August 16, 2018

Delivered via www.regulations.gov to Docket No. EPA-HQ-OA-2018-0259

Andrew R. Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Re: EPA Proposed Rule: Strengthening Transparency in Regulatory Science. 83 *Fed. Reg.* 18,768 (Apr. 30, 2018); Docket Number EPA-HQ-OA-2018-0259.

Dear Administrator Wheeler:

The National Stone, Sand and Gravel Association (NSSGA)[1] with allied trade associations NAPA (the National Asphalt Pavement Association)[2] and NRMCA (the National Ready Mixed Concrete Association)[3] (hereinafter "associations," "we," and "our") jointly submit the following comments on the captioned EPA proposed rule ("the proposal").

[1] NSSGA (www.nssga.org) is the leading voice and advocate for the construction aggregates industry. NSSGA advances public policies that protect and expand the safe, environmentally responsible use of aggregates that build America's infrastructure and economy. NSSGA members—stone, sand & gravel producers and the equipment manufacturers and service providers who support them—supply the essential raw materials found in every home, building, road, bridge and public works project. The industry employs more than 100,000 highly-skilled men and women at 5,000 separate worksites, in all 50 states. Our members are committed to maintaining a sustainable environment for all, and to providing a safe and healthful work environment for their employees, whose daily efforts in today's economy provide vital support to their families and the communities in which they live.

[2] NAPA (www.asphaltpavement.org) represents the interests of the asphalt pavement producers and contractors on the national level before Congress, government and regulatory agencies, and national trade and business organizations. This includes advancing innovation, research, and deployment programs aimed at improving the value and quality of asphalt pavements; advocating for highway and airport funding investment; promoting the use of sustainable asphalt pavements by communicating their engineering, economic, environmental, and social benefits; and conducting and supporting programs that promote worker health and safety. Overall, the U.S. asphalt industry employs 260,000 people and produces more than 350 million tons of asphalt each year. More than 1,100 companies are members of NAPA.

[3] NRMCA (www.nrmca.org), founded in 1930, represents more than 2,250 companies and more than 135,000 American workers who manufacture and deliver ready mixed concrete (RMC). Our members include national and multinational companies that operate in every U.S. congressional district. The industry includes more than 72,500 RMC trucks and 6,500 RMC plants. Roughly 85% of all RMC companies in the U.S. are small businesses. From roads and bridges, to homes and high-rises, our built environment could not be realized without RMC. This important building material is created by combining fine and coarse aggregates, cement and water. In 2017 alone, the industry produced some 350 million cubic yards of RMC, representing a value in excess of $35 billion. Virtually every construction project in America uses RMC.

Our associations—and the more than one-half-million U.S. workers in the industries that we represent—do not oppose sensible, evidence-based regulations. Our members are directly impacted by the Agency's regulations under a host of federal statutes. We believe that the foundations of the regulatory process will be immensely strengthened, and its benefits greatly increased, when the underlying models, assumptions, methods, and data that support regulatory research findings are made publicly available in a manner sufficient to permit independent validation.[4]

I. GENERAL COMMENTS

We salute the leadership shown by EPA in clarifying and proposing to codify the bedrock principles for scientific inquiry that led to a host of valid discoveries and beneficial action, but which have been deteriorating in the U.S. over time.

First and foremost, the Agency should continue to endeavor to ensure that the research methods and findings it relies on will pass rigorous scientific and legal review. This concept has been recognized for decades in the courts[5] and in many other contexts.[6] The limitations of such reviews are now well documented, but they still provide a useful first-step toward valid science.

Tremendous environmental progress in the U.S. has been made in the last five decades. The Agency should be credited for its role in changing not only the state of the environment but also the way Americans think about the air, water, and land we all share.

Much environmental progress to date, however, has represented the "low-hanging fruit." We are now in a time when many regulations depend on complex, assumption-laden mathematical models or constructs and ambiguous data sets—all of which are open to various interpretations. At the same time, no attempt is made to replicate the majority of

[4] See §30.5. "Information is publicly available in a manner sufficient for independent validation when it includes the information necessary for the public to understand, assess, and replicate findings." (We believe that "sufficient for independent validation" should instead read "sufficient to permit independent validation.")

