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Via Regulations.gov

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Re: Scientific Integrity Policy Draft for Public Comment;
Docket EPA-HQ-ORD-2023-0240

Dear Dr. Grifo:

I. Executive Summary

The Dow Chemical Company (Dow) strongly supports the U.S. Environmental Protection Agency's (EPA) proposal to strengthen its Scientific Integrity Policy. Sound science must underpin all EPA's actions to facilitate and to ensure that the agency makes informed, consistent, and nonarbitrary science-driven decisions.

At Dow, our core values of integrity, respect for people, and protecting our planet drive our company toward achieving our ambition of being the most innovative, customer-centric, inclusive, and sustainable materials science company in the world. Dow appreciates this opportunity to provide EPA with comments on its draft Scientific Integrity Policy (the 2024 Draft SI Policy) and believes that the core tenets of the 2024 Draft SI Policy should focus on transparency and accountability.

Transparency should be vigorously enforced by EPA and the scientific community:

- Allows for the best minds to be working on the issue;
- Allows for replicability and predictability;
- Allows for a determination of conflict of interest or lack thereof; and
- Allows for inclusivity for differing scientific opinions, which would maximize the chance for utilization of the best available science.

Accountability is necessary to ensure the policy is more than aspirational:

- Allows a mechanism for accountability within the policy, as transparency without accountability can lead to flawed outcomes;

- Accountability does not mean punitive action, but it should mean that EPA has an obligation to address errors and take corrective actions; and
- Administrative and court challenges should not be the only remedies for resolving disputes, which, if anything, has the potential to limit transparency and chill meaningful engagement between EPA and the public.

Updating the EPA's Scientific Integrity Policy is fundamental to ensuring that EPA's determinations are conducted fairly and openly while evaluating the weight of scientific evidence in fulfilling the agency's mission of protecting human health and the environment. Dow respectfully submits the following comments for the agency's consideration.

II. Purpose

Lines 28-31 of the 2024 Draft SI Policy state: "The purpose of this policy is to enhance and promote a continuing culture of scientific integrity. This policy aims to ensure the integrity of ***all aspects of activities*** that include proposing, conducting, reviewing, managing, communicating about science and scientific activities, and using the results of science." (Emphasis added.)

Dow agrees that it is vital to enhance and promote a culture of scientific integrity at EPA as part of the purpose of the 2024 Draft SI Policy. However, as written, the 2024 Draft SI Policy appears to limit the scope of inclusivity to internal activities while excluding scientific integrity concerns expressed from entities external to EPA or other federal agencies. The policy expressly discusses internal activities, but is silent on its numerous external activities, including EPA providing substantive responses to interagency comments, public comments, requests for correction (RFC) of information, and requests for reconsideration (RFR) of information submitted under the Information Quality Act (IQA). Exclusion of these external activities does not comport with EPA's aim to ensure the integrity of "all aspects of [its] activities."

Dow believes that the apparent exclusion of external activities is inadvertent. Dow therefore recommends that EPA revise the 2024 Draft SI Policy to expressly include external activities. To the extent that EPA intends to exclude its external activities, Dow requests EPA to explain how the exclusion comports with EPA's aims to be inclusive of "all aspects of activities."

III. Background and Core Values

Lines 44-45 of the 2024 Draft SI Policy state: "At EPA, promoting a culture of ***scientific integrity is closely linked to transparency***. The Agency remains ***committed to transparency*** in its interactions with all members of the public and its internal processes and procedures as allowable by applicable law." (Emphasis added.)

Dow suggests that scientific integrity is not just closely linked to transparency. Scientific integrity is inextricably intertwined with transparency. EPA defined "Transparency" on lines 287-288 of the 2024 Draft SI Policy as follows:

> [E]nsuring all relevant data and information used to inform decision making or actions are visible, accessible, and easily usable by affected parties to the extent permitted by law.

Our concern with this definition is that it does not address the temporal aspect of transparency, which includes releasing all information, to the maximum extent permitted by law, at the same time EPA releases its draft or final documents. Dow therefore respectfully recommends the following updates to EPA's definition of "Transparency":

> [E]nsuring all relevant data and information used to inform decision making or actions ***are available at the time EPA releases such information to the public and/or peer reviewers and that such information is presented in a format that is*** visible, accessible, and easily usable by affected parties to the extent permitted by law [emphasis added].

The proposed edits to this definition are consistent with the requirements EPA places on regulated entities. For example, EPA will reject a scientific study if EPA concludes that it is unable to reconstruct the study due to the absence of raw data.[1] We note that this determination is made contemporaneously with EPA's review and decision-making.

Furthermore, Dow respectfully disagrees that EPA has demonstrated a commitment to transparency. We discuss several representative examples below.

In 2012, EPA began evaluating N-methylpyrrolidone (NMP) under the Toxic Substances Control Act (TSCA) as a Work Plan chemical risk assessment. EPA subsequently published the final Work Plan chemical risk assessment for NMP in 2015.[2] As part of its hazard assessment at that time, EPA concluded that the reproduction and developmental study performed by Sitarek and Stetkiewicz (2008) was "unreliable" due to inconsistencies in the published data.[3] In comparison, EPA assigned a data quality rating of "High" to that study in the final risk evaluation for NMP.[4]

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1 EPA (1995), *Guidelines for Study Rejection Based on GLP Considerations*, at 2, available at https://www.epa.gov/sites/default/files/2013-09/documents/glpstudyrejection.pdf.

2 EPA (2015), *N-Methylpyrrolidone: Paint Stripper Use, CASRN 872-50-4, TSCA Work Plan Chemical Risk Assessment*, 740-R1-5002, available at https://www.epa.gov/sites/default/files/2015-11/documents/nmp_ra_3_23_15_final.pdf.

