STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE RULEMAKING

OVERVIEW

- Proposed on April 30, 2018
- 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
- OPD is leading the Agency workgroup for this Tier 1 action
- Representatives from OAR, OGC, OLEM, OP, OW, OCSPP, R4, R5 and R7
  - Have started assessing some issues
- ORD team representatives from OSP, OSA, NHEERL, NERL, OSIM, NCEA

PUBLIC COMMENT

- Public Hearing was held on July 17, 2018
  - 150 attendees and 91 speakers
- Public comment period closed August 16, 2018
  - Comments are still being processed but as of August 21, 2018 there were almost 600,000 public comments of which more than 9,000 are unique comments
- In the process of organizing and reviewing the comments

- Comments submitted by
  - Professional organizations and journal editors
    - E.g. SOT, ACS, AAAS
  - States, Tribes and Localities
  - State associations
  - Industry
  - Environmental groups
  - Health groups
  - Labor Unions
  - Universities
  - Public
    - including former environmental professionals

PUBLIC COMMENT

- Major categories of comments
  - Comparison of the proposed rule requirements with statutory findings and procedures in environmental statutes
  - What problem is the proposed rule intended to fix?
  - Consistency with the Administrative Procedures Act
  - Degree of consistency with scientific norms
  - Type and extent of data that would be excluded
  - PI
  - Clarity of regulatory text
  - Costs
  - Peer review
  - Dose-response models

PUBLIC COMMENT