[5] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

[6] See, *e.g.*, Gori, G.B., 2016. An appeal for the integrity of science and public policy. *Toxicology* 371: 1-11. ("we urge legislators to embed the rules of evidence of the scientific method in statutes governing administrative policy and regulations.")

peer-reviewed scientific papers and, indeed, many or most cannot be replicated when such attempts are made.[7] Research findings from numerous scientific disciplines are affected.[8]

Society's need for a healthy environment must consider the needs of all those affected by its regulations. A transparent regulatory process—informed by accessible, reproducible scientific methods, data, and findings—provides the best opportunity for achieving both imperatives.[9] That is particularly true considering the deference that courts provide to regulators' choices of research methods and models. Petitioners today cannot rely on the courts to question an agency's regulatory processes or conclusions, no matter how opaque, irreproducible, speculative, or erroneous their scientific foundation.

EPA's proposal recognizes and catalogs ample convincing evidence that the Agency's present rulemaking process is inadequate and should be modernized. The proposal lays out sensible and thoughtful steps that will vastly improve the scientific basis for technical regulations. Importantly, many of the ideas embodied in the proposal originated primarily outside the Agency before the current administration took office.[10]

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[7] See, *e.g.*, (a) Ioannidis, J.P.A., 2005. Why Most Published Research Findings are False. *PLoS Medicine* 2(8): 696-701; (b) Arnaud, C.H., 2014. Confronting Irreproducibility. *Chemical & Engineering News*, Dec. 15, pp. 28-30; (c) Simmons, J.P., L.D. Nelson, and U. Simonsohn, 2011. False-Positive Psychology: Undisclosed Flexibility in Data Collection and Analysis Allows Presenting Anything as Significant. *Psych. Sci.*, 22(11): 1359-66.

[8] See, *e.g.*, (a) Taub, G. and C.C. Mann, 1995. Epidemiology Faces Its Limits (Special News Report). *Science*, 269: 5221. July 14, 1995; (b) Ioannidis, J.P, 2011. An Epidemic of False Claims. *Scientific American*, June 1, 2011; (c) Begley, G.C., and L.M. Ellis, 2012. Raise standards for preclinical cancer research. *Nature*, 483:531-533; (d) Grant, B., 2016. The Zombie Literature. *The Scientist Magazine*. May 1, 2016; (e) Anon., 2014. Texas Student Falsified Data. *Chemical & Engineering News*, Dec. 15, 2014, p. 9.

[9] Indeed, the opposite condition could prevail if the regulatory process becomes less transparent or less well grounded in reality; regulation run amok is a potential outcome. Regulatory processes should not only be transparent but designed from the start to exclude ideas cloaked in untestable "scientific theories" (e.g., certain cosmogonic narratives), or—in the most extreme cases—flawed or distorted scientific theories that can support wholly undemocratic activities (e.g., eugenics and Lysenkoism). The latter category has been referred to as "historical examples of massive production of wrong evidence or distortion of evidence." Ioannidis, J.P.A., 2012. Why Science is Not Necessarily Self-Correcting. *Perspectives Psych. Sci.*, 7(6):645-54.

[10] See, *e.g.*, (a) U.S. Office of Management and Budget, 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*. (Quality is "…the encompassing term, of which 'utility,' 'objectivity,' and 'integrity' are the constituents. [ ] 'Objectivity' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.") 67 *Fed. Reg.* at 369, Jan. 3, 2002; 67 *Fed. Reg.* at 8452, Feb. 22, 2002; (b) Presidential Memorandum of March 9, 2009 for the Heads of Executive Departments and Agencies: *Scientific Integrity*. 46 *Fed. Reg.* at 10,671; (c) Presidential Memorandum of Jan. 21, 2009 for the Heads of Executive Departments and Agencies: *Transparency and Open Government*. 74 *Fed. Reg*. at 4685, Jan. 26, 2009. ("Transparency promotes accountability and provides information for citizens about what their Government is doing."); (d) Presidential Executive Order 13642, May

We fully support the Agency's proposal and suggest certain refinements and extensions. Our support is not a novel position for our members. For example, NSSGA supported both *The Honest and Open New EPA Science Treatment Act of 2017* ("HONEST Act"; H.R. 1430) and the *EPA Science Advisory Board Reform Act of 2017* (H.R. 1431).