3 *Id*. at 58.

4 EPA (2020a), *Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP) CASRN: 872-50-4*, EPA-740-R1-8009, at 227, available at https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_n-methylpyrrolidone_nmp_casrn_872-50-4.pdf.

Under the systematic review method used in the final risk evaluation for NMP, a data quality rating of High was defined to mean:[5]

> No notable deficiencies or concerns are identified in the domain metric that are likely to influence results [score of 1].

EPA did not, however, provide its rationale for reassigning a data quality rating of High to Sitarek and Stetkiewicz (2008) in the final risk evaluation for NMP, nor did EPA mention the inconsistencies between its conclusions on this study in the Work Plan chemical risk assessment versus the risk evaluation. The lack of an explanation for this change in rating is deeply troubling and in conflict with the principles of scientific transparency. In order to engage with the agency meaningfully, Dow (and others) must be able to understand and to rely on EPA's method(s) of rating studies. Thus, an explanation was critical in order to understand how a study previously deemed unreliable subsequently gained a "High" quality rating. Was EPA's initial assessment that the study was unreliable incorrect? If so, what went awry with the initial assessment? Were the same criteria used? If not, what was EPA's rationale for changing the criteria? Without this type of explanation, it would be difficult to conclude that EPA was being transparent. And it leaves the agency susceptible to criticisms that its assessments either were not methodical, or worse, arbitrary.

On January 14, 2021, EPA issued a TSCA Section 4(a)(2) test order on *trans*-1,2-dichloroethylene (Chemical Abstracts Service Registry Number® (CAS RN®) 156-60-5).[6] EPA concluded that "environmental hazard data were identified for *trans*-1,2- dichloroethylene and four of the nine identified analogues to assess all relevant pathways in the environmental conceptual model in regards to exposed aquatic organisms, except for benthic invertebrate toxicity data due to acute and chronic exposure via sediment."[7] EPA stated, however, that "the *Final Risk Evaluation for Trichloroethylene* has sufficient environmental hazard information for use as analogue data for *trans*-1,2-dichloroethylene on benthic invertebrate toxicity data due to acute and chronic exposure via sediment."[8] On August 5, 2022, EPA reissued a second test order on *trans*-1,2-

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5 EPA (2018), *Application of Systematic Review in TSCA Risk Evaluations*, 740-P1-8001, at 33, available at https://www.epa.gov/sites/default/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.

6 EPA (2021a), *Order Under Section 4(a)(2) of the Toxic Substances Control Act*, EPA-HQ-OPPT-2018-0465, available at https://www.epa.gov/sites/default/files/2021-01/documents/tsca_section_4a2_order_for_trans-12-dichloroethylene_on_ecotoxicity_and_occupational_exposure.pdf.

7 *Id*. at 6.

8 *Id*.

dichloroethylene, originally issued in March 2022.[9] This time, however, EPA ordered testing on sediment-dwelling organisms, without providing a justification for its different conclusion in the January 14, 2021, test order, and only stated that "No toxicity data for benthic invertebrates exposed for acute or chronic durations were identified."[10] As its basis for concern for benthic invertebrates, EPA stated that chlorinated compounds were found in sediment and cited to the U.S. Geologic Survey (USGS) website without proving the detail necessary to reproduce EPA's search. EPA may be correct on the basis and need for data, but without the reasoning—clearly set forth and disclosed timely—external stakeholders cannot evaluate the scientific basis for the changes.

On July 10, 2023, EPA announced the availability of and public comment period on the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation (the 2023 Draft 1,4-DX Supplement).[11] EPA stated in the 2023 Draft 1,4-DX Supplement that "The updated search for peer-reviewed and gray literature relevant references was completed in October 2021 and January 2022, respectively . . . ." EPA went on to state that "The evaluation of physical and chemical properties, fate properties and environmental and human hazard information ***did not differ*** from the respective information provided in the Final Risk Evaluation for 1,4-Dioxane . . . therefore no additional references were identified for these respective topics or underwent systematic review for these disciplines." (Emphasis added.)[12]

Although EPA's search of the gray literature was completed in January 2022, EPA did not reference two relevant sources from the gray literature that arrived at a different conclusion than EPA about the carcinogenic mode of action (MOA) for 1,4-dioxane.

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[9] EPA (2022a), *Order Under Section 4(a)(2) of the Toxic Substances Control Act*, EPA-HQ-OPPT-2018-0465, available at https://www.epa.gov/system/files/documents/2022-06/9544-01_TestOrder%20trans1%2C2%20DCE_v2_signed.pdf.

[10] *Id*. at 9.

[11] EPA (2023a), *1,4-Dioxane; Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Meeting and Request for Comment*, FEDERAL REGISTER, Vol. 88, 43562-43565, available at https://www.govinfo.gov/content/pkg/FR-2023-07-10/pdf/2023-14445.pdf.

[12] EPA (2023b), *Draft Supplement to the Risk Evaluation for 1,4-Dioxane, CASRN 123-91-1*, EPA-740-D-23-001, at 187-188, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0027/content.pdf.

In March 2021, Health Canada concluded that:[13]

> Since 1,4-dioxane acts through a non-genotoxic MOA and demonstrates dose-related non-linear kinetics, a non-linear (threshold) risk assessment approach is considered appropriate.

In September 2021, the European Chemicals Agency (ECHA) issued a document titled "ECHA Scientific report for the evaluation of limit values for 1,4-dioxane at the workplace."[14] ECHA concluded that:[15]

> [A]lthough there is some uncertainty on the mode of action, the carcinogenicity of 1,4-dioxane is considered to be related to non-genotoxic mechanisms, involving saturation of the metabolic capacity and irritation at high exposure levels. Therefore, there is no need for a risk calculation for the purpose of this report (limit values).

