



## National Tribal Air Association's Fact Sheet on EPA's Strengthening Transparency in Regulatory Science

### What is the U.S. EPA's Strengthening Transparency in Regulatory Science Proposed Rule?

On April 30<sup>th</sup>, 2018, the U.S. Environmental Protection Agency (EPA) proposed a rule to establish the transparency of EPA regulatory science. The proposed rule outlines the criteria for scientific evidence used for significant regulations which include publically sharing underlying data and models for outside validation and analysis<sup>1</sup>. The proposed rule establishes a policy for “pivotal regulatory science” and the underlying data, “dose response data and models”. The rule provides a definition of “Pivotal regulatory science” and states these studies “are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks, and other impacts on which a final regulation is based”<sup>2</sup>. The rule also requires the EPA to identify all regulatory science it relied on and conduct an independent peer review on all pivotal regulatory science use to justify regulatory decisions. This proposed rule could significantly impact rulemakings under the Clean Air Act (CAA) which requires the EPA to rely on the best available science for regulatory actions.

### How does the Transparency in Regulatory Science Proposed Rule Impact Tribal Air Programs?

The rule could drastically limit the types of scientific studies that can be used to inform EPA regulations regarding air pollution, toxic chemicals, water contaminants and the impact on human health. The new proposal would require scientific studies to publish their data, models, and assumptions. There are many studies that follow data sharing policies but in some cases, all data cannot be shared openly including health-related studies without invading participants' privacy. EPA could fail to protect human health by excluding these health-related studies on the basis they disclose the identity of their research participants.

Tribes and Alaska Native Villages have a unique position in regards to Tribal sovereignty and governing their information. A number of Tribes have a unique protocol or have established Tribal Institutional Review Boards (IRB) in order to conduct research on Tribal Lands under Title 45 of Federal Regulations Part 46 – Protection of Human Subjects. Research is evaluated in order to promote and enhance the interests of Tribes while proceeding in an ethical and culturally sensitive manner. This proposed rule could impact tribal data and sovereignty over the publication and application of this information.

---

<sup>1</sup><https://www.epa.gov/osa/strengthening-transparency-regulatory-science>

<sup>2</sup><https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>

## Where Can I Find More Information and Submit Comments?

You can access the full documents and more information here:

<https://www.epa.gov/osa/strengthening-transparency-regulatory-science>

Submit your comments, identified by Docket ID No. [EPA-HQ-OZ-2018-0259], to the Federal eRulemaking Portal: <http://www.regulations.gov/> Follow the online instructions for submitting comments. *Comments must be received on or before August 16, 2018.*

Agency Contact:

Tom Sinks, Office of Research and Development  
US Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
Telephone number: 202.564.0221, Email: [staff\\_osa@epa.gov](mailto:staff_osa@epa.gov)

The NTAA has submitted comments and will have a template letter for Tribes to use at [www.ntaatribalair.org](http://www.ntaatribalair.org), under the Policy Response Kits tab. For additional information, please contact Andy Bessler, NTAA Project Director, at [Andy.Bessler@nau.edu](mailto:Andy.Bessler@nau.edu), or (928) 523-0526.

<sup>1</sup><https://www.epa.gov/osa/strengthening-transparency-regulatory-science>

<sup>2</sup><https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>