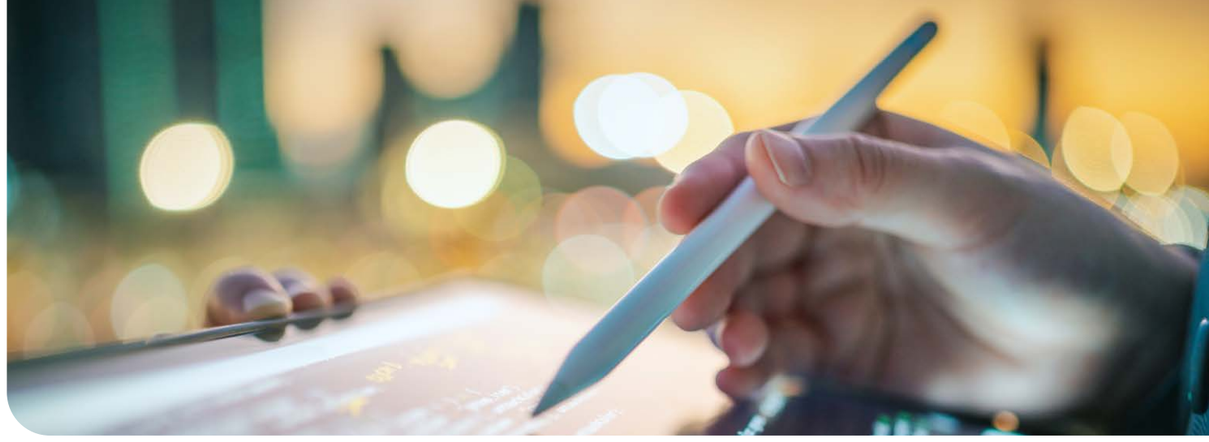
FDA

The FDA issued 61 food and drink recalls in October 2026, up 41.1% from the monthly average of 43.22 events for the first three quarters of 2026. However, the number of units recalled in October decreased to 2.38 million units compared to the monthly average of 8.87 million for January 1 through September 30.

Undeclared allergens were the leading cause of FDA food recalls in October with 31 events, including four recalls each for colors, soy, and wheat. Bacterial contamination was the second leading cause with 12 events, including five for Salmonella and three for E. coli. This was followed by undeclared ingredients with four recalls.

Undeclared allergens also impacted the largest volume of FDA food recalled, accounting for 878,336 units in October 2026. This included a single recall of 646,500 mayonnaise packets for undeclared mustard and soy. No FDA food recall in October impacted more than one million units.

Bacterial contamination was the second-highest concern by volume, linked to 569,622 units. This included a recall of 519,815 units of cheese for E. coli. Undeclared ingredients were third with 434,563 units impacted, nearly all from a single recall of 430,164 cans of enchilada sauce.



USDA

There were three USDA recalls in October, which combined impacted 1.59 million pounds. This compares to a monthly average of 2.44 events impacting 4.16 million pounds for the first three quarters of 2026.

Nearly all of October's volume came from a single recall of 1.58 million pounds of meat and poultry products due to temperature abuse. The other two recalls were for beef jerky that had not been inspected and pork cracklings that were ineligible for export.

Pharmaceutical:

There were 49 pharmaceutical recalls in October 2026. This is up 61.5% from the monthly average of 30.33 events for the first three quarters of 2026. However, the number of units recalled fell to 17.38 million compared to the monthly average of 59.48 million units for January 1 through September 30.

In October 2026, the most common hazard by event was failed specifications with 14 recalls. Foreign materials were second with eight events, followed by sterility with seven recalls and mislabeling with five.

Failed specifications were also the leading pharmaceutical recall risk by volume, accounting for 39.09% of all pharmaceutical units recalled in October and impacting 6.80 million units. This included a 6.63 million unit recall of lubricant eye drops. Sterility had the second-highest volume with 5.11 million units affected, including another recall of 4.85 million units of lubricant eye drops. cGMP deviations were third with 4.64 million units recalled, largely due to a single recall of 4.30 million units of fluoride toothpaste.

