5 Ways Trump Could Change Food Safety Compliance

What will happen to food safety—and FSMA—in the Trump Era?

What could President Trump, who famously called the FDA "the food police" on the campaign trail, do to change food safety regulations and enforcement over the next four years? Will regulations change much?

These questions touch on all aspects of compliance—including some FSMA regulations—and could affect millions of consumers and thousands of businesses, at home and abroad.

ICIX recently discussed these options with Joanne Hawana, an attorney with expertise in food safety and compliance at national law firm Mintz Levin.

"I don't expect major immediate changes to food safety as it's currently implemented and enforced. But in the near future, it's easy to foresee substantial effects from what the administration could do via administrative action or tying FDA's hands through budget or staff cuts," she says.

However, she cautions that uncertainty is going to remain high, as the possibility for citizen lawsuits against the government has skyrocketed due to President Trump's recent executive orders related to his administration's deregulatory efforts.

"Administrative process for all of this is going to be a nightmare," says Hawana, because any attempt to repeal existing rules under the Administrative Procedure Act (APA) also requires notice-and-comment procedures to be followed. At least one lawsuit has already been filed against the White House on the grounds that the President's so-called "Two-for-One" Executive Order, which he signed on January 30th, violates the U.S. Constitution.

And to make matters even more confusing, Congress could rewrite several long-standing APA rules and the legal requirements that govern agency rulemaking procedures. These changes are already in the works, and include changes due to H.R. 5, the "Regulatory Accountability Act of 2017," which was one of the first bills to be passed by the House of Representative since the 115th Congress convened in January.

Hawana cautions that even if federal enforcement, rules or rule interpretations change, food safety and FSMA will remain important—both to avoid consumer blowback and to avoid civil suits over carelessness leading to illness.

"Even if federal rules change, you're still open to lawsuits—maybe even class actions—if you're not following food safety rules and people get sick. And even people who dislike government regulation don't want their kids to die of listeria."

"Most of the FSMA rules won't go away, even if they're delayed or their enforcement modified slightly. Everyone still needs to keep working toward implementing FSMA—regardless of the potential for some changes," she says.

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Attorney
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

But *how* could food safety regulation change? Let's look at five ways that the Trump administration could change food safety regulation.

1 Use the Congressional Review Act (CRA) to roll back regulations finalized in the last few months of the Obama Administration, possibly including the Intentional Adulteration Final Rule.

Before the convening of the 115th Congress this year, the CRA had only been used once, by the George W. Bush Administration, to overturn a workplace ergonomics rule promulgated during President Clinton's second term.

But this year, says Hawana, "It's potentially in play for tons of rules, not just food safety," says Hawana. Indeed, as of early April, President Trump had signed 13 resolutions to repeal a diverse set of public safety and consumer protection rules.

How the Congressional Review Act could change food safety

Although much more complicated procedurally, in essence the CRA allows an incoming administration to reverse regulations that were finalized in the waning days of the previous administration (Obama's, in this case).

Timing could be everything on this one, most legal scholars say. For example, the Intentional Adulteration Rule became final at the end of May 2016, so it was one of the rules at risk. So were the new food labeling rules, also finalized in May 2016.

How would the CRA lead to reversal of food safety laws?

"President Trump could ask Congress to do a joint resolution of disapproval under the CRA. And certainly the President could always ask the FDA to undo an older regulation by agency rule-making, although that would be more controversial and also subject to legal challenge if there is no defensible reason for eliminating a rule," says Hawana. Until the law is potentially revised by Congress, agency actions are still governed by the APA standard that an agency cannot act in a manner that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with governing law.

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On March 30, 2017, however, the deadline passed for introducing new CRA resolutions for Congress to vote on to send rule reversals to President Trump's desk. This makes it unlikely that the Intentional Adulteration or revised Nutrition Fact Label final rules will be repealed in this manner.

However, under Trump's deregulatory executive orders—including one that requires individual agencies to establish "Regulatory Reform Task Forces" in order to identify regulations for repeal, replacement, or modification based on the Administration's priorities – we may nonetheless see changes to existing food safety rules.

Besides repeal of an existing rule, efforts are also under to identify any Federal regulations or significant guidance documents that were never filed with Congress as required under the CRA. This may offer the Administration a "technical" loophole through which to undo even much older governmental requirements than those implemented under President Obama. Under this interpretation of the law's requirements, many laws passed since the CRA was passed in 1996 could be challengeable, in food safety as well as many other areas, for any law that has had no formal report to Congress. It's unclear which—if any—parts of FSMA fall into this loophole.

It's also important to understand that since the CRA has only been used once in more than 20 years, it remains to be seen whether courts will accept this interpretation.

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2 Weaken or get rid of certain discretionary programs being undertaken within the FDA's Center for Food Safety and Applied Nutrition (CFSAN), or defund CFSAN so much that inspections and other activities cannot be completed.

Among its many other roles, CFSAN receives and collects adverse event reports for conventional food and dietary supplement products (as well as cosmetics). Late last year, CFSAN unveiled a public version of this database, called the CFSAN Adverse Event Reporting System or "CAERS."

When CFSAN announced this new initiative in December 2016, it noted that the goals were to "increase transparency and improve access to government data for consumers, health care providers, researchers and academics." But by the same token, such data could be used to target food manufacturers with lawsuits based on adverse event trends, and President Trump's pro-business approach to governing could make this transparency effort simple to eliminate.