EPA's failure to discuss these two reports is troubling. While the agency may not agree with Health Canada's and/or ECHA's scientific conclusions on the carcinogenic MOA for 1,4-dioxane, EPA is required to consider these conclusions, both under scientific integrity principles and under EPA's express statutory mandate. For example, TSCA Section 26(k) states:

> In carrying out sections [4, 5, and 6], the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

The Health Canada and ECHA conclusions are reasonably available to the Administrator. We note this because EPA applied the linear (non-threshold) approach for evaluating cancer risks

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[13] Health Canada (2021), *Guidelines for Canadian Drinking Water Quality, Guideline Technical Document, 1,4-Dioxane*, at 39-40, available at https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-1-4-dioxane/1-4-dioxane-pdf-eng.pdf.

[14] ECHA (2021), *ECHA Scientific Report for the Evaluation of Limit Values for 1,4-Dioxnae at the Workplace*, Prepared by the European Chemicals Agency, 27 September 2021, available at https://echa.europa.eu/documents/10162/ffebd37d-e38c-0b15-7376-229481dd9619.

[15] *Id*. at 49.

it derived in the 2020 Final Risk Evaluation for 1,4-Dioxane[16] to the 2023 Draft 1,4-DX Supplement and stated that "Because cancer is the primary risk driver for 1,4-dioxane, results presented [in the 2023 Draft 1,4-DX Supplement] are cancer risk estimates."[17] Here, scientific integrity principles and transparency requires EPA to make publicly available its conclusions and scientific rationale for not agreeing with Health Canada and ECHA. This is particularly important when various stakeholders directed EPA to these studies in their public comments.[18]

IV. Effective Date and Policy Amendments

Lines 106-108 of the 2024 Draft SI Policy state: "This policy will be reviewed at least every three years by the Scientific Integrity Committee to ensure its effectiveness and adherence with applicable laws and regulations. Updates to this policy will be led by the SIO [Scientific Integrity Official], recommended by the Scientific Integrity Committee, and approved by the Chief Scientist. Future revisions will be communicated to the Director of OSTP [Office of Science Technology Policy] and posted to EPA's public website no less than 30 days prior to their implementation."

Dow respectfully disagrees with EPA's proposal that once the agency posts its updates to the 2024 Draft SI Policy that it becomes final. This process does not comport with scientific integrity and eliminates external stakeholder engagement with EPA. There can be no dispute that transparency goes beyond simply posting updates to EPA's public website. Instead, EPA must gather input from stakeholders and the public, as it has done for the 2024 Draft SI Policy. Dow recommends that the same process take place as part of future reviews regarding EPA's scientific-integrity practices. As we discussed above and elsewhere in these comments, stakeholders, and the public, are oftentimes aware of potential vulnerabilities and/or lapses (perceived or actual) in EPA's commitment to transparency and scientific integrity, which may otherwise go unnoticed or unacknowledged by individuals overseeing the review of potential updates to the 2024 Draft SI Policy. And it does not comport with EPA's statutory obligations and scientific integrity principles for EPA to exclude stakeholders and the public from a process that critically undergirds all of the agency's actions.

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16 EPA (2020b), *Final Risk Evaluation for 1,4-Dioxane, CASRN: 123-91-1*, EPA-740-R1-8007, at 174, available at https://www.epa.gov/sites/default/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf.

17 EPA (2023b), *supra* note 12, at 21.

18 ACI (2023), *Appendix A, Analysis of EPA's Draft Supplement to the Risk Evaluation of 1,4-Dioxane*, Submitted by the American Cleaning Institute, September 08, 2023, at 5-6, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2016-0723-0120/attachment_3.pdf.

V. Definitions for the Purposes of This Policy

EPA's list of definitions in the 2024 Draft SI Policy require updating to reflect fully the stated purpose and aims of the 2024 Draft SI Policy.

EPA defined "Differing Scientific Opinion (DSO)" on lines 176-179 of the 2024 Draft SI Policy as:

> [A] differing opinion of an EPA scientist who is or was substantively engaged in the science that may inform an EPA decision. It generally contrasts with a prevailing staff opinion included in a scientific product under development.

This definition excludes from having DSO, among others, non-EPA scientists, including scientists from academia, non-governmental organizations, and industry, as well as individuals performing research in emerging modes of science, such as participatory science and community-engaged research. EPA has not offered any reason for excluding non-EPA scientists from the definition of DSO.

Dow does not recommend EPA exclude non-EPA scientists from the definition of DSO. It would run counter to EPA's professed commitment to scientific integrity to exclude external scientists, who are "substantively engaged in the science that may inform an EPA decision." EPA acknowledged as part of the DSO definition on lines 183-184 of the 2024 Draft SI Policy that "[s]cientific differences of opinion . . . are part of the scientific process." It is therefore inexplicable—and troubling—that EPA would as a matter of policy ignore DSOs of non-EPA scientists. The exclusion is concerning because it almost certainly would stifle the scientific process and erode the public's trust in EPA's decision-making.

We therefore propose that DSO should be defined as:

> [A] differing opinion of an individual who is or was substantively engaged in the science that may inform an EPA decision. It generally contrasts with a prevailing staff opinion included in a scientific product under development.

We also note that EPA's proposed definition of DSO conflicts with EPA's definition of "Inclusivity," which EPA defined in part on lines 212-213 of the 2024 Draft SI Policy as:

> [T]he practice of intentionally ensuring full participation of all people and all groups, including marginalized, underserved, and underrepresented contributors, without bias or prejudice.

We mention this because EPA's decision-making should include information provided by "all people and all groups." EPA defined "Scientist" on lines 282-283 of the 2024 Draft SI Policy to mean:

> [A]nyone who collects, generates, uses, or evaluates scientific data, environmental information, analyses, or products.

