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Comments on U.S. EPA's Draft Toxic Substances Control Act (TSCA) Risk Evaluation of Formaldehyde and Peer Review by the Science Advisory Committee on Chemicals (SACC); Docket ID: EPA–HQ–OPPT–2023–0613; 88 Federal Register (FR) 18933 (March 15, 2024)

Assistant Administrator Freedhoff,

Hexion Inc. (Hexion) appreciates the opportunity to comment on U.S. EPA's draft TSCA risk evaluation of formaldehyde under TSCA as part of the Agency's jointly administered public comment and peer review process involving the SACC. Based in Columbus, Ohio, Hexion is a leading producer of formaldehyde solutions and derivatives, formaldehyde-based resins, and other performance materials for a wide variety of applications in the wood products, agriculture, transportation, construction, and energy sectors.[1]

U.S. EPA's draft risk evaluation, the underlying assessments upon which it is based, as well as the rushed, haphazard peer review and public comment process currently being undertaken are inconsistent with requirements under TSCA, the Federal Advisory Committee Act (FACA), other statutes, EPA regulations, and EPA or White House policies or guidance related to peer review, scientific integrity, and information quality. This truncated, limited process appears to be driven more by deadlines in a proposed consent decree for which EPA and U.S. Department of Justice are still seeking comment[2] than a commitment to regulation based on the best available science. This is not an academic exercise; EPA's draft risk evaluation, including its "unreasonable risk" determinations and draft occupational exposure values have been excluded from the scope of the peer review, yet have direct and significant economic impacts for Hexion, our workers and our customers, and essential uses of formaldehyde for public health and safety, national security, economic growth, and critical infrastructure.

I. EPA's Sequencing and Combination of Public Comment and Peer Review is Inappropriate

As a preliminary matter, we object to the highly unusual and inappropriate co-mingling of public comment and peer review activities, particularly since U.S. EPA has chosen to not grant more than a dozen reasonable requests from Members of Congress, other federal agencies, trade associations, and

[1] Hexion participates in the American Chemistry Council (ACC), National Association of Manufacturers, Composite Panel Association, and other trade groups, and we share concerns raised in their respective comments on this draft risk evaluation. Hexion supported 2016 amendment to TSCA and has been actively engaged in the science of formaldehyde for decades, including participating in previous EPA-initiated peer review activities with the National Academies of Sciences, Engineering, and Medicine (NASEM; 2011 and 2023) and Human Studies Review Board (2023) as well as commenting on other draft Agency assessments of formaldehyde under the Integrated Risk Information System (IRIS) in 2010 and 2022.

[2] 89 FR 32424. The proposed consent decree requires that "EPA shall transmit to the Office of Federal Register notices of availability of final risk evaluations for… formaldehyde… by no later than December 31, 2024" (https://www.regulations.gov/document/EPA-HQ-OGC-2024-0192-0003). Comments are due May 28, 2024: https://www.federalregister.gov/documents/2024/04/26/2024-08936/proposed-consent-decrees-toxic-substances-control-act-suit.

companies to extend the public comment period[3] and/or hold in-person peer review meeting(s) consistent with recent Agency practice,[4] The failure to keep distinct EPA's public comment process and the SACC's peer review process undermines the necessary rigor and independence of both processes to ensure a fair and balanced review as intended by Congress.

EPA is maintaining a single docket for both functions, making it unclear whether comments should be directed to EPA or the supposedly independent SACC. Further, some comments filed several days in advance of SACC peer review meetings have not been made available on Regulations.gov. EPA's *Peer Review Handbook* highlights the value of a clear separation between public comments and the peer review panel's comment process as well as differences in docketing requirements for peer review and regulatory activities.[5] The *Handbook* also highlights that EPA's adherence to a public comment deadline that precedes a peer review meeting by a week or more is directly contrary to Agency policy:

> For this reason, a completed peer review is desirable before issuing any regulatory proposal for public comment. If that is not possible logistically because of court or statutory deadlines, or other appropriate reasons, every effort should be made to complete the peer review before the close of the comment period. Because peer review comments on such work products could be of sufficient magnitude to warrant a revision to the proposed action or rule, every effort should be made to complete the peer review prior to the proposal stage.[6]

It is highly inappropriate to limit public comments to an arbitrary deadline prior to the substantive peer review process, especially for a draft risk evaluation that makes threshold "unreasonable risk" determinations with enormous regulatory significance. Hexion strongly shares the concerns regarding this peer review process, including violations of TSCA, FACA, and other statutory requirements, outlined by ACC's Formaldehyde Panel on March 8, 2024.[7]

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[3] https://downloads.regulations.gov/EPA-HQ-OPPT-2023-0613-0128/attachment_6.pdf; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0091; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0080; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0085; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0082; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0095; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0083; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0081; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0084; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0097; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0098; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0137.

[4] For example, the American Chemistry Council (ACC) Formaldehyde Panel's March 25, 2024 comments identified at least six in-person meetings of EPA advisory committees in recent months as well as numerous examples of public comment periods that extend at least two weeks beyond a public meeting; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0081.

[5] https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf; "Accepting public comments before peer review has two benefits: (1) the Agency can consider public comments on the scope of the charge before the selection of peer reviewers so that appropriate expertise is included to address all charge questions; and (2) the Agency's public comment process is kept distinct from the peer review panel's comment process. When employing a public comment process prior to the peer review, EPA offices should provide peer reviewers with access to public comments that address significant scientific or technical issues whenever practical." (pg. 86); "Public comment frequently is open to all issues, and may be solicited for policy purposes or as part of the regulatory process, whereas the peer review process focuses on scientific and technical issues specified in the peer review charge." (pg. 24).

[6] https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 28-29).

[7] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/march-8-2024-panel-letter-to-epa-on-the-sacc-peer-review-process.

II. EPA Disregards Formaldehyde's Critical Use as a Building Block Chemistry for all of Society, Resulting in Arbitrary and Capricious Approach to Risk Management Including Use Bans and Unachievable Workplace Standards[8]

Hexion is a leading global producer of formaldehyde solutions and derivatives, formaldehyde-based adhesives, and performance materials, serving customers in more than 60 countries. Hexion has more than 1,200 associates and operates 16 U.S. manufacturing sites across nine states. Hexion is based in Columbus, Ohio and has operated for more than a century. It is among the largest producers of formaldehyde-based chemistries and wood adhesives in North America. As discussed in greater detail below, Hexion operates robust programs related to environmental, health, and safety,[9] product stewardship[10] (including dedicated resources beyond safety data sheets and safe handling guidelines to "provide the general public with a high-level overview of formaldehyde, including its uses, properties and health and environmental considerations"[11]), Responsible Care®,[12] and sustainability.[13]

Hexion and other formaldehyde producers help to support nearly one million jobs and over $500 billion in sales, payroll, and other U.S. economic activity each year.[14] EPA's preliminary "unreasonable risk" determinations, while excluded from the purview of this peer review process, apply to nearly all uses of formaldehyde and formaldehyde-based products evaluated by EPA, including all manufacturing, import, processing (including as a reactant, into articles, or in formulations, mixtures, or reaction products), repackaging, recycling, distribution in commerce, disposal, and industrial uses and nearly all commercial and consumer uses.[15] TSCA provides for potential exemptions for certain uses and there is a suite of approaches U.S. EPA can take to address unreasonable risks.[16] However, the current Agency approach to risk management involves granting

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[8] Hexion acknowledges that TSCA limits EPA to evaluating "unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors." However, many of these risk-based trade-offs, including the negative impacts to health, safety, and the environment that emanate from "unreasonable risk" determinations or subsequent risk management activities for uses of formaldehyde, should be incorporated into both the risk evaluation and peer review process, and constitutes available information for consideration, assessment, and integration (as required under Sections 6 and 26 of TSCA). For the first time, U.S. EPA has incorporated draft occupational exposure values, which are not contemplated under TSCA as part of the risk evaluation process, into this draft evaluation of formaldehyde. In addition, Congress directed under Section 26(o) of TSCA that the SACC was created to "provide independent advice and expert consultation… with respect to the scientific and technical aspects of issues relating to implementation" of TSCA. If U.S. EPA's "unreasonable risk" determinations or draft occupational exposure values result in actions that increase risk of injury to health or the environment, this factor is unquestionably relevant and likely constitutes reasonably available information necessary to integrate in the risk evaluation or risk management process. This is similar to the U.S. Supreme Court's decision in *Whitman v. American Trucking Associations*, where the Court recognized in the context of setting National Ambient Air Quality Standards (where consideration of cost is prohibited), that "advice concerning certain aspects of 'adverse public health ... effects' from various attainment strategies is unquestionably pertinent." See *Whitman v. American Trucking Assns.*, 531 U.S. 470 n.2 (2001) and U.S. EPA's *Back-to-Basics Process for Reviewing National Ambient Air Quality Standards*: https://www.epa.gov/sites/default/files/2018-05/documents/image2018-05-09-173219.pdf.

[9] https://www.hexion.com/en-US/company/responsibility/.

[10] https://www.hexion.com/en-US/company/responsibility/sustainability/market-innovation/product-stewardship.

[11] https://www.hexion.com/docs/default-source/responsibility/upwd_hex-31211_13271_hxn-163_pss-formaldehyde_update2.pdf?sfvrsn=91323083_8.

[12] https://www.hexion.com/docs/default-source/press-releases/ten-hexion-sites-recognized-with-american-chemistry-council-responsible-care-awards-2024.pdf?sfvrsn=d3615729_2.

[13] https://www.hexion.com/en-us/company/responsibility/sustainability.

[14] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-producers-boost-us-economy.

[15] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-unreasonable-risk-determination-public-release-hero-march-2024.pdf.

[16] See examples: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-existing-chemicals-under-tsca#process.

rare, narrow, time-limited exemptions and addressing unreasonable risks primarily through bans or potentially unachievable workplace exposure standards.

