POLITICO

MAGAZINE PRO E&E NEWS

THE FDA'S FOOD FAILURE

A POLITICO investigation based on more than 50 interviews finds the FDA is failing to meet American consumers' expectations on food safety and nutrition.

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04/08/2022 05:00 AM EDT

By the time FDA officials figured out it was spinach that was making people sick in 10 states – sending three people into kidney failure – it was too late. It was mid-November 2021 and the packaged salad's short shelf life had passed. There was no recall. By the time FDA officials got inspectors on the ground, spinach season was over. The fields and

the production facilities were empty, which made it impossible to pinpoint the source of contamination.

Whatever caused the outbreak was likely never fixed.

This wasn't supposed to happen. It's been more than 11 years since Congress passed a sweeping food safety law designed to prevent this type of health risk. In that time, FDA has failed to put in place safety standards for the water used to grow fresh produce, as mandated by that law, despite knowing that water is one of the main ways fresh fruits and vegetables become contaminated with deadly pathogens. Congress has ramped up FDA funding over the past decade, but deadly outbreaks keep happening and it often takes the agency too long to respond.

Read the four major findings from our investigation.

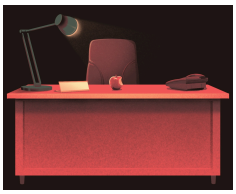
Have you complained to the FDA about the Similac recall or another infant formula problem? We want to hear from you.

Many consumers would be surprised to learn this anemic, slow response is typical for an agency that oversees nearly 80 percent of the American food supply, but slow is what insiders in Washington have come to expect from FDA, regardless of administration. A monthslong POLITICO investigation found that regulating food is simply not a high priority at the agency, where drugs and other medical products dominate, both in budget and bandwidth – a dynamic that's only been exacerbated during the pandemic. Over the years, the food side of FDA has been so ignored and grown so dysfunctional that even former FDA commissioners readily acknowledged problems in interviews.

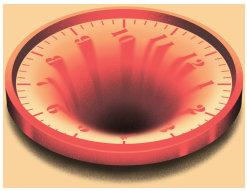
"The food program is on the back burner. To me, that's problem No. 1," said Stephen Ostroff, who twice served as acting commissioner of FDA, and held several other senior roles at the agency, most recently as top food official. When POLITICO called Ostroff for this story, he was so eager to discuss the agency's problems, he prepared a laundry list of his concerns.

"There are a lot of things that languish," Ostroff said. "There's nobody really pushing very hard to get them done in the same way that you're pushing very hard to get the Covid vaccines out there and authorized. We don't have that imperative and that pressure to actually make things happen on the food side of the Food and Drug Administration."

OUR INVESTIGATION



‘IT’S A STRUCTURE THAT’S DESIGNED TO FAIL’



‘A BIT OF A BLACK HOLE’

THE RAGE OF A MILLION PARENTS

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Indeed, POLITICO’s investigation found that the Center for Food Safety and Applied Nutrition, the little-known food arm of FDA, has repeatedly failed to take timely action on a wide range of safety and health issues the agency has been aware of for several years, including dangerous pathogens found in water used to grow produce and heavy metal contamination in baby foods. The agency has been slow to acknowledge numerous other chemicals of concern, including PFAS, so-called forever chemicals, which can be found in the food supply and are used in food packaging. FDA has dragged its feet on major nutrition issues, even as diet-related disease rates in the U.S. have continued to worsen. For example, FDA has spent the better part of a decade working on voluntary sodium reduction goals for food companies while many other countries moved ahead with their own years ago.

“They just kick the can down the road,” said Scott Faber, senior vice president at the Environmental Working Group, who used to work for the food industry’s top trade association. “We’re global laggards.”

This government dysfunction has a real impact on people's lives. The CDC estimates that more than 128,000 people are hospitalized and 3,000 people die from foodborne illnesses each year – a toll that has not lessened after a sweeping update to food safety a decade ago. A recent outbreak tied to contaminated infant formula, in which at least four babies were hospitalized and two died, is a stark reminder of what’s at stake when the food safety system fails. The first hospitalization was reported to federal health officials five months before the FDA and formula-maker Abbott Nutrition finally recalled the product – in what would become the largest infant formula recall in memory.

By all accounts, the country is also in the middle of a diet-related disease crisis, something that made millions of Americans even more vulnerable to severe illness and death from Covid-19. Even before the pandemic, poor diet was one of the biggest drivers of health care costs and premature death in the United States.

> "There's just no question that the agency isn't meeting the moment."
>
> — SAM KASS, FORMER WHITE HOUSE ADVISER

This is not your run-of-the-mill slow-churning Washington bureaucracy. FDA's food division is so slow, it's practically in its own league. For this story, POLITICO spoke with more than 50 people, including current and former FDA officials, consumer advocates and industry leaders. Some were granted anonymity to speak candidly. There is a remarkable level of consensus that the agency is simply not working. Current and former officials and industry professionals used terms like "ridiculous," "impossible," "broken," "byzantine" and "a joke" to describe the state of food regulation at FDA.

"There's just no question that the agency isn't meeting the moment," said Sam Kass, who served as senior policy adviser on nutrition to President Barack Obama and was a key figure behind former first lady Michelle Obama's childhood obesity campaign.

During the Obama administration, FDA was able to get some significant things done, including an update to Nutrition Facts labels to disclose added sugars, a ban on trans fat and a new requirement to list calories on menus – actions that FDA had mulled for many years. Requiring calorie counts be posted on chain restaurant menus was such a long slog it took eight years from when Congress asked for the policy as part of the Affordable Care Act to when the labels were finally implemented, in 2018. The requirement was temporarily suspended during the pandemic.

Kass, who's now a venture capital investor in food startups, acknowledged that many of the issues facing FDA are complicated and tough to work on, but the

lack of progress can be maddening, he said. “There’s a real need in this country to put pressure and regulatory oversight on an industry that’s producing food that's undermining the public good.”

A POLITICO investigation found that there are basic structural problems that contribute heavily to the current failure. FDA is housed under the Department of Health and Human Services, which means the commissioner, while Senate confirmed, isn’t part of the Cabinet. FDA commissioners almost always come from the medical side and historically also have almost no experience with food issues, a mismatch that means big policy questions can get bogged down in layers of approval below them. There’s a long-running joke among FDA officials that the “F” in FDA is silent. Commissioners have also been known to slip up and accidentally call it the Federal Drug Administration. Aside from a relative lack of interest in food issues, there’s also just been a straight-up lack of leadership at FDA: The agency has had five commissioners in three years, three of whom have been acting.