We note that EPA's definition does not include a requirement that an individual possess a scientific degree or that an individual is an EPA employee. This implies that EPA should be receptive to information provided by all stakeholders. EPA has a long history of soliciting information from the public, including reports of environmental violations,[19] which may inform EPA's science-based decision-making. We therefore encourage EPA to revise its definition of DSO, as we proposed, to ensure alignment with EPA's definition of "Inclusivity."

VI. Policy Provisions -- Protecting Scientific Processes

The problematic definition of "DSO" is also apparent elsewhere in the 2024 Draft SI Policy. EPA's introduction to its provisions for "Protecting Scientific Processes" in the 2024 Draft SI Policy states on lines 339-342 that "Scientific integrity is essential for and fosters honest scientific investigation, open discussion, refined understanding, and a firm commitment to evidence. It also requires consideration of differing scientific opinions (DSOs) and their transparent documentation and other well-established processes that ensure scientific integrity."

We endorse these statements, but as discussed *supra* Section V, the definition of DSO must include individuals external to EPA. It is not unusual for individuals external to EPA to disagree with EPA's scientific assessment on a topic. It is, however, vital to the public trust that EPA address such disagreements in a scientifically grounded and transparent way, regardless of the point of view of the external stakeholder. We also note that the self-imposed limitations EPA included in its definitions will hinder open discussions with non-EPA stakeholders and limit transparency of DSOs to only those formulated from within EPA, thereby undermining processes that are intended to ensure the integrity of EPA's scientific decisions.

Below, we provide comments on specific provisions in the 2024 Draft SI Policy intended to "protect the integrity of the scientific process."

Lines 378-379 of the 2024 Draft SI Policy state that "it is the policy of EPA to:"

> Design and implement scientific products and activities independent of any ***pre-determined desired outcome*** [emphasis added].

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[19] *See, e.g.*, EPA (2023c), *Report Environmental Violations*, Enforcement and Compliance History Online, U.S. Environmental Protection Agency (EPA), available at https://echo.epa.gov/report-environmental-violations

As we discussed previously, EPA announced the availability of the 2023 Draft 1,4-DX Supplement on July 10, 2023.[20] In that same announcement, EPA stated that the public comment deadline was September 8, 2023, and that EPA would convene the TSCA Science Advisory Committee on Chemicals (SACC) to review the 2023 Draft 1,4-DX Supplement on September 12-15, 2023.[21] We mention this because EPA issued a notice on July 26, 2023, that it "has preliminarily determined that 1,4-dioxane, as whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use."[22] The timing for this notice suggests a "pre-determined desired outcome" given that it was issued *prior to* the TSCA SACC's peer-review of the 2023 Draft 1,4-DX Supplement and prior to EPA receiving the TSCA SACC's final peer-review report. EPA may be justified in coming to that conclusion but doing so prior to review by the TSCA SACC suggests that EPA had pre-determined its desired outcome and the TSCA SACC's review was irrelevant or immaterial in EPA's conclusion.

EPA's activities on formaldehyde provide another representative example. On August 9, 2023, the National Academies of Sciences, Engineering, and Medicine (NASEM) released its report titled "Review of EPA's 2022 Draft Formaldehyde Assessment (2023)."[23] NASEM noted in its report, which EPA sponsored, that:[24]

> The committee…was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, nor did its statement of task call for a review of alternative opinions on EPA's formaldehyde assessment.

We highlight this because limiting the scope of the NASEM review by excluding "other interpretations" or "alternative opinions" creates an appearance that EPA had a "pre-determined desired outcome," that is, EPA's statement of task to NASEM creates an appearance that EPA was not interested in possible DSOs nor the transparent documentation of any DSOs that may have conflicted with EPA's interpretation of the science on formaldehyde.

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20 EPA (2023a), *supra* note 11.

21 *Id*. at 43562.

22 EPA (2023d), *1,4-Dioxane; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment*, FEDERAL REGISTER, Vol. 88, 48249-48259, at 48249, available at https://www.govinfo.gov/content/pkg/FR-2023-07-26/pdf/2023-15846.pdf.

23 NASEM (2023), *Review of EPA's 2022 Draft Formaldehyde Assessment*, available at https://nap.nationalacademies.org/catalog/27153/review-of-epas-2022-draft-formaldehyde-assessment.

24 *Id*. at 1.

Lines 400-404 of the 2024 Draft SI Policy state that "To protect the integrity of scientific processes, it is the policy of EPA to:"

> ***Ensure*** the independent validation of scientific and laboratory methods and models and ***that all novel methods or models are appropriately peer reviewed prior to use***. Appropriate instruction on the application of the methods or models and the peer review of these instructions should be developed and ***finalized before the method or model is used in Agency scientific products or decision making*** [emphasis added].

On January 21, 2022, EPA issued a notice on the availability of and public comment period on the "Draft Toxic Substances Control Act (TSCA) Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities [the 2022 Draft Fenceline Approach]."[25] In that same notice, EPA stated that the TSCA SACC would review the 2022 Draft Fenceline Approach on March 15-17, 2022.[26] On May 16, 2022, the TSCA SACC issued its final report on the 2022 Draft Fenceline Approach.[27] The TSCA SACC noted a series of limitations with the 2022 Draft Fenceline Approach, including:[28]

> The accuracy and/or completeness of the data used to develop the screening analysis was not adequately supported in the document, the Committee decided it did not defensibly represent actual exposure of fenceline communities.
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[25] EPA (2022b), *Science Advisory Committee on Chemicals (SACC); Notice of Public Meeting and Request for Comments on Draft Toxic Substances Control Act (TSCA) Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities*, FEDERAL REGISTER, Vol. 87, 3294-3296, available at https://www.govinfo.gov/content/pkg/FR-2022-01-21/pdf/2022-01185.pdf.