EPA's "ban all uses" approach directly contradicts TSCA, which specifically directs EPA to "consider… whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute…" (Section 6(c)(2)). EPA is to evaluate uses for whether risk management would "significantly disrupt the national economy, national security, or critical infrastructure" as well as whether they are "critical or essential use[s] for which no technically and economically feasible safer alternative is available" or the use "provides a substantial benefit to health, the environment, or public safety" (Section 6(g)).

Formaldehyde's versatile properties make it essential to a wide variety of end-uses, and formaldehyde and formaldehyde-based resins lack viable cost-effective or technically feasible alternatives. In most instances, because of formaldehyde's unique physical and chemical properties, no compounds can replace it as a raw material without reducing critical performance characteristics or significantly increasing costs. In many cases, substitutes simply do not exist. For example, earlier this year, the Composite Panel Association released cradle-to-grave lifecycle assessments of North American particleboard[17] and medium density fiberboard (MDF),[18] critical components in the building, construction, and housing industries. In each case, 100 percent of resins used for particleboard and MDF production were amino-phenolic resins (including urea formaldehyde, melamine urea formaldehyde, and phenol formaldehyde resins) or polymeric methylene diphenyl di-isocyanate resins, all of which depend on the chemistry of formaldehyde manufacturing or import as a critical feedstock.

U.S. EPA has failed to consider, assess, and integrate available information on the significant health, environmental, public safety, economic, security, and infrastructure benefits of formaldehyde usage. These omissions are part of an inconsistent, arbitrary, and capricious approach, with unclear criteria, for how EPA decides which uses and risks it evaluates and how it determines "unreasonable risk" for these uses. ACC has catalogued the critical and essential sectors which rely on formaldehyde, including housing, building and construction, food and agriculture, aerospace, science and preservation, semiconductors, automotive, national security, and medicine and medical technologies.[19]

EPA's failure to consider TSCA-required tradeoffs in "unreasonable risk" determinations is highlighted in Congressional correspondence. Among numerous, often bipartisan letters to the Agency documenting legislative concerns about the health, safety, agriculture, and defense implications of EPA's TSCA and IRIS activities on formaldehyde since 2022,[20] Congressman Bruce Westerman of Arkansas, Chairman of the U.S. House Committee on Natural Resources, directed an

[17] https://www.compositepanel.org/wp-content/uploads/PB-Cradle-to-grave-LCA-Final.pdf (pg. 27).
[18] https://www.compositepanel.org/wp-content/uploads/MDF-Cradle-to-grave-LCA-Final.pdf (pg. 28).
[19] https://www.americanchemistry.com/industry-groups/formaldehyde/benefits-applications; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-building-construction-applications; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-contributing-to-a-sustainable-future-for-wood-products; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-is-essential-to-safety-and-economic-stability-in-food-agriculture-sectors; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-automotive-applications; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-national-security-applications; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-semiconductors; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-applications-in-science-and-preservation; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-aerospace-applications; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-medicine-medical-applications.
[20] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0128.

April 2024 letter to U.S. EPA and other agencies.[21] He argued that EPA's formaldehyde activities could violate interagency consultation requirements under the Endangered Species Act by jeopardizing endangered or threatened species or critical habitat due to formaldehyde's important role in "developing more efficient wood products, preventing unnecessary deforestation, and protecting forest-dwelling animals and birds" as well as "protecting salmon and steelhead populations, which is critical to hatcheries and fisheries across the United States, by controlling for disease and parasites." Manufacturing, importing, and processing formaldehyde allows for: wood products that use more than 95 percent of a tree;[22] FDA-approved therapeutants to combat fungi and ectoparasites for aquaculture facilities raising endangered or threatened species;[23] housing affordability;[24] sterilants and disinfectants to inactivate African Swine Fever;[25] and slow-release fertilizers that increase yields, reduce runoff, and protect aquatic organisms.[26]

EPA's draft risk evaluation and draft charge questions omit any reference to these important provisions of TSCA that deal with critical uses that improve health, safety and environment and potential trade-offs, including Section 6(c)(2) and Section 6(g), as well as tools to exempt "de minimis" exposures identified in EPA's risk evaluation framework rules and recent risk management rules.[27] This is a missed opportunity for the Agency to seek comments on these key uses early in the regulatory process and receive expert advice from the SACC on these issues. Given the unique nature of formaldehyde and its ubiquity across a suite of important uses, EPA should consider and seek public and peer review comment on:

- How to consistently evaluate whether economically or technically feasible alternatives exist for a use;
- Health, safety, security, economic, and infrastructure tradeoffs associated with uses subject to "unreasonable risk" determinations, including whether non-cost-based or health-health tradeoffs justify a "reasonable risk" determination;
- The extension of any use exemptions upstream (including manufacturing, import, and processing) to enable the continuation of that use;
- The extension of formaldehyde-based exemptions that have been deployed by EPA or other federal agencies. For example, EPA should consider:
    - Exempting amino-phenolic resins classified as non-Hazardous Air Pollutant (HAP) resins under EPA's 2023 National Emissions Standards for Hazardous Air Pollutants for the Plywood and Composite Wood Products Sector rulemaking (including for resins containing less than 0.1% percent formaldehyde);[28]
    - Exempting products, uses, or volumes not required to be reported under Toxics Release

[21] https://westerman.house.gov/media-center/press-releases/icymi-westerman-expresses-concerns-epa-iris-program-risk-assessment.
[22] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-contributing-to-a-sustainable-future-for-wood-products; https://www.compositepanel.org/wp-content/uploads/White-paper-on-WCPs-and-alternatives-final.pdf; https://www.iands.design/sustainability/article/10171691/composite-wood-panels-the-big-green-picture.
[23] https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0126.
[24] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-building-construction-applications.
[25] https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0058.
[26] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-is-essential-to-safety-and-economic-stability-in-food-agriculture-sectors.
[27] For example, see 82 FR 33729 ("Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate").
[28] https://www.federalregister.gov/d/2023-10067/p-260; https://www.regulations.gov/document/EPA-HQ-OAR-2016-0243-0420; https://www.regulations.gov/document/EPA-HQ-OAR-2016-0243-0409.

Inventory de minimis reporting thresholds;[29]

- Exempting products with formaldehyde levels below which are required to be included in safety data sheets consistent with OSHA's Hazard Communication Standard;[30]
- Exempting products and uses not affect by the Consumer Product Safety Commission's strong sensitizer interpretation for the Federal Hazardous Substance Act.[31]

III. U.S. EPA's Draft Risk Evaluation and Peer Review Process Do Not Make Decisions Based on the Weight of Scientific Evidence

Section 26(i) of TSCA requires that EPA "make decisions under" TSCA "based on the weight of the scientific evidence"[32] and Section 6(b)(3)(F) directs that, in conducting a risk evaluation, "the Administrator shall… describe the weight of the scientific evidence for the identified hazard and exposure."[33] U.S. EPA established a regulatory definition of "weight of scientific evidence" that means "a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."[34] Congress endorsed a similar definition as part of passage of 2016 TSCA amendments.[35]

EPA's draft formaldehyde risk evaluation and underlying draft IRIS assessment are both not based on the weight of scientific evidence as required by TSCA, resulting in arbitrary and capricious Agency actions. As ACC has catalogued on numerous occasions since 2022, the draft IRIS assessment of formaldehyde is the only IRIS assessment undergoing development for which no pre-established systematic review protocol was released, including for public comment.[36] EPA's February 2024 IRIS Program Outlook makes clear that the formaldehyde assessment is the only assessment out of 17 under development for which the Agency deviated from this practice.[37] In its review of the 2022 draft IRIS assessment of formaldehyde, a committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) was highly critical of the absence of a pre-established systematic review protocol in 2023, noting "EPA did not develop a set of specific protocols for the 2022 Draft Assessment in a fashion that would be consistent with the general state of practice that evolved during the prolonged period when the assessment was being developed…. The committee concluded that prepublished protocols are essential for future IRIS assessments to ensure transparency for systematic reviews in risk assessment."[38] These issues continue for the draft risk evaluation; As noted below, EPA's formaldehyde evaluation fails to consider, assess, or integrate decision-critical studies and information.

In addition, U.S. EPA has failed to integrate past peer review advice on its approach to systematic review. In May 2018, the Agency released *Application of Systematic Review in TSCA Risk*

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[29] https://www.epa.gov/system/files/documents/2023-01/Toxics%20Release%20Inventory%20Basis%20of%20OSHA%20Carcinogens.pdf.
[30] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200.
[31] https://www.ecfr.gov/current/title-16/chapter-II/subchapter-C/part-1500/section-1500.13.
[32] 15 U.S.C. 2625(i).
[33] 15 U.S.C. 2605(b)(3)(F).
[34] 40 CFR § 702.33.
[35] https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf (pg. 33).
[36] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/2023-inconsistencies-between-fa-assessment-and-iris-handbook-033123; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-comments-on-the-charge-questions-and-committee-task-for-peer-review-of-draft-formaldehyde-assessment; https://www.regulations.gov/comment/EPA-HQ-ORD-2010-0396-0103; https://www.americanchemistry.com/content/download/12170/file/Letter-to-NASEM-on-Procedural-Issues-and-Attachment.pdf.
[37] https://www.epa.gov/system/files/documents/2024-02/iris_program_outlook_feb2024.pdf.
[38] https://nap.nationalacademies.org/login.php?record_id=27153 (pg. 5).

Evaluations.[39] Prior to completing the first ten risk evaluation under TSCA, U.S. EPA asked that NASEM review this document. In February 2021, the NASEM committee released its study report and concluded that EPA's 2018 systematic review document did not meet the criteria of "comprehensive, workable, objective, and transparent" and that "[t]he OPPT approach to systematic review does not adequately meet the state-of-practice."[40] U.S. EPA subsequently stated publicly that it "is not using, and will not again use" the 2018 systematic review document.[41] However, the Agency used the 2018 document in its August 2020 *Final Scope of the Risk Evaluation for Formaldehyde*.[42] U.S. EPA did not, however, revise or replace the 2020 Final Scope, even after it publicly acknowledged that its use of the 2018 systematic review document did not have pre-established systematic review protocol as required under TSCA. U.S. EPA appears to have also failed to integrate direction from its updated 2021 systematic review protocol for certain streams of evidence. For example, the Agency describes a "fully elucidated mode of action… or adverse outcome pathway" as "highly preferred" in weighing mechanistic evidence, approaches eschewed in the underlying IRIS assessment.[43]

U.S. EPA's draft charge fails to seek appropriate SACC feedback on these issues. They do not reference EPA's definition of "weight of scientific evidence," "systematic review," or any associated "protocol." U.S. EPA has missed the opportunity to seek TSCA-relevant comments on the draft risk evaluation or underlying draft IRIS assessment approach to weight of scientific evidence and scientific quality and appropriateness of their protocols.