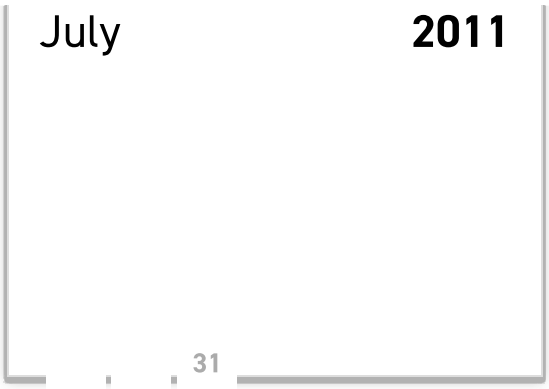
Robert Califf, a cardiologist with a clinical research background, in mid-February became commissioner, a position he’d previously held for about a year during the Obama administration. It had been more than a year since the agency had a Senate-confirmed leader, even as it was under extreme pressure to work on vaccines, tests and treatments during the pandemic.

Aside from the lack of attention to food at the top, there are also unique problems within CFSAN, the branch that handles food issues. The division – which is dwarfed by the medical products side of the agency – suffers from a deep-seated culture of avoiding hard decisions and a near-paralyzing fear of picking serious fights with the food industry. A Trump-era change in leadership structure set up a power struggle between the two top officials, further strengthening the status quo of inaction, which often benefits industry. The agency is adrift, without leadership, and currently plagued by turf battles.

The result is that the agency fails to come anywhere close to meeting most American consumers’ basic expectations of government oversight on food safety and nutrition, even as Congress has directed more resources to tackle food safety problems.

Deadly outbreaks and slow recalls

Outbreak: Listeria-contaminated **cantaloupes**



People sickened: 147

Hospitalized: 143

The melons were recalled on Sept. 14, more than a month after the first case was reported.

Current FDA officials, in interviews with POLITICO, argued that the food side of FDA is a priority but lacks the budget to do everything being asked of it.

“They have too many programs and not enough resources,” acknowledged Janet Woodcock, FDA’s principal deputy commissioner, who served as acting

commissioner the first year of the Biden administration. “And the mismatch is profound.”

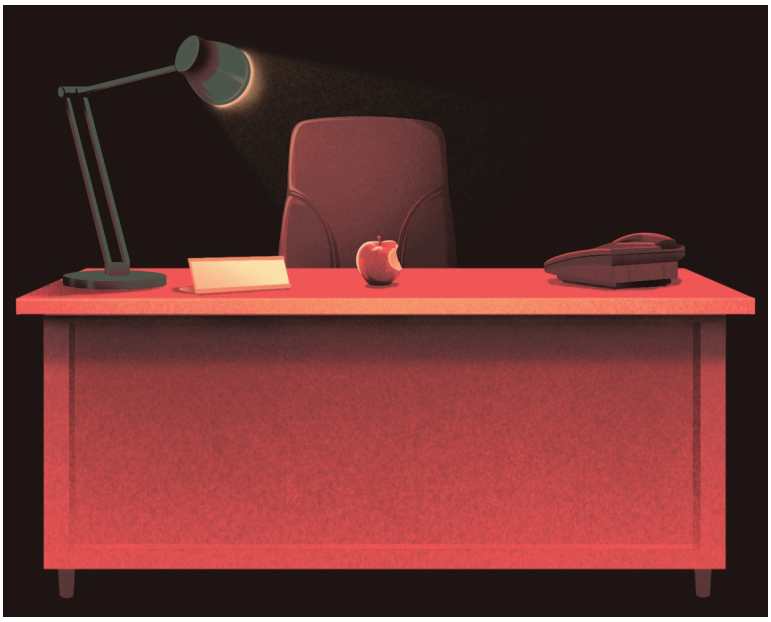
“It's really important, but it's very under-resourced,” she said of the food division.

Consumer advocates, former FDA officials and members of Congress, however, have increasingly been questioning whether the agency is making the best use of its roughly $1 billion food budget. The vast majority of its funding – about two thirds – goes to the Office of Regulatory Affairs to pay for inspections, but the number of food safety inspections performed each year has been going down despite increased resources.

House Appropriations Chair Rosa DeLauro (D-Conn.) and Rep. Sanford Bishop (D-Ga.), chair of the appropriations subcommittee that oversees FDA, last year wrote to the agency raising concerns about the Office of Regulatory Affairs’ “substantial overhead and lack of transparency and accountability” about how food resources are being used at the agency.

CHAPTER 1

‘IT’S A STRUCTURE THAT’S DESIGNED TO FAIL’



The FDA, and CFSAN in particular, is an incredibly insular and hard to understand place. Even those who have worked there, or worked closely with the agency across government, say they are mystified by the glacial pace of decisions. They say FDA's food division essentially answers to no one. Its food officials are rarely asked to testify before Congress. The agency has a way of escaping scrutiny on Capitol Hill.

"There just simply is no accountability in Congress," said Richard Williams, who worked at CFSAN as an economist for more than three decades, during which time he became increasingly disillusioned with the agency. "I guess most of their staff really don't understand the risk issues that FDA faces," he said, of Capitol Hill. "They don't really know what to say to FDA to hold them accountable."

Congress tends to pay more attention to pharma and tobacco and other issues before FDA – an agency that oversees about 20 percent of overall consumer spending (cosmetics and microwaves are also oft-forgotten). In December, the Senate Health, Education, Labor and Pensions Committee held a confirmation hearing for Califf, Biden's then nominee to serve as FDA commissioner. In the two-hour hearing, lawmakers asked one question about food and it was Sen. Tammy Baldwin (D-Wis.) asking Califf to please crack down on dairy alternative products using terms like "milk" and "cheese" (such as almond milk), something the country's – and Wisconsin's – dairy producers have wanted the agency to do for decades.