Summary of Responses and Recommendations

1. We fully support the proposed rule and urge EPA to continue the rulemaking process as rapidly as practicable.

2. The Agency's proposal, along with EPA's subsequent policy and guidance documents,[11] sufficiently addresses concerns about unauthorized access to confidential business information and private personal information.[12]

9, 2013. Making Open and Machine Readable the New Default for Government Information. 78 *Fed. Reg*. at 28111, May 14, 2013. ("General Principles. Openness in government strengthens our democracy, promotes the delivery of efficient and effective services to the public, and contributes to economic growth. As one vital benefit of open government, making information resources easy to find, accessible, and usable can fuel entrepreneurship, innovation, and scientific discovery that improves Americans' lives and contributes significantly to job creation."); (e) Gori, G.B., 2016. An appeal for the integrity of science and public policy. *Toxicology*, 371: 1-11. This appeal was endorsed by 185 signatories from at least 24 countries, 63 percent of whom listed a university or government affiliation. ("Our concern is motivated by the importance of adhering to the self-evident precepts of the scientific method in arriving at defensible conclusions. Those precepts require observational and experimental data that are authentic and of known measurement error; experimental variables that are relevant to the hypotheses being tested; the control of externalities that may confound observations and experimental results; and reproducibility by other performers or counterfactual verification.")

See also: Dudley, S.E. and M. Peacock, 2016. Improving Regulatory Science: A Case Study of the National Ambient Air Quality Standards. *Supreme Court Economic Review* 2016, 24:1, 49-99.

[11] See, *e.g*., the following EPA documents: (a) TSCA Chemical Substances; Unique Identifier Assignment and Application Policy. 83 *Fed. Reg*. at 30,168. June 27, 2018; (b) Guidance on Expanded Access to TSCA Confidential Business Information. 83 *Fed. Reg.* at 30,171. June 27, 2018; (c) Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting Under the Toxic Substances Control Act. 83 *Fed. Reg.* at 30,173. June 27, 2018; (d) Access to Toxic Substances Control Act, Confidential Business Information: A guide for access to TSCA CBI for state, local, and tribal governments. EPA 745B18001. OCSPP, June 2018; (e) Access to Toxic Substances Control Act, Confidential Business Information: A Guide for access to TSCA CBI for medical and environmental professionals in non-emergency situations. EPA 745B18002. OCSPP, June 2018; (f) Access to Toxic Substances Control Act, Confidential Business Information: A guide for access to TSCA CBI in emergency situations. EPA 745B18003. OCSPP, June 2018; (g) *TSCA CBI Protection Manual*. EPA Office of Pollution Prevention and Toxics, Washington, D.C. Oct. 30, 2003. For more information: https://www.epa.gov/tsca-cbi/guidance-requesting-access-confidential-business-information.

[12] A number of potential remedies exist if parties disagree on the types of scientific information that should be made publicly available. For example, EPA could confer with the data owner and the party seeking access to determine which research information could be disclosed without compromising confidential personal or business information. Alternately, the Agency could continue to contract with independent third parties to work towards an amicable resolution between the data owner and party seeking access. (The Agency already requires individuals desiring access to CBI to obtain and annually renew official CBI clearance. EPA requires certain business and personal information about the contracting company and each contractor employee requesting CBI clearance, the justification for such clearance, and the

3. The proposal's objectives are consistent with EPA's authority under the numerous environmental statutes that it implements, which emphasize the need for regulatory decisions to be guided by sound science and informed public participation while also recognizing the need to protect important privacy interests. For example, the Toxic Substances Control Act ("TSCA") requires EPA to make regulatory decisions based on the "best available science," including the "degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented."[13] At the same time, TSCA recognizes the importance of certain privacy interests, such as protecting confidential business information and private personal information.

4. Generally, the Agency's requirements should apply to research information including assessments, models, criteria documents, and regulatory impact analyses[14] that provide the basis for EPA's policies, procedures, guidance, and proposed and final regulatory decisions. The requirements should apply first to proposed regulations for which rulemaking is already in progress, then prospectively to proposed and final rules alike. We specifically urge EPA to clarify that the proposed requirements will also apply to risk evaluations performed under Section 6(b) of TSCA, and to assessments performed by the Agency's Integrated Risk Information System (IRIS) Program.

