



Environmental Council of the States

50 F Street NW, Suite 350 | Washington, DC 20001
(202) 266-4920 | www.ecos.org

August 16, 2018

Mr. Tom Sinks
Office of the Science Advisor
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Via [regulations.gov](https://www.regulations.gov): [Docket No. EPA-HQ-OA-2018-0259]

RE: Strengthening Transparency in Regulatory Science

Dear Mr. Sinks:

The Environmental Council of States (ECOS) submits the following comments to the U.S. Environmental Protection Agency (EPA) on the proposed rule, Strengthening Transparency in Regulatory Science. As state environmental agency leaders implementing regulations delegated to the states by the federal government, we count on EPA to write rules and establish standards based on the best available scientific information. While we support transparency and the open exchange of information, we are concerned with possible negative impacts and unintended consequences of the proposed rule.

States understand EPA's desire to be transparent with the public and we work hard to achieve this where possible. However, states are concerned that requiring all data used in scientific studies that underpin environmental and public health protection regulations be publicly available will lead to issues. For example, under the Toxic Substances Control Act (TSCA), EPA regularly relies on industry testing and data to make decisions on whether a chemical presents an unreasonable risk to human health or the environment. But some of this data is protected from public access under confidential business information claims. Additionally, many studies that look at human health effects cannot make all underlying data publicly available due to the Health Insurance Portability and Accountability Act (HIPAA). These confidentiality requirements do not make these chemical and health studies any less scientifically valid. So, this research and any other scientifically valid, peer-reviewed investigations and studies that rely upon data that is not publicly available should not be categorically excluded from consideration solely on the basis of data transparency.

EPA's mission statement says that to protect human health and the environment the agency will ensure that "National efforts to reduce environmental risks are based on the best available scientific information." The proposed rule's transparency requirements could cause best available scientific studies to be rejected not on scientific merits but solely because some data is not publicly available.

Like EPA's mission statement, several of the federal statutes that provide authority for the agency's work call for use of the best science without regard for data transparency. For example, TSCA as amended under the Frank R. Lautenberg Chemical Safety for the 21st Century Act requires the EPA Administrator to use "scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." The statute states that this best available science should be clear and complete, but it does not require it to be publicly available. Like TSCA, the Safe Drinking Water Act (SDWA) calls on the Administrator to use "the best available, peer-reviewed

Todd Parfitt
Wyoming Department of
Environmental Quality
ECOS President

Becky Keogh
Arkansas Department of
Environmental Quality
ECOS Vice President

Jim Macy
Nebraska Department of Environmental
Quality
ECOS Secretary-Treasurer

John Linc Stine
Minnesota Pollution
Control Agency
ECOS Past President

Sambhav (Sam) Sankar
ECOS Executive Director &
General Counsel

science and supporting studies conducted in accordance with sound and objective scientific practices.” SDWA specifically calls on the Administrator to make information on public health effects available including peer reviewed studies. But it qualifies the requirement with the phrase “to the extent practicable” and does not require that all the data underlying the studies be publicly available. It appears that the proposed rule could reject some of the best available science and may result in a finding that the rule contradicts the federal statutes.

As states take on delegated federal work, their regulatory entities set varying standards as they make decisions on acceptable risk, exposure paths and models, and other factors. This variability is already confusing for the public as apparent in per- and polyfluoroalkyl substances (PFAS) issues. Citizens have already raised questions about why their state has made decisions about whether or not to regulate PFAS and at what levels. Under the proposed rule, if some states use peer-reviewed scientific results to make regulatory decisions, but EPA ignores those same studies because the data is not publicly available, then the variability between standards will likely increase.

When faced with chemicals of emerging concern like PFAS or other evolving environmental issues, many states are concerned that the proposed rule could delay federal action. For example, there is strong public concern and fairly limited research on the public health and environmental risks of the full suite of PFAS. If this proposed rule were to cause delays, then it would run counter to EPA’s goal of quickly making progress on PFAS.

We understand that this rule would only be used prospectively and urge EPA to retain that limitation. But, EPA will need to clearly define how to address setting future standards that are based on existing ones as current standards may have been developed using studies that do not comply with this transparency rule. This presents increased litigation risk for states who rely on existing rules and standards set by the EPA and it increases regulatory uncertainty.

As you consider EPA action on this proposed rule, ECOS urges you to carefully consider the concerns and issues raised in this letter. If you would like to speak with ECOS about these comments, please contact me at ssankar@ecos.org or 202-266-4929.

Sincerely,



Sambhav (Sam) Sankar