

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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| COMMUNITY IN-POWER AND |) | |
| DEVELOPMENT ASS'N., INC., et al., |) | |
| |) | Case No. 1:23-cv-02715-DLF |
| Plaintiffs, |) | |
| |) | |
| v. |) | Hon. Dabney L. Friedrich |
| |) | |
| UNITED STATES ENVIRONMENTAL |) | |
| PROTECTION AGENCY, et al., |) | |
| |) | HEXION INC.'S MOTION FOR LEAVE |
| Defendants, |) | TO INTERVENE AS A DEFENDANT |
| |) | |
| and |) | |
| |) | |
| HEXION INC. |) | |
| 180 East Broad Street |) | <u>ORAL HEARING REQUESTED</u> |
| Columbus, OH 43215, |) | |
| |) | |
| Defendant Intervenor- |) | |
| Movant. |) | |
| |) | |

Pursuant to Rule 24(b) of the Federal Rules of Civil Procedure, Hexion Inc. (“Hexion”) hereby moves this Court for leave to intervene permissively as a defendant in this proceeding for the limited purpose of objecting to the proposed consent decree reportedly reached by the Plaintiffs Community In-Power and Development Association, Inc., et al. (“CIDA Plaintiffs”) and the EPA Defendants. The proposed consent decree would require EPA to issue its “final risk evaluation[] [under Section 6 of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2605,] for ... formaldehyde ... by no later than December 31, 2024.”¹ Prop. Consent Decree, ¶1.b. Hexion maintains that this arbitrary deadline, which is less than five months away, is

¹ The Proposed Consent Decree would also require EPA to issue final risk evaluations for 19 other “Subject Chemicals” by December 31, 2024, 2025 or 2026. *Id.*, ¶1.b.-d. However, Hexion objects only to the Proposed Consent Decree’s December 31, 2024 deadline for the final TSCA risk evaluation for formaldehyde. Hexion takes no position on the Proposed “ACC/CIDA” Consent Decree relating to the chemicals DIDP and DINP reached in the consolidated case of *ACC v. EPA*, Case No. 1:23-cv-03736.

unreasonably short and will not allow EPA to conduct a proper risk evaluation for formaldehyde in accordance with applicable TSCA standards.

The grounds for this Motion are more fully set forth in the attached Memorandum in Support below.

Pursuant to LCvR 7(m), counsel for Hexion has conferred with counsel for the existing Parties with regard to this Motion. Lakendra Barajas, counsel for the CIDA Plaintiffs, has indicated that the CIDA Plaintiffs reserve their position until they have an opportunity to review this Motion. Sarah Izfar, counsel for the EPA Defendants, likewise advised that the EPA Defendants reserve their position until they have an opportunity to review this Motion. Nessa Horewitch Coppinger, counsel for Plaintiff American Chemistry Council (“ACC”), has indicated that ACC takes no position on this Motion.

Dated: August 30, 2024

Respectfully submitted,

/s/ Jeremy W. Dutra

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| |) | MEMORANDUM IN SUPPORT OF |
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The CIDA Plaintiffs filed this action on September 18, 2023 under Section 20(a)(2) of TSCA, alleging that the EPA Defendants had failed to perform non-discretionary duties under 15 U.S.C. § 2605(b)(4)(G) by failing to timely complete risk evaluations under Section 6 of TSCA for 20 Subject Chemicals,² including formaldehyde. The CIDA Plaintiffs also alleged that EPA

² The 20 Subject Chemicals are: (1) 1,3-butadiene; (2) butyl benzyl phthalate; (3) dibutyl phthalate; (4) o-dichlorobenzene; (5) p-dichlorobenzene; (6) 1,1-dichloroethane; (7) 1,2-dichloroethane; (8) trans-1,2-dichloroethylene; (9) 1,2-dichloropropane; (10) dicyclohexyl phthalate; (11) di-ethylhexyl phthalate; (12) di-isobutyl phthalate; (13) ethylene dibromide; (14) formaldehyde; (15) 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (HHCB); (16) 4,4'-(1-methylethylidene)bis[2,6- dibromophenol (TBBPA); (17) phosphoric acid, triphenyl ester (TPP); (18) phthalic anhydride; (19) 1,1,2-trichloroethane; and (20) tris(2-chloroethyl) phosphate (TCEP). Complaint at pp. 1-2. The Complaint alleges that EPA was required to complete the risk evaluations for all 20 of these Subject Chemicals by June 20, 2023. *Id.* at ¶39.

has failed to timely complete TSCA risk evaluations for two other chemicals (namely, DIDP and DINP) requested by certain manufacturers.