There are also unique structural and cultural problems within CFSAN that have escaped any real scrutiny. One of the most pressing is an open power struggle between CFSAN's director and FDA's deputy commissioner for food policy – a vestige of a little-known reorganization of leadership during the Trump administration that was in part recommended by the consulting firm McKinsey & Co. While the goal at the time was to reduce bureaucracy and give then-Commissioner Scott Gottlieb more of a direct line into the various FDA centers, the change meant eliminating a powerful deputy commissioner position that used to oversee the entire foods program and left the decision-making structure unclear.

Under the new structure, Frank Yiannas is deputy commissioner for food policy and response, reporting directly to the commissioner, but his post doesn't actually have authority over the foods program. Susan Mayne is the director of CFSAN, which means she oversees the foods program, but she also reports directly to the commissioner and doesn't report to Yiannas. It's an unconventional setup that tends to pit the two top officials against each other.

"It's a structure that's designed to fail," said one former senior FDA official. "You couldn't come up with a better way to keep the program from working well."

The two leaders also do not get along, according to numerous current and former officials. Several described Mayne as "competitive" with Yiannas, a dynamic that has created uncomfortable friction at the top of an agency that already struggles to make decisions or move policy forward. One person close to the agency described Mayne as trying to "cut his knees out." Another described it as a "bureaucratic fight" that they didn't want to get in the middle of.

There are competing views about who is to blame for the leadership friction, according to another person familiar with the situation.

Yiannas, who joined FDA from Walmart in 2018, is seen by agency watchers as having a much more private-sector-like speed and ethos: The agency needs to

move ahead. The agency needs deadlines. Current and former officials described Yiannas as frustrated by his limited ability to move things forward. Yiannas' approach runs counter to Mayne's, who often goes to great lengths to try to forge consensus on controversial issues. Several insiders described Mayne, who joined FDA in 2015 from Yale University, where she was a professor, chair of the epidemiology and chronic disease department at the School of Public Health, and associate director for population sciences at the Yale Cancer Center, as overly cautious and "indecisive," running things much more like an academic institution. Current and former staff members described numerous meetings and very few decisions.

The extremely different leadership styles of the two top officials only adds to the structural dysfunction – and the situation is confusing for those trying to work with the agency. Who is actually making decisions? For the past few years, there has been a sort of unspoken division between the two officials: Yiannas has food safety and Mayne has nutrition, but even those lines are not always clear.

The breakdown at FDA is so widely recognized that at least a handful of food trade groups are starting to talk internally about how to press for a reorganization to make the agency work better.

It's common, for example, for Yiannas and Mayne to disagree about how to investigate or respond to a foodborne illness outbreak, according to two people with knowledge of the dynamic. Yiannas has a tendency to press for more root cause analysis, more pathogen testing, and quicker reports to the public, something that's well known to cause friction. Another person familiar with the tensions between Yiannas and Mayne blamed FDA's onerous clearance processes for friction over how quickly the agency can move things out.

"A lot of talented people are working hard to implement [food-safety reform] and meet other public expectations, but FDA's fragmented structure and cautious culture are built-in obstacles to strong leadership and timely

decisions," said Michael Taylor, who served as deputy commissioner for foods and veterinary medicine during the Obama administration, a position that then held direct oversight over CFSAN.

FDA declined to make Yiannas and Mayne available for interviews. FDA Commissioner Califf, in an interview, did not directly address the power struggle, but suggested that he's thinking about how to move forward.

"We are already working on the teamwork part of this very directly," Califf said. He noted that he thinks it's "good to have people that have different perspectives," but acknowledged that "we can't have people working at counter purposes."

Gottlieb – who was FDA commissioner when the leadership structure was changed and was unusually involved in food policy compared with other commissioners – believed the reorganization would reduce bureaucracy and allow for more direct involvement from the commissioner, according to former FDA officials. In an interview, Gottlieb acknowledged that the move resulted in leadership challenges after his departure, but argued that inadequate staffing and budget are the division's biggest problems. He described CFSAN as lacking the institutional bandwidth to handle the increasing complexity of the food system.

The center charged with overseeing the vast majority of the country's food supply has roughly the same number of staff as it did a decade ago, according to a POLITICO analysis of budget documents. While other parts of the agency, including drugs and tobacco, have grown considerably, the policy staff for foods has remained pretty much flat even as responsibilities have grown.

"That just reflects the under-resourcing of the center over time, even as the regulatory missions expanded dramatically," Gottlieb said in an interview.

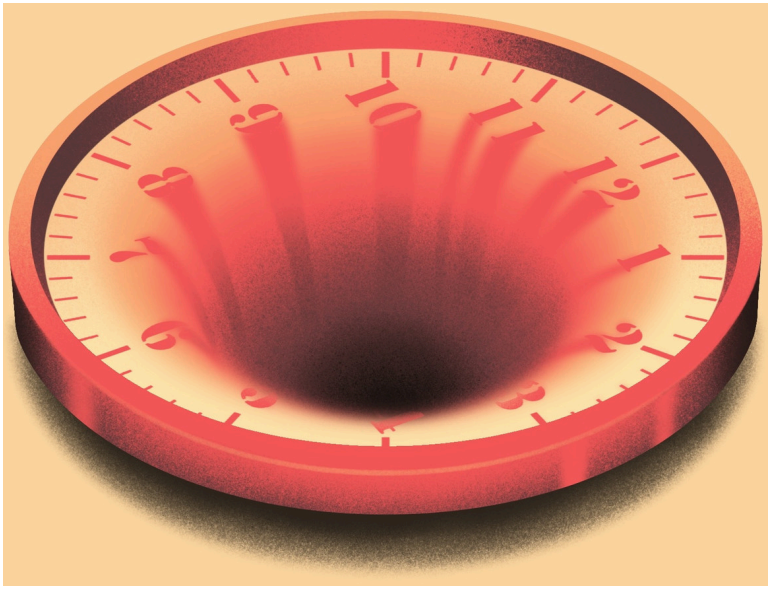
Gottlieb said he was particularly interested in food issues because he believed things like nutrition had the potential to have a far greater public health impact than just about anything else the agency works on. FDA also faces much, much greater political pushback on food issues than it does on the medical side, he said, which makes it difficult to move big policies forward.

"The food industry is lobbying USDA, which in turn puts pressure on FDA through the White House and Capitol Hill, in a way that's unproductive and this spans multiple administrations," Gottlieb said. "It wasn't just under the Trump administration, although I felt it during the Trump administration."

