



The Association of State Wetland Managers, Inc.

“Dedicated to the Protection and Restoration of the Nation’s Wetlands”

May 18, 2020

U.S. Environmental Protection Agency
EPA Docket Center
Office of Research and Development Docket
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Submitted via www.regulations.gov:

Docket ID No. EPA-HQ-OA-2018-0259

Re: Strengthening Transparency in Regulatory Science

To Whom It May Concern:

These comments were prepared by the Association of State Wetland Managers (ASWM) in response to the March 18, 2020 *Federal Register* supplemental notice of proposed rulemaking (SNPRM) for “Strengthening Transparency in Regulatory Science” (Docket ID No. EPA-HQ-OA-2018-0259).

ASWM is a nonprofit professional organization that supports the use of sound science, law, and policy in development and implementation of state and tribal wetland programs. Since 1983, our organization and our member states and tribes have had long standing positive and effective working relationships with federal agencies in the implementation of regulatory programs designed to protect our nation’s aquatic resources such as state and federal dredge and fill permit programs including § 404 of the Clean Water Act; development of water quality standards for wetlands; and § 401 Certification of federal permits and licenses. Thus, although we recognize the broad scope of the proposed regulation, our comments are focused on the potential impact of the proposed rule on these specific areas of public policy. ASWM [previously provided comments](#) dated August 1, 2018 in response to the April 30, 2018 *Federal Register* notice (83 FR 18768) on the proposed rule.

ASWM has reviewed the SNPRM and finds that we have similar comments and concerns to those expressed in our August 1, 2018 letter. We repeat the following major comment: The stated intent of the proposed rule is “to strengthen the transparency of EPA regulatory science” by “ensuring that the data underlying [pivotal regulatory decisions] are publicly available in a manner sufficient for independent validation.” ASWM strongly agrees that environmental regulatory decisions should be based on the best available science, including both peer-reviewed science and other pertinent information. However, we are greatly concerned that the proposed rule would unnecessarily limit the use of available sound science to an extent that would undermine EPA’s mission to protect public health and the environment. We question whether there is a need for greater public access to raw data, given the extensive measures already in place to ensure scientific transparency.

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Applicability to States and State Authorized or Delegated Programs.

Although the proposed rule says it applies to EPA actions, it is unclear whether the rule applies to State programs that are authorized or delegated by EPA. We recognize that the SNPRM states that “this SNPRM does not regulate any entity outside the Federal Government.” However, this is not stated in the regulatory language. Nor is it clear that the rule doesn’t apply to state programs that are authorized or delegated by EPA. We suggest that § 30.1 be revised to say that the rule only applies to direct EPA actions, not those delegated nor authorized through another entity.

Need for the proposed rule.

We previously suggested that EPA provide documentation of the inability of the public to review important data, and the resulting environmental impact. We also requested examples of how additional review by the public could improve the regulatory process without adding an unacceptable cost or delay, and/or excluding information essential to the validity of decision making. This information was not included in the April 30, 2018 proposed rulemaking nor the March 18, 2020 SNPRM.

Existing published literature often plays a role in decision making and predicts environmental and economic impacts. Scientific journals typically have a peer review system in place to evaluate the soundness of the research submitted for publication; many also provide a discussion forum where other researchers can provide their own similar or confounding results. Together, peer review and discussion provide a well-tested mechanism for ensuring the soundness of science. It is unclear when and why use of this type of information would require more transparency, as methods of data collection and analysis are clearly described to inform the results and conclusions.

Applicability to Wetland Management

The revised proposal has clarified that the rule, if adopted in its current scope, would apply to actions beyond dose-response data. We believe that typical uses of wetland data do not neatly fit the requirements and extent of additional validation in this rule for numerous reasons:

- Wetland data is frequently collected according to peer-reviewed procedures approved by EPA through State Wetland Program Development Grants and 106 programs.
- While not unique to the topic of wetlands, states and tribes typically have limited independent resources for wetland data collection and rely on peer-reviewed publications for science applicable to their management concern.
- Wetland data, when published in peer-reviewed journals, doctoral dissertations or masters’ theses represent very specific situations and often limited geographic areas making independent validation difficult to conduct or inappropriate for informing managers in other areas or for similar, but related water resources. Some data are collected on private land and the landowner(s) may not allow others to access these sites.
- More current data is often unavailable. However, many older, but still critical data and analyses remain useful in making technical and scientific assessments that can guide management decisions.
- Formal literature reviews which achieve the rigor of research best practices and peer review should be included in available science used by EPA when used in concert with the data from the original studies. The in-depth comparative analysis of a formal literature review can add insights from the body of science about a specific topic.

- Wetland management is highly influenced by stream management. Stream management often relies on use of engineering models, which typically are in the public domain for use by applicants for regulated activities.

ASWM believes and recommends that the existing protocols provide adequate transparency and should be retained as meeting the intent of the proposed rule.

Consistent treatment of data regardless of source.

