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Summary and Key Points of *Final Rule – Transparency in Significant Regulatory Actions and Influential Scientific Information* (40 CFR Parts 30.1-30.7)

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This memorandum provides a brief overview of *Final Rule – Transparency in Significant Regulatory Actions and Influential Scientific Information* (the Rule) finalized by the US Environmental Protection Agency (EPA) on January 6, 2021. Much of the language in this summary is directly from the Rule preamble, EPA's Rule FAQ or the Rule itself or has been slightly adapted for readability.

On August 9, 2018, ACWA provided comments to EPA on the 2018 Proposed Rule. Access the letter here.

Rule in Brief

Effect of the Rule

When characterizing the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect, EPA will identify pivotal science and give greater consideration to pivotal science for which the underlying dose-response data are available in a manner sufficient for independent validation.

Dates and Applicability

Section II(a-b) and Section III(d) describe the rulemaking history and applicability. The 2018 Proposed Rule was released on April 30, 2018. In response to comments, EPA issued a Supplemental Notice of Proposed Rule Making (2020 SNPRM) on March 18, 2020. The Rule was finalized and became effective on January 6, 2021. The Rule does not retroactively apply to EPA actions. For future significant regulatory actions and influential scientific information, the Rule applies equally to all dose-response data underlying studies used as pivotal science, regardless of when the study or the data was created.

Summary

Section I(b) and Section III(a) describes the purpose and functions of the rule. The Rule is intended to increase transparency by codifying internal EPA procedural requirements regarding how EPA considers certain data in the process of promulgating significant regulatory actions and/or

developing and using influential scientific information. Section III(f) describes applicable information provided by §30.6. Applicable information, for this iteration of the Rule, includes studies underpinned by dose-response data only and does not also include dose-response models. The procedure created by the Rule is to provide consistency when EPA weighs and utilizes pivotal science where the underlying dose-response data are, or are not, available for independent validation. Independent validation is sought by the Rule to enable subject matter experts to reanalyze study data to re-affirm original study conclusions in support of ad-hoc or cyclical reviews (e.g., national primary drinking water regulations). The Rule notes that EPA will not categorically exclude any studies in EPA actions, but will give certain studies less consideration if their underlying data are not or cannot be made publicly available. The Rule applies to EPA- and externally-generated influential scientific information.

While an objective of the Rule is creating a consistent procedure relating to EPA's use of studies that include dose-response data, §30.5(e) provides that on a case-by-case basis, EPA will review each study's default assumptions and methods and evaluate their appropriateness.

Additionally, Section III(g) describes the EPA Administrator's authority to exempt an applicable study from the procedural requirements when at least one of five criteria are met. Regardless of procedural outcome, EPA is to publish its rationale for all studies evaluated for potential use in the proposed rule stage of EPA actions.

Major Requirements of the Rule

1. Section III (a)(2) describes how, when promulgating significant regulatory actions or developing influential scientific information, EPA will determine which studies constitute pivotal science. While EPA is to give greater consideration to pivotal science which "can be validated" per the Rule, EPA will continue to use the following established factors to assess the quality of studies:
    a. Soundness
    b. Applicability and Utility
    c. Clarity and Completeness
    d. Uncertainty and Variability
    e. Evaluation and Review
2. The Rule sets the overarching structure and principles for transparency of pivotal science in significant regulatory actions and influential scientific information. If implementing the Rule results in any conflict between the Rule and EPA-administered statute (and their implementing regulations), the Rule yields and the statutes and regulations will be controlling.

    Section III(c) provides an example. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), entities are required to submit data to EPA to support pesticide registrations. This may include dose-response data that supports EPA's FIFRA obligation to make pesticide-specific unreasonable adverse effects determinations. These FIFRA data may include studies or scientific information containing Confidential Business Information (CBI), Personally Identifiable Information (PII), or other data which, consistent with the Rule, may be given lesser consideration if said data cannot be made available for

independent review. However, the Rule clarifies that the EPA-administered environmental statute (FIFRA), not the Rule, controls. Thus, the Rule would not apply to this scenario.

3. EPA shall clearly identify all science that serves as the basis for informing a significant regulatory action and shall make it publicly available to the extent practicable using standards for protecting PII. However, the Rule does not compel EPA to make all applicable information publicly available.
4. Section III(h) describes how the Rule establishes requirements for the independent peer review of pivotal science at §30.6, consistent with the OMB final Information Quality Bulletin for Peer Review and EPA's Peer Review Handbook. If the Agency conducts peer review on pivotal science, EPA shall ask peer reviewers to articulate the strengths and weaknesses of the justification for the assumptions applied in analyzing dose-response data and the implications of those assumptions for the results.
5. §30.7 of the Rule provides criteria for the EPA Administrator to grant case-by-case exemptions and provides criteria for the EPA Administrator to consider when doing so.

Differences Between the Rule, 2018 Proposed Rule, and 2020 SNPRM

Section III(b) is noteworthy for describing the 2018 Proposed Rule's data scope, which included a broad range of information supporting risk assessments (e.g., bioaccumulation data, data on environmental releases, exposure estimates used by EPA across environmental statutes, studies that identify data for toxicokinetic adjustments that inform calculation of human-equivalent point of departure, etc.). The Rule clarifies that EPA will incrementally apply the principles of science transparency to its procedures, and chose the following, more narrow scope for this iteration of the Rule: *studies consisting of the data integral to characterizing dose-response relationships.*

The 2018 Proposed Rule's applicability was limited to EPA significant regulatory actions. The 2020 SNPRM expanded applicability to include influential scientific information generated or otherwise used by EPA. This broader scope was maintained in the Rule.