IV. U.S. EPA's Peer Review Process and Panel Formation Process Violate TSCA and FACA Requirements, as well as Agency Scientific Integrity and Public Involvement Policies

Section 26(o) of TSCA requires that EPA establish the SACC, stating that "[t]he purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of" TSCA.[44] Congress further specified: "The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry…" This SACC review process is also governed by provisions of FACA which requires the membership of an advisory committee "be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee."[45]

Hexion's position is that U.S. EPA's peer review process for this draft risk evaluation runs afoul of statutory and Agency requirements for several reasons.

First, U.S. EPA's draft charge questions exclude critical questions, including "with respect to the scientific and technical aspects of issues relating to the implementation" of TSCA, from the peer review process. This includes the absence of any inquiries regarding the following: the scientific underpinnings for the Agency's "unreasonable risk" determinations and draft occupational exposure values, previously referred to as "existing chemical exposure limits (neither of which are mentioned in the draft charge); the draft IRIS assessment which provides the basis for nearly all U.S. EPA human health conclusions; TSCA scientific standards related to "best available science" and "weight of scientific evidence"; and modeling methods used to estimate formaldehyde in ambient air. The SACC must be tasked by EPA to analyze these critical scientific issues that are at the heart of the risk

[39] https://www.epa.gov/sites/default/files/2018-06/documents/final_application_of_sr_in_tsca_05-31-18.pdf.
[40] https://nap.nationalacademies.org/resource/25952/TSCA%204-pager%20final.pdf.
[41] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/draft-protocol-systematic-review-tsca-risk-evaluations.
[42] https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf (pg. 61).
[43] https://www.epa.gov/system/files/documents/2021-12/draft-systematic-review-protocol-supporting-tsca-risk-evaluations-for-chemical-substances_0.pdf (pg. 589).
[44] 15 U.S.C. 2625(o).
[45] 5 U.S.C. 1004(b)(2)

assessment and determination

Second, this narrow, constrained draft charge is at odds with related Agency policies. U.S. EPA's 2024 Scientific Integrity Policy directs that EPA and its advisory committees "[d]esign and implement scientific products and activities independent of any pre-determined desired outcome" and "[e]nsure peer review charge questions address all relevant scientific questions, including those raised in [differing scientific opinions], and are free from any interference, especially interference that may inappropriately limit the scope of the review."[46] U.S. EPA's *Initiatives to Enhance Public Involvement in Advisory Activities* also requires that "advisory committees will not accept a charge from the agency that unduly narrows the scope of an advisory activity."[47] Concerns raised by peer reviewers at the May 7 meeting regarding the scope of the review are further supported by EPA's *Peer Review Handbook* recommendations on charge questions.[48] EPA has violated its own policies by issuing such narrow charge questions to SACC.

Third, despite the nomination of qualified experts, U.S. EPA failed to select individuals with expertise in key areas, including information quality, risk analysis, physiologically-based pharmacokinetics, biologically-based dose-response modeling, quantitative adverse outcome pathways, pathology, human sensory perception of irritation, occupational epidemiology, exposure reconstruction, industrial hygiene, occupational exposure assessment, consumer product exposures, new approach methodology, ambient air quality, indoor air quality, interpretation of environmental release data, and emissions inventories.[49] Several of these disciplines were specifically mentioned in U.S. EPA's December 26, 2023 solicitation of ad hoc peer reviewers.[50] EPA should act now to appoint SACC members with this needed additional expertise.

Fourth, the SACC and group of ad hoc reviewers lack diverse, balanced, representative viewpoints, and U.S. EPA's process has resulted in no such representation of required perspectives. In Section 26(o) of TSCA, Congress clearly intended EPA to appoint a diverse group of expert representatives, which does not exist here. As the May 7 preparatory peer review meeting clarified, all reviewers have been on-boarded as "Special Government Employees" or SGEs. U.S. EPA's *Essential Guide for Members Serving on Federal Advisory Committees at the EPA* (along with numerous other Agency policies and guidance documents) makes clear that "[r]epresentative members are selected to represent the point of view of a group… such as industry, labor, consumers, academia, or any other recognizable group of persons having an interest in matters before the committee" whereas SGE "members are appointed to provide the Agency with their own best independent judgment based on their individual expertise. As a SGE member, you are speaking for yourself as an expert in your field."[51] Again, EPA should act now to appoint SACC members with these needed additional viewpoints.

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[46] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 11, 13).
[47] https://sab.epa.gov/ords/sab/r/sab_apex/sab/publicinvolvementinaa.
[48] https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 83, B-15,B-16, H-1); See also: https://www.americanchemistry.com/industry-groups/formaldehyde/resources/march-8-2024-panel-letter-to-epa-on-the-sacc-peer-review-process; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-comments-on-the-charge-questions-and-committee-task-for-peer-review-of-draft-formaldehyde-assessment.
[49] https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0003.
[50] https://www.federalregister.gov/d/2023-28430/p-27 ("Individuals nominated for this SACC peer review, should have expertise in one or more of the following areas: Indoor air quality; ambient air quality; exposure science with experience in air modeling and monitoring (for review of air exposure analysis); risk assessment (experience in chemicals and environmental fate of chemicals with background in risk assessment, aggregate exposure and risk assessment, industrial hygiene, ecological/terrestrial exposure); inhalation toxicology; dermal sensitization; statistics (experience in air quality data for review of interpretation of available monitoring data, experience in interpretation of environmental release data (e.g., Toxic Release Inventory (TRI) and National Emissions Inventory (NEI))); epidemiology; and toxicology with expertise in interpreting gastrointestinal toxicity data associated with oral chemical exposure").
[51] https://www.epa.gov/faca/essential-guide-members-serving-federal-advisory-committees-epa.

Fifth, even if EPA views these SGE reviewers as "representatives" of key groups identified in TSCA, this group is not "fairly balanced in terms of the points of view represented." The peer review body has a dearth of individuals with backgrounds in government, animal protection, and industry. As noted in March 14, 2024 comments from ACC's Formaldehyde Panel, U.S. EPA has selected peer reviewers who lack independence and possess perspective that cannot be balanced while creating the appearance of a lack of impartiality.[52]

Finally, the operation of the SACC's May 7 meeting raises concerns regarding the opportunity for independent advice as well as a potential chilling effect on public participation. U.S. EPA has recognized in its risk evaluation "framework" rulemaking that public participation in an open peer review process is critical to achieving TSCA scientific standards, noting "[o]ne important element in ensuring that decisions are consistent with the best available science and based on the weight of scientific evidence is to have an open, transparent and independent peer review process along with opportunities for public comment."[53] ACC's Formaldehyde Panel has also documented numerous ways in which public participation is critical to achieving scientific and legal standards for federal advisory committees through comments and letters over the last two years.[54]

EPA's *Peer Review Handbook* encourages engagement of EPA advisory committees with the public, noting that "members of the public can submit relevant comments pertaining to the group providing advice, the EPA's charge questions, EPA review of background documents, and draft advisory reports prepared by a [federal advisory committee] or its panels."[55] The May 7 meeting included public comments at the very end of the meeting, with interruption of public commenters who were raising legitimate concerns regarding the scope of peer review. We think it is necessary for the U.S. EPA and the SACC to review the Agency's *Peer Review Handbook* as well as *Initiatives to Enhance Public Involvement in Advisory Activities.*[56]

EPA has received numerous comments as part of the IRIS Assessment process that fails to utilize best available science or consider the weight of evidence. Despite this criticism, EPA has not yet requested any peer review body to review whether EPA has used best available science or considered the weight of evidence during any part of its review and assessment of the TSCA review of formaldehyde. It is incumbent that EPA task the SACC, and the SACC consider for the first time, whether the risk assessment, and the science upon which is based, used the best available science or considered the weight of scientific evidence. An open, transparent peer review process with appropriate charge questions relevant to TSCA would help remedy this longstanding issue.

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[52] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0074.
[53] 88 FR 73207.
[54] https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0130; https://www.americanchemistry.com/content/download/14023/file/ACC-Formaldehyde-Panel-Letter-to-HSRB.pdf; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-letter-to-samet; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/2023-letter-to-nasem-post-jan-30th-public-meeting; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/letter-to-nasem-post-oct-12th-public-meeting; https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2023/acc-challenges-lack-of-independence-transparency-for-peer-review-of-epa-s-draft-formaldehyde-iris-assessment.
[55] https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf (pg. 86, 94).
[56] https://sab.epa.gov/ords/sab/r/sab_apex/sab/publicinvolvementinaa ("Following public comments at advisory committee meetings, chairs will ask committee or panel members if they have clarifying or follow-up questions for public presenters"; "Chairs will offer a second brief opportunity for additional clarifying remarks from agency representatives or members of the public later in the meeting, as the committee or panel deliberates on responses to the charge questions"; "Advisory committee reports will acknowledge scientific information from the public that was helpful in forming the committee's conclusions and recommendations"; "…public comments are welcome on all technical materials prepared for or by an advisory committee, including the charge to the committee…").