[26] *Id*. at 3295.

[27] EPA (2022c), *Transmittal of Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Virtual Meeting "Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0" held on March 15-17, 2022*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0415-0095/content.pdf.

[28] *Id*. at 15-16.

> Overall, the Committee indicated the basis for several model inputs was insufficiently transparent and that, in particular, daily life activities of all communities disproportionately impacted by chemical exposures was missing in this current version.

Despite receiving the TSCA SACC's final report more than a year and half ago, EPA has not finalized the 2022 Draft Fenceline Approach. EPA has, however, continued to employ the 2022 Draft Fenceline Approach in its scientific products and decision-making. For example, EPA stated the following in the 2023 Draft 1,4-DX Supplement:[29]

> EPA evaluated exposures and risks for communities located near release sites (fenceline communities) because they are the members of the general population that are expected to be PESS due to their greater exposure. EPA applied the methodology presented in the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities* [footnote to the 2022 Draft Fenceline Approach omitted] to evaluate risks from industrial air releases to fenceline communities.

We interpret "appropriately peer-reviewed prior to use" to mean that EPA will refine its models in response to the peer-review comments or state the scientific basis for not making refinements as recommended in peer-review comments. EPA has not done either, and it has not indicated whether it will do so. Further, EPA used a number of additional models "that have not been previously peer reviewed and . . . utilized [these models] in . . . [the] 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation [the 2023 Draft 1,4-DX Supplement]."[30] Public commenters expressed concern about this approach, that is, simultaneously peer reviewing non-peer-reviewed models and using those models in EPA's scientific products (*e.g.*, the 2023 Draft 1,4-DX Supplement).[31] We therefore urge EPA to resolve this inconsistency.

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29 EPA (2023b), *supra* note 12, at 37.

30 EPA (2023e), *1,4-Dioxane; Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Meeting and Request for Comment*, FEDERAL REGISTER, Vol. 88, at 43562-43565, at 43564, available at https://www.govinfo.gov/content/pkg/FR-2023-07-10/pdf/2023-14445.pdf.

31 ACI (2023), *Appendix A, Analysis of EPA's Draft Supplement to the Risk Evaluation of 1,4-Dioxane*, Submitted by the American Cleaning Institute, September 08, 2023, at 27, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2016-0723-0120/attachment_3.pdf.

More recently, EPA issued a notice on December 26, 2023, requesting nominations for *ad hoc* expert reviewers to serve on the TSCA SACC for peer-reviewing EPA's draft risk evaluation for formaldehyde.[32] In that same notice, EPA stated that:[33]

> [T]he Agency is not intending to request review on the modeling methods used to estimate formaldehyde exposure in ambient (outdoor) air as the methods used have been previously peer reviewed. SACC already reviewed both the Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities, Version 1.0 [the 2022 Draft Fenceline Approach] and the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation [the 2023 Draft 1,4-DX Supplement]. Furthermore, feedback from these reviews have been incorporated into the draft formaldehyde risk assessment.

As we noted above, EPA has not issued its final 2022 Draft Fenceline Approach, per the TSCA SACC's peer review. It remains unclear at this time whether EPA has substantively addressed the TSCA SACC's feedback, whose 111-page final report on the 2023 Draft 1,4-DX Supplement was submitted on November 16, 2023,[34] some five weeks prior to EPA's notice on December 26, 2023. To hew to its transparency commitment, we respectfully request EPA to disclose the extent of its TSCA SACC review, the criteria for incorporation of feedback, and what EPA incorporated.

Lines 411-414 of the 2024 Draft SI Policy state that "To protect the integrity of scientific processes, it is the policy of EPA to:"

> Ensure that science-based decisions are informed by best available science. As permitted by law and necessary to ensure all regulatory decisions are fully informed and based on the best available science, ***EPA should request scientific data and full documentation*** from

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[32] EPA (2023f), *Formaldehyde; Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Request for Nominations of ad hoc Expert Reviewers*, FEDERAL REGISTER, Vol. 88, 88910-88913, available at https://www.govinfo.gov/content/pkg/FR-2023-12-26/pdf/2023-28430.pdf.

[33] *Id*. at 88912.

[34] EPA (2023g), *Transmittal of Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Public Virtual Meeting "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation" held on September 12-14, 2023*, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0078/content.pdf.

registrants, permittees, coregulators or other sources [emphasis added].

We note that EPA requires "scientific data and full documentation" from the entities that it regulates. We believe, however, that to meet its commitment to transparency and inclusivity, this should be stated as a reciprocal obligation on EPA. In other words, EPA also must provide scientific data and full documentation for its decision-making, to the maximum extent authorized by law. And where certain statutory prohibitions preclude EPA from full transparency, EPA should note that it has withheld certain information pursuant to the mandates of the specifically identified statute(s).

VII. Reviewing Science, Including the Use of Federal Advisory Committees

Lines 466-468 of the 2024 Draft SI Policy state that "It is the policy of EPA to:"

> ***Ensure peer review charge questions address all relevant scientific questions***, ***including those raised in DSOs***, and are ***free from any interference***, especially interference ***that may inappropriately limit the scope of the review*** [emphasis added].