Section III(e) discusses the 2020 SNPRM's proposed categorical exclusion of studies not meeting the dose-response data review threshold. Categorical exclusion of studies was not included in the finalized Rule and all relevant studies are to be considered, to varying extents per the Rule.

Significance

Section III(a)(2-3) describe the Rule's relationship with research in support of EPA developments or actions supporting human health and environmental protection. EPA and other public health authorities rely on risk assessments to target regulations and permits governing discharges to the environment and risk reduction of one or more pollutants, contaminants, or substances. The underlying dose-response data that inform the quantitative value used to evaluate and mitigate potential risk are critical to understanding the assessment or regulatory action. In addition, the data underlying the dose-response assessment are more distinct than the broad range of data informing an entire risk assessment. Therefore, the Rule seeks to increase transparency on a well-defined step in the quantitative assessment of risk supporting specific EPA actions.

Risk-based management approaches and National Recommended Water Quality Criteria (NRWQC), as well as other human health or aquatic life benchmarks, are supported by risk

assessments underpinned by risk characterization, including dose-response relationships. EPA and other public health authorities, as a matter of practice, often denote information gaps that inhibit their ability to generate such benchmarks, while research strategies or individual researchers may seek to respond by "closing" information gaps. To some extent, the Rule will limit the availability of research that underpins development of new or revised pollutant-specific public health and environmental protection benchmarks generated by EPA as well as other entities that utilize EPA-generated influential scientific information for this purpose. If researchers wish to increase the likelihood that their studies receive greater consideration by EPA, they may take steps to ensure that the underlying dose-response data are available to the greatest extent possible. But under the Rule, any such response would be purely voluntary.

Guidance and Promulgations Relating to the Rule

Section III(e) notes that EPA plans to promulgate either statute-specific transparency regulations or programmatic guidance for implementing the Rule. For example, EPA intends to promulgate a regulation or issue guidance clarifying how "pivotal science" will be applied under the CWA, as well as the SDWA, CAA, etc. Clarifications may include the process for designating studies as pivotal science, activities under statute where the Rule may apply, documenting the availability of dose-response data, and requesting the EPA Administrator's exemption to the Rule per §30.7.

Definitions

Section III(c) describes the evolution of the definitions finalized in Rule below, as well as some noteworthy caveats (for example, EPA interpretation of *best available science* is not defined or altered by the Rule). These final definitions are found in §30.2.

a. *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.
b. *Dose-response data* means the data used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect.
c. *Independent validation* means the reanalysis of study dose-response data by subject matter experts who have not contributed to the development of the study to evaluate whether results similar to those reported in the study are produced.
d. *Influential scientific information* means 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.
e. *Pivotal science* means the specific dose-response studies or analyses that drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information.
f. *Publicly available* means lawfully available to the general public from Federal, state, or local government records; the internet; widely distributed media; or disclosures to the general public that are required to be made by Federal, state, or local law. The public must

be able to access the information on the date of publication of the proposed rule (or, as appropriate, a supplemental notice of proposed rulemaking, or notice of availability) for the significant regulatory action or on the date of dissemination of the draft influential scientific information for public review and comment.

g. *Reanalyze* means to analyze exactly the same dose-response data to determine whether a similar result emerges from the analysis by using the same methods, statistical software, models, or statistical methodologies that were used to analyze the dose-response data, as well as to assess potential analytical errors and variability in the underlying assumptions of the original analysis.

h. *Science that serves as the basis for informing a significant regulatory action* means studies, analyses, models, and assessments of a body of evidence that provide the basis for EPA significant regulatory actions.

i. *Significant regulatory actions* means final regulations determined to be "significant regulatory actions" by the Office of Management and Budget pursuant to Executive Order 12866.

Authority and Downstream Effects Assessment

Section I(c) describes the basis of the Rule in statute and case law in response to public comments that the rule may impose unlawful substantive requirements. The Rule is based on the precept that EPA's use of science in rulemakings and scientific activities are subject to Executive Department housekeeping authorities (5 U.S.C. 301) regarding internal agency affairs (i.e., internal procedure, rather than substantive, rules as adjudicated in *Chrysler Corp.* v *Brown* etc.). While EPA is not an Executive Department, the Rule preamble notes EPA was granted sufficient housekeeping authorities in EPA's creation document, the federal Reorganization Plan No. 3 of 1970.

Even if there could be downstream practical effects on the voluntary behavior of outside parties – for example, a perception by researchers that they should strive to produce studies containing dose-response data only if that dose-response data can meet EPA's higher-consideration criteria in the Rule – such impacts do not render this procedural Rule substantive. Section III(j) explains, under this rationale, why EPA did not publish a benefit-cost estimate, including potential costs to third-party researchers and their institutions to make their raw data available and protect PII/CBI through data-masking, de-identification, or deposition in public data repositories. Similarly, Section II(a)(3) discusses EPA's view that the Rule's approach to considering available science would not inhibit its ability to protect human health and environment consistent with statute, nor result in EPA developing regulatory decisions that are (1) not based on high-quality studies or the best available science or (2) potentially biased towards regulated parties.