V. U.S. EPA's Draft Risk Evaluation Fails to Consider, Assess, and Integrate Relevant Information

TSCA contains several important requirements for considering, assessing, and integrating information into risk evaluations. Section 6(b)(3)(F) states: "In conducting a risk evaluation… the Administrator shall… integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator."[57]

Section 26(k) directs the Administrator to "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"[58] and Section 26(j) requires EPA to make certain information available to the public, including "a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies."[59] Finally, Section 9(b) directs the EPA Administrator to "consider, based on information reasonably available to the Administrator, all relevant aspects of the risk..."[60]

Unfortunately, U.S. EPA's draft charge questions do not elicit feedback from the peer reviewers that would enable confirmation as to whether the Agency used relevant, available information, including alternative approaches, and satisfied these TSCA requirements. For example, the draft charge questions do not reference the need to "integrate" key information available to the Agency, and only reference "available information" or "alternative approaches" in the context of the last charge question (7.2).[61]

EPA's draft risk evaluation, as well as the underlying draft IRIS assessment, fails to consider, assess, or integrate the following information:

- More than 100 key publications directly relevant to the evaluation of "best available science" and on hazards and exposures for the conditions of use of formaldehyde. These include peer-reviewed studies, peer review reports, reviews by other authoritative bodies, and journal responses.[62] Among these publications are important 2024 works related to formaldehyde and sensory irritation, exposure modeling, weight of evidence, and systematic review methods.[63]

- Conclusions and methods from other authoritative bodies like the European Union Scientific

[57] 15 U.S.C. 2605(b)(3)(F).
[58] 15 U.S.C. 2625(k).
[59] 15 U.S.C. 2625(j)(4).
[60] 15 U.S.C. 2608(b).
[61] https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0058.
[62] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/acc-formaldehyde-panel-comments-for-may-3-2024-sacc-meeting (pg. 23-33).
[63] Vincent, Melissa J., Seneca Fitch, Lauren Bylsma, Chad Thompson, Sarah Rogers, Janice Britt, and Daniele Wikoff. "Assessment of associations between inhaled formaldehyde and lymphohematopoietic cancer through integration of epidemiological and toxicological evidence with biological plausibility." *Toxicological Sciences* (2024); Goyak, Katy, and Stewart Holm. "Sensory irritation and use of the best available science in setting exposure limits: Issues raised by a scientific panel review of formaldehyde human research studies." *Regulatory Toxicology and Pharmacology* (2024): 105587; Lauer, Daniel J., Anthony J. Russell, Heather N. Lynch, William J. Thompson, Kenneth A. Mundt, and Harvey Checkoway. "Triangulation of epidemiological evidence and risk of bias evaluation: A proposed framework and applied example using formaldehyde exposure and risk of myeloid leukemias." *Global Epidemiology* 7 (2024): 100143; Salthammer, Tunga. "The reliability of models for converting formaldehyde emissions from wood-based materials to different environmental conditions." *Building and Environment* 247 (2024): 111041.

Committee on Occupational Exposure Limits.[64]

- Conclusions regarding formaldehyde from other U.S. EPA offices, including its Office of Air and Radiation (OAR) and Office of Pesticide Program, regarding the IRIS dose-response approach, failure to address NASEM recommendations, biologically-based dose-response modeling, and acceptable risk. For example, the Agency's air office has repeatedly determined that IRIS's dose-response approach to formaldehyde does not "represent the best available science in the peer reviewed literature" and that, even if that approach is used, industrial sources do not constitute unacceptable risk. OAR has also committed: "EPA will fully address all the NRC recommendations on formaldehyde"; "The EPA will follow the NAS report recommendations and will present results obtained by implementing the biologically based dose response model (BBDR) for formaldehyde"; and "Furthermore, where the IRIS assessment substantially lags the current scientific knowledge, we have committed to consider alternative credible and readily available assessments. For our use, these alternatives need to be grounded in publicly available, peer-reviewed information. Formaldehyde is an example of this situation…. For formaldehyde, we do not use the dose-response value reported in IRIS. The dose-response value in IRIS is based on a 1987 study, and no longer represents the best available science in the peer-reviewed literature."[65]

- Comments and criticisms from other federal agencies on the 2010 and 2022 draft formaldehyde IRIS assessments, including suggestions for important peer review charge questions.[66]

- Reasonably available information that would enable EPA and the SACC to correct fundamentally flawed and erroneous assumptions contained in U.S. EPA's Consumer Exposure Assessment. Many of the Agency's "unreasonable risk" determinations are driven by dermal and inhalation exposures that assume unrealistic and physically impossible mean and maximum concentrations of formaldehyde in liquid and solid products. These include modeling parameters that include 10 percent formaldehyde content for wood articles like hardwood floors and furniture as well as glues and adhesives, as well as 30 percent for some plastic and rubber products.[67] While not explicitly stated in the draft risk evaluation, it appears that these figures may have been derived from safety data sheets for individual products or, in some cases, from Chemical Data Reports submitted by companies like Hexion for individual sites dating back to 2012.

  This is not the best available science and, despite having expansive authority under TSCA to gather the best available, current information, EPA has misused this data that is not representative nor appropriate for this purpose.[68] U.S. EPA has failed to integrate available information utilized by other parts of the Agency that would have corrected these fundamental errors. For example, U.S. EPA's Office of Air and Radiation determined in a 2023 rulemaking that nearly all amino-phenolic resins – which represents 50 percent or more of formaldehyde used in the U.S. – are "non-hazardous air pollutant" in part due to containing formaldehyde at levels below 0.1 percent.[69] In addition, U.S. EPA has failed to integrate research from other parts of the Agency

[64] https://www.estambiente.it/wp-content/uploads/2017/03/2016-06-30-SCOEL-REC-125-Formaldehyde.pdf.
[65] https://www.regulations.gov/comment/EPA-HQ-OAR-2004-0489-0263.
[66] https://iris.epa.gov/document/&deid=353316; https://iris.epa.gov/document/&deid=223603; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/march-8-2024-panel-letter-to-epa-on-the-sacc-peer-review-process.
[67] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-consumer-exposure-assessment-for-formaldehyde-public-release-hero-march2024.pdf (Table 2.1).
[68] Out of an abundance of caution, Hexion is revisiting and making amendments to its 2012 and 2016 CDR for certain sites to avoid misinterpretation and the use of information that is not the best available science. We call on U.S. EPA to rectify these erroneous inputs as well as to reach out to individual companies that may be the source of these modeling assumptions to provide clarity and context for any use by the Agency, consistent with TSCA requirements to consider, assess, and integrate information which is available or reasonably available.
[69] https://www.federalregister.gov/d/2023-10067/p-260; https://www.regulations.gov/document/EPA-HQ-OAR-2016-0243-0420; https://www.federalregister.gov/documents/2023/05/18/2023-10067/national-emission-

regarding formaldehyde content and associated emissions for different species of wood.[70]

- Available information on health and safety programs operated by companies that manufacture, import, process, or otherwise use formaldehyde or formaldehyde-based products. This includes peer-reviewed literature on training programs[71] and ACC material[72] on industrial hygiene and PPE programs that has been transmitted to EPA on several occasions. For example, Hexion manages any worker dermal and inhalation exposures through long-standing and robust health and safety programs. In addition to protections afforded by engineering, work practices, and administrative controls, we implement a comprehensive respiratory protection program that includes the proper use of PPE as well as training. Exposure to formaldehyde in the workplace is readily controlled by good engineering and process controls, sufficient ventilation and proper handling and storage techniques. Examples include: local exhaust ventilation systems; proper protective equipment such as eye protection; suitable work clothing which covers arms and legs; formaldehyde-resistant gloves; and NIOSH-approved respirators in situations where exposure exceeds allowable exposure limits and/or ventilation alone is not sufficient.[73]

- Important information from other Agency offices regarding the relative contributing sources to ambient/outdoor air, including the overwhelming contribution of biogenic and fire-related emissions. U.S. EPA and state agencies have frequently cautioned against these misinterpretations in the use of National Emissions Inventory, AirToxScreen, National Air Toxics Assessment, and AMTIC data.[74] The Agency has also failed to integrate the latest information, including from satellite measurements, on urban and rural formaldehyde concentrations (driven by biogenic and fire emissions) above the draft occupational exposure value.[75] In addition, EPA has not integrated the latest peer reviewed publications on the influence of outdoor formaldehyde levels for indoor and occupational concentrations when looking at unnecessarily low health benchmarks (as under consideration here). Many of these studies describe a so-called “formaldehyde dilemma” in which risk management of “primary” indoor air faces diminishing returns compared to high relative background concentrations from ambient or residential air.[76]

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standards-for-hazardous-air-pollutants-plywood-and-composite-wood-products#p-260.

[70] https://www.epa.gov/sites/default/files/2016-03/documents/veneer-dryer-hap-voc-emissionfactors.pdf.

[71] https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0119.

[72] https://www.americanchemistry.com/industry-groups/formaldehyde/research/acc-formaldehyde-brochure-compliance-with-ppe-requirements-is-required-by-osha; https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0118.

[73] https://www.hexion.com/docs/default-source/responsibility/upwd_hex-31211_13271_hxn-163_pss-formaldehyde_update2.pdf?sfvrsn=91323083_8.

[74] https://epd.georgia.gov/document/document/georgia-epd-comments-2017-airtoxscreen-pdf/download; https://www.regulations.gov/comment/EPA-HQ-OAR-2004-0489-0263 (pg. 24-25); https://www.epa.gov/system/files/documents/2023-02/AirToxScreen_2018%20TSD.pdf (pg. 25, a-2); https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=88282&Lab=NERL; https://www.epa.gov/sites/default/files/2020-07/documents/nata_2014_summary_of_results.pdf; https://www.epa.gov/AirToxScreen/airtoxscreen-assessment-methods.

[75] https://www.sciencedirect.com/science/article/abs/pii/S1352231002005587; https://www.mdpi.com/2072-4292/14/9/2191; https://agupubs.onlinelibrary.wiley.com/doi/full/10.1029/2020JD032881; https://acp.copernicus.org/articles/19/8363/2019/.