ASWM notes that the proposed rule applies to the transparency of data used by federal agencies in significant regulatory decisions and release of influential scientific information. We recommend that the rule make it clear that federal agencies apply the same stringent standards for transparency and quality of data to all information used in decision-making regardless of its source, whether provided by public agencies, the academic community, regulated entities or other sources. Moreover, we believe that scientific transparency would be increased by requiring information regarding the entity providing financial support for the related research. Funding by federal agencies and many foundations are typically identified in research reports, but corporate and other private funders may not be.

Expansion of Rule to Data Used in Influential Scientific Information

ASWM has significant concerns about this expansion. It is very unclear how “influential scientific information,” defined as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions” will be used differently than has already been done by EPA in the past consistent with the OMB guidance on peer reviews and the Data Quality Act. It is also unclear how EPA will make the decision on whether something is “influential scientific information” and what the detailed criteria would be for that evaluation. We suggest that the final rule make this clear.

ASWM supports the use of numerous types and sources of data and information in decision-making and dissemination of information to the general public and stakeholders. Use of the broadest possible range of information increases the validity and accuracy of decisions and should not be limited by overly burdensome requirements as described by the proposed rule. The public and stakeholders may have unique experiences allowing them to make decisions on how the information may be applied to their own actions.

Burden on Individual Permit Decisions

If the rule is to be read that individual permits are exempt from consideration, then ASWM does not have a comment on this language. ASWM believes that the statement in Section §30.5 “except where explicitly stated otherwise that provisions of this subpart do not apply to any other type of agency action, including individual party adjudications, enforcement activities or permit proceedings” should be interpreted to mean that that individual permits are not covered by this rule. However, ASWM would have significant concerns about the impact of this change in language on states and tribes, should it include individual permits.

Many times, individual permits can be required as part of a State Corps General permit with protected species, large scale projects, or other public interest factors. For example, in New Hampshire, U.S. Army Corps individual permits may be required for impacts of 1 acre or more and are required for 3 acre impacts or more. The discretion to require an individual permit is left to the federal resource agencies (EPA, USFWS, ACOE) through the state general permit process.

States are committed to efficient and effective wetland regulatory programs and most actions reviewed are authorized in a prompt manner with limited adverse impact. However, there are novel actions which rely on obtaining additional data, either collected or interpreted in the field. States must make use of what is deemed the most appropriate information for decision making. For either federal agencies making wetland regulatory decisions, or states making these decisions on behalf of federal agencies, there are adequate appeal processes and public involvement steps in place for challenging the validity of an agency's decision without adding the additional steps and criteria in the proposed rule.

§ 30.5 What requirements apply to EPA's use of data and models underlying pivotal regulatory science and pivotal science?

ASWM interprets this section as describing how EPA will handle studies when data and models underlying science that is pivotal EPA's significant regulatory decisions and influential science information. We understand the two options to be: 1) use pivotal regulatory science or pivotal science only if data and models are available for independent validation; or 2) give greater consideration to studies with data available for independent validation or reanalysis, but allowing for tiered emphasis based on the extent of available data, if able to mitigate privacy risks.

SUGGESTION: Again, if the rule can be interpreted to mean that individual permits are considered significant regulatory actions under the rule, re-analysis or independent validation of data associated with a permit could represent a burden on state agencies with regulatory programs implementing § 401 or an assumed § 404 program. Agencies should employ a modified approach allowing for use of studies where information is not available. Older studies may still provide useful information and should not be penalized by limiting their use simply because they are older.

Should the proposed rule apply retroactively to data collected prior to the effective date of the rule?

It is difficult to envision how the proposed rule could be applied retroactively to the science developed through long term experience in the implementation of various regulations and standards. Exclusion of research that was accepted as scientifically valid in the past could only result in the need to duplicate such research, adding needless cost and delay to the process of decision making. Furthermore, there are already EPA mechanisms for revising regulations and standards based on new data and analyses. For these reasons, ASWM objects to this concept.

Current regulations under the CWA have evolved over decades, supported by extensive peer reviewed science and other data collected by federal agencies, state and local agencies, academic institutions, stakeholders, and the general public. Supporting data includes the results of long-term monitoring of the impact and effectiveness of previous regulations, thereby supporting adaptive management and adjustments needed to address those impacts. Reports of such studies are readily available.

Requests comment on how much consideration should be given to studies when there is limited or no access to underlying data or models.

SUGGESTION: ASWM suggests that EPA accept approved theses/dissertations from accredited colleges/universities; published peer reviewed articles; other studies conducted according to federal/state/local QA/QC, as well as citizen science if data were collected with approved QA/QC. All these sources of information follow established quality review processes, which impacts credibility to results.

Requests comment on how to ensure that more data is available over time to ensure independent validation, while preventing unauthorized disclosure and identification.

SUGGESTION: Access to information can be limited by for-profit publications requiring payment to view full peer-reviewed articles. All work funded in part by the federal government should allow free full access to published articles. Offer incentives and support to researchers to increase access to data.

Requests comment on factors other than age that are a technological barrier.

SUGGESTION: Data from articles in journals published outside the United States may be considered a technological barrier.

Definitions.

ASWM has suggestions for improving the definitions:

- Data means the set of recorded factual material commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed and that is capable of being analyzed by either the original researcher or an independent party.

