

The “Regulatory Freeze”: What it Means for Key Food Regulatory Initiatives

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Food, Beverage, and Dietary Supplements

On Friday, President Trump (through his Chief of Staff) issued a memorandum directing all federal agencies to place a freeze on new or pending federal regulations so that the Trump Administration can review them. This alert explains the scope of this action and analyzes its potential impact on key food regulatory initiatives.

Overview

The regulatory freeze applies to “new or pending regulations,” which, with some exceptions described in more detail below, include regulations ready to be sent to the Office of the Federal Register for publication, regulations already sent to the Office of the Federal Register but not yet published, and regulations that have been published in the Federal Register but are not yet effective.

The term “regulation” includes any regulatory action as defined in Executive Order 12866: “any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.” It also includes guidance documents and any other agency statement “that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.”

The memorandum directs federal agencies to perform three primary actions with regard to the regulations described above:

- **Regulations ready to be sent:** Delay sending any regulation to the Office of the Federal Register until an official designated by the President reviews and approves the regulation.
- **Regulations sent but not yet published:** Immediately withdraw any regulation that has already been sent to the Office of the Federal Register but not yet published so that an official designated by the President can review and approve the regulation.
- **Regulations not yet effective:** Temporarily postpone (for 60 days from January 20, 2017) the effective date of any regulation that has been published in the Federal Register but is not yet effective, to allow for a review of questions of fact, law, and policy that the regulations raise; for certain regulations, consider proposing further notice-and-comment rulemaking and postponing the effective date for a longer period of time.

The memorandum does *not* apply to any regulations subject to statutory or judicial deadlines. It also does *not* apply to any exceptions that the Office of Management and Budget allows for

emergency situations or for other urgent circumstances relating to health, safety, financial, or national security matters.

Analysis

A regulatory freeze upon a change in administration is not uncommon; President Obama issued a nearly identical memorandum in 2009. While this is one step towards the Trump Administration managing new and pending federal regulation, the regulatory freeze is limited in scope. Specifically, it does not direct federal agencies to stop working on new regulations -- it does not impact comment periods for dockets that are currently open nor does it prevent agencies from considering comments already submitted. It also does not impact regulations that have already taken effect.

From a food regulatory perspective, this means that the regulatory freeze will not impact the regulations that FDA issued under the Food Safety Modernization Act in 2015 and 2016, nor will it impact the Nutrition Facts Label final rule, as the effective date for all of those regulations has already passed.¹ The regulatory freeze will only impact any regulations that FDA or USDA plan to send to the Office of the Federal Register in the next few months (including any currently under review at the Office of Information and Regulatory Affairs), as well as any regulations that were recently published but not yet effective, unless those regulations are subject to statutory or judicial deadlines.

We did not identify any food-related regulations that have been sent to the Federal Register but have not yet been published. We have identified the following anticipated and recently issued food-related regulations that could potentially be impacted by the regulatory freeze:

- USDA Final Rule adding new requirements to the National Organic Program for livestock handling and avian living conditions (published in the Federal Register on January 19, 2017; effective date March 20, 2017)
- FDA Proposed Rule to remove GRAS affirmation for partially hydrogenated menhaden oil and partially hydrogenated rapeseed oil (under review at OIRA since July 2016).

USDA also very recently sent an advance notice of proposed rulemaking on implementing the national bioengineered food disclosure standard to OIRA for review, which is the final step before publication in the Federal Register. This standard is subject to a statutory deadline, as the statute directs USDA to establish a national mandatory bioengineered food disclosure standard by July 2018, so the advance notice of proposed rulemaking could be considered outside the scope of the regulatory freeze.

The regulatory freeze could also potentially delay the publication of any additional regulations that FDA or USDA complete in the near future (including guidance documents, such as further guidance on the implementation of FSMA or the revised Nutrition Facts Label requirements). It is important to note that, while the regulatory freeze is, on its face, limited in scope, there may

¹ The effective date of a regulation is the date on which the regulation becomes law. The compliance date is the date on which the entities covered by the regulation must comply with the regulation. For most FDA and USDA regulations, the effective date is generally 30 to 60 days after publication in the Federal Register.

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be other avenues through which the Trump Administration could prevent, restrict, or delay the implementation of food regulations that are already in effect. Food companies that would like to explore these avenues further should consider how best to engage the Trump Administration regarding such regulations.

Covington & Burling LLP continues to monitor developments in food regulatory requirements under the new administration. If you have any questions concerning the issues discussed in this alert or other food regulatory matters, please contact any of the following attorneys in our Food & Drug Practice group or visit our [food, beverage and dietary supplements practice](#) website:

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