   Ultimately, the requirements should also apply on a case-by-case basis to retrospective assessment of research information; and to individual party adjudications, enforcement activities, and permit proceedings, to the extent that such actions are based or depend on research information, as defined here. [15]

signature of the employee to an agreement with respect to access to and use of CBI. Failure to provide the requested information will prevent a contractor employee from obtaining clearance for CBI. Contractors who willfully disclose CBI to unauthorized persons are subject to criminal penalties including fines and imprisonment. TSCA §14(d)).

[13] TSCA §26(h).

[14] We support EPA's advance notice of proposed rulemaking titled "Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process." 83 *Fed. Reg*. at 27,524, June 13, 2018.

[15] EPA should phase-in the requirements for retrospective assessments, starting with Agency actions and documents having the most widespread effects, e.g., the highest number of permit applications, alleged violations, etc., and the least transparent by the modernized criteria. (However, ordinarily there should be no need for the Agency to retroactively assess NAAQS that are subject to scheduled reviews.) We recognize that the effort to uncover the original data for existing regulations may be difficult, costly and infeasible. In such cases, where new studies would provide at least the same information, EPA should begin anew under the modernized transparency requirements, with research protocols vetted by an independent organization such as the National Academy of Sciences. See response at §30.8, on p. 14.

5. The requirements should include a transparency-certification process with specific procedures and benchmark criteria for documenting and ensuring that the affected activities and related documents and research information are independently verifiable. In each instance of a proposed regulation and certain other Agency actions, EPA must ensure *and certify* that the Agency has rendered pertinent details of the underlying methods, data, models, etc., publicly available in a manner sufficient to permit independent verification.

6. Adherence to the proposed requirements should become the default condition for the Agency's rulemaking activities and certain other Agency actions.[16] All Agency staff and contractors should be required in each instance to follow and document their adherence to the requirements. The documentation should become part of the Agency record. The ultimate responsibility for ensuring that the regulation is fully implemented should reside solely within the Office of the Administrator.

7. Exemptions and exclusions related to the requirements should be made only by the Administrator on a case-by-case basis, following clear, objective, and well-documented *a priori* guidelines and criteria that would be specifically established by the Agency for that purpose. In all but the most extreme cases, the Administrator's decisions should be made public and subject to judicial review. In such extreme cases the relevant documentation should be made accessible to appropriate Congressional oversight committees.

8. Concurrent with the Agency's actions described in the proposal, the Agency should modernize its entire conceptual framework for making regulatory decisions.[17] The framework should at least describe, to the extent possible, how the Agency manages its risk assessment methods, assumptions, and models; how it manages its treatment of uncertainty; and how it manages its risk management functions, including the use of non-risk factors at the risk management stage.

[16] See Summary Response 4, on p. 5.

[17] See, *e.g.,* Peacock, M.C., S.E. Miller, and D.R. Perez, 2016. Public Interest Comment to the Commission of Evidence-Based Policymaking. George Washington University, Regulatory Studies Center. Washington, D.C., Nov. 8, 2016.

II. COMMENTS ON STATUTORY AUTHORITY FOR THIS PROPOSAL

EPA has issued its proposed rule on Strengthening Transparency in Regulatory Science pursuant to its authority under several environmental statutes that that it implements, including the Clean Air Act; Clean Water Act; Safe Drinking Water Act; Resource Conservation and Recovery Act; Comprehensive Environmental Response, Compensation, and Liability Act; Emergency Planning and Community Right-To-Know Act; Federal Insecticide, Fungicide, and Rodenticide Act; and TSCA.[18] This proposed action is fully consistent with the authorities and objectives laid out in those statutes. EPA must ensure that any final action it takes on this proposal continues to respect the balance reflected in those statutes between sound, transparent science and legitimate privacy interests.

In its proposal, the Agency recognizes that "[t]he best available science must serve as the foundation of EPA's regulatory actions."[19] This is true not only as a matter of good governance, but as a statutory requirement. In particular, TSCA requires EPA to "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models . . . in a manner consistent with the best available science" when making regulatory decisions that are based on science.[20] Further, Congress directed EPA to consider the following five specific factors in doing so:

1. the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

2. the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

3. the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

4. the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

[18] 83 *Fed. Reg*. at 18,769.