On December 19, 2023, ACC filed a separate Complaint styled *ACC v. EPA*, Case No. 1:23-cv-03736, asserting similar claims with respect to the chemicals DIDP and DINP. By minute order entered on January 17, 2024, this Court consolidated both cases.

However, the EPA Defendants have not yet answered the Complaints. Defendants recently filed an Unopposed Motion for Extension of Time to File Answer or Other Response to Both Complaints (ECF No. 25, filed 8/14/24). The Motion stated that the extension was necessary to allow sufficient time for Defendants to “continue to review” comments received “on one of the proposed consent decrees ... and deliberate on next steps.” *Id.* at ¶¶5, 6. By minute order issued on August 15, 2024, the Court granted the Unopposed Motion and ordered that Defendants may have until September 16, 2024 to answer or respond to both Complaints.

I. BACKGROUND

A. The Draft TSCA Risk Evaluation for Formaldehyde.

On March 15, 2024, EPA announced the availability for public comment of the draft TSCA risk evaluation for formaldehyde, and submitted the draft to the Science Advisory Committee on Chemicals (“SACC”) for peer review. 89 Fed. Reg. 18,933 (March 15, 2024). According to the March 2024 Executive Summary of the Draft Risk Evaluation for Formaldehyde, “**EPA preliminarily finds that formaldehyde presents an unreasonable risk of injury to human health.**” <https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0019>, p. 2. Under EPA’s approach to reviewing high-priority existing chemicals under TSCA, a final determination of “unreasonable risk” results in a requirement to impose restrictions to eliminate unreasonable risk, which could include bans or onerous workplace

standards, within two years. See <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

EPA explained the ubiquitous nature of formaldehyde:

Formaldehyde is found nearly everywhere. Living things—plants, animals, and people—produce and release formaldehyde just through natural life (biogenic) processes. It is also produced when other chemicals break down in the environment and is released into the air when things burn, such as when automobiles emit exhaust, when furnaces and stoves operate, and through forest fires. Formaldehyde is also used to make many things, including composite wood products, plastics, paints, adhesives, and sealants. Over time, formaldehyde can be released from these products. The formaldehyde sources that EPA evaluates in this draft risk evaluation involve, in general, the production and use of these products that are subject to TSCA (as opposed to those products that are excluded from TSCA, such as pesticides). The unique challenge associated with this evaluation is that the formaldehyde released from these commercial activities and products that are subject to TSCA is mixed in with the naturally formed formaldehyde released from all the activities and processes mentioned above.

Id.

However, “Formaldehyde is not expected to last long (persist) in water, sediment, or soil based on its physical and chemical properties. For this reason, in this draft evaluation EPA has been able to preliminarily conclude that formaldehyde does not pose a risk to the environment.”

Id. at 3.

In its March 2024 Executive Summary, EPA made clear that EPA based its preliminary “unreasonable risk ... to health” determination upon “the chronic hazard values calculated in EPA’s IRIS Toxicological Review of Formaldehyde –Inhalation.”

<https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0019>, p. 3. In its

December 26, 2023 Federal Register notice announcing the SACC peer review of the draft

Formaldehyde evaluation, EPA again explained: “For chronic inhalation exposure and the cancer inhalation unit risk (IUR), the Agency intends to defer to the draft 2022 Integrated Risk

Information System [IRIS] Toxicological Review of Formaldehyde and associated 2023 review

by the NASEM [National Academy of Science, Engineering, and Medicine].”