"Some plaintiffs could use the database to come up with arguably frivolous class action claims," says Hawana. "It would be really easy to cut down on that risk and protect business interests, by either getting rid of the public version of that database, or limiting consumers' access to it," she says.

In addition, simply cutting the amount of funding going to CFSAN or handicapping its ability to hire inspectors and other staff could have a tangible negative effect on food safety enforcement efforts. Also at risk are educational and outreach efforts to industry, which the Agency has been expending lots of resources on since the seven foundational FSMA rules were finalized.

And although the White House's first "budget blueprint" for FY 2018 – released on March 16, 2017 – included a nearly 18% cut to the Department of Health and Human Services (DHSS), where FDA sits, the DHSS section does not specifically address food safety or funding to implement FSMA. One of President Trump's early executive orders also imposed a Federal hiring freeze on certain civilian employees, and observers of FDA know that being short-staffed is a chronic problem for the Agency.

More critical for the short-term, perhaps, is Trump's recent proposal to slash FDA appropriations for the remainder of FY 2017 (which ends on September 30) by $40 million, a savings that would be achieved by reducing staff. Congress will have to tackle a Continuing Resolution to fund the government after it returns from a two-week Easter recess, as the current CR runs out at the end of April.

3 Use executive orders to impose new burdens on rule makers, with the aim of slowing down regulatory activity.

The so-called "Two-for-One" Executive Order requires two new regulations to be repealed for every new one that is added. Importantly, this order has been interpreted by the White House Office of Management and Budget (OMB) as potentially applying to significant guidance documents as well as regulations enacted via notice-and-comment procedures.

It's not clear exactly how this deregulatory order would be enforced, and whether there are enough old, rarely used, unpopular rules that could be easily retired to allow new rulemaking to proceed. But as agencies inventory possible rules to render obsolete—through the Regulatory Reform Task Forces ordered by the President in February or in the course of normal rulemaking activities—this executive order could become more important.

Even more difficult for a public health agency like the FDA is the novel requirement stemming from this order that new economic analyses be completed even for the two rules that would be repealed. Since the FDA is operating with a very minimal staff of economists, FDA insiders expect that this mandate will undoubtedly slow down the regulatory process, especially new changes or repeals.

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4 Reverse any "enforcement guidance" or executive orders issued by previous administrations.

Executive orders from previous administrations often can be undone unilaterally at the new president's bidding, such as by issuing a new executive order or simply issuing new guidance reversing the old. Sometimes, it's a directive not to enforce executive orders of previous administrations.

And in general, it's usually pretty easy to slow or stop enforcement of a previous administration's priorities, especially if the basis for enforcement was a previous executive order.

5 Appoint regulation-averse people to key enforcement positions at the FDA and USDA, just don't fill the positions, or eliminate the positions.

This might be the easiest way to step down enforcement of existing laws. Enforcement personnel could be cut, and Trump appointees may believe that the president feels that strong enforcement of safety rules could jeopardize jobs, which he has publicly made a priority. In any case, much of the attention given to high-level FDA appointees has so far focused on drugs, which can command much higher prices and profits, than on food safety.

It is worth noting, perhaps, that Trump's nominee to become the next FDA Commissioner—Dr. Scott Gottlieb—indicated a willingness to consider postponing the compliance deadline for the new Nutrition Facts Label, during his first appearance before the Senate HELP Committee on April 5. This FDA final rule was issued in May 2016, with a compliance date for most food companies set for July 2018. The food industry has already petitioned DHHS Secretary Tom Price for an extension until May 2021. If, as widely expected, Gottlieb is confirmed to lead FDA, it should come as no surprise if this rule is postponed.

In general, however, Dr. Gottlieb was not asked much about FDA's food authorities during his April 5th confirmation hearing, and so he did not talk about the issue much other than to say that he would implement FSMA "fully." So we do not yet have a strong sense of how he would prioritize the enforcement of existing food laws once he is sworn in as FDA Commissioner.

Dr. Scott Gottlieb, nominee for FDA Comissioner in his first confirmation hearing, said that he would "fully" implement FSMA.

Best advice: Automate as much as you can

In the near term, while there will continue to be uncertainty and speculation about potential changes to food safety rules, there is no uncertainty about the paramount importance of food safety. Additionally, as outlined in the arguments above and reinforced by Gottlieb's statements, it doesn't look like the core of FSMA is in jeopardy.

That's why many food retailers and manufacturers are automating as much of their compliance and reporting as possible. And with a flexible system, any changes that may come—whether it's to required procedures, certifications, or other documentation—can be made quickly, throughout your system.

Following potential food safety rules changes can be time-consuming and maddening, which is why many food retailers and manufacturers are automating as much of their compliance, documentation and reporting as possible. That way, changes to things like certifications and required forms can be made quickly, throughout a product line.

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"A lot of companies have decided that one of the easiest ways to prepare is to automate whatever they can, so they can manage by exception," says Matt Smith, founder of ICIX.

"That way, when things change, they're protected. Plus, as we've seen at several conferences lately, the overwhelming feeling in the food industry is that government requirements are the lowest possible bar," he adds.

Joanne agrees, concluding "If I were a betting person, I'd bet that the Food Labeling Final Rule will probably be delayed or changed—but everyone still needs to keep working toward implementing the rest of FSMA."

"Regardless of what the rules are, one or two well-publicized food safety problems can really hurt a brand—and nobody wants that," Smith concludes.

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Founder
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