We request clarification on how and when EPA would ensure this process. The 2024 Draft SI Policy does not—but should—contain provisions to ensure the objectivity of EPA personnel, who are from the same office responsible for developing a draft work product, with preparing charge questions that address all relevant scientific questions and/or selecting members on Federal Advisory Committees. This question stems from EPA's statement of task for the NASEM peer review on formaldehyde, which appeared to exclude "other interpretations" or "alternative opinions," thereby limiting the scope of NASEM's review. We agree with EPA's 2024 Draft SI Policy that "[s]cientific differences of opinion . . . are part of the scientific process." Therefore, EPA's exclusion of potential differences of opinion raises concerns about adherence to the agency policy on scientific integrity with regard to, among other activities, EPA's sponsored review and whether non-scientific factors were at play (*e.g.*, EPA already had its preferred result and did not seek a conflicting view). A solution to this perceived conflict is beyond the scope of these comments and will likely require further deliberation within EPA and engagement with external stakeholders.

EPA's peer review activities on the 2023 Draft 1,4-DX supplement provide another representative example. As we discussed *supra* Section III, Health Canada and ECHA completed their respective evaluations on the carcinogenic MOA for 1,4-dioxane in March 2021 and September 2021, respectively.[35,36] Each concluded that 1,4-dioxane is a non-linear (threshold) carcinogen. In contrast, EPA concluded that 1,4-dioxane is a linear (non-threshold) carcinogen and

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[35] Health Canada (2021), *supra* note 13.

[36] ECHA (2021), *supra* note 14.

maintained this conclusion in the 2023 Draft 1,4-DX Supplement. According to EPA, its review of the gray literature up until January 2022 did not reveal additional references that would require re-evaluating its conclusion that 1,4-dioxane is a linear (non-threshold) carcinogen in the 2023 Draft 1,4-DX Supplement.[37]

Additionally, EPA is limiting the scope of the TSCA SACC's peer review on the 2023 Draft 1,4-DX Supplement. EPA's draft charge questions contained the following limitations, which left a relevant scientific question (*i.e.*, carcinogenic MOA for 1,4-DX) unanswered:[38]

> EPA is seeking Science Advisory Committee on Chemicals (SACC) review of the tools and approaches used in the 2023 draft supplement [*i.e.*, the 2023 Draft 1,4-DX Supplement].
>
> . . .
>
> Specifically, ***the Agency is not asking for feedback on the*** physical and chemicals properties, life-cycle information, environmental fate and transport information, ecological hazard and risk characterization, or ***human health hazard characterization for 1,4-dioxane, including points of departure and dose-response analysis*** [emphasis added].
>
> Lines 492-493 of the 2024 Draft SI Policy state that "It is the policy of EPA to:"
>
> ***Ensure EPA decisions are based on or informed by science that has completed independent peer review and has been finalized*** [emphasis added].

EPA's Scientific Integrity Policy should not serve as a mechanism for protecting EPA scientists' scientific decisions and/or EPA's scientific documents from external scrutiny. Rather, the policy must work to ensure the overall scientific integrity of EPA decision-making.

As discussed throughout these comments, EPA consistently has used draft documents/models to inform its decisions under TSCA. For example, EPA used its 2021 "*Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances*" (the

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37 EPA (2023b), *supra* note 12, at 130.

38 EPA (2023h), *Draft Charge Questions, Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals (SACC) Peer Review of 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation*, at 1, available at https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0040/content.pdf.

2021 Draft Systematic Review Protocol) to inform the 2023 Draft 1,4-DX Supplement.[39] EPA stated that it included "clarifications and updates made to the 2021 Draft Systematic Review Protocol to better address assessment needs for [the 2023 Draft 1,4-DX Supplement]."[40] This does not, however, remedy EPA's use of the not yet final 2021 Draft Systematic Review Protocol for its decision-making. As we noted previously, EPA's application of the 2021 Draft Systematic Review Protocol did not identify relevant information in the gray literature on 1,4-dioxane (*i.e.*, Health Canada's and ECHA's evaluations on the carcinogenic MOA of 1,4-dioxane). This raises concerns that because the 2021 Draft Systematic Review Protocol did not capture reasonably available information, it would be susceptible to criticism and potential legal challenges that it is not fit-for-purpose in TSCA risk evaluations.

More recently, EPA stated in its notice on formaldehyde that "[f]or chronic inhalation exposure and the cancer inhalation unit risk (IUR), the Agency intends to defer to the draft 2022 Integrated Risk Information System [IRIS] Toxicological Review of Formaldehyde and associated 2023 review by the NASEM."[41] This is concerning because NASEM noted that:[42]

> The committee . . . was not charged with commenting on other interpretations of scientific information relevant to the hazards and risks of formaldehyde, nor did its statement of task call for a review of alternative opinions on EPA's formaldehyde assessment.

We acknowledge that NASEM peer-reviewed the draft IRIS Toxicological Review of Formaldehyde. The peer-review was, however, limited in scope and did not fulfill the intent of the 2024 Draft SI Policy, that is, to preserve the integrity of scientific processes. We also note that the NASEM review is the subject of ongoing litigation over concerns that the review did not comply with the Federal Advisory Committee Act standards for "independence, transparency, and balance."[43]

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39 EPA (2023b), *supra* note 12, at 38.

40 *Id.*

41 EPA (2023f), *supra* note 32, at 88911.

42 NASEM (2023), *supra* note 23, at 1.

43 American Chemistry Council, Inc., Plaintiff v. National Academy of Sciences; U.S. Environmental Protection Agency; Michael S. Regan, in his official capacity as Administrator of the U.S. Environmental Protection Agency, Defendants, CAS No. 23-cv-2113, In the United States District Court for the District of Columbia, at 1, available at https://www.americanchemistry.com/media/files/acc/industry-groups/formaldehyde/files/nas-litigation-reply-response-on-file.