[76] Salthammer, Tunga. "The formaldehyde dilemma." *International journal of hygiene and environmental health* 218, no. 4 (2015): 433-436; Salthammer, Tunga. "Formaldehyde in the ambient atmosphere: from an indoor pollutant to an outdoor pollutant?." *Angewandte chemie international edition* 52, no. 12 (2013): 3320-3327; Liu, Cong, Xinyao Miao, and Jingguang Li. "Outdoor formaldehyde matters and substantially impacts indoor formaldehyde concentrations." Building and Environment158 (2019): 145-150; Qiu, Shuolin, Zirui He, Guangdong Liu, Zhen Ding, Zhongming Bu, Jianping Cao, Wenjing Ji et al. "Ambient formaldehyde concentrations in summer in 30 Chinese cities and impacts on air cleaning of built environment." *Energy and Built Environment* 5, no. 4 (2024): 493-499; Qu, Meihua, Jing Lu, and Rongqiao He. "Formaldehyde from environment." *Formaldehyde and cognition* 1 (2017): 1-19; Salthammer, Tunga. "Emerging indoor pollutants." *International Journal of Hygiene and Environmental Health* 224 (2020): 113423; Zhang, Hemiao, Zihao Zheng, Tao Yu, Cong Liu, Hua Qian, and Jingguang Li. "Seasonal and diurnal patterns of outdoor formaldehyde and

- As noted in more detail below, key recommendations and findings from past peer reviews of the underlying science, including from NASEM and the Human Studies Review Board.

- Relevant risk information related to other federal and state regulatory programs including, in some cases, the failure to acknowledge the existence of some of these occupational or product standards:
  - Department of the Navy's Navy Safety and Occupational Health Program Manual for Forces Afloat[77] and Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants.[78]
  - NASA's Spacecraft Maximum Allowable Concentrations for Airborne Contaminants[79]
  - Department of Veteran Affairs' Safety Training Manual[80] and Formaldehyde Training for VAAAHS Research Service.[81]
  - Fish and Wildlife Service Formaldehyde Exposure Control.[82]
  - Agency for Toxic Substances Disease Registry Medical Management Guidelines.[83]
  - FDA Formalin Approvals for Aquaculture.[84]
  - HUD Streamlining and Aligning Formaldehyde Emission Control Standards for Certain Wood Products in Manufactured Home Construction With Title VI of TSCA[85]
  - Multiples agencies' Formaldehyde Exposure in Homes Reference for States[86]
  - OSHA Formaldehyde Standards.[87]

VI. U.S. EPA's Draft Risk Evaluation and Peer Review Process is Not Consistent with the Best Available Science

Section 26(h) of TSCA requires that EPA, in making decisions based on science, "shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science," including the: "extent of independent verification or peer review" of the science; the "extent to which the variability and

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impacts on indoor environments and health." *Environmental research* 205 (2022): 112550; Lin, Yaolin, Tao Huang, Wei Yang, Xiancun Hu, and Chunqing Li. "A Review on the Impact of Outdoor Environment on Indoor Thermal Environment." *Buildings* 13, no. 10 (2023): 2600.

[77] https://www.secnav.navy.mil/doni/Directives/05000%20General%20Management%20Security%20and%20Safety%20Services/05-100%20Safety%20and%20Occupational%20Health%20Services/5100.19F.pdf.

[78] https://nap.nationalacademies.org/catalog/11170/emergency-and-continuous-exposure-guidance-levels-for-selected-submarine-contaminants.

[79] https://www.nasa.gov/wp-content/uploads/2023/03/jsc-20584-rev-b-final-rev-b-signed-0.pdf?emrc=65b416dc849e1.

[80] https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.research.va.gov%2Fprograms%2Forppe%2Fpolicy%2Fdraft%2Fother%2F2019-SafetyTrainingManual.doc&wdOrigin=BROWSELINK.

[81] https://www.annarbor.research.va.gov/ANNARBORRESEARCH/docs/Formaldehyde_Training_for_VAAAHS_Research_Service_2019.pdf.

[82] https://www.fws.gov/policy-library/242fw9.

[83] https://www.atsdr.cdc.gov/MHMI/mmg111.pdf.

[84] https://www.fda.gov/animal-veterinary/aquaculture/approved-aquaculture-drugs.

[85] https://www.federalregister.gov/documents/2020/01/31/2020-01474/streamlining-and-aligning-formaldehyde-emission-control-standards-for-certain-wood-products-in.

[86] https://www.cdc.gov/nceh/ehhe/trailerstudy/pdfs/08_118152_compendium%20for%20states.pdf.

[87] OSHA operates standards addressing dermal and inhalation exposures for general industry, maritime, construction, and other workplaces across more than 25 sections of the Code of Federal Regulations. These include: 29 CFR 1910.1048, Formaldehyde; Appendix A (for information related to substance technical guidelines for formalin); Appendix C (information related to medical surveillance – Formaldehyde); Enforcement Procedure for Occupational Exposure to Formaldehyde (CPL 02-02-052); 29 OSHA-approved State Plans oversee standards that may be more stringent.

uncertainty" of the science is evaluated and characterized; and the extent to which this science is "reasonable for and consistent with the intended use of the information."[88] The Agency has failed to use best available science for four reasons:

First, U.S. EPA defers almost entirely to a draft IRIS assessment of formaldehyde which is not consistent with best available science and was not peer reviewed or independently validated for TSCA scientific standards. The Agency's human health hazard assessment is wholly reliant on EPA's draft IRIS assessment and its review.[89] It delegates virtually all conclusions regarding human health to this draft IRIS assessment, citing the 2022 draft IRIS assessment and the NASEM review more than 100 times in its 58 pages. U.S. EPA makes clear that no other information has been integrated. For example: "OPP and OPPT are relying on the draft IRIS assessment for these chronic inhalation hazard values (see Section 1.2.2.1)"; "For the inhalation route, OPP and OPPT relied on the systematic review performed to support the draft IRIS assessment…. Therefore, these studies were not further assessed for use in the OPP or OPPT assessment. OPP and OPPT are relying on the chronic cancer and non- cancer hazard values derived in the draft IRIS assessment"; and "Evidence presented below for effects associated with inhalation exposures is primarily summarized from the draft IRIS assessment for formaldehyde." Additionally, the sole basis in U.S. EPA's human health hazard assessment for causal determinations related to formaldehyde and pulmonary function, immune-mediated effects like allergies and asthma, respiratory tract pathology, reproductive and developmental effects, and neurological effects is the 2022 draft IRIS assessment of formaldehyde.[90]

As noted previously, EPA's December 26 solicitation of formaldehyde peer reviewers[91] and draft charge questions exclude critical issues associated with the underlying IRIS assessment. However, EPA's TSCA risk evaluation framework rule makes clear that TSCA peer review is required even when the Agency intends to "defer" to another assessment. EPA justified this conclusion by stating: "It would be necessary to make certain the best available science and weight of the scientific evidence approaches were used properly, as they may not have been required under the process by which the comparable evaluation was conducted."[92] The draft IRIS assessment was clearly not developed to achieve TSCA scientific standards and the NASEM peer review (including the "statement of task" and resulting report) fail to mention TSCA or "best available science" a single time.

Second, U.S. EPA has excluded questions about "best available science," which is not referenced in the draft charge, from this peer review. Despite this omission, based on recent Agency practice, U.S. EPA is likely to cite this SACC peer review process as the basis for claiming that its "unreasonable risk" determinations and occupational exposure values (or ECELs) are based on the "best available science" and the "weight of scientific evidence."[93] For example, EPA's TSCA risk management rule for carbon tetrachloride (CTC) states: "EPA considers the CTC ECEL to represent the best available science under TSCA section 16(h), because it was derived from information in the 2020 Risk Evaluation for Carbon Tetrachloride, which was subject to peer review…"[94] The 2023 TSCA risk management rule for perchloroethylene similarly argues: "As in the case of the unreasonable risk

[88] 15 U.S.C. 2625(h).
[89] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-hazard-assessment-for-formaldehyde-public-release-hero-march2024.pdf.
[90] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-hazard-assessment-for-formaldehyde-public-release-hero-march2024.pdf (pg. 13-14).
[91] https://www.federalregister.gov/documents/2023/12/26/2023-28430/formaldehyde-draft-risk-evaluation-peer-review-by-the-science-advisory-committee-on-chemicals-sacc; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0007 (pg. 4-10).
[92] https://www.federalregister.gov/d/2017-14337/p-168.
[93] See other examples at: https://www.federalregister.gov/documents/2024/03/28/2024-05972/asbestos-part-1-chrysotile-asbestos-regulation-of-certain-conditions-of-use-under-the-toxic#p-332; https://www.federalregister.gov/d/2023-23010/p-287; https://www.federalregister.gov/documents/2023/05/03/2023-09184/methylene-chloride-regulation-under-the-toxic-substances-control-act-tsca#p-97; https://www.federalregister.gov/d/2023-09184/p-441.
[94] https://www.federalregister.gov/d/2023-15326/p-101.

determination, risk management decisions for this proposed rule… were based on a risk evaluation that was subject to public comment and independent, expert peer review, and was developed in a manner consistent with the best available science and based on the weight of the scientific evidence…"[95] U.S. EPA wraps its regulatory and policy determinations in this peer review process, despite the fact that no prior SACC review specifically sought comment on whether U.S. EPA's draft risk evaluations and scientific underpinnings were based on the "best available science."[96]

Third, U.S. EPA has not used best available science or independently validated its scientific decisions because it has failed to integrate key recommendations from past peer reviews relevant to the draft risk evaluation and draft IRIS assessment. These key findings, recommendations, and findings include scientific, methodological, and procedural issues fundamental to the scientific quality of this risk evaluation from reviews that emanate from NASEM and EPA's Human Studies Review Board (HSRB). As Dr. Harvey Checkoway, Professor, University of California, San Diego School of Public Health and Member of the 2010/2011 National Academies' Committee to Review EPA's Draft IRIS Assessment of Formaldehyde explained in his May 2024 comments: "Based on my review of the draft EPA report, I do not find that its conclusions are grounded in the best available science and also fails to fully incorporate key recommendations from previous peer reviews."[97]