The FDA classified nine pharmaceutical recalls in October 2026 as Class I, affecting 305,446 units. There were 35 Class II recalls, which impacted 16.82 million units, and five Class III recalls affecting 261,955 units.

Medical device:

In October 2026, there were 95 medical device recalls, an 11.6% increase from the monthly average of 85.11 events for the first three quarters of 2026. However, the number of units recalled fell 83.1% from a monthly average of 110.81 million units from January 1 through September 30 to 18.71 million units in October.

In terms of events, software was the most commonly cited cause for medical device recalls in October 2026 with 14 events. Sterility and mislabeling tied for second with 10 recalls each, followed by device failure and parts issues with nine events each.

Mislabeling was the leading cause of recalls by volume and impacted 13.72 million units, mostly tied to a single recall of 12.84 million vinyl instrument guards. Quality issues were the reason for the second-highest number of medical device units recalled with 1.41 million, largely due to a single recall of 1.22 million microbiology test panels. This was followed by contamination with 872,953 units impacted, nearly all from a single recall of 860,450 blood collection tubes.

The FDA classified five medical device recalls in October as Class I. These recalls impacted a total of 177,783 units. There were 87 Class II recalls in October, which affected 18.37 million units, and three Class III recalls affecting 169,393 units.

Conclusion

Looking ahead, several regulatory changes have the potential to make a significant impact. NHTSA announced lower Corporate Average Fuel Economy standards, projecting a combined fleet average of 34.9 mpg in model year 2031—well below the 50.4 mpg path set in 2024. The new targets take effect on November 30, 2026.

The Federal Communications Commission added foreign-produced power inverters, drones, routers, and advanced robotic devices to its Covered List. New models on the list cannot receive the equipment authorization required for most electronics before they can be imported or sold in the U.S.

The FDA published a proposed rule that would convert the voluntary Generally Recognized as Safe (GRAS) notification program into a mandatory one, including substances added indirectly from food packaging. For medical devices, Medical Device User Fee Amendments for fiscal years 2028 through 2032 are under discussion. In addition, the FDA began accepting applications for an Expedited Investigational New Drug Pilot that pairs sponsors with outside research institutions in an effort to shorten the path to first-in-human trials.

Product safety is an increasingly complex business challenge, shaped by evolving regulatory expectations, global supply chain dependencies, technological change and shifting consumer demands. For organizations, the consequences of a product safety issue can extend well beyond a recall, disrupting operations, exposing financial vulnerabilities and undermining customer and stakeholder confidence.

Effective risk management demands more than contingency planning. It requires the foresight, resources and specialist capabilities to anticipate emerging threats, make informed decisions and maintain control when incidents occur. Whether strengthening preparedness or managing an active event, an experienced external partner can provide the expertise and operational capacity to navigate regulatory and litigation challenges, minimize disruption and protect long-term business value.





Sedgwick Recall

A product recall is a defining moment for any organization.

Beyond the immediate safety concerns, it places significant demands on decision-making, operational resources and stakeholder relationships, often across multiple markets and regulatory environments. How effectively an organization responds can have lasting implications for its customers, reputation and commercial performance.

For more than 30 years, Sedgwick Recall has helped organizations respond to these challenges.

Since 1995, we have managed more than 8,000 events across over 150 countries, involving more than 500 million units. This depth of experience gives us a broad understanding of the decisions, risks and operational demands that shape a recall, and the insight to help clients navigate them with confidence.

No two recalls are the same. The nature of the issue, the products involved, the markets affected and the scale of the response all influence what is required. Sedgwick brings together specialist expertise and established operational capabilities across the full recall lifecycle, from planning and response strategy to consumer engagement, product recovery, remedy and final disposition. Our services can be delivered as a complete recall management program or tailored to specific requirements, giving organizations access to the support they need without imposing a one-size-fits-all approach.

Discover how Sedgwick Recall can support your organization at every stage of the recall lifecycle.

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