Beyond the above EPA-specific examples, we note that the 2024 Draft SI Policy does not contain provisions that address proposals from other regulatory agencies, which may have the appearance of inappropriately interfering with scientific activities. For example, the European Chemicals Agency (ECHA) unilaterally changed the testing requirements for specific OECD test guidelines without those changes going through the OECD's normal validation process for revising test guidelines. As an example, ECHA now requires a 10-week pre-breeding period as part of the "Extended One-Generation Reproductive Toxicity Study (EOGRTS)", whereas the underlying guideline requires a two- to four-week pre-breeding period.[44] ECHA also prohibits registrants from using nonlinear toxicokinetic data in dose selection, also in contradiction to OECD TG 443.[45] We mention this because these requirements conflict with the OECD's mutual acceptance of data (MAD) agreement and will ultimately impact the quality of data that EPA receives from regulated entities that perform regulatory testing in the European Union and the United States.

VIII. Other Scientific Review

Lines 553-554 of the 2024 Draft SI Policy state that "It is the policy of EPA to:"

> Ensure that comments received on draft scientific documents during any interagency review are made in writing and made public.

We view this as an important update to the 2024 Draft SI Policy. To comport with EPA's aims for its scientific integrity policy to cover all aspects of the agency's activities, Dow recommends that EPA extend this requirement to RFCs/RFRs, when submitters request that "EPA share its draft response [on RFCs/RFRs] with OMB [the Office of Management and Budget] prior to releasing the response."[46]

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[44] OECD (2018), *Extended Once-Generation Reproductive Toxicity Study*, 443, OECD Guideline for the Testing of Chemicals, Adopted 25 June 2018, at 3, available at https://www.oecd-ilibrary.org/environment/test-no-443-extended-one-generation-reproductive-toxicity-study_9789264185371-en.

[45] *Id*. at 6.

[46] *See, e.g.*, N-Methylpyrrolidone Producers Group, Inc. (2023), *Request for Correction of Information on the Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone*, at 14, available at https://www.epa.gov/system/files/documents/2023-05/RFC%2023001%20N-Methylpyrrolidone.pdf.

IX. Supporting Decision-Making Processes

Line 688 of the 2024 Draft SI Policy states that "It is the policy of EPA to:"

> [***Ensure***] ***that science-based decisions are informed by the best available science*** [emphasis added].

A representative example on this point is EPA's activities on trichloroethylene (TCE) under TSCA Section 6. EPA stated in the 2020 Risk Evaluation for Trichloroethylene (the 2020 TCE RE) that "[A]cute immunosuppression and chronic autoimmunity were ***the best overall non-cancer endpoints for use in Risk Evaluation under TSCA***, based on the best available science and weight of the scientific evidence . . . [emphasis added]."[47]

On January 9, 2023, EPA released a final revision to the risk determination for the 2020 TCE RE. In that announcement, EPA stated it "views the peer reviewed hazard and exposure assessments and associated risk characterization [in the 2020 TCE RE] as ***robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i)*** [emphasis added]."[48] EPA also issued a press release on January 9, 2023, that it will develop "existing chemical exposure limits [ECELs for TCE] based on both the immune endpoint [*i.e.*, the best available science, as described by EPA in the above referenced conclusions] and the CHD endpoint [*i.e.*, fetal cardiac defects; not the best available science according to the above referenced conclusions] in support of risk management."[49] We mention this because EPA proposed the ECEL for the CHD endpoint in its draft risk management rule on TCE.[50] EPA does not explain why it chose to base its ECEL on the CHD endpoint for a regulatory purpose, after it concluded that the endpoints for acute immunosuppression and chronic autoimmunity represented the "best available science and weight of scientific evidence."

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47 EPA (2020c), *Risk Evaluation for Trichloroethylene, CASRN: 79-01-6*, 740R18008, at 280, available at https://www.epa.gov/sites/default/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf.

48 EPA (2023i), *Trichloroethylene (TCE); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability*, FEDERAL REGISTER, Vol. 88, at 1225, available at https://www.govinfo.gov/content/pkg/FR-2023-01-09/pdf/2023-00116.pdf.

49 EPA (2023j), *EPA Finds Trichloroethylene Poses an Unreasonable Risk to Human Health*, Released on January 09, 2023, available at https://www.epa.gov/chemicals-under-tsca/epa-finds-trichloroethylene-poses-unreasonable-risk-human-health.

50 EPA (2023k), *Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA)*, FEDERAL REGISTER, Vol. 88, 74712-74794, at 74731, available at https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23010.pdf.

Ensuring the Free Flow of Scientific Information

Lines 563-565 of the 2024 Draft SI Policy state:

> Scientific research and analysis comprise the foundation of many EPA policy decisions. Therefore, the Agency should vigilantly ensure that scientific research and results are presented openly and with integrity, accuracy, and timeliness ***when developing high-quality science*** [emphasis added].

We note that this implies that EPA may develop scientific products that are not based on high-quality science. We, therefore, suggest revising the bolded text to state "to ensure the development of high-quality science." This proposed change aligns with our recommended changes to EPA's definition of "Transparency," which is captured, in part, in the above statement (*i.e.*, "presented openly") and includes a temporal element (*i.e.*, "timeliness").

Lines 644-645 of the 2024 Draft SI Policy state "It is the policy of EPA to:"

> Ensure that responses to Congressional inquiries, official testimony, and ***other requests*** that include scientific information accurately represent the science [emphasis added].

We encourage EPA to expand this provision to include "other requests" beyond Congressional inquiries, such as RFCs/RFRs filed under the Information Quality Act.

Lines 663-664 of the 2024 Draft SI Policy state "It is the policy of EPA to:"

> Allow EPA scientists to respond to internal or external scientific criticisms of EPA scientific products, findings, or conclusions that they were significantly involved in developing.

We strongly endorse this provision.

Supporting Decision-Making Processes

Lines 696-698 of the 2024 Draft SI Policy state "It is the policy of EPA to:"

> ***Ensure that scientific data, environmental information, and research used to support policy decisions undergo review by qualified experts***, where feasible and appropriate, and consistent with law [emphasis added].

