



# Strengthening Transparency in Regulatory Science Rulemaking

Office of Research and Development

June 5, 2019

- **The proposed rule was published on April 30, 2018**
- **It proposes a regulation intended to strengthen EPA regulatory science**
- **The proposed rule would require that for significant regulatory actions, the underlying data for pivotal regulatory science be made publicly available to support independent validation of the studies**



# Proposed Requirements

- **Establishes the scope of the rule**
  - **Applies prospectively to final significant regulatory actions**
    - **Significant per E.O. 12866; not limited to major rules**
  - **Applies retrospectively and prospectively to dose-response data and models considered to be pivotal regulatory science in future significant regulatory actions**
    - **Requires that all underlying raw data and computer codes, regardless of who generated or funded it, be made publicly available**
    - **Applies regardless of when the data and computer codes were generated**
- **Defines certain terms, e.g., “pivotal regulatory science,” “regulatory science,” “regulatory decisions”**
- **Requires that EPA identify all studies (or other regulatory science) used for any final Agency action and that EPA should make those studies available to the public to the extent practicable**



# Proposed Requirements

- **For dose-response models, requires that EPA evaluate on a case-by-case basis the appropriateness of using default assumptions**
- **Requires for each model assumption that EPA conduct sensitivity analysis of alternative assumptions**
- **Identifies criteria for identifying high priority studies based on a study's consideration of a range of dose-response models and assumptions**
- **Identifies peer review requirements**
- **Provides the Administrator with the ability to grant exemptions to the requirements of the proposed rule**



# Request for Comment

- **The preamble includes 20 requests for comment that primarily fall in the following areas**
  - **Statutory Authority**
  - **Scope**
    - **Narrow or expand**
      - **Actions other than significant regulatory actions**
      - **Other Agency assessments**
      - **Exceptions**
  - **Dose-response data and models**
  - **Personal identification information, confidential business information, national security data, other sensitive data**
  - **Implementation**
    - **Infrastructure for managing data**
    - **Requirements regarding data in cooperative agreements and grants**



## Public Comment

- **Public Hearing was held on July 17, 2018**
  - **150 attendees and 91 speakers**
- **Public comment period closed August 16, 2018**
  - **There are 597,083 public comments, of which 9,276 are unique**
- **Comments submitted by**
  - **Professional organizations and journal editors**
    - **e.g., American Chemical Society, American Association for the Advancement of Science, Society of Toxicology, Science, Nature**
  - **States, Tribes and Localities; State associations**
  - **Industry**
  - **Environmental groups; Health groups; Labor Unions**
  - **Universities**
  - **DoD**
  - **Public**



# Public Comment

- **Major categories of comments**
  - **Comparison of the proposed rule requirements with statutory requirements (e.g., use of best available science) and procedures in environmental statutes**
  - **Identification of the problem the proposed rule is intended to fix**
  - **Consistency with the Administrative Procedures Act**
  - **Statutory authority to promulgate the rule**
  - **Degree of consistency with scientific norms**
  - **Type and extent of data that would be excluded**
  - **Personal Identification Information**
  - **Clarity of regulatory text and additional definitions**
  - **Peer review**
  - **Dose-response models**



## SAB Workgroup Questions

- **SAB Workgroup questions relate to issues raised in public comments**
- **EPA is in the process of evaluating the public comments and will consider these questions as part of its consideration of the public comments**



# SAB Consultation

- **Next steps**
  - **Background on existing regulations for protecting CBI and practices for protecting PII**
  - **Dedicated public conference call**
    - **Mid-summer**



**Questions?**