"The only place we routinely had industry going outside FDA to lobby the Hill, other agencies or the White House, without really litigating the issue inside FDA, was food and tobacco."

CHAPTER 2

‘A BIT OF A BLACK HOLE’



The story behind why the U.S. does not have a produce water safety standard in place 11 years after President Barack Obama signed the biggest update to food safety law in a century – a law that was partly sparked by a deadly spinach outbreak in 2006 – is emblematic of the problems within FDA that keep important things from being done in a reasonable time frame.

The FDA, to its credit, implemented several major food safety regulations that were required under the Food Safety Modernization Act, a process that was by and large praised for being functional and collaborative by both consumer advocates and the food industry. But the agency has failed to complete one of the most important pieces of the new regimen: standards for agricultural water

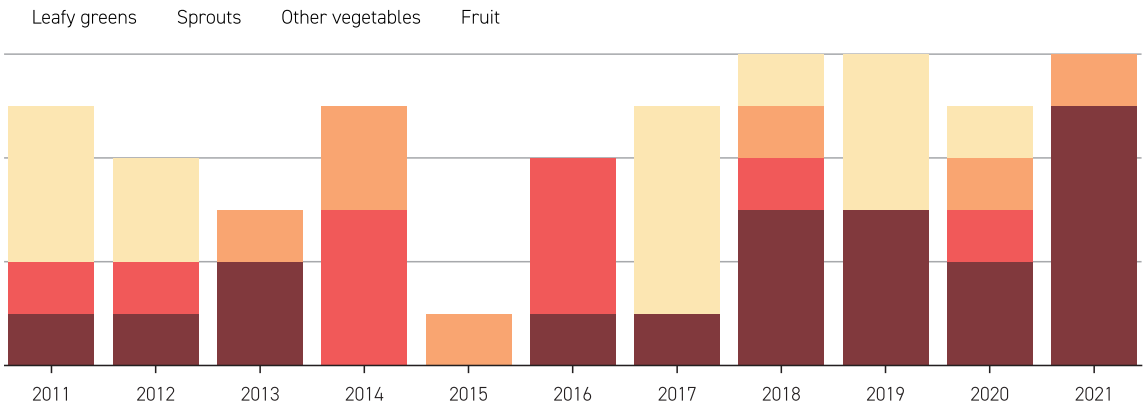
aimed at keeping manure and other sources of pathogens out of the water used to grow fresh produce.

The agency first tried to come up with a water standard as part of its broader produce safety rule in 2015, but the policy was widely panned for being too complicated. It required growers to test their water a certain number of times per year and do logarithmic calculations to gauge how safe the water was to use. Just about everyone agreed it wouldn't work. It was also based on outdated science, using an EPA standard for recreational water that has little to do with food safety. After lots of industry pushback, FDA in 2017 scrapped the first water standards and said it would try again.

It would be another four years before a new proposal would come out. In the meantime, there were several major outbreaks tied to fresh produce, including some deadly ones related to contaminated water. In 2018, for example, 210 people were sickened in an E.coli O157:H7 romaine lettuce outbreak traced to Yuma, Ariz. Of those who fell ill, 96 were hospitalized, 27 suffered from kidney failure and five died. Several months later, FDA said it found a similar bacterial strain in the canal water used to irrigate crops in the area.

Deadly outbreaks continue 11 years after major food safety law

In 2011 President Barack Obama signed the Food Safety Modernization Act to protect Americans from food-borne illnesses. Since then, the FDA has failed to put in place agricultural water standards meant to keep deadly pathogens out of fresh produce.



Note: "Leafy greens" include lettuce, spinach, basil and salad greens.
Source: POLITICO analysis of CDC data
Taylor Miller Thomas / POLITICO

What exactly happened at the agency during those four years is a mystery to everyone, including some within the agency. There were no real progress updates.

FDA has a reputation of caving to what industry wants, even if that's not always the case. But when it came to ag water, major produce industry groups contend they weren't lobbying against a redo of the rule, they really just wanted to see the policy. They wanted to weigh in on the plan, and at the very least, give their members clarity on what was coming.

"Everyone – everyone! – wanted some sort of decision and finality from FDA," said Jennifer McEntire, chief food safety and regulatory officer at the International Fresh Produce Association. "It wasn't like there was disagreement over whether or not there should be a rule related to ag water."

"It becomes difficult to understand why it would possibly take so long," she added. McEntire and other leaders in the produce industry constantly asked FDA officials how the rulemaking was going. When could they expect to see it? "The answer was always we're working on it," she said. The years dragged on. Industry leaders offered to help. Did the agency need data or technical assistance? Were there particular sticking points?

"It was a bit of a black hole," she recalled.

After Frank Yiannas came on the job in late 2018 – he'd been recruited by then-FDA Commissioner Gottlieb – he publicly said, in early 2020, the agency hoped to get the rule done by the end of the year. "That was exciting," McEntire recalled. "Wow. So someone is willing to actually put a date out there."

The agency blew right through this timeline. The pandemic understandably changed the FDA's focus.

> "People are literally going to die because of FDA's surrender to agriculture on pathogens and irrigation water."
>
> — SCOTT FABER, ENVIRONMENTAL WORKING GROUP

In fairness, McEntire and others conceded setting standards for ag water is not easy. A federal rule that applies to everything from irrigation ditches to drip irrigation and open reservoirs is logistically and technically difficult. What is the best way to ensure that water isn't contaminated? For example, a microbiological test from an open water source like a flowing irrigation canal can only tell growers how clean that particular scoop of water is, not how safe the water will be later that day or the next because the water is flowing constantly.

After a lengthy delay, the ag water rule hit another snag on its way out the door. In the final months of the Trump administration, FDA actually submitted its

revamped rule to the White House Office of Management and Budget – which reviews major regulations before they can go out – but, as is common in administration transitions, the rule was sent back to the agency when the Biden administration took over in early 2021.

Nearly a year later, in December 2021, FDA finally unveiled a proposed rule to replace its 2015 attempt. The standards were praised by industry as being appropriately flexible and panned by consumer groups as being too lax. The updated rule essentially asks producer growers to identify their own potential hazards and control them – so if cattle manure might get in their water, they could treat it with a dose of chlorine before using it – but critics were quick to point out that the rule doesn't specifically mandate any testing. Consumer advocates were not pleased.