SUGGESTION: This limits data to that which can be analyzed by a third party, but due to tiering and exemptions, some of this is not practically done. This would seem to exclude information from the “data” definition. Suggest revising definition to: *Data means the set of recorded factual material with supporting QA/QC information commonly accepted in the scientific community as necessary to validate research findings in which obvious errors, such as keystroke or coding errors, have been removed.*

- Independent validation means the reanalysis of study data by subject matter experts who have not contributed to the development of the study to demonstrate that the same analytic results reported in the study are capable of being substantially reproduced.

SUGGESTION: This should not be limited to same data. Methods and models may need to be validated and applicability to other physical sites.

- Reanalyze means to analyze exactly the same data to see if the same result emerges from the analysis by using the same or different statistical software, models, and statistical methodologies that were originally used to analyze the data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.

SUGGESTION: ASWM recommends developing different terms for analyzing the exact same data and method vs. different method or model for analysis. In particular, models can be biased toward certain outcomes. ASWM recommends measures be in place to prevent rejection or acceptance of results due to bias in analysis.

SUGGESTION: The proposed rule should consider alternative sites, or methods, rather than the same data. These can also be corroborative findings or show limitations or expansion of using results. This is particularly for field studies in wetlands and waters, where regional site characteristics may provide

differing results. Reasons for the difference can be further explored, but some results may be more applicable for certain uses or areas than others and should be considered.

SUGGESTION: Peer-reviewed formal literature reviews, which synthesize and conduct comparative analysis on relevant studies should continue to be considered in concert with review of the specific studies included in the literature review, as these literature reviews can provide valuable insights around the body of literature on a topic.

§ 30.6 What additional requirements pertain to the use of data and models underlying pivotal science or pivotal regulatory science?

ASWM supports EPA's intent to 1) describe and document any assumptions and methods used and describe variability and uncertainty; 2) evaluate the appropriateness of using default assumptions on a case-by-case basis 3) clearly explain the scientific basis for critical assumptions used in the analysis that drove the analytical results and subsequent decisions and analyses showing the sensitivity of the modeled results to alternative assumptions. We are less certain about how EPA would "give explicit consideration to high quality studies, including but not limited to those that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity."

ASWM notes that the examples given in the above paragraph are more suited to dose-response models and not the data typically used by wetland managers. Wetland data is mostly obtained from field rather than laboratory analyses, (e.g. plant species occurrence and distribution, and surface and groundwater levels and movement) though results from laboratory analysis may be used if the results are found useful by wetland managers. Additional complications stem from evaluating results in different wetland types and regional responses based on factors such as local climate and geology. Wetland managers rely on the expertise in the literature and their own expertise in determining whether or not their data or other reports yield usable information with implications for wetland management.

§ 30.7 What role does independent peer review have in this section?

The proposed rule states "EPA shall conduct independent peer review on all pivotal regulatory science used to justify significant regulatory decisions and on all pivotal science underlying influential scientific information, consistent with the requirements of the OMB Final Information Quality Bulletin for Peer Review and the exemptions described therein."

SUGGESTION: Independent peer review would be impractical for some specific wetland data. Much of the data used to influence wetland management and regulatory decisions has undergone some sort of peer review through a journal or university committee, or was collected with approved quality control plans, often already approved by EPA. Thus, independent peer review of wetland-related data is not necessary for all wetland data as current procedures and practices are sufficient. After EPA conducts an independent peer review to justify significant regulatory decisions, ASWM recommends that EPA provide written justification of its findings.

§ 30.9 May the EPA Administrator grant exemptions to this part?

The proposed rule states "The Administrator may grant an exemption to this part on a case-by case basis if he or she determines that compliance is impracticable because technological barriers render sharing of the data or models infeasible, the development of the data or model was completed or updated before [EFFECTIVE DATE

OF FINAL RULE] or making the data and models publicly available would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security.”

It is unclear why an exemption from compliance with the rule would be needed if the final rule is not excessively burdensome; how that discretionary authority will be exercised; and what, if any, standards would be applied by the Administrator in determining exemptions. In our experience, consistent application of regulations and standards is necessary to provide the clarity and predictability needed in carrying out science-based programs. This authority could be applied very differently over time as EPA leadership changes, with unintended consequences for applicant clarity or sound management of environmental resources.

SUGGESTION: The Administrator should produce written detailed findings and rationale for the exemptions, including: a summary and citations of information used in decision making; entities or persons consulted if outside the agency; sources of the information, unless prohibited for national or homeland security reasons, and reasons for how /why the decision was made. ASWM suggests that the rule be explicit that HIPAA is especially considered when granting an exemption for health-related information.

ASWM appreciates the opportunity to comment on EPA Docket No. EPA-HQ-OA-2018-0259. While these comments have been prepared by ASWM with input from the ASWM Board of Directors, they do not necessarily represent the individual views of all states and tribes; we therefore encourage your full consideration of the comments of individual states and tribes and other state associations. Please do not hesitate to contact me should you wish to discuss these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Marla J. Stelk". The signature is fluid and cursive, with a long horizontal stroke at the end.

Marla J. Stelk
Executive Director
Association of State Wetland Managers