<https://www.federalregister.gov/documents/2023/12/26/2023-28430/formaldehyde-draft-risk-evaluation-peer-review-by-the-science-advisory-committee-on-chemicals-sacc#p-18>. This was despite the fact that the IRIS toxicological review of Formaldehyde was still in draft form at the time.³

B. The SACC Peer Review.

Section 26(o) of TSCA, 15 U.S.C. § 2625(o), establishes the SACC 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 this subchapter.” Section 26(h) of TSCA mandates that Administrator decisions be consistent with “the best available science” including the “the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.” *See* 15 U.S.C. § 2625(h).

As EPA explained:

EPA will be soliciting comments from the SACC on the Office of Pollution Prevention and Toxics (OPPT) and Office of Pesticide Programs (OPP) joint hazard assessments for human and ecological health; and the OPPT exposure and risk characterizations. This SACC peer review is in addition to prior external peer reviews by the National Academies of Science, Engineering, and Medicine (NASEM), the EPA’s Human Studies Review Board (HSRB) and SACC peer reviews of scientific approaches used in previous TSCA risk evaluations. These previous peer reviews have informed the 2024 draft risk evaluation for formaldehyde.

89 Fed. Reg. at 18,934. EPA noted the importance of the SACC peer review by further stating:

Recommendations from the formaldehyde SACC review and public comments will be considered in the development of the final TSCA risk evaluation for

³ On August 20, 2024, EPA posted its final IRIS assessment for Formaldehyde, including a 10-page executive summary, a 927-page Toxicological Review, and 1,143 pages of supplemental information and appendixes. (Further discussed in Sec. II.B. below.)

formaldehyde and may inform other EPA efforts related to the assessment and regulation of formaldehyde. The Agency will be seeking SACC review of its data analyses and methodologies relevant to human health hazard and exposure analyses that have not been previously peer reviewed.

89 Fed. Reg. at 18,935.

EPA received written comments on the draft risk evaluation through May 14, 2024, and held a virtual peer review public meeting on May 20-23, 2024. *Id.* Hexion submitted formal public comments on the draft TSCA risk evaluation on May 14, 2024.

<https://www.regulations.gov/comment/EPA-HQ-OPPT-2023-0613-0260>. Hexion's comment letter stated:

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 [and other federal laws, regulations, and policies] 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 than a commitment to regulation based on the best available science.

Id. at 1.

SACC recently completed its peer review of the draft TSCA risk evaluation for formaldehyde and issued its 152-page Meeting Minutes and Final Report ("SACC Report") on August 1, 2024. <https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0298>. As detailed in Sec. II.A. below, the SACC Report included critical comments on the TSCA Risk Evaluation, and recommended that EPA take adequate time to properly address them.

C. The Proposed Consent Decree.

By notice in the Federal Register on April 26, 2024, EPA announced that it had reached agreement with the CIDA Plaintiffs on a Proposed Consent Decree Regarding High-Priority Chemical Risk Evaluation Deadlines (hereinafter the “Proposed Consent Decree”),⁴ and requested public comment thereon. 89 Fed. Reg. 32,424. The Proposed Consent Decree would require EPA to issue:

- a. *draft* risk evaluations for “at least seven” of the 20 Subject Chemicals (including 1,3-butadiene) by December 31, 2024;
- b. final risk evaluations for TCEP, formaldehyde and 1,1-dichloroethane by December 31, 2024;
- c. final risk evaluations for seven Subject Chemicals (including 1,3-butadiene) by December 31, 2025; and
- d. final risk evaluations for the remaining ten Subject Chemicals by December 31, 2026.

Prop. Consent Decree, ¶1.a.-d. Hexion objects solely to the proposed consent decree’s arbitrary deadline of December 31, 2024 for finalization of the TSCA risk evaluation for Formaldehyde, which is less than five months away, is unreasonably short and will not allow EPA to conduct a proper risk evaluation in accordance with applicable TSCA standards.

