

National Tribal Air Association  
Supplemental Notice of Proposed Rulemaking (SNPRM) for  
Strengthening Transparency in Regulatory Science  
April 7, 2020



# Webinar Agenda

- Introductions – **Andy Bessler, NTAA Project Director**
- Summary of the Proposed Supplemental Rulemaking including the 2018 Transparency in Regulatory Science Rulemaking - **Dara Marks-Marino, NTAA Senior Research Specialist**
- The Use of Best Available Science by EPA - **Melinda Ronca-Battista, ITEP Research Associate**
- Summary of NTAA's Comments on the Proposed Rulemaking – **Ian Fisher, NTAA's Policy Advisory Committee Member**
- Summary of NTAA's Policy Resource Kit for Tribes – **Dara Marks-Marino, NTAA Senior Research Specialist**
- Q&A Session – **Andy Bessler, NTAA Project Director**



# Today's Speakers

- **Dara Marks Marino** is the Research Specialist Senior for both the Tribes and Climate Change program and the National Tribal Air Association. Dara has a Master's of Science in Climate Science and Solutions from Northern Arizona University, a BA in Humanities from the University of Colorado, and a Post-Bac in Elementary Education from Arizona State University. Dara spent most of her adult years as a professional mountain bike racer and triathlete, as well as a coach for other cyclists and triathletes, before pivoting to environmental work. She and her husband have a mini-me daughter who also shares her mom's fervor for both social and environmental justice. Favorite family pastimes include backpacking, skiing, and mountain biking.



# Today's Speakers

**Melinda Ronca-Battista** has worked for the Tribal Air Monitoring Support Center, which is a collaboration between Northern Arizona University and the US EPA, for 20 years. Before working at the TAMS Center, she spent 7 years as a contractor conducting radiation safety audits of military bases, nuclear power plants, laboratories, and private facilities handling radioactive materials. In her first life, she spent 6 years at the EPA Office of Radiation and Indoor Air in Washington DC, where her work developing the original radon measurement protocols and radon measurement proficiency program led to the Administrator's gold medal for exceptional service to the EPA mission.

Melinda is responsible for assisting all federally-recognized tribes with data management, analysis, and reporting, as well as quality assurance issues such as preparation of QAPPs. Melinda develops software, educational videos, conducts online and classroom courses, travels to tribal agency environmental offices and works extensively with tribes via email.



# Today's Speakers

**Ian Fisher** is an Associate Attorney with Jill Grant & Associates in Washington, D.C., where he provides legal counsel to tribes on environmental issues and assists with implementation of new policies and legislation to protect tribal lands, resources, and sovereignty. In his practice, Mr. Fisher assists tribes in developing and enforcing air quality and other environmental regulations. Mr. Fisher previously worked at the Natural Resources Defense Council where he litigated a Clean Air Act citizen suit enforcement case against a coal fired power plant, and at the Native American Rights Fund, where he represented tribal interests in negotiations leading to the Paris climate change agreement.

Mr. Fisher is admitted to practice law in Colorado, Washington D.C. and Illinois.



# Summary of 2018 Proposal

- 2018 Strengthening Transparency in Regulatory Science: restrict the use of scientific studies used in regulatory processes that do not provide public accessibility to the data and models used
- The rule could drastically limit the types of scientific studies that can be used to inform EPA regulations regarding air pollution, toxic chemicals and the impact on human health
- Establishes a policy for “pivotal regulatory science” and the underlying data, “dose response data and models”
- 600,000 comments including NTAA’s comment with majority that desires a broader approach



# Summary of the Supplemental Proposal

- SNPRM seeks comments only on the changes and additions to the original proposal
- 2020 Supplemental Proposal: provides definitions for a number of terms which expand the scope of qualifying studies and expands the scope to include past data and models
  - Example: 1993 Harvard University project that provided the foundation for today's air quality regulations by proving the link between air pollution and premature deaths



# Best Available Science

- Science is a METHOD, that always includes peer review, because
- Fundamental definition of SCIENCE is *repeatability* by others
- Repeatability may be demonstrated by new measurements or reviews of existing data and models
- Repeatability for existing data means:
  - Reviewing the assumptions and performing the same analyses to determine whether the same conclusions are reached
  - Only the relevant data are provided to peers, excluding
    - Confidential Business Information (CBI)
    - Personal Identifying Information (PII)

# Best Available Science

- Widely used in many local and federal agencies to make decisions
- Endangered Species Act (1973) is one of the 1<sup>st</sup> laws to require the use of BAS and has been widely litigated
- Accurate (quantitatively unbiased and free of systematic error)
- Reliable (study design, assumptions, analytical approach, and conclusions, should be well-referenced and described to allow repeat of the analysis)
- Representative (appropriate temporal and spatial scales, and can be extended to other relevant populations)

# Peer Review is required element of science

- Ensures transparency
- Publicly published correspondence and rebuttals
- Ongoing development and refinement of models, assumptions, and applicability to other populations
- Time consuming (except in emergencies such as re: COVID-19) but and in ALL cases made public
- Peer review already requires that the underlying research data "**are publicly available in a manner sufficient for independent validation**"

# EPA already has system for using BAS that works

- The EPA Science Advisory Board, with the explicit mission to base Agency actions on sound scientific data, analyses, and interpretations
- New agency projects are brought to SAB, with periodic meetings for the SAB to verify that EPA staff are using sound and relevant studies
- All EPA published works are reviewed by the appropriate SAB subcommittee
- The SAB follows the National Academy of Sciences *Transparency and Openness Promotion (TOP) standards*

