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# MEMORANDUM

**From**: Joseph A. Levitt
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**Date**: May 17, 2019

**Re**: **OMB Issues Memorandum Guidance on Executive Departments' and Agencies' Compliance with the Congressional Review Act**

The Office of Management and Budget (OMB) recently issued an updated memorandum to the heads of executive departments and agencies entitled, "Guidance on Compliance with the Congressional Review Act" (2019 Memo). 1/ The 2019 Memo, effective on May 11th, "reinforces the obligations of Federal agencies" under the Congressional Review Act (CRA) to submit rules to Congress, and also clarifies when a rule is to be considered "major" by OMB's Office of Information and Regulatory Affairs (OIRA). The criteria and process the 2019 Memo sets for triggering OIRA "major" designation are the more significant aspect of the document, as they have the potential to noticeably impact FDA issuance of guidance documents.

## Background on Congressional Review Act (CRA) and Prior OMB Memos

OMB/OIRA review of rulemaking is traditionally linked with "significant regulatory actions" as defined by President Clinton's Executive Order 12866 (EO 12866) as having an industry impact of over $100 million. The CRA operates as a second chance for regulatory actions that do not meet "significant regulatory action" under EO 12866 to be classified as "major rules" requiring OMB review. In particular, a regulatory action that imposes a "disproportionate burden" on a particular industry or sector may be designated as significant, despite having an annual economic impact under $100 million.

Passed in 1996, the CRA requires Federal agencies submit *all* final rules to Congress for approval. A rule can be invalidated by Congressional joint resolution signed by the President or enacted over Presidential veto. Rules invalidated this way cannot be reissued without substantial changes or the enactment of a law after the disapproval that specifically authorizes the rule.

To streamline Congressional review, CRA requires agencies to indicate whether the rule is "major," a determination that is checked and confirmed by OIRA. "Major" rules must undergo a lengthier

1/ Guidance on Compliance with the Congressional Review Act (Apr. 11, 2019), available at: https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf.

review process wherein they are submitted to OMB/OIRA for review and to Congress. 2/ Unless exempted, a "major" rule cannot take effect until 60 calendar days after it has been submitted to Congress.

**The 2019 Memo**

OMB's earlier memo ("1999 Memo") defined "rule" by referencing the Administrative Procedures Act ("APA") definition, 5 U.S.C. 551(4), and suggested agencies seek advice of their legal staffs, the Justice Department, and court decisions. In practice, agencies would discuss such matters informally with OMB and determine which documents, if any, needed OMB review. The 2019 Memo expressly states that the term "encompasses a wide range of . . . regulatory actions, including . . . [notice-and-comment rules,] *guidance documents*, general statements of policy, and interpretive rules." (Emphasis added.) 3/ Therefore, under the 2019 Memo, at least 30 days before publication, agencies will need to submit guidance to OIRA for a determination on whether it is "major," and if guidance receives a "major" determination, the effective date will be delayed by 60 days.

The 2019 Memo emphasizes and expands upon the analysis required under Section 804(2)(B) and (C). For example, the 2019 Memo highlights that "Section 804(2)(B) suggests that a rule may qualify as major under the CRA if it imposes *disproportionate costs* on a particular group, in comparison to the burdens experienced by other groups or benefits experienced by the burdened group." (Emphasis added.) 4/

The 2019 Memo also clarifies the "major" determination process for regulatory actions not submitted to OIRA through the EO 12866 process. The 2019 Memo identifies a six-step process all agencies should follow, in consultation with OIRA desk officers, noting that some categories of rules may be designated as "presumptively not major" and therefore not subject to the 2019 Memo at all. However, this presumptive category may be revoked at any time. Therefore, the actual status of FDA guidance documents is still to be determined, on either a case-by-case or category-by-category basis.

**Practical Effects on FDA Food Policymaking**

The 2019 Memo has the potential to significantly affect FDA, an agency that relies increasingly on guidance documents to implement its policies. The first step for FDA will be to determine which guidance documents are deemed to either require OMB review, or be exempted under the "presumptively not major" category. If OMB review is needed, this could trigger the need for a full-blown economic analysis, just as FDA does for major proposed regulations. Upcoming guidance documents in the food area that could fall under this new process could include anticipated guidance documents on Not-Ready-To-Eat (NRTE) foods, environmental testing for listeria, food defense, and voluntary sodium reductions, as well as a host of guidance documents FDA has in the pipeline to implement the FDA Food Safety Modernization Act (FSMA). Moreover, under the 2019 Memo, "[i]nsufficient or inadequate analysis may delay OIRA's determination and an agency's ability to publish a rule and to make the rule effective." 5/

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2/ There is also an intermediate step for major rules involving the General Accountability Office (GAO). *See* https://www.gao.gov/legal/other-legal-work/congressional-review-act.
3/ 2019 Memo at 3.
4/ 2019 Memo at 7.
5/ 2019 Memo at 5.

## Conclusion

The 2019 Memo's express incorporation of guidance documents as a category falling under the realm of OMB review marks a concerted extension of previous OMB policy. Time will tell how the Agency works with OMB to determine what guidance documents do actually need to undergo OMB review and how that review, and attendant economic analyses, affected the ultimate timetable for issuance of FDA guidance documents.

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We will continue to monitor OMB policies and procedures regarding the CRA and approval of Federal agency rules, guidance, interpretive statements and the like. Please contact us if you have any questions on this or any other matter in the meantime.