Clearly, there is nothing special about the December 31, 2024 deadline. After all, the CIDA Plaintiffs allege that EPA was required to complete the risk evaluations for all 20 of the Subject Chemicals by June 20, 2023 (*see* Complaint at ¶39), yet the final risk evaluations for *seven* of the Subject Chemicals are not due until December 31, 2025 and the final risk evaluations for the remaining *ten* Subject Chemicals are not due until December 31, 2026.

⁴ Contemporaneously, EPA announced that it had reached agreement with the CIDA Plaintiffs and ACC on a separate Proposed Consent Decree Regarding Manufacturer-Requested Risk Evaluation Deadlines relating to DIDP and DINP. Hexion takes no position on that separate proposed consent decree.

The Proposed Consent Decree does not provide for extension of the deadline in the event that the TSCA risk evaluation for Formaldehyde requires additional time beyond December 31, 2024. If EPA anticipates that it is reasonably likely to fail to meet any deadline set forth herein for any reason other than for a lapse of appropriations, EPA must contact Plaintiffs and the Parties must confer about the reason for the delay and the terms of a possible joint motion to extend the deadline. Prop. Consent Decree at ¶3.

If the Parties are unable to reach agreement on a joint motion, however, EPA must file a unilateral motion to extend a deadline set forth herein, after concluding that a deadline extension is necessary. *Id.* at ¶4. The Parties may not challenge the terms of this Consent Decree in subsequent proceedings. *Id.* at ¶5.

D. Hexion.

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. Hexion operates robust programs related to environmental, health, and safety, product stewardship (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”), Responsible Care®, and sustainability.

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. Hexion and its

associates and customers will be negatively impacted by the Proposed Consent Decree and the resulting final risk evaluation, which is set to include “unreasonable risk” determinations for many formaldehyde uses. These determinations will directly prompt Agency risk management regulations, which could include formaldehyde use bans or unachievable workplace standards, under Section 6 of TSCA.

Hexion submitted public comments on the Proposed Consent Decree to U.S. EPA by letter dated May 28, 2024. <https://www.regulations.gov/comment/EPA-HQ-OGC-2024-0192-0007>. Hexion requested that EPA and DOJ “not agree to the rushed December 31, 2024 deadline associated with formaldehyde based on the significant adverse impact of an expedited process likely to run afoul of TSCA scientific standards and other requirements.” *Id.* at 1. Hexion’s comments have identified numerous TSCA violations and EPA’s potential failures to perform non-discretionary duties in the draft risk evaluation of formaldehyde (detailed below). Fulfilling these non-discretionary duties will require fundamental revisions to the Agency’s draft risk evaluation and process, and will require additional time beyond the December 2024 proposed deadline.

Hexion also noted that the Proposed Consent Decree’s deadline is inappropriate and improper because EPA’s TSCA risk evaluation of formaldehyde is dependent upon and intertwined with two other recently developed Agency assessments of formaldehyde under the Integrated Risk Information System (IRIS) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). *Id.* at 4. The IRIS assessment has been subject to substantial criticism from peer reviewers and public commenters. *See* Sec. II.B. below. Finally, additional time is needed for inter- and intra-agency consultation and coordination as required by TSCA. However, EPA has posted no response to Hexion’s public comments.

II. LAW AND ARGUMENT

Intervention is required in order for a non-party like Hexion to oppose a proposed consent decree. *See, e.g., United States v. ABA*, 118 F.3d 776, 783 (D.C. Cir. 1997) (“intervention ... [is] a prerequisite for challenging a district court’s approval of a consent decree.”); *Howard v. McLucas*, 782 F.2d 956, 961 (11th Cir. 1986) (“we conclude the district court abused its discretion in denying the motion to intervene” in order to challenge a proposed consent decree); *United States v. New York City Hous. Auth.*, 326 F.R.D. 411, 418 (S.D. N.Y. 2018) (“this Court exercises its informed discretion to grant permissive intervention for the limited purpose of opposing the Proposed Consent Decree.”).

