EPA'S PROPOSED RULE TO STRENGTHEN TRANSPARENCY IN REGULATORY SCIENCE

Sunil Kumar
Principal Environmental Engineer

MWAQC-TAC
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Introduction

- EPA proposed rule – April 30, 2018
- Purpose - According to EPA, rule is intended to strengthen the transparency of EPA regulatory science
- Proposal
  - Data used in scientific studies used in rulemaking process need to be made publicly available for independent validation
  - EPA soliciting comments on this proposal and how it can best be promulgated and implemented in light of existing law and prior federal policies that already require increasing public access to data and influential scientific information used to inform federal regulations
  - Comments must be received on or before May 30, 2018
  - Submit your comments, identified by Docket ID No. EPA–HQ–OA–2018–0259, at https://www.regulations.gov

Proposal Details

- Intends to ensure that the data and models underlying scientific studies that are pivotal to the significant regulatory actions are available to the public in a manner consistent with statutory requirements for protection of privacy and confidentiality of research participants, protection of proprietary data and confidential business information, and other compelling interests
- Designed to increase transparency in the preparation, identification, and use of science in policymaking
- Consistent with principles underlying the Administrative Procedure Act, programmatic statutes, and executive orders

Proposal Details

- Takes into consideration the policies or recommendations of third party organizations who advocated for open science
  - The Administrative Conference of the United, States' Science in the Administrative Process Project; National Academies' reports on Improving Access to and Confidentiality of Research Data, Expanding Access to Research Data, and Access to Research Data in the 21st Century; the Health Effects Institute; Center for Open Science; members of the Risk Assessment Specialty Section of the Society of Toxicology, the Dose Response Section of the Society for Risk Analysis, and the International Society for Regulatory Toxicology and Pharmacology; and the Bipartisan Policy Center's Science for Policy Project
- These policies are informed by the policies recently adopted by some major scientific journals, spurred in some part by the "replication crisis"

  https://www.nature.com/articles/s41562-016-0021 http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124 http://science.sciencemag.org/content/343/6168/229.long https://www.economist.com/news/leaders/21588069-scientific-research-has-changed-worldnow-it-needs-change-itself-how-science-goeswrong http://stm.sciencemag.org/content/8/341/341ps12.full
- Focuses on dose response data and models that drive the magnitude of the benefit-cost calculation and the level of standard
- Use of peer-reviewed information, standardized test methods, consistent data evaluation procedures, and good laboratory practices to ensure transparent, understandable, and reproducible scientific assessments

Proposal Details

- EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty
- EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis
- EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions
- When available, EPA shall give explicit consideration to high quality studies that explore a broad class of parametric dose-response or concentration-response models, a robust set of potential confounding variables, nonparametric models that incorporate fewer assumptions, various threshold models across the dose or exposure range, and models that investigate factors that might account for spatial heterogeneity

Seeking Comments On

- How to balance appropriate protection for copyrighted or confidential business information, including where protected by law, with requirements for increased transparency of pivotal regulatory science
- Whether there are other compelling interests besides privacy, confidentiality, national and homeland security that may require special consideration when data is being released
- For the National Ambient Air Quality Standards program, in which future significant regulatory actions may be based on the administrative record from previous reviews - particularly where the governing statute requires repeated review on a fixed, date-certain cycle - EPA seeks comment on the manner in which this proposed rule should apply to that previous record
- EPA also solicits comments on whether and how the proposed rule should apply to dose response data and models underlying pivotal regulatory science if those data and models were developed prior to the effective date

Seeking Comments On

- How the prospective or retrospective application of the provisions for dose response data and models or pivotal regulatory science could inadvertently introduce bias regarding the timeliness and quality of the scientific information available
- How to address a circumstance in which EPA has a statutory requirement to make a determination for which scientific information publicly available in a manner sufficient for independent validation does not exist
- Any additional implementation challenges not discussed in this notice that commenters may be aware of as well as suggestions for addressing them
- Whether the disclosure requirements applicable to dose response data and models in the proposed rule should be expanded to cover other types of data and information, such as for example economic and environmental impact data and models that are designed to predict the costs, benefits, market impacts and/or environmental effects of specific regulatory interventions on complex economic or environmental systems