[19] *Id.*

[20] TSCA §26(h).

5. the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models. [21]

EPA's proposed action will help the Agency to carry out TSCA's requirements regarding the use of the "best available science." By ensuring greater transparency into the data, assumptions, and methodologies used in the studies on which EPA relies, this proposed rule will facilitate EPA's analysis of the factors specified in TSCA §26(h)—particularly with respect to suitability, documentation, and consideration of uncertainty and variability.

The concern that some opponents of this proposed action have expressed—that it will inhibit or preclude use of certain studies that they believe to be relevant and useful, but for which data sufficient to permit independent verification are not publicly available—should be offset by recognizing that it is an explicit intent of the Agency to rely on the best *available* science. Science, studies, and conclusions from data that are not available for independent verification do not meet this requirement. They are not suitable for use as a basis for rulemaking insofar as they cannot be independently inspected and verified.

As the Agency recognizes in its proposal, this greater transparency serves a dual function in EPA's efforts to implement its statutory duties. Greater transparency can help to "[strengthen] the integrity of EPA's regulatory actions and its obligation to ensure the Agency is not arbitrary in its conclusions."[22] By supporting application of the "best available science" analysis, the proposed rule will help EPA reach regulatory decisions grounded in sound, quality science that will withstand judicial review—which, in the TSCA context, means decisions that are supported by "substantial evidence."[23] At the same time, greater transparency will "enhanc[e] the public's ability to understand and meaningfully participate in the regulatory process."[24] Public input is a fundamental part of the administrative process, and TSCA provides for public comment at multiple steps of the decision-making process under several of its provisions.[25] The proposed rule will improve

[21] *Id.*

[22] 83 *Fed. Reg*. at 18,769.

[23] TSCA §19(c).

[24] 83 *Fed. Reg*. at 18,769.

[25] See, *e.g.*, TSCA §6(b)(4)(H), 6(c)(3).

the public's access to data necessary to make informed comments on the science underpinning EPA's actions.

We note that while EPA's statutory authorities clearly support increased scientific transparency, these statutes also recognize and protect specific privacy interests that must be preserved as part of any attempt to improve transparency. For example, TSCA §14 provides explicit protections for CBI that is submitted to EPA for the purposes of TSCA implementation if specific criteria are met. Thus, TSCA itself recognizes that specific, limited classes of information should remain confidential, even if they play a role in decisions that the Agency makes pursuant to TSCA. EPA should ensure that any final action it takes on the proposed rule respects this balance, encouraging transparency while making limited exceptions to accommodate legitimate, protected privacy interests such as CBI. EPA's proposed provision at 40 C.F.R. §30.9, which would allow the Administrator to grant certain exemptions, can serve this purpose if properly cabined by clear, objective criteria for what circumstances may justify an exemption.

III. SPECIFIC RESPONSES TO THE PROPOSED RULE

We agree with the proposal's language except as noted in our comments herein. However, we reserve the right to provide additional comments at the appropriate time.

§30.1 What is the purpose of this subpart?

RESPONSE: Accessible and reproducible data, research methods and findings are the foundation of technical regulations. It is imperative that such research methods and findings become available for independent replication, verification, validation, and alternative analyses, while safeguarding truly confidential information. See Summary Responses 4, 5, 6, and 7, on pp. 5-6.

As stated in a recent text on law and economics, "The key aspects of enhancing confidence in the results of empirical studies are to allow others to be able to verify the integrity of the data, to replicate results, and to test the robustness of the results to various statistical manipulations." [26]

[26] Winter, H., 2017. *Issues in Law and Economics*. p.4. University of Chicago Press.

§30.2 What definitions apply to this subpart?

RESPONSE:

1. *Dose response data and models.* The first part of the proposed definition refers to "the" quantitative relationship between dose or exposure and the magnitude of predicted impact, without clarifying *which* quantitative relationship, specifically, is meant. There are many such quantitative relationships between exposures and responses, including ratios (*e.g.*, excess mortalities per ppm-year of exposure), regression coefficients, total and partial correlation coefficients, total causal effects (measured in various ways), direct causal effects, indirect and mediated causal effect, and others.