ACC has similarly laid out the ways in which the draft IRIS assessment and its associated NASEM review failed to resolve previous NASEM recommendations, thus violating FACA, TSCA, Clean Air Act, and EPA policy requirements.[98] NASEM acknowledged this limitation in its approach,[99] noting "the present committee did not review specific changes in the 2022 Draft Assessment against the recommendations in the 2011 NRC report…" ACC has also documented in significant detail how the NASEM review did not provide "independent" validation and was operated in violation of FACA Section 15, thus prohibiting EPA from using the results.[100]

This failure to independently validate key approaches, methodologies, and scientific decisions extends to dozens of critical recommendations – Below is a small sample of the critical suggestions that the Agency has failed to integrate from NASEM and the HSRB:

- Human Studies Review Board, 2023[101]
    - "EPA should provide justification for relying on both self-report, cross-sectional studies and intentional exposure studies for the proposed WOE PODs, when the scientific rigor differs between these study types. In particular, EPA states that 'TSCA requires that…EPA must use scientific standards and base those decisions on the best available science and on the weight of the scientific evidence.['] EPA also states that the weight of evidence may include considerations of the data quality 'and the extent to which effects can be replicated with a laboratory and across different laboratories.'" (pg. 10)
    - "Additionally, HSRB recommends that an uncertainty factor is not necessary when the POD is based on sensory irritation." (pg. 9)
    - "The HSRB strongly recommends that the EPA clarify the scope of HSRB review and

[95] https://www.federalregister.gov/d/2023-12495/p-618.
[96] Links to charge questions for TSCA chemical risk evaluations can be found in the associated dockets at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under. For example, U.S. EPA's charge questions for carbon tetrachloride review by the SACC do not mention "best available science" or "unreasonable risk": https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0499-0034.
[97] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0140.
[98] https://www.americanchemistry.com/industry-groups/formaldehyde/resources/formaldehyde-panel-follow-up-letter-to-epa; https://www.americanchemistry.com/industry-groups/formaldehyde/resources/2023-nas-2011-recommendations-summary-033123.
[99] https://www.americanchemistry.com/chemistry-in-america/news-trends/blog-post/2023/national-academies-buries-the-lede-in-review-of-epa-formaldehyde-assessment.
[100] https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2023/acc-challenges-lack-of-independence-transparency-for-peer-review-of-epa-s-draft-formaldehyde-iris-assessment.
[101] https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde_0.pdf.

how their review will be used in conjunction with other efforts within and external to the EPA. This clarification includes clearly communicating the charge question to the HSRB, as well as noting when and how each individual review will be used as part of a larger effort (e.g., a weight-of-evidence)." (pg. 9)
    - "HSRB recommends that EPA conduct a more coordinated approach with other entities (e.g., National Academies of Sciences, Engineering, and Medicine (NASEM), TSCA Science Advisory Committee on Chemicals (SACC)) regarding advice in establishing PODs for formaldehyde as well as reviewing recommendations from these and other entities on formaldehyde exposure. To further this recommendation, the HSRB recommends that the EPA share this HSRB report with the NASEM and TSCA SACC, and that EPA consults with other State and Federal agencies working on formaldehyde guidance/regulations, as appropriate." (pg. 9)
    - The HSRB disagrees with EPA's assumption of Haber's Law for formaldehyde and recommends that EPA not make duration adjustments to develop the PODs. EPA should consider their previous approach to derive exposure criteria for chloropicrin whereby uncertainty factors were removed, and the evaluation was conducted for younger individuals (EPA 738-R-09-308). (pg. 10)
    - "Of the studies the HSRB evaluated, the controlled chamber studies (e.g., Mueller et al. (2013) and Lang et al. (2008)) have preferred study design and greater scientific rigor than the observational studies (e.g., Hanrahan et al. (1984) and Liu et al. (1991)). Public comments provided a summary comparison of the two types of studies in the context of this review; the HSRB appreciates the detail in the presentation. The HSRB recommends that EPA use exposure levels from chamber studies rather than observational studies. (pg. 10).
- NASEM, 2023[102]
    - "Yet, while the steps in the systematic review process used in preparing the Draft Assessment are generally consistent with those outlined in the 2014 NRC report, the assessment does not satisfactorily follow recommendations for problem formulation and protocol development. EPA did not develop a set of specific protocols for the 2022 Draft Assessment in a fashion that would be consistent with the general state of practice that evolved during the prolonged period when the assessment was being developed…. . The committee concluded that prepublished protocols are essential for future IRIS assessments to ensure transparency for systematic reviews in risk assessment." (pg. 5)
- NASEM, 2011[103]
    - "The committee notes that the Krzyzanowski et al. (1990) findings are inherently limited by the cross-sectional nature of their study and found that the study design is not sufficiently described in the published report." (pg. 72-73)
    - "As with the respiratory tract cancers, the draft IRIS assessment does not provide a clear framework for causal determinations. As a result, the conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data, and the lack of mechanistic data." (pg. 9)

Fourth, as noted above, other parts of EPA as well as other authoritative bodies have concluded that the draft risk evaluation approach to key issues, including "unreasonable risk," derivation of occupational limits, and associations with leukemia, are not based on the best available science.

VII. U.S. EPA's Draft Occupational Exposure Values are Unreasonable, Unlawful, and Inappropriately Excluded from the Peer Review Process

U.S. EPA's acute, intermediate and chronic draft exposure values, previously known as "existing chemical exposure limits" or ECELs and included in Appendix E of the draft human health risk

[102] https://nap.nationalacademies.org/download/27153.
[103] https://nap.nationalacademies.org/download/13142.

assessment,[104] constitute an unreasonable, unworkable, unachievable, and potentially unmeasurable starting point for risk evaluation or risk management. While U.S. EPA's draft risk evaluation suggests these occupational values are likely to change in the future,[105] that projection is insufficient given the Agency's track record and the absence of additional peer review in TSCA risk management. U.S. EPA has previously established the role of these values in making fundamental determinations regarding risk: "EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health from occupational inhalation exposures for conditions of use identified as presenting unreasonable risk under TSCA."[106]

Several comments during the May 7 SACC meetings as well as in the docket from ACC, the Composite Panel Association, and experts in formaldehyde science and TSCA emphasized the absurdity of EPA's draft occupational exposure values, which extend down to 11 parts per billion for chronic and intermediate noncancer effects. U.S. EPA's draft risk evaluation acknowledges that this value is below levels seen in U.S. residences, government office buildings, classrooms, ambient air, and associated with behaviors like the burning of candles or incense.[107] Based on a review of the GESTIS database maintained by the Institute for Occupational Safety and Health of the German Social Accident Insurance,[108] this draft value is more than 27 times lower than the time-weighted average occupational limits for the European Union, Australia, Austria, Denmark, Finland, France, Germany, Ireland, Italy, Latvia, New Zealand, Norway, Romania, South Korea, Sweden, Switzerland, U.S. OSHA, and the United Kingdom. It is also below the detection limit for several NIOSH and OSHA-approved analytical methods[109] and just above levels in exhaled human breath.[110]

As numerous comments on U.S. EPA's recent "framework" rule for TSCA risk evaluations, including from the Louisiana Attorney General and ACC, establish,[111] Congress did not provide authority for the Agency to: propose draft occupational exposure values or existing chemical exposure limits as part of existing chemical risk evaluations under Section 6 of TSCA; fundamentally change and alter its position regarding key elements of its process for risk evaluations following 2017 rulemaking required in TSCA Section 6(b)(4); or unilaterally trump TSCA requirements to evaluate conditions of use, hazard, and exposure through policy decisions to render single risk determinations for a "whole chemical" or to exclude any consideration of personal protective equipment and other industrial hygiene practices.

These are clearly "major questions" that constitute a "transformative" change in the Agency's authority, as the U.S. Supreme Court warned in *West Virginia v. EPA*. Additionally, the inclusion of draft occupational exposure values violates the prohibition in TSCA Section 9(c) Section 9(c) ("In exercising any authority under this chapter, the Administrator shall not, for purposes of section

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[104] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf (pg. 142-145).
[105] "In general, any existing chemical exposure limit (ECEL) used for occupational safety risk management purposes could differ from the draft occupational exposure value presented in this appendix based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c), and this is certain to be the case for formaldehyde." https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf (pg. 142).
[106] https://downloads.regulations.gov/EPA-HQ-OPPT-2020-0592-0007/content.pdf.
[107] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-indoor-air-exposure-assessment-for-formaldehyde-public-release-hero-march2024.pdf.
[108] https://ilv.ifa.dguv.de/limitvalues/29311.
[109] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-human-health-risk-assessment-public-release-hero-march-2024.pdf (pg. 145-151).
[110] https://iris.who.int/bitstream/handle/10665/260127/9789289002134-eng.pdf?sequence=1 (pg. 111).
[111] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0217; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0253; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0249; https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0251.

653(b)(1) of title 29, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health").

Especially considering this is the first TSCA risk evaluation to contain occupational exposure values or ECELs, EPA and the SACC should reject these values and their derivation as inconsistent with TSCA and its scientific requirements. EPA's draft charge questions fail to even mention these draft occupational exposure values, nor seek the Committee's comment on whether they are derived based on the best available science and other TSCA scientific standards. These values, and their scientific underpinnings, are clearly within the purview of the SACC which was established by Congress and chartered to "provide independent advice and expert consultation… with respect to the scientific and technical aspects of issues relating to the implementation of" TSCA.[112]

VIII. U.S. EPA Fails to Follow Other, Relevant TSCA Non-Discretionary Duties

In addition to violating core TSCA scientific standards, EPA's draft risk evaluation and recent practice is also at odds with a variety of TSCA non-discretionary duties designed to improve transparency and enable meaningful public comment as well as rigorous peer review. Failure to follow these clear requirements undermines the process for release and comment on this draft risk evaluation and EPA's implementation of TSCA existing chemical review process in general. As opposed to rushing through this truncated peer review and public comment process, the Agency should endeavor to rectify these TSCA violations:[113]

- Inter- and Intra-Agency Consultation and Coordination. Section 9 of TSCA focuses on the relationship with other federal laws and includes several non-discretionary duties for EPA regarding interagency and intra-agency consultation related to identifying and addressing unreasonable risks under TSCA and other federal authorities. It does not appear that EPA has followed key requirements in the context of this draft risk evaluation. For example:
    - Section 9(d) of TSCA states: "In administering this chapter, the Administrator shall consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this chapter while imposing the least burdens of duplicative requirements on those subject to the chapter and for other purposes."[114] Based on a review of the draft risk evaluation docket[115] and the White House Office of Management and Budget's search for actions that have undergone interagency review,[116] there is no evidence that EPA has sought comments from other federal agencies or engaged in any meaningful formal or interagency review of the draft formaldehyde evaluation or draft charge questions from agencies like the White House Office of Management and Budget, NASA, USDA, or the Department of Defense.