# EPA should simply refer to their own requirements for grantees

- Data Quality Objectives widely used and understood by all scientists
- Element 24 of a QA Plan defines data validation as data that is of sufficient quality and is “fit for use”
- Data Review, Verification, and Validation requirements are those criteria for deciding to accept, reject, or qualify project information
- EPA’s own requirements for data quality assessments can be applied by EPA to data validations of pivotal science

# EPA must follow its mission: Protect Public Health and the Environment as the Default

- Precautionary Principle: assumption that concentrations greater than background cause harm
  - Why Europe will not accept GMO products
- This “null hypothesis” requires the provision of data to prove false, e.g., that the concentration is safe
- Current approach by EPA is the opposite: that concentrations are assumed to be safe, until data demonstrates harm

# Possible Motivations for this Rule

- Changing the models used to estimate air pollution exposures that were linked to health effects in the “Harvard 6 Cities” study, resulting in relaxation of the criteria pollutant standards
- Deviation from the national (NRC) and international (IAEA) consensus on the use of the “linear no-threshold” model for radiation as well as other pollutant exposures (and including the “theory” of hormesis: that low levels of exposure to cancer-causing substances are actually beneficial)

# 2020 Proposal Objections:

- Objections to the 2018 proposal have not been addressed
- Vague and undefined statements (no def'n of "pivotal science") allows for inconsistency
- Current peer review system used all over the world and by EPA already includes mechanisms for excluding CBI and PII
- The US already has rules for using personal data: IRS provides taxpayer data for research purposes with PII excluded (CFR title 26 6103)
- "Tiered" system of ranking studies to be used in decision-making is itself non-transparent and judgmental
- Precautionary principle should be the default assumption (that higher-than-background pollution causes harm) rather than the reverse, to become consistent with the international approach

# Summary of NTAA Comments

- Comment Period is Inadequate
- Opposition to Proposed Expanded Scope
- Opposition to EPA Administrator Exemption Discretion
- Lack of Authority for Proposal
- Failure to Consider Tribes and Environmental Justice Communities

# Comment Period is Inadequate

- Originally provided 30 days, since extended to 60 days
- This is an important and far reaching proposal
- Tribes' attention is rightfully focused elsewhere
- NTAA had asked for 90-day extension
- Make sure to use updated Tribal template letter on NTAA website

# Opposition to Proposed Expanded Scope

- Proposal for alternatives when all data and models are not publicly available
  - Exclude consideration or give less weight
- Proposal expands applicability from “significant regulatory actions” to “influential scientific information” and “data and models” rather than just “dose-response models”
- Proposal for tiered access based on other federal agency programs
- Proposal applies regardless of when the study was performed

# Opposition to Proposed Expanded Scope (continued)

- Agency decision-making must be based on the best available science
  - Some environmental statutes explicitly say this, others its implied and appears in regulations and court decisions
  - **Proposal will cause valid and relevant science to be excluded or given less weight**
- Proposal to address protected health information is vague and doesn't address concerns about feasibility or cost
- Expanding the applicability makes these problems worse, doesn't fix vagueness issues

# Opposition to EPA Administrator Discretion

- Proposed exemption that Administrator can grant, now includes factors
- Puts trust in Administrator without mandatory standards
  - Could be used positively – exempting public health studies
  - Could be used negatively – exempting industry chemical registration studies
- Suggested mandatory exemption for certain studies

# Lack of Authority

- Proposal has changed the authority EPA seeks to rely on
  - Solely on housekeeping authority statute for “Executive Departments”
  - In combination with corrected environmental statutes listed in original proposal
- Backwards rulemaking – proposing an action and then asking for help finding authority
- Cited authority doesn’t authorize the rule
- Note: in event of conflict, proposal says the other statute or regulation will control

# Failure to Consider Responsibilities to Tribes and Environmental Justice Communities

- No analysis performed of Tribal implications or Environmental Justice implications
- EPA actions (whether “significant regulatory actions” or “influential scientific information”) impact Tribal communities
- EPA must hear and address Tribal concerns

# Example If Rule is Finalized: PM<sub>2.5</sub> NAAQS

- Clean Air Act requires EPA to designate National Ambient Air Quality Standards (NAAQS) for each criteria air pollutant (PM<sub>2.5</sub>, ozone, CO, Pb, SO<sub>2</sub>, NO<sub>2</sub>)
  - “shall accurately reflect the latest scientific knowledge...” CAA § 108(a)(2)
- CAA requires review every five years by independent scientific review committee. CAA § 109(d)
- At each step EPA considers scientific studies and under proposed rule would be limited in those the agency can consider

Planning – science policy workshop to gather input, EPA prepares integrated review plan

Integrated Science Assessment (ISA) – comprehensive review of policy relevant science

Risk/Exposure Assessment (REA) – characterizes exposures and associated risks to human health or the environment

Policy Assessment (PA) – staff analysis of the scientific basis for policy options for consideration by EPA management

Rulemaking – EPA develops and publishes a notice of proposed rulemaking, receives comments, and finalizes rule

# NTAA's Policy Resource Kit

- [www.ntaatribalair.org/policy-resource-kits](http://www.ntaatribalair.org/policy-resource-kits)
- Comments due by May 18, 2020 here:  
<https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322>
- [Fact Sheet](#)
- [Tribal Template Letter](#)
- Slides and recording of this webinar will be posted today
- NTAA Comment Letter will be posted on 5/18/20



**ANY QUESTIONS?**