Fed. R. Civ. P. 24(b)(1)(B) broadly authorizes permissive intervention as follows: “On timely motion, the court may permit anyone to intervene who ... has a claim or defense that shares with the main action a common question of law or fact.” “In evaluating such motions, ‘the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights,’ Fed. R. Civ. P. 24(b)(3), and may also consider ‘whether parties seeking intervention will significantly contribute to ... the just and equitable adjudication of the legal question presented.’” *Sierra Club v. McCarthy*, 308 F.R.D. 9, *12 (D. D.C. 2015) (citing *Ctr. for Biological Diversity v. EPA*, 274 F.R.D. 305, 313 (D.D.C. 2011) (quoting *Aristotle Int’l, Inc. v. NGP Software, Inc.*, 714 F. Supp. 2d 1, 18 (D.D.C. 2010))).

In *Nuesse v. Camp*, 385 F.2d 694, 704 (D.C. Cir. 1967), the Court of Appeals found that Rule 24(b) provides “that anyone may be permitted to intervene if his claim and the main action have a common question of law or fact.... Although the rule speaks in terms of a ‘claim or defense’ this is not interpreted strictly so as to preclude permissive intervention....

[I]ntervention has been allowed in situations where ‘the existence of any nominate ‘claim’ or

‘defense’ is difficult to find.’” (Citation omitted).⁵ In *Nuesse*, the Court reversed the district court’s denial of permissive intervention for “lack of appropriate interest,” which the Court of Appeals found was reversible error. *Id.* at 706.

Denial of permissive intervention is reviewable under the abuse of discretion standard. *See, e.g., EEOC v. National Children’s Ctr.*, 146 F.3d 1042, 1046, 1048 (D.C. Cir. 1998) (citing *Twelve John Does v. District of Columbia*, 117 F.3d 571, 575 (D.C. Cir. 1997) (reversing district court’s denial where intervenor “plainly satisfied all three of the requirements for permissive intervention under Rule 24(b)(2)” and the denial was “without explanation.”) *Id.* at 1048, 1049.

At as the D.C. Circuit has recognized, “[a]n independent jurisdictional basis is simply unnecessary when the movant seeks to intervene only for the limited purpose,” such as obtaining access to documents covered by seal or by a protective order, “because the third party does not ask the court to rule on the merits of a claim or defense. Because [the Intervenor] does not seek intervention to litigate a substantive claim, ... the general requirement of an independent jurisdictional basis would not prevent the district court from granting her motion to intervene.” *EEOC*, 146 F.3d at 1047. Likewise, Hexion is seeking permissive intervention only for a limited purpose—namely, to object to and oppose the Proposed Consent Decree’s December 31, 2024 deadline for finalization of the TSCA risk evaluation for formaldehyde. Hexion is not seeking to intervene in order to litigate an independent substantive claim or defense.⁶

⁵ Accordingly, Hexion requests that it be excused from Rule 24(c)’s and LCvR 7(j)’s requirement that its motion for leave to intervene “be accompanied by a pleading that sets out the claim or defense for which intervention is sought.”

⁶ For this same reason, Hexion is not subject to the intervention standard set forth in *EEOC v. National Children’s Ctr.*: “In order to litigate a claim on the merits under Rule 24(b)(2), the putative intervenor must ordinarily present: (1) an independent ground for subject matter jurisdiction; (2) a timely motion; and (3) a claim or defense that has a question of law or fact in common with the main action.” *Equal Employment Opportunity Comm’n v. National Children’s Ctr.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998) (emphasis added).

Nonetheless, as Hexion’s May 28, 2024 comment letter demonstrates, there are numerous independent statutory grounds for subject matter jurisdiction justifying its permissive intervention in this case. See <https://www.regulations.gov/comment/EPA-HQ-OGC-2024-0192-0007>. These independent statutory grounds include, *inter alia*, the following EPA failures to fulfill its non-discretionary duties under TSCA:

- a. 15 U.S.C. § 2625(i) requires that “The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence;”
- b. 15 U.S.C. § 2605(b)(4)(F)(ii) requires that “In conducting a risk evaluation under this subsection, the Administrator shall ... describe the weight of the scientific evidence for the identified hazard and exposure;”
- c. 15 U.S.C. § 2605(b)(4) (F)(i) requires that “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;”
- d. 15 U.S.C. § 2625(j)(4) requires that “The Administrator shall make available to the public ... a list of the studies considered by the Administrator in carrying out each such risk evaluation, along with the results of those studies;”
- e. 15 U.S.C. § 2625(h) requires that “In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science;”
- f. 15 U.S.C. § 2608(b)(2) requires that “In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this subchapter with respect to a chemical substance ... 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 described in paragraph (1) 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;” and
- g. 15 U.S.C. § 2608(d) requires that “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, etc., 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.”