      Comments from the U.S. Small Business Administration on this draft risk evaluation[117] as well as December 2023 comments on EPA' TSCA risk evaluation "framework" rule[118] underscore the lack of consultation and coordination, noting "EPA should recommit to a robust interagency process for review of the draft and final risk evaluations…. Unfortunately, neither the preamble nor current EPA practice reflect the commitment to

[112] 15 U.S.C. 2625(o); https://www.epa.gov/tsca-peer-review/science-advisory-committee-chemicals-charter.
[113] Section 20 of TSCA (15 U.S.C 2619) provides for citizen civil actions "to compel the Administrator to perform any act or duty under this chapter which is not discretionary" or against any person or agency "who is alleged to be in violation of this chapter… to restrain such violation."
[114] 15 U.S.C. 2608(d).
[115] https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613/document.
[116] https://www.reginfo.gov/public/do/eoAdvancedSearchMain.
[117] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0091.
[118] https://advocacy.sba.gov/wp-content/uploads/2023/12/Comment-Letter-TSCA-Process-Rule-508.pdf.

interagency collaboration." The failure to coordinate and consult on a draft evaluation of formaldehyde is also at odds with even the informal, EPA-led interagency comment process for draft IRIS assessments (which include pre-dissemination opportunity for agency comments on draft assessments as well as draft charge questions).[119] As noted in public comments provided on May 7, EPA's exclusion of federal agency consultation and coordination has deprived the Agency, the SACC, and public of important information to consider, including suggestions to improve the draft charge.

- Section 9(e) of TSCA requires that "if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency."[120] The draft risk evaluation contains numerous examples of formaldehyde exposure, including in the average American home, classrooms, government office buildings, ambient air (driven primarily by biogenic and fire-related sources), urban air, and associated with behaviors like residential wood burning or burning of candles, which are above the levels assessed to be "unreasonable risks." Based on a review of the docket, there is no evidence that EPA has made such information available to these EPA or other federal offices. This is further confirmed by a May 8, 2024 article in *Inside TSCA*, which stated that "[t]hough [TSCA] directs EPA to consult with other regulators as it considers how to address unreasonable risks from existing chemicals, so far it has declined to refer any of the issues it identified in risk evaluations to other programs -- despite industry groups' arguments that doing so breaks with lawmakers' intent in adding that provision to the law."[121]

- Section 9(b) of TSCA requires that "[t]he Administrator shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator," specifying that in "making a determination… that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk… and a comparison of the estimated costs and efficiencies of the action to be taken under this subchapter and an action to be taken under such other law to protect against such risk."[122]

  Based on a review of the docket, there is no evidence that U.S. EPA has considered relevant aspects of risks nor the estimated costs and efficiencies for action under TSCA versus other laws. In fact, it is not clear from EPA's draft risk evaluation that it has identified other federal requirements related to formaldehyde (see noted above). In addition, despite evidence suggesting a wide variety of background, residential, educational, and behavioral exposure exceeding "unreasonable risk" levels, EPA has arbitrarily, capriciously, and inconsistently picked which exposures for which it rendered "unreasonable risk" determinations.

- Prohibition on Prescribing Standards Affecting Occupational Safety and Health. Section 9(c) of TSCA states: "In exercising any authority under this chapter, the Administrator shall not, for purposes of section 653(b)(1) of title 29, be deemed to be exercising statutory authority to

[119] See examples of federal agency comments on EPA's "Interagency Science Consultation Drafts" for IRIS assessments of formaldehyde in 2021 and 2010: https://iris.epa.gov/document/&deid=353316; https://iris.epa.gov/document/&deid=223603.
[120] 15 U.S.C. 2608(e).
[121] *Inside TSCA*, "Pending Chemical Reviews Could Deepen TSCA's Links To Other Programs," May 8, 2024, https://insideepa.com/tsca/insider?page=0.
[122] 15 U.S.C. 2608(b).

prescribe or enforce standards or regulations affecting occupational safety and health." While excluding these values from the peer review process, U.S. EPA's inclusion of draft occupational exposure values, including non-cancer values down to 11 parts per billion, in the Human Health Risk Assessment of this risk evaluation violates this prohibition.

- Annual Plan on Risk Evaluations. Section 26(n)(2) of TSCA requires that, "At the beginning of each calendar year, the Administrator shall publish an annual plan that… identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion…" Based on a review of U.S. EPA's website, it appears that the Agency acknowledged this requirement but such a plan has not been published since 2021.[123] In addition, U.S. EPA excludes draft and final risk evaluations from the semiannual Unified Agenda of Regulatory and Deregulatory Actions.[124] Publication of such a plan would significantly improve transparency and meaningful public comment.

- Establishment of TSCA Assistance Office for Manufacturers and Processors. Section 26(d) of TSCA states: "The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this chapter applicable to such manufacturers and processors, the policy of the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements."[125] Based on a review of EPA's website as well as comments from the U.S. Small Business Administration and trade associations representing small entities,[126] it does not appear such an identifiable office has been established.

- Annual Reporting Requirements to Congress and the President on TSCA Implementation and Interagency Coordination. Section 30 of TSCA requires: "The Administrator shall prepare and submit to the President and the Congress… on or before January 1 of each succeeding year a comprehensive report on the administration of this chapter during the preceding fiscal year. Such reports shall include…. a summary of major problems encountered in the administration of this chapter; and …such recommendations for additional legislation as the Administrator deems necessary to carry out the purposes of this chapter."[127] Section 9(d) further specifies that this annual report include "actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this chapter with the authority granted under other Acts…"[128] While U.S. EPA does appear to have complied with separate reporting requirements on capacity to implement aspects of TSCA under Section 26(m)(1),[129] there is no evidence EPA has fulfilled this annual requirement since 2016. These annual reports would provide important information on the risk evaluation and interagency process, as well as topics for Congressional attention.

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[123] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/annual-plan-tsca-risk-evaluations.

[124] https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=2000&csrf_token=0533BCFB2CEAF327E2E45ADA021A6FA726D2946CFF1E5828C2CB52AB739A1299678679492E258F0BED19DE95D2700C237B5C.

[125] 15 U.S.C. 2625(d).

[126] https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0091; https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0126.

[127] 15 U.S.C. 2629.

[128] 15 U.S.C. 2608(d).

[129] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/initial-report-congress-epas-capacity-implement-certain; https://www.epa.gov/system/files/documents/2022-10/October%202022%20Report%20to%20Congress%20on%20the%20EPAs%20Capacity%20to%20Implement%20Certain%20Provisions%20of%20the%20Frank%20R.%20Lautenberg%20Chemical%20Safety%20for%20the%2021st%20Century%20Act.pdf.

IX. The Process to Develop U.S. EPA's Draft Risk Evaluation is Procedurally Defective and Inconsistent with Other Statutory, Regulatory, or Policy Requirements

In addition to inconsistencies with TSCA, FACA, and related regulatory and policy requirements, U.S. EPA's process for developing this draft risk evaluation is inconsistent with other statutory requirements and Agency policies. Addressing these issues would improve transparency, clarity, stakeholder engagement, and the scientific quality of the risk evaluation and subsequent regulation. For example:

- U.S. EPA has failed to grant reasonable requests to engage small businesses on the formaldehyde risk evaluation. A group of small business trade associations, including the American Feed Industry Association, American Home Furnishings Alliance, Catfish Farmers of America, Composite Panel Association, Kitchen Cabinet Manufacturers Association, and National Aquaculture Association, wrote to EPA in October 2023 seeking that EPA establish a small business panel, pursuant to the Small Business Regulatory Enforcement Fairness Act, for the forthcoming draft risk evaluation of formaldehyde. Noting that many risk management decisions are pre-ordained by EPA's risk evaluation process, these groups requested "that this panel be held before completion of the draft risk evaluation, in order to inform the risk assessment, as well as to keep open regulatory options that would reduce small firm burdens."[130] It does not appear that U.S. EPA has acted on this request based on a review of the docket and the Agency's list of Small Business Advocacy Review panels (despite convening such panels on other TSCA activities).[131]

- In addition to requirements for interagency coordination and consultation under TSCA Section 9, U.S. EPA has also failed to follow interagency regulatory review requirements pursuant to long-standing executive orders, including Executive Order 12866, and White House guidance regarding the need for interagency comment on "significant" policies or guidance as well as "influential" scientific documents.[132]

- U.S. EPA may also be statutorily required to provide the draft risk evaluation to the Agency's Science Advisory Board. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) directs the EPA Administrator to establish a standing Science Advisory Board. Congress further required that "[t]he Administrator, at the time any proposed criteria document, standard, limitation, or regulation under… [TSCA]…, or under any other authority of the Administrator, is provided to any other federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based."[133]

- While indicating in its December 2019 notice of high-priority substance designations under TSCA that "the Agency is committed to consultation and coordination with Tribes" as part of the risk evaluation process[134] and in a manner consistent with the *EPA Policy on Consultation with Indian Tribes*,[135] EPA has taken no action to carry out these obligations with respect to formaldehyde. Concerningly, EPA's draft risk evaluation, draft IRIS assessment, Final Scope of the Risk

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[130] https://nfda.org/Portals/0/HCHO%20SBREFA%20LETTER%20FINAL%2010-6-23.pdf.
[131] https://www.epa.gov/reg-flex/small-business-advocacy-review-sbar-panels.
[132] https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf; https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-13.pdf; https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.
[133] 42 U.S.C. § 4365(c). See also: https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0249 (pg. 39-40).
[134] https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0438-0021.
[135] https://www.epa.gov/system/files/documents/2023-12/epa-policy-on-consultation-with-indian-tribes-2023.pdf.