"People are literally going to die because of FDA's surrender to agriculture on pathogens and irrigation water," said Scott Faber of the Environmental Working Group, who helped craft FSMA when he was a lobbyist at the Grocery Manufacturers Association more than a decade ago.

"It was the single-most important provision of FSMA because it was going to by far do the most to reduce the number of people who get sick and die from foodborne illness," he said. "And they've completely and utterly surrendered."

FDA officials argue that regulating water quality is "complex and challenging," which is in part why it's taken so long to develop a regulation. Yiannas, for his part, told POLITICO in January that FDA's redo of the water rule was aimed at being flexible because the agency believes it will result in greater compliance.

"We understand the concern about the length of time it took to issue the proposed rule," an FDA spokesperson said in response to questions from POLITICO about ag water. "The process has been rigorous, including time to gather and review information, developing a new conceptual framework, and undertaking the process for issuing proposed changes to the regulation."

The agency said the new proposed rule is “thorough” and builds off what FDA has learned from recent produce outbreak investigations. “The agency believes that, if finalized, it will help bend the curve of foodborne illness and provide benefits for generations to come,” a spokesperson said.

Califf, who has been FDA commissioner for just shy of two months, did not defend the agency’s lengthy timelines.

“I think it's good for you to poke at timelines,” Califf said. “It's our job to try to make it go faster.”

Califf, who joined FDA after serving as a top adviser on health strategy and policy for Alphabet, the parent company of Google, said he was hoping to make significant updates to FDA’s tech systems to help the agency work better.

“I have a pretty good concept of what computing can bring to the table,” Califf said. “But that doesn't necessarily solve a lot of what you're raising here – if there's anything which is not like software engineering, it's politics.”

CHAPTER 3

THE RAGE OF A MILLION PARENTS

In recent weeks, FDA's oversight of the food supply has come under more scrutiny after an outbreak of Cronobacter sakazakii – a rare but deadly bacteria – sparked a massive recall of infant formula, exacerbating already strained supply chains. The agency is still investigating the incident, but so far four hospitalizations and two deaths have been linked to formula produced by Abbott Nutrition at a single plant in Sturgis, Mich., including Similac, the most popular formula brand on the market.

The agency has so far refused to explain why it took months to inspect the plant and subsequently recall product. As POLITICO first reported, the first infant illness was reported to federal health officials in September. Inspectors were not sent to the plant to investigate until late January. Product was not recalled until February. A handful of key Democrats on Capitol Hill are now pressing for answers. DeLauro, the House Appropriations chair, recently requested an inspector general investigation into the agency's response.

A year ago, however, FDA was in the hot seat over a completely different issue tied to babies: A congressional report had flagged concerns about heavy metals and other neurotoxins in baby food, sparking a wave of mainstream press coverage and throngs of furious parents.

Several years before this blew up, top FDA officials were on a call about the issue.

It was Friday, Oct. 27, 2017. The agency had reached out to the Clean Label Project, a small nonprofit based in Colorado, because the group had two days earlier published a report based on its testing of 500 samples of baby food and infant formulas. The group tested for lead, arsenic, mercury and even Bisphenol A, a commonly used plastic in food packaging, among other contaminants. It found that 25 percent of all products tested "exceeded at least one state or federal guideline." The report – which generated a fair amount of media buzz – revealed that 30 percent of all products tested had detectable levels of lead. Over half of the infant formula samples contained arsenic.

Initially, it seemed like FDA's outreach was a promising sign. Jaclyn Bowen, executive director of Clean Label Project, however, recalled being disappointed with the call, even though it included really high-level staff, including CFSAN Director Susan Mayne, as well as Conrad Choiniere, who is now heading up a toxic elements work group. FDA officials essentially cast doubt on the group's findings, suggesting that the agency's own testing data was more trustworthy and the group's report was off base.

In response, one of the scientists at Ellipse Analytics, the lab that had conducted the tests, sent a memo back to the agency detailing why the findings were actually in line with FDA's own periodic testing of the food supply. In other words, FDA's own testing over a period of decades corroborated that concerning levels were commonly found in these products. The agency never responded to the memo.

A few days after the conference call, Bowen wrote the group of FDA officials to follow up: "In terms of next steps, I'd welcome an opportunity to see how Clean Label Project can support FDA in the creation of additional infant formula and baby food regulations," she wrote. Bowen further suggested that the agency start with setting maximum tolerances for at least lead and mercury in infant formula, which is the exclusive source of nutrition for more than half of all babies born in the U.S. each year.

None of the seven officials she wrote to responded to her email. Bowen followed up again in April 2018. By that point, another major report had come out, this time from the group Healthy Babies Bright Futures, which found that arsenic levels in infant rice cereals were many times higher than in other types of infant cereals, such as oatmeal.

"Clean Label Project remains committed to supporting the FDA in the creation of additional infant formula and baby food regulations," Bowen wrote, to the same seven officials who had joined the call months earlier. "Does FDA have intentions to establish further policy on the maximum tolerances of heavy metals and other industrial and environmental contaminants for products marketed to infants and children?"

There was no response. The agency did not dispute this interaction. However, an FDA spokesperson suggested that the nonprofit didn't fully respond to all of the questions officials originally had about the group's 2017 testing.

Behind the scenes, FDA officials were apparently starting to feel some pressure. In 2017, the agency quietly launched a toxic elements work group, partly in response to a study conducted by EPA that found – using FDA's own testing data – that food was a surprisingly significant source of lead exposure for young children. (EPA had conducted the analysis as a response to the lead water crisis in Flint, Mich., that began in 2014.)

Attention was slowly turning to toxic elements in food. Around the same time, the Environmental Defense Fund analyzed FDA's own food tests and found there were measurable lead levels in 20 percent of baby products tested. The group noted that no safe level of lead has been identified. Lead exposure in children, in particular, can cause behavioral problems and lowered IQ. If the U.S. could completely eliminate lead exposure to children, the group estimated that societal benefits would exceed $27 billion each year.

In April 2018, FDA publicly announced that it had formed a work group to "help shape what FDA will do to protect consumers of all ages from these metals when present in foods." The agency posted a lengthy interview with the leader of that

effort, but there was no mention of forthcoming standards or even guidance. There were no timelines or plans for action.