EPA’s failure to fulfill any of these mandatory non-discretionary duties under TSCA is exacerbated by the unreasonable time constraints that would be placed upon it by the proposed December 31, 2024 deadline. EPA’s failures ultimately may become actionable by way of the citizen suit under Section 20 of TSCA “to compel the Administrator to perform any act or duty under this chapter which is not discretionary.” 15 U.S.C. § 2619(a)(2). However, as the D.C. Circuit has stated, “it is not enough to deny intervention ... because applicants may vindicate their interests in some later, albeit more burdensome, litigation.” *Natural Resources Defense Council v. Costle*, 561 F.2d 904, 910 (D.C. Cir. 1977).

A. SACC Peer Review Comments.

Some of the SACC peer reviewers’ comments have been critical of EPA’s overlapping peer reviews, and support an extension of the proposed deadline for finalization of the TSCA risk evaluation for formaldehyde:

- “As a SACC member, I really wish we had more time to carefully review...everything EPA provided to us.... We only have like six, five or six working days. This is really difficult I think for the members to try to fully or deeply, you know, review all the documents.”⁷
- “I want to echo my co-committee members’ comments about the lack of time.... [I]t’s really also doing a disservice to the many, many, many pieces of information that are supposed to feed into this, including over 200 public comments that were made.... I was to reiterate that personally I feel that I’ve been hamstrung by not having the time or final documents to review for this.”⁸
- Peer reviewers noted fundamental concerns about EPA’s draft formaldehyde risk evaluation and the need for major revisions. One reviewer noted: “It is certainly in my professional opinion that they [EPA] are far, far away from a finished

⁷ <https://youtu.be/Z9FwC4emTC8?t=4734>.

⁸ <https://youtu.be/Z9FwC4emTC8?t=4895>.

document. As an editor I would recommend to the authors you're going to have to go back to the drawing board for substantial work in reorganizing reanalyzing material.”⁹

- Peer reviewers also noted EPA's failure to follow TSCA requirements for inter- and intra-agency consultation and coordination.¹⁰

In a recent Inside EPA.com (May 23, 2024) article titled “SACC Criticism of TSCA Formaldehyde Evaluation Could Delay Final Release” (attached hereto as **Exhibit A**), some of the SACC Peer Reviewers (as well as EPA officials) reportedly were even more blunt in their comments, and EPA officials even recognized that the December 31, 2024 deadline may need to be postponed to adequately address the peer reviewers' comments:

- Udayan Apte, a professor at the University of Kansas and SACC's lead reviewer for the evaluation's section on chronic inhalation hazards, said in the May 21, 2024 peer review session that “many members expressed reservations” about basing a TSCA document on a draft IRIS assessment that had not resolved peer reviewer recommendations. *Id.* at 1;
- Anna Lowit, senior science advisor to EPA's toxics program and one of the top agency officials in attendance for the peer review, suggested that if SACC intends to recommend greater alignment between TSCA and IRIS' eventual finished products, the only way to ensure that may be to **postpone release of the final TSCA evaluation**: “We have been working closely with them and our expectation, maybe up until yesterday, was that they would be finalizing that either in parallel or prior to the completion of the OPPT risk evaluation.” “But given the comments yesterday I think we are going to have to have dialogue internally on the status of that, to the extent that we have [federal advisory committee] reports that are in conflict with each other.” *Id.* (emphasis added);
- SACC panelist Cynthia Graham, an independent toxicology consultant from Denver, questioned whether such deadlines should be EPA's priority, asking Lowit, “since each risk assessment would be important, shouldn't EPA be more concerned with an accurate risk evaluation than staying within the timeline?” *Id.*;
- Lowit told Graham that Michal Freedhoff, the chemicals office's assistant administrator (AA), “is committed to completing a number of risk evaluations, not just formaldehyde, by December of this year. But we're looking for your

