

Shutdown Threatens To Keep Product Safety Rules On Shelf

By **Greg Ryan**

Law360, New York (October 17, 2013, 9:11 PM ET) -- The government shutdown may have ended after 16 days, but it could take the U.S. Food and Drug Administration and other product safety agencies longer than that to play catchup, attorneys say, with further delays likely for food safety and automotive regulations that are already long overdue.

Furloughed employees at the FDA, Consumer Product Safety Commission and National Highway Traffic Safety Administration returned to work Thursday after the U.S. House of Representatives and the Senate approved a bill to reopen the government and keep the country from defaulting on its debt.

However, the negative consequences of the shutdown are far from over, according to attorneys. Under the best of circumstances, the FDA, CPSC and NHTSA struggle to stretch their limited funding and manpower to fulfill their safety mandates, they said. Now, in addition to performing their usual duties, the agencies will have to catch up on more than two weeks worth of activity.

The shutdown came at an inopportune time for each of the agencies from a rulemaking perspective. The FDA, for instance, has been ordered by a California federal court to propose rules stemming from the Food Safety Modernization Act by Nov. 30, including an anti-terrorism rule that it continues to insist it needs more time to develop.

"If they were under pressure before ... they're not in a position to have extra time," Roetzel & Andress LPA partner Edgar Asebey-Birkholm said. "I wouldn't be surprised if they went back and asked for an extension due to circumstances out of their control."

The FDA also projected earlier in 2013 that it would release a rule on tobacco products — believed by many to be long-awaited regulations governing the sale and marketing of electronic cigarettes — by the end of October. FDA spokeswoman Jenny Haliski said only that the proposal had already been sent to the White House for review.

FDA representatives declined comment on the agency's plans for the outstanding FSMA rules. An Oct. 4 filing by the agency in the case noted that "the government may at a later time address the impact of the federal shutdown" on its ability to propose the rules by the court-ordered deadline.

The FDA will also have to catch up on routine inspections of drug and food facilities, which were

suspended during the shutdown.

As the FDA did with the FSMA rules, NHTSA now faces a court action over its failure to promulgate a rule requiring automakers to put rearview cameras or other technology in new vehicles. Consumer groups demanded in September that NHTSA issue a final rule within 90 days, arguing that Congress required the rule to be finalized by February 2011. NHTSA did not work on any rulemakings over the shutdown.

“Whatever work could have been done during those two weeks has been lost,” said Allan Kam, a former NHTSA enforcement attorney.

NHTSA also did not conduct any defect investigations during the shutdown, creating a backlog of consumer complaints. Investigators, unable to handle existing, neglected and incoming complaints simultaneously, may focus more on closing existing investigations than opening new ones, Kam said.

The agencies not only lost precious time to fulfill their safety mandates during the shutdown, they lost time beforehand, preparing for the cutoff in funding, according to Crowell & Moring LLP partner Cheryl Falvey, formerly general counsel at the CPSC.

In addition, while each agency drew up detailed plans to wind down operations in the event of a shutdown, they may not have drawn up plans for how to start up again post-shutdown, she said.

A vote on a closely watched CPSC proposed rule, at least, appears likely to take place as scheduled next week, according to Timothy Reggev, who works in CPSC Commissioner Nancy Nord's office.

The agency's five commissioners are set to consider whether to propose a rule that would set guidelines for how voluntary recalls should be communicated to the public. The vote was originally supposed to take place at a public meeting on Oct. 23, but Reggev told Law360 that the commissioners may now vote by ballot instead.

The shutdown came at a crucial time for the CPSC. Had it lasted 10 more days, Nord would have lost the opportunity to vote on the voluntary recall proposal, since she is required by law to step down from her position on Oct. 26. Nord, a Republican, expressed strong concerns about the proposal at a September hearing.

CPSC Chairman Inez Tenenbaum's term expires this month, but commissioners are allowed to serve up to a year after the expiration of their terms, as Nord did.

The CPSC also decided not to push back a public hearing on Tuesday related to a notice of proposed rulemaking related to magnets. The proposal would ban high-powered magnet sets such as those manufactured by Buckyballs maker Maxfield & Oberton Holdings LLC and Zen Magnets LLC. The agency has sued the two companies over their refusal to recall the sets due to an alleged defect.

Even if the shutdown didn't delay the CPSC's consideration of the two proposed rules, it will hamper the agency going forward in other ways, Falvey said. It will take the agency time to ramp up to even the highest-priority items, she said. Companies that have brought product hazard concerns to the agency that don't involve a risk of serious injury will have to wait even longer.

The shutdown could also delay the replacement process for Nord and Tenenbaum, according to Falvey.

“There had been rumors in August that this fall they'd be putting up a Republican and a Democrat, but now, who knows?” she said.

--Editing by John Quinn and Philip Shea.

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