   We propose a more specific rewording of this passage, *e.g.*, "*Dose-response data and models* refer to the data and models used to characterize the quantitative causal relationship between the amount received of dose or exposure to a pollutant, contaminant, or substance (and possibly its time pattern or duration) and the magnitude of a predicted health or environmental risk or impact. The dose-response concept is explicitly about causation, not just association, and specifically refers to the increase in risk of response directly caused by exposure."

2. *Regulatory decisions*. As noted in our comments on proposed §30.3 and in Summary Response 4 on p. 5, the transparency requirements of this proposed rule should not be limited to "regulatory decisions" as defined in this proposal. Rather, the definitions proposed in this section should be amended to reflect the broader scope of any final action and certain other Agency actions.

3. *Regulatory Science*. See Summary Response 4, on p. 5. In addition, the definition should include the study protocol. When a study is conducted, the most important step is the careful production of a protocol which addresses all aspects of the study. These should at a minimum include objectives, study design, methods for collection of data, methods for handling the data, methods of analysis, and how results will be interpreted and reported. All the basic parameters should be documented, and include, sensitivity, specificity, variability, reproducibility, bias etc. The *a priori* definition of how results will be interpreted avoids the temptation to look at the data and perform analyses which have the potential to be biased. Of course, further analysis and mining of the data are acceptable but are fully recognized as such. Studies that are hypothesis generating should not be used as hypothesis testing studies. Making protocols available to the public for research funded by EPA could go a long way towards improving the

underlying science. All too often research is carried out and variables that should have been identified at the outset are considered after the study results are examined and the data reanalyzed or interpreted differently in the light of information obtained after completion of the research.

§30.3 How do the provisions of this subpart apply?

RESPONSE: The requirements should extend beyond "significant regulatory decisions," to include research information as described in Summary Response 4, on p. 5. Notably, these requirements should apply during all stages of the rulemaking process, including proposed rules. There is no point expending public and private resources to create a proposed rule that ultimately fails the transparency requirements as a final rule.

The Agency should apply the proposed requirements to a limited and special class of laboratory samples, the analytical results of which (from non-destructive testing) may become an essential element of the research that underpins a given regulation. Not only can different laboratory analysts reach different conclusions by analyzing the same sample, it is common for analytical methods to improve over time. Improved analytical methods provide researchers with the opportunity to re-analyze properly archived samples, potentially yielding more accurate and even different results. It should become part of the researchers' protocol to retain and properly archive this special class of samples when the analytical results are likely to inform or inspire the regulatory process. That is particularly true for research conducted by or for EPA and its contractors; and by any party conducting research with the intent to inform or inspire a specific regulatory action. (While it is true that certain types of samples cannot be retained because they are inherently unstable chemically and/or physically, other types of samples can remain stable for decades when properly archived.)

§30.4 What requirements apply to EPA's use of studies in taking final action?

RESPONSE:

1. EPA should state that it has a duty to make regulatory science material publicly available in a manner sufficient to permit independent validation.

2. Replace the proposed text: "EPA should make all such studies available . . ." with: "EPA shall make all such studies available . . . "

3. We note that this proposed provision would apply to "final agency actions" and not the narrower set of "regulatory decisions" as defined in proposed §30.2. We agree that the identification and availability requirements should not be limited to "regulatory decisions," but also believe the requirements (and the other requirements of the proposed subpart) should extend to research information as described in Summary Response 4, on p. 5.

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

RESPONSE:

1. The desire to have non-identifiable data for dissemination should not require the researcher to destroy any original identification. It is not uncommon for researchers to find ways to report study results which have involved access to confidential information, but which have been rendered into non-identifiable form. Often questions that arise when examining study results, or follow-up studies require access to the original data. Of course, in the long term, these must be stored and access stringently restricted, but nevertheless the original researchers or subsequent researchers should be able to access identifiable data should the need arise. This can be extremely important in health outcomes which have very long latencies where early studies may be inadequate to identify or quantify risks. Further this can be important when other agents are uncovered which may explain the results of previous research.

2. Replace the proposed text: "The agency shall make all reasonable efforts to explore methodologies . . ." with: "The agency shall make and thoroughly document all reasonable efforts to explore methodologies . . ."

3. The requirements should extend beyond "significant regulatory actions," to include research information as described in Summary Response 4, on p. 5.

