EPA Extends Time to Comment on Proposed Science Transparency Rule

By Kenneth von Schaumburg, William J. Walsh, Amanda L. Tharpe, Jane C. Luxton / Jun 12, 2018

On May 25, 2018, EPA extended its comment deadline to August 16 on a regulatory reform proposed rule on *Strengthening Transparency in Regulatory Science* ("Science Transparency Rule"). The two aspects of the proposal that have drawn the greatest attention are requirements that would (1) impose "transparency," limiting EPA in rulemaking largely to reliance on studies that make underlying data available for replication and critique by other researchers, and (2) direct increased EPA consideration of alternative dose-response models. Many of the transparency requirement are similar to those outlined in the proposed "Honest Act" legislation (see previous Clark Hill alert), which has generated considerable reaction among interested parties. The stakes are high for businesses subject to scientifically based regulation, and affected interests should take advantage of the extended comment period to engage.

The proposed rule would encourage EPA, to the extent possible, to make the scientific studies underpinning EPA regulations publicly available, and to rely only on this "transparent science." Opponents argue the rule could prevent important scientific data from being used to write public health regulations if the data is based on confidential private health information. They object to the proposal's lack of clarity on how EPA would actually implement these requirements. Conversely, supporters counter that the rule will ensure the scientific data underpinning EPA regulations, particularly those for which the public bears the cost of compliance, is fully transparent and publicly available for independent review and replication. They further argue this added transparency will instill greater confidence and integrity in EPA's regulatory process, help to prevent arbitrary conclusions, and promote more meaningful public participation.

With respect to alternative dose-response models, the proposal specifically focuses on risk assessment approaches that include the possibility that health effects attributed to a chemical may have a threshold, below which evidence of harm is not evident. EPA's traditional practice has been to use a "linear no threshold" ("LNT") model, which assumes adverse effects continue on a dose-response curve well beyond any observed results, although EPA's written guidance allows use of linear (threshold) models. No current rule specifies the use of the LNT model, and the D.C. Circuit has unanimously held in an *en banc* decision in *NRDC v. EPA*, 824 F.2d 1146, 1164–65 (D.C. Cir. 2005), that EPA's overwhelming default to use of the LNT model is a policy-based, not scientifically required, decision. EPA's existing cancer assessment guidance directs risk assessors to use a threshold approach when "there is an absence of sufficient information on modes of action," or the available information "indicates that the dose-response curve at a low dose is or is expected to be linear." While supporters of EPA's proposal argue it simply reinforces EPA's existing (but often ignored) direction and more current scientific thinking, opponents are concerned the new language will lead to greatly increased reliance on alternative models (including linear, threshold, U-shaped, J-shaped, and bell-shaped dose-response curves) that are less conservative.

At a May 31 meeting, EPA's Science Advisory Board ("SAB") voted unanimously to conduct additional review on the proposed transparency rule, after reviewing a work group memo that questioned the proposed rule's relationship with previous public transparency efforts and the feasibility of making certain types of data publicly available. The work group acknowledged the need for and benefits of transparency, but suggested the rule take into account situations in which it is not possible to publicly release data in its entirety, noting the need to balance privacy concerns and other factors. The group's comments on the dose-response model issue favored a greater emphasis on considering alternative approaches on a case-by-case basis. Some commentators have characterized the SAB's decision as critical of EPA's proposal, while others viewed it as calling for more clarification and detail on implementation of the proposed changes.

Since the rule was proposed, the EPA has received more than 150,000 comments. In addition to extending the comment period, EPA announced a public hearing on the proposal that will take place July 17 in Washington, D.C. This rule may well influence how major EPA regulations are written for the foreseeable future, and although the issues are complex, they are undeniably important. Regulated entities affected by this proposal – likely to be a significant segment of the economy – should use these additional opportunities to provide their views to EPA individually or through trade associations or coalitions.

Clark Hill attorneys are experienced in working with clients to develop effective legal strategies and advocacy approaches to address regulatory and deregulatory initiatives. For more information, please contact Jane C. Luxton at jluxton@clarkhill.com | (202) 572-8674; Kenneth von Schaumburg at kvonschaumburg@clarkhill.com | (202) 772-0904; Amanda L. Tharpe at atharpe@clarkhill.com | (202) 772-0913; William J. Walsh at wwalsh@clarkhill.com | (202) 772-0924; or another member of Clark Hill's Environment, Energy & Natural Resources practice group.