Evaluation for Formaldehyde, and associated dockets fail to meaningfully mention tribes, Executive Order 13175, or plans to consult.[136] Limited interagency consultation on the draft IRIS assessment appears to have excluded the Burau of Indian Affairs and other parts of the Department of Interior.[137] EPA's IRIS and TSCA activities on formaldehyde are both not included in the current EPA Tribal Consultation Opportunities Tracking System.[138]

- As numerous ACC comments in late 2023 and early 2024 have documented,[139] U.S. EPA has failed to follow Agency and White House requirements for information quality and peer review for "influential" science. EPA's formaldehyde risk evaluation is clearly a "highly influential scientific assessment" or "influential scientific information" that should follow EPA and OMB peer review and information quality guidelines. EPA is required under the White House Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*[140] and its own information quality guidelines to post on their web site a Peer Review Agenda[141] that includes all planned and ongoing "influential scientific information" developed by EPA and an attendant "Peer Review Plan," in part to provide the public an opportunity to comment on peer review timing as well as which peer review bodies will be engaged. These requirements are also discussed in detail in EPA's *Peer Review Handbook*.[142] "Influential scientific information" is defined as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions."

  EPA has failed to include the formaldehyde weight of evidence approach for acute inhalation, its draft TSCA risk evaluation for formaldehyde, or risk assessment activities for FIFRA in its Peer Review Agenda. EPA appeared to share this view for other TSCA risk evaluations as the Peer Review Agenda includes peer review plans for TSCA risk evaluations for perchloroethylene, carbon tetrachloride, asbestos, methylene chloride, NMP, and trichloroethylene (but not for any other chemicals undergoing risk evaluations, including formaldehyde).[143]

- A November 2023 ACC Formaldehyde Panel letter also documents how U.S. EPA's failure to acknowledge, address, or incorporate prior public and peer reviewer comments, including on the underlying draft IRIS assessment and in a docket dedicated to the risk evaluation of formaldehyde, violates Agency and White House policies as well as statutory requirements.[144] This deficiency has not been rectified in the intervening six months, and the draft risk evaluation does not incorporate these relevant comments.

X. U.S. EPA's Draft Risk Evaluation Violates Agency Scientific Integrity Policies

In addition to the inconsistencies with TSCA and other statutory, regulatory, and Agency requirements, U.S. EPA's draft risk evaluation is also in tension with important provisions of its

[136] https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=544587; https://www.epa.gov/sites/default/files/2020-09/documents/casrn_50-00-0-formaldehyde_finalscope_cor.pdf; https://www.regulations.gov/docket/EPA-HQ-ORD-2010-0396/document; https://www.regulations.gov/docket/EPA-HQ-OPPT-2018-0438/document.
[137] https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=353316.
[138] https://tcots.epa.gov/ords/tcotspub/f?p=106:1.
[139] https://www.americanchemistry.com/content/download/15460/file/ACC-FA-Panel-Extension-Request-for-SACC-Nominations.pdf (pg. 2); https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0130/attachment_1.pdf (pg. 4); https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0496-0249 (pg. 39).
[140] https://cfpub.epa.gov/si/m05-03.pdf.
[141] https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.
[142] https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015.
[143] https://cfpub.epa.gov/si/si_public_pr_agenda.cfm.
[144] https://downloads.regulations.gov/EPA-HQ-OPPT-2018-0438-0130/attachment_1.pdf.

Scientific Integrity Policy (Policy),[145] particularly in the following areas:

- Scope of Peer Review and Inclusion of All Relevant Scientific Questions. U.S. EPA's January 2024 updated Policy directs the Agency to "[e]nsure peer review charge questions address all relevant scientific questions, including those raised in [differing scientific opinions], and are free from any interference, especially interference that may inappropriately limit the scope of the review."[146] As previously discussed, EPA's draft charge questions and solicitation of nominees indicate a narrow charge that eliminates key TSCA scientific standards and excludes key determinations and elements of the evaluation from review. EPA's charge questions also do not solicit input from the SACC on the carcinogenic mode of action for formaldehyde. The Agency has adopted the draft IRIS assessment's linear, low-dose approach without seeking comment on whether non-linear, threshold approaches utilized by the World Health Organization and European Chemicals Agency are more consistent with TSCA scientific standards.[147]

- Basing Decisions on Peer Reviewed and Final Science. The Agency's Policy also directs that EPA: "Ensure EPA decisions are based on or informed by science that has completed independent peer review and has been finalized"; "Ensure that draft documents released as part of transparency efforts are not relied upon for decision making"; and "Ensure… 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."[148] In addition to relying on a draft IRIS assessment of formaldehyde that has not been finalized or addressed peer review comments,[149] EPA has also failed to finalize, including incorporation of 2022 and 2023 SACC comments on the following documents or methods (which are referenced in this draft risk evaluation and excluded from the scope of peer review[150]):

    - *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0*[151](SACC review completed July 2022)[152]
    - *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities, Version 1.0* (SACC review completed May 2022)[153]
    - *Draft Supplement to the 1,4-Dioxane Risk Evaluation* (SACC review completed November 2023)[154]

- The Use of Proper and Appropriate Scientific Methods. EPA's updated Policy also calls on EPA to "[r]equire the use of proper and appropriate methods and processes in conducting research and adherence to practices that ensure the quality of research and other scientific activities."[155] As

[145] https://www.epa.gov/scientific-integrity; https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf; https://www.epa.gov/scientific-integrity/building-epas-updated-scientific-integrity-policy.
[146] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 13).
[147] https://www.ncbi.nlm.nih.gov/books/NBK138705/pdf/Bookshelf_NBK138705.pdf (pg. 141); https://echa.europa.eu/documents/10162/cc0acabf-6e82-f2ed-5dbe-8058f48ce6c4 (pg. 38).
[148] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 11, 14, 19).
[149] EPA's draft IRIS assessment is currently at step 5 of the 7-step process, "Revise Assessment": https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419
[150] 88 FR 88910 ("[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 and the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation. Furthermore, feedback from these reviews have been incorporated into the draft formaldehyde risk assessment.")
[151] http://www.govinfo.gov/content/pkg/FR-2021-12-20/pdf/2021-27437.pdf.
[152] https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0414-0044/content.pdf.
[153] https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0415-0095/content.pdf.
[154] https://downloads.regulations.gov/EPA-HQ-OPPT-2022-0905-0078/content.pdf.
[155] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 11).

noted previously, EPA has failed to correct its use of a 2018 systematic review document that does not meet key criteria or the state of practice.

- Decisions based on Best Available Science. Similar to TSCA, EPA's updated Policy also directs the Agency to "[e]nsure that science-based decisions are informed by best available science."[156] As noted, EPA's reliance on the draft IRIS assessment and exclusion of TSCA scientific standards from the ongoing and prior peer reviews are not consistent with decisions based on the best available science

- Document Interagency Comments. In addition to interagency requirements under TSCA Section 9, EPA's updated Policy also directs that the Agency: "Ensure that comments received on draft scientific documents during any interagency review are made in writing and made public."[157] As of May 14, EPA has not posted interagency comments on its draft risk evaluation of formaldehyde into the docket suggesting that the Agency is undermining transparency against a core value of its Policy or has failed to coordinate and consult with other agencies as required by TSCA.

- Use of Transparent Criteria. EPA's Policy also directs it to "[u]se transparent criteria in instances where a statute gives the Agency discretion in weighing scientific information in its actions and make the criteria publicly available."[158] The draft risk evaluation fails to use transparent criteria in its selection of which risks to evaluation, how EPA evaluated "unreasonable risk" against high background and residential levels of formaldehyde, and the approach to excluding more than one hundred critical studies.

- Resolving Differing Scientific Opinions. EPA's Policy and 2020 *Approaches for Expressing and Resolving Differing Scientific Opinions*[159]extend to special government employees and emphasize "differing scientific opinions as a legitimate and necessary part of the scientific process.[160] This 2020 document outlines the importance of transparency for policymakers on these differing opinions: "If a differing scientific opinion is not resolved through internal deliberations or addressed through peer review, it should be reflected in the deliberative documents considered by the policy makers. This is to ensure that policy makers are aware of the differing opinions."

Given the number of fundamental scientific, legal and policy issues raised here and in other comments in the docket, including violations of TSCA scientific standards and other requirements, Hexion urges EPA and the SACC to:

- Reset the risk evaluation process for formaldehyde to ensure that EPA's key conclusions and scientific underpinnings are grounded int he best available science, the weight of scientific evidence, and the integration of available information;
- Reject the use of a draft IRIS assessment that is out of step with the scientific and international community, fails to integrate past peer review recommendations, and is unfit for regulatory purposes;
- Start over at a more logical starting point for the consideration of "unreasonable risk" for important uses of formaldehyde as well as the derivation of potentially unachievable occupational values; and
- Recommit to a meaningful public comment and rigorous peer review process that embraces scientific quality over rushed deadlines.

[156] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 12).
[157] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 15).
[158] https://downloads.regulations.gov/EPA-HQ-ORD-2023-0240-0002/content.pdf (pg. 19).
[159] https://www.epa.gov/system/files/documents/2021-09/epas_approaches_for_expressing_and_resolving_differing_scientific_opinions.pdf.
[160] https://www.epa.gov/scientific-integrity/policies-and-practices#Scientific-policies.

Thank you for the opportunity to comment.

Sincerely,
Clint Woods
Global Director, Product Stewardship & Regulatory Affairs

cc:
Dr. George P. Cobb, SACC Chair
Ms. Tamue Gibson, SACC Designated Federal Official