4. Prospectively, EPA should include the transparency requirements in all future contracts between EPA and third parties for research that will or may be used to support regulations and include research information as described in Summary Response 4, on p. 5. The Agency should make the requirements specific and up front, with noncompliance jeopardizing both the research funding and reliance by EPA on those studies. See Summary Responses 5, 6, and 7, on p. 6.

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

RESPONSE:

1. EPA should make clear that this provision sets forth a mandatory duty and should require documentation of uncertainty and variability commensurate with its requirement for other "assumptions and methods used" as described in this proposed provision.

2. Replace the proposed text: "and should describe variability and uncertainty . . ." with: "and shall describe and thoroughly document variability and uncertainty . . ."

3. EPA should require, as a default, the application of causal analytics in studies that include, but are not limited to, dose-response or concentration-response models or data, and models that investigate factors that might account for spatial heterogeneity.

4. The Agency should expand the first sentence as follows:

   "EPA shall describe and document any assumptions and methods used. It should describe variability, uncertainty, and treatment of missing data, exposure estimation errors, covariate estimation and classification errors, omitted explanatory variables, model specification errors and biases, data selection biases, missing data, assumptions made to support causal interpretations of dose-response or exposure-response data (e.g., unit homogeneity, no hidden confounders, etc.), and results of any tests performed to validate these assumptions and to rule out non-causal interpretations and threats to internal and external validity of causal inferences."

5. The Agency should also consider high-quality studies that address (a) collider biases (e.g., selection, stratification, and Berkson's bias), and (b) latent as well as observed confounders and colliders.

6. See Summary Responses 4, 5, 6, and 7, on pp. 5-6.

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

RESPONSE:

1. EPA should specify that it will require documentation of its independent peer review efforts.

2. Replace the proposed text: "EPA shall conduct independent peer review . . ." with: "EPA shall conduct and thoroughly document independent peer review . . ."

3. See Summary Responses 4, 5, 6, and 7, on pp. 5-6.

§30.8 How is EPA to account for cost under this subpart?

RESPONSE:

1. Minimizing the costs of EPA's regulatory requirements is an important and worthy goal. However, we believe that the costs of implementing EPA's transparency requirements should be considered in relation to the benefits they afford and not merely in absolute terms. For example, requiring EPA research grant recipients to adopt data-masking procedures may impose some additional costs on those recipients, but those costs may be justified by the greater transparency offered into the data underlying that research. For that reason, instead of implementing the proposed requirements "in a manner that minimizes costs," EPA should commit to implement these requirements in a manner that optimizes the costs and benefits.

2. See Summary Response 4, on p. 5.

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

RESPONSE:

1. Granting an exemption without sufficient justification and documentation is simply an invitation to ignore the need for regulatory transparency—and would defeat the purpose of the proposal. Yet, an exemption process provides the necessary route for the Administrator to limit disclosure of information in highly unusual circumstances that the proposal might not currently envision. Thus, we support the use of a reasonable exemption process. However, EPA should add regulatory text that allows the public to hold the Administrator accountable for any decision to grant discretionary waivers, including through documentation and judicial review.

2. Add a new paragraph after §30.9(b): "The Administrator shall thoroughly document the justification for granting an exemption according to a specific process and criteria to be developed by EPA. The Administrator's decision to grant an exemption shall be published in the *Federal Register* and shall be subject to judicial review."

3. Although we support granting the Administrator discretionary waiver authority, the proposed regulatory text is too vague to properly constrain the Administrator's use of that waiver authority. In order to ensure that the proposed transparency requirements are applied whenever practicable, and to bring transparency and predictability to the waiver process itself, EPA should formulate clear, objective criteria for granting

exemptions that constrain the Administrator's waiver authority to circumstances in which it is truly not feasible to make underlying data available but the regulatory process would nonetheless be harmed by excluding the regulatory science in question from consideration.

4. See Summary Response 7, on p. 6.

We congratulate the Agency for a sound and useful model that all other federal and state regulatory bodies and research entities should emulate.

The Associations appreciate the opportunity to submit these Comments. Please send any correspondence on this matter to our attention.

Sincerely,

NATIONAL STONE, SAND AND GRAVEL ASSOCIATION

Michael W. Johnson
President and CEO

NATIONAL ASPHALT PAVEMENT ASSOCIATION

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