Meanwhile, the bad press just kept coming. A few months after the work group was announced, Consumer Reports tested 50 popular baby food products and found two-thirds contained "worrisome levels" of at least one neurotoxin such as arsenic, cadmium and lead. It reported that 15 of the products tested would pose health risks to children if regularly consumed. There was more media coverage.

In 2019, yet another report garnered headlines. This time, a large study from Healthy Babies Bright Futures, which tested nearly 170 products and found heavy metals and other contaminants present in 95 percent of their samples. Most foods had relatively low levels, but certain product categories stood out with higher levels, including lead in carrots and sweet potatoes and particularly arsenic in rice. Four of the seven infant rice cereals tested exceeded FDA's limits for inorganic arsenic.

"Our worst fears were confirmed."

This time, Congress took notice. A House Oversight subcommittee, led by Rep. Raja Krishnamoorthi (D-Ill.), began digging into the industry. It sent information requests to major baby food companies, including requests for testing data and other internal documents. Staff were horrified by what was turned over to them.

"Our worst fears were confirmed," a senior Democratic committee aide told POLITICO.

The staff report, released in February 2021, revealed that many of the ingredients and products that were tested by companies themselves contained heavy metals and other toxic elements at levels that exceed even generous voluntary limits set by FDA for some products and even some companies' own internal quality standards.

It's not clear how representative the testing data in the report was, but some of the examples were eye-popping: Happy Baby, an organic baby food brand, sold products that tested positive for lead at levels as high as 641 ppb, many times FDA's limits for lead in other foods like candy, and arsenic as high as 180 ppb, nearly twice the agency's limit for infant rice cereal. (The FDA has not otherwise set limits for toxic elements in baby foods.) Nearly 20 percent of the company's finished products contained over 10 ppb of lead, according to the committee. (The company that makes Happy Baby responded to the report by saying all its products are safe and the company employs "best-in-class" testing.)

By the time the subcommittee published the findings of its report – which sparked immediate public outrage – it had been roughly four years since the FDA had formally begun working on the issue. The agency had little to show for

its work. Officials had been holding internal meetings, but there were still no plans for action, nor were there timelines.

A spokesperson for the agency noted that during that time the work group was working on related issues. It finalized a long-delayed arsenic infant rice cereal guidance, updated "internal standards for assessing lead exposure risk from foods," updated the agency's understanding of lead and cadmium exposure and modernized its routine testing of the food supply, among other things.

"The agency used its best understanding of public health risks and benefits in order to focus its limited resources and was able to accomplish these actions despite the limited resources available," the spokesperson said, later adding: "The FDA was actively monitoring the food supply for toxic elements and developing the scientific base for action levels long before the congressional report."

FDA responded publicly to the subcommittee's report nearly a month after it was released by saying the agency would focus on the issue, but still did not set any timelines for action.

> "Now we really have to ask some searching questions: What's going on here? Why can't we get our act together?"
>
> — REP. RAJA KRISHNAMOORTHI, D-ILL.

"Research has shown that reducing exposure to toxic elements is important to minimizing any potential long-term effects on the developing brains of infants and children," FDA said in a statement at the time. "As such, this issue is among FDA's highest priorities and we are actively working to make progress on identifying and implementing impactful solutions to make foods commonly consumed by infants and young children safer."

In the "near term," FDA said it would look at developing new standards, ramp up enforcement efforts and issue guidance to help food companies lower their levels.

Advocates and members of Congress noted the lack of timelines or deadlines and criticized the agency for not committing to timely action. A month later, FDA tried again and rolled out a "Closer to Zero" action plan. By this point, the agency had, under pressure, set some deadlines, but its timeline extended out more than three years. The agency said that within a year it could set draft limits for lead in certain categories of foods for babies and young children. (The agency is on track to miss its April deadline, but said it's aiming for later this spring.) Draft limits for arsenic would come sometime between 2022 and 2024, FDA said. Other neurotoxic elements like cadmium and mercury are on even longer tracks, with the agency proposing, but not committing, to come up with draft limits sometime beyond 2024.

Advocates started to darkly joke about how old their kids and grandkids would be by the time there were standards in place for baby foods. “So let me get this straight, my kiddo is going to be in the second grade, and you're going to tell me what kind of baby food to give him?” Bowen said, of the lengthy timeline.

An FDA spokesperson responded that “the estimated timelines in Closer to Zero may appear lengthy, but it is important to understand that this is a complex process both scientifically and procedurally.”

“The FDA is committed to moving as quickly as possible,” the spokesperson added.

Krishnamoorthi, chair of the subcommittee that’s been investigating baby food, said his staff has repeatedly asked FDA what the agency needs to move more quickly. They haven’t gotten clear answers.

“They’re not moving fast enough,” the Illinois Democrat said in an interview. “Now we really have to ask some searching questions: What’s going on here? Why can’t we get our act together? The people that they are responsible to, the American people, will not tolerate any more delay in this area.”

Meanwhile, the FDA lacks a strong track record of enforcing the one important baby food standard it put on the books: a suggested limit of 100 parts per billion for inorganic arsenic in infant rice cereal, which is the first solid food millions of families feed their babies.

The standard has, by all accounts, substantially helped to reduce arsenic levels in rice cereal. Food producers quickly cut down the average levels in rice cereals to be below that threshold, though many health advocates note the limit was based on what was feasible for industry and is still too high to be protective of babies’ health.

But it’s also not clear the agency is consistently enforcing that standard. The FDA does little routine testing of infant rice cereals. The congressional panel

that's been investigating baby foods issued a follow up report last fall revealing that testing done by the state of Alaska (which had been funded by FDA), flagged two products as being over the FDA's limit for inorganic arsenic in the summer of 2021: Beech-Nut and Gerber brands. Beech-Nut responded by issuing a recall – the first ever under the arsenic standard – and went as far as to exit the infant rice cereal food market, citing difficulty obtaining rice that wasn't too high in inorganic arsenic. Nestle, which owns Gerber, didn't issue a recall at all. When POLITICO asked why, a spokesperson for the company said that FDA had told the company a recall wasn't necessary.

The agency confirmed this.

