

ARTICLE

EPA Guidance Documents: New Process = Greater Transparency

September 16, 2020

This article was originally published in Wiley's The WELL blog.

On September 14, the Environmental Protection Agency (EPA) announced a new rule for agency guidance documents that will appear in the Federal Register shortly. The prepublication copy of the final rule is posted at <http://www.epa.gov/sites/production/files/2020-09/documents/prepub-guidance-final-20200914.pdf>.

A key question surrounding the authority EPA uses as the basis for developing this rule is whether its effect is predominantly internal or external. Agency guidance documents routinely establish interpretations that have substantive effects. EPA took the position that the actions described in the rule are a matter of agency organization, procedure, or practice that lack the force and effect of law. Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3) (A), EPA can issue interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice without providing notice and an opportunity for public comment. However, in this case EPA determined, as a matter of good government, to seek comment from the public and many good comments were submitted.

The October 9, 2019 White House Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents on which it is based is posted [here](#).

The agency's press release promotes the rule as "perhaps the biggest change in administrative procedures in a generation" that "guarantees the transparency the public deserves". The rule adds procedures to guide the development of certain guidance documents that have not been previously guaranteed. The main operating

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provisions are the following:

- The rule provides for public participation (in the form of a 30 day comment period) in developing “significant” guidance documents, with exceptions for emergencies and good cause; comment opportunities for other guidance documents will remain within the discretion of the agency,
- Public access to agency guidance documents are ensured through the establishment of an electronic portal on EPA’s website,
- EPA is establishing a formal petition process to modify, withdraw or reinstate a guidance document, and
- EPA Regional Offices have to receive concurrence from the relevant Assistant Administrator or an official who is serving in the acting capacity at EPA headquarters who is responsible for administering the national program before issuing a new guidance document developed by an EPA Regional Office.

Despite this new rule, courts will continue to grapple, as they have over the years, with whether EPA guidance documents create new substantive obligations (e.g., *Appalachian Power v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207 (D.C. Cir. 2007)). This trend could lessen with time if the public comment period serves as an early correction mechanism on this point. Also, despite comments urging these to be in scope, EPA has positioned IRIS assessments as outside this rule, even though the agency defines “guidance document” to include the term “technical issue” and considers the term “scientific” to be a subset of “technical.”

In July, EPA finalized a new resource portal that includes over 9,000 guidance documents at <http://www.epa.gov/guidance>. Bear in mind that this is a resource with decidedly substantive implications - any guidance document (as defined in this regulation) excluded from the portal “does not represent an active guidance document” and “will have no effect except to establish historical facts.”

With respect to the Toxic Substances Control Act (TSCA), older but still useful guides on the R&D exemption and import/export notification requirements are being retained on EPA’s portal. In addition, EPA has included the draft questions and answers document for the new chemicals program on the portal. While this guidance was never formally finalized, it remains an important public resource for interpretive questions on impurities, byproducts, articles, and other TSCA exemptions from new chemical notification requirements.

There are some important compliance areas of TSCA that are largely interpreted through letter exchanges with the American Chemistry Council and others in industry. Examples of letter guidance that we see missing from the portal includes correspondence on statutory mixtures, the article exemption, non-isolated intermediates, and the exemption for physicochemical properties at 40 C.F.R. 720.30(h)(7). EPA has posted a limited amount of correspondence, such as 1994 letters concerning the jurisdictional boundary between TSCA and the Federal Food, Drug, and Cosmetics Act (FFDCA), and interpretive letters for recycling and other issues with respect to Chemical Data Reporting. However, an unintended effect of this rule is to effectively relegate these other interpretive exchanges to historical use only. It may be advisable to approach EPA to add these exchanges to the portal, as the agency invites companies and groups to do in the preamble to the final rule.

Under the new rule, it also will be possible to petition EPA to reinstate these exchanges as “active guidance” to ensure continuity in these areas in the future.