⁹ <https://www.youtube.com/live/jId4MytcFaM?si=egP81nf7tkwGqTxb&t=20732>

¹⁰ <https://www.youtube.com/live/C5APRhHgdjQ?si=PznhHFywJVgVfWdq&t=10923>

feedback. And if the feedback from the panel, if it sends us in a direction we did not anticipate, we'll be assessing that. But our preference is to stay on schedule and to comply with the request of our AA." *Id.* (emphasis added).

On August 12, 2024, SACC *ad hoc* peer reviewer Roger McClellan submitted a letter to EPA offering a "Differing Scientific Opinion and Recommended Path Forward," which he requested be entered into the official public record of the SACC Peer Review. *See* Aug. 12, 2024 Comment Ltr. from Roger O. McClellan, copy attached as **Exhibit B** hereto. It stated:

- The key point I would like to highlight in this Differing Scientific Opinion and Recommended Path Forward letter is that the External Scientific Advisory work of the SACC (Formaldehyde) HAS NOT BEEN COMPLETED with submission of its Meeting Minutes and Final Report based on the May 20-23, 2024, Virtual Meeting. The 150-page Report identifies numerous scientific issues that were not adequately addressed in the Draft Report. In my opinion, these issues must be addressed in a Revised Risk Evaluation for Formaldehyde. Moreover, it is crucial that the SACC (Formaldehyde) be reconvened in a **person-to-person public meeting** to ensure that the Revised Report appropriately addresses the substantial scientific recommendations made in the SACC Report just provided to the Agency. The Revised Report must provide a scientifically sound exposition of the available science on Formaldehyde's hazards to inform the Policy Judgements that must be made by Senior EPA Officials to provide Policy, Regulatory Guidance and Standards for Formaldehyde in accordance with the Toxic Substances Control Act (As amended), thereby enhancing the safe use of Formaldehyde in the future (*Id.* at 2, emphasis added);
- It soon became apparent to me that the EPA's approach to managing the SACC was very PROCESS and CALENDAR DRIVEN (*Id.*);
- In my opinion, the advisory tasks assigned to the SACC (Formaldehyde) are NOT COMPLETE. The Committee should be re-convened in a person-to-person Public Meeting when a revised TSAC-oriented Formaldehyde Hazard Assessment Report is available for review. This approach has been regularly used by the EPA in the past for other external scientific advisory activities, very few are treated in a "one meeting and done" fashion, let alone "one virtual meeting and done" fashion (*Id.* at 3);
- I expect the EPA to have a modus operandi for obtaining and using external scientific advice in a manner that all EPA actions are based on the best available science appropriately interpreted. In my opinion, that is not happening with the SACC meeting in virtual sessions to review chemical after chemical and WITHOUT FOLLOW UP REVIEW of the Agency's revised documents (*Id.* at 4);

- [A] scientifically sound Revised Formaldehyde Risk Assessment is needed to provide you and other EPA Senior Policy makers a concise document that reviews, evaluates and synthesizes the relevant scientific information required by Senior EPA Officials to make the CRITICAL POLICY JUDGEMENTS that are needed to establish the Policies, Standards and Regulations required by the TSCA to guide the future use of Formaldehyde, a vital commodity chemical. It is important that the SACC (Formaldehyde) Committee be reconvened to conduct a thorough review of the Revised Documentation to ensure it is Scientifically Adequate (*Id.*).

The SACC Report includes several specific comments and recommendations which cannot be squared with EPA's IRIS and TSCA actions nor with the proposed consent decree's establishment of a December 31, 2024 deadline for final risk evaluation of formaldehyde. For example:

- “Several Committee members disagreed with using the toxicity values in the current Draft Risk Evaluation (DRE) for formaldehyde, and the majority of committee members recommended incorporating NASEM and HSRB recommendations