"The FDA did not recommend a recall based on the Gerber sample results, because testing by the Alaska State laboratory did not provide sufficient certainty that the inorganic arsenic level in the food sample exceeded the action level, among other factors," an FDA spokesperson said in an email to POLITICO last year. "The FDA did, however, follow-up with Gerber reminding them of their legal obligation to ensure the safety of their foods and discussed with the company mitigation strategies for reducing arsenic in their products."

Meanwhile, the infant rice cereal remained on the market.

(A company spokesperson later said that since mid-2021 Gerber has tested every batch of infant rice cereal, as well as rice, "an extra step we take to reassure our consumers that our products meet the FDA action level.")

CHAPTER 4

'OUR FOOD IS MAKING US SICK'

There is sometimes tension between those who work on the food problems that quickly kill people, like foodborne illnesses, and the food problems that slowly kill people, like highly processed foods laden with too much salt, sugar, starch and fat.

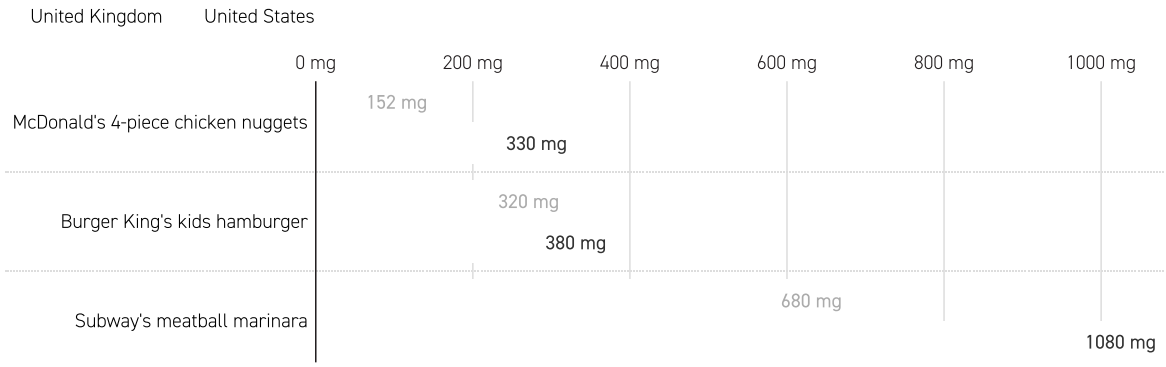
An E. coli outbreak leaves identifiable victims in its wake: Hospitalizations, kidney failure, sometimes death. Those victims and their surviving family members sometimes join consumer advocates to push for more regulations – that's one of the reasons Congress passed a major update to food safety reform more than a decade ago. Dietary quality faces an entirely different dynamic. Nutrition advocates sometimes quietly grumble that hypertension, diabetes and other diet-related diseases kill way more people than foodborne bugs each year, but these deaths don't make headlines. There's no recalls or fuss in the media.

Congress passed a food safety law that gave FDA a big to-do list over the past decade, but the agency missed many of its statutory deadlines and was sued multiple times by the Center for Food Safety, an advocacy group, for these delays. The push to reform food safety at FDA has been slow. The push to get FDA to help make the American food supply healthier has been so slow it's almost hard to fathom, health advocates say.

Sodium is a prime example. Michael Jacobson, founder of the Center for Science in the Public Interest, one of the most important nutrition groups in Washington, spent his entire career pushing the FDA to use its enormous power to reduce sodium across the food supply as a way to reduce high rates of hypertension. The group first petitioned FDA to crack down on sodium in 1978.

The same menu items can be twice as salty in the United States as they are abroad

Excessive sodium consumption is linked to thousands of premature deaths in the U.S. Countries like the United Kingdom have already rolled out extensive sodium reduction goals.



Note: Original values have been converted to milligrams.
Source: A POLITICO analysis of McDonald's, Burger King's and Subway's online menus
Helena Bottemiller Evich and Rishika Dugyala / POLITICO

Over the next four decades, numerous outside health groups, government advisory panels, doctors, and even the FDA itself repeatedly said the government needed to get serious on cutting sodium. Another petition came. Then a lawsuit. In the 1980s, FDA started requiring that some food products disclose their sodium levels. About a decade later, almost all packaged foods would have to disclose sodium, though levels still remained high. In the following years, CSPI launched more petitions and lawsuits seeking stronger action. In 2010, the Institute of Medicine advised the FDA to set mandatory sodium standards, estimating that cutting sodium intake nationwide could prevent more than 100,000 deaths and save billions in health care costs each year.

At the time, Americans were consuming an estimated 3,400 milligrams of sodium per day, on average, even though the government currently recommends limiting consumption to 2,300 milligrams per day.

The Obama White House was interested in moving on sodium from the beginning, former officials said, but quickly found that FDA was going to need time to work on the policy. It took the agency a few years to come up with its first stab at draft sodium reduction goals across more than 150 categories of food. At one point, the agency sent a cost-benefit analysis to the Obama White House and Sam Kass was so horrified by the agency's work – he believed it had massively inflated the potential costs and downplayed the potential health benefits – he sent the proposal back. "It was astronomical. A fucking disaster,"

he later told Jacobson, as recounted in Jacobson's book, "Salt Wars." Kass feared that the industry, which was fighting against sodium reduction, would take a bloated cost estimate and use it to torpedo the whole thing. "It was fundamentally inaccurate," he said.

Needless to say, this exchange slowed things down. (Some officials have blamed Kass for the delay. Kass maintains he was urging FDA to move more quickly the entire time. Some FDA officials came to bristle at his involvement on food issues, dismissively referring to him as "the chef.") In any event, by the time the whole guidance was getting ready to send to the White House for approval, it was starting to get close to Obama's reelection – and there was broad recognition that nothing big, nothing in any way controversial was getting out of OMB as White House officials grew skittish of being labeled as anti-business ahead of the election.

"You end up with an agency that's terrified of doing anything controversial."

It would still be several years before the sodium reduction goals – which, again, are voluntary – would see the light of day. Obama was reelected in November 2012. In 2015, CSPI sued FDA. In June 2016, FDA finally released both short-term (two year) and long-term (10 year) targets, with the overall goal of slowly dialing down sodium across food categories, ranging from pickles to pizza. The delay in Obama's second term was disappointing to senior FDA leaders, considering that the administration had made nutrition issues a priority.