We agree with this provision and also encourage EPA to include a provision in the 2024 Draft SI Policy that ensures "that scientific data, environmental information, and research used to support policy decisions are ***developed by qualified EPA experts***." We suggest this because EPA is in the process of hiring new employees, who may or may not possess the requisite expertise to oversee the development of scientific-support documents for EPA's decision-making under TSCA. It is our understanding that EPA's contractors develop EPA's draft TSCA risk evaluations. It is, however, an inherent government function for EPA employees to ensure that contractor-written drafts meet the scientific standards under TSCA Section 26. We recognize that new EPA employees often learn on the job; a senior staff reviewer or manager suggesting changes to the employee's work product is not presumptively interference in the employee's scientific view. That being said, such suggestions must fall within the 2024 Draft SI Policy when issued in final.

Lines 704-705 of the 2024 Draft SI Policy state "It is the policy of EPA to:"

> Use ***transparent criteria*** in instances where a statute gives the Agency discretion in weighing scientific information in its actions and make the criteria publicly available [emphasis added].

TSCA Section 26 requires EPA to use the best available science and weight of scientific evidence in its decision-making. TSCA does not define these terms, which gives EPA discretion to interpret them. EPA codified definitions for these terms under 40 C.F.R. Section 702.33.[51] EPA has, however, eliminated these definitions, as part of its proposed amendments to the "*Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*."[52] Dow encourages EPA to maintain these definitions.

x. Ensuring Accountability

Lines 771-773 of the 2024 Draft SI Policy state "It is the policy of EPA"

> To the extent possible, and as allowed by law, keep confidential the identities of submitters, subjects, witnesses, and experts interviewed by the Scientific Integrity Program as part of an initial assessment, fact-finding, or investigation.

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[51] 40 C.F.R. § 702.33 Definitions, available at https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-702.

[52] EPA (2023*l*), *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, FEDERAL REGISTER, Vol. 88, 74292-74326, at 74295, available at https://www.govinfo.gov/content/pkg/FR-2023-10-30/pdf/2023-23428.pdf.

We agree with this provision. We recommend that EPA strengthen the provision further by aligning the requirements with the Public Health Service (PHS) Policies on Research Misconduct, which include:[53]

> (d)(2) Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.
>
> (d)(3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.
>
> (d)(13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

We also note that the 2024 Draft SI Policy is silent on disciplinary actions for ensuring accountability. For example, the 2024 Draft SI Policy does not cite to EPA's "Guidance on Corrective Discipline," which discusses EPA's disciplinary system for offenses and penalties for general schedule employees (*i.e.*, EPA Order 3120.1) and members of the senior executive service (*i.e.*, EPA Order 3120.2). Under paragraph 45 "Scientific misconduct" of EPA Order 3120.1, the first offense for "Ordering, advising, or suggesting a subordinate engage in scientific misconduct" is a "30-day suspension to removal." Under paragraph 5, "Making false, malicious or unfounded statements against coworkers, supervisors, subordinates or Government officials which tend to damage the reputation or undermine the authority of those concerned" of EPA Order 3120.1, the first offense is "Written reprimand to removal."

We strongly urge EPA to update the 2024 Draft SI Policy to include reference to the disciplinary measures enumerated under EPA Orders 3120.1 and 3120.2. These measures will ensure the protection of individuals from reprisal who in good faith make allegations of lapses/losses of scientific integrity, as well as ensuring accountability for individuals who are found to have made bad faith allegations of lapses/losses of scientific integrity.

In summary, Dow strongly supports EPA's efforts to update its SI Policy and appreciates the opportunity to submit comments on this vital effort. Dow respectfully suggests that revisions, clarifications, and additional measurements to the 2024 Draft SI Policy must be implemented to ensure scientific integrity and transparency. As discussed throughout these comments, Dow

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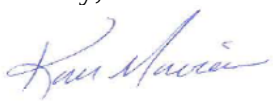
[53] 40 C.F.R. § 50.103 Assurance-Responsibilities of PHS awardee and applicant institutions, at 169-170, available at https://www.govinfo.gov/content/pkg/CFR-2000-title42-vol1/pdf/CFR-2000-title42-vol1-part50.pdf.

believes that the 2024 Draft SI Policy must be strengthened by providing clearer definitions (*e.g.*, transparency) and expanding the coverage of DSOs to include individuals external to EPA. We also believe that the 2024 Draft SI Policy would better align with EPA's stated commitment to transparency if EPA provides definitive procedures for identifying compliance/non-compliance with the 2024 Draft SI Policy provisions. As written, the 2024 Draft SI Policy contains 104 instances of "ensure" or "ensuring", yet the 2024 Draft SI Policy does not address a mechanism by which EPA will ensure compliance and accountability for those who do not comply. We provided a recommendation for EPA to include reference to its Guidance on Corrective Discipline, but this recommendation only provides direction to EPA once a violation has occurred. It does not, however, address how EPA will enhance and promote a culture of scientific integrity in which scientists are encouraged to exchange differing views in a respectful and scientifically sound way, which is ultimately required to ensure compliance with the 2024 Draft SI Policy.

With that said, Dow believes that the 2024 Draft SI Policy is a critical step in strengthening EPA's scientific integrity, protecting its employees, and shoring up public trust. Using the best available science, providing transparency, and ensuring that good faith DSOs are resolved through scientific review rather than disciplinary actions are all vital goals. The examples discussed above are provided as examples of how EPA actions, when such actions do not meet the provisions as stated in the 2024 Draft SI Policy, undermine EPA's scientific integrity, even if the actions are, ultimately, found to be scientifically supportable.

Thank you for your consideration of these comments.

Sincerely,



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