"I see the White House holding back the draft targets until near the end of the administration as a costly failure of public health will, grounded in political cowardice," said Michael Taylor, who was FDA's deputy commissioner for foods and veterinary medicine from 2010 to 2016.

Jacobson retired in 2017, before the agency was able to implement any of its sodium work.

"I used to say FDA stood for foot-dragging artists," Jacobson said in an interview. There are many things that contribute to policy paralysis at FDA, Jacobson said.

"You end up with an agency that's terrified of doing anything controversial," he added.

Indeed, there was intense pushback from some corners of the food industry. For the better part of two years, an appropriations rider barred the agency from working on the targets until a major scientific panel took another look at how much sodium Americans should be eating. (The panel did, and ultimately confirmed the government's recommendations.)

During the Trump administration, Gottlieb surprised some by doubling down hard on the agency's long, albeit slow, push to reduce sodium.

"There remains no single more effective public health action related to nutrition than the reduction of sodium in the diet," Gottlieb said during a sweeping speech on the administration's nutrition agenda at a Consumer Federation of America conference in Washington in March 2018. He said the sodium targets would get finalized the next year. They did not. Another round of industry lobbying kicked into gear, as POLITICO reported at the time. Gottlieb left the agency in the spring of 2019. Sodium reduction again went into hibernation.

It wasn't until October 2021 that FDA finalized that policy, and when it did, it did so only for the short-term targets, which are easier to meet. The long-term targets have not been finalized. At this point, it's taken so long to get the policy out, all of the reduction goals are based off of data that's more than a decade old. Food companies are now formally encouraged to help cut salt across the food supply by 2024. It's not clear when the agency might tackle longer-term targets – and there is no clarity on what the agency will do if food companies do not voluntarily meet these goals.

"The FDA plans to monitor the food supply, evaluate progress toward the voluntary targets, and engage with industry to inform revised targets in a few years – taking an iterative approach," a spokesperson said. Based on that, the agency said, it "expects to issue revised subsequent targets in the next few years."

A recent study, co-authored by Jacobson and published in the journal Hypertension, estimated that the agency's recent four-year delay finalizing the targets may result in more than 250,000 unnecessary deaths over about a

decade and a half because sodium levels across the food supply are higher than they might have been.

“Our food is making us sick,” acknowledged one former FDA official.

An FDA spokesperson did not provide an explanation for the lengthy timeline, but noted that the agency’s sodium work was complex and thorough and that Covid-19 slowed things down the past two years “as the agency focused on responding to the pandemic while recognizing that the food industry was also affected by the pandemic.”

CHAPTER 5

‘THEY IGNORE EVERYONE’

While FDA is often deferential to industry when it does make decisions – something that infuriates consumer advocates – the agency isn’t working particularly well for industry, either. Every food industry leader POLITICO spoke with for

this story expressed a level of frustration over having to deal with a slow-moving and opaque agency.

Consider the case of yogurt. Roughly 40 years ago, yogurt-makers petitioned FDA to update its arcane standards of identity rules for yogurt, which stipulate things like minimum levels of milkfat and what types of ingredients are allowed. They didn't get any traction. Years went by and no progress was made. Decades later, FDA officials would tell the industry that they didn't have enough staff bandwidth to update the standard.

Industry leaders responded by working with Congress over the course of three years to get FDA an additional $12.5 million to staff up. Still, they got little traction. Eventually, they got language into a spending bill that mandated FDA to give a progress update on yogurt to Congress. The agency ignored it.

"They ignore everyone," said Michael Dykes, president and CEO of the International Dairy Foods Association. "They ignore everything."

This past June, FDA finally updated the standard of identity for yogurt. Yogurt-makers hated it.

"We've been asking for this for 40 years," Dykes said. "And when they finally did it, we had no choice but to object to it. It didn't even come close to acknowledging the things that our members do to make yogurt."

IDFA has formally objected to the final rule, an extreme step that is rare in policymaking. The group has sent at least two letters to FDA and the agency has not formally responded. Late last month, the agency paused its rulemaking. The 40-year journey for an updated definition of yogurt is now indefinitely on hold.

"This is broken," Dykes said, lamenting a complete lack of transparency, accountability and unwillingness to set deadlines or even provide industry basic updates. "The public deserves better, consumers deserve better, the industry deserves better."

An FDA spokesperson acknowledged the long delay.

“The FDA recognizes that the timeline for updating the yogurt [standard of identity] took too long; new resources have allowed the agency to hire and train new staff to better support this work,” the spokesperson said. “The FDA is committed to addressing the objections to the final rule amending the yogurt [standard of identity] in a timely manner.”

There are numerous other examples of food producers going to FDA for updates to archaic standards, either because they want stricter rules to weed out fraud or more flexibility in their labeling and marketing. The bakery industry in 1992 asked FDA if it would define the term “fresh” so bread-makers could use it on their labels in the bakery aisle. (Currently the term “freshly baked” is allowed but “fresh” is reserved only for bread that was just baked in store.) The agency never ruled on it and the industry eventually gave up.

“They just wear you down,” said Robb MacKie, the longtime president and CEO of the American Bakers Association and co-chair of the Food and Beverage Issue Alliance. The food side of the agency is “kind of out of sight, out of mind.”

“We need a strong, competent, FDA,” he added. “We used to be the gold standard [in the world]. I think the goal should be to get back to the gold standard.”

Last year, the agency finally proposed revoking a restrictive standard of identity for frozen cherry pies – a full 15 years after the bakery association petitioned the agency to do so. The policy has not yet been finalized.

When FDA announced it was working to free cherry pies from their regulatory tyranny – something bakers hadn’t pressed for more than a decade – MacKie said he “half-jokingly” asked his staff to check and see whether the group had filed any other petitions in the 1970s or 1980s that might spring free out of nowhere, so they could be prepared.

It’s probably not a bad idea. The FDA in January surprised everyone and no one by announcing it had finally revoked an overly restrictive decades-old standard of identity for French dressing – something of such little importance you’d be hard-pressed to find anyone who cares.

A spokesperson for FDA said the move was the result of Trump’s deregulatory push and cited overall staffing constraints. A dressings and sauces trade group had asked the FDA to do this in 1998. The trade group did not respond to a request for comment.

FDA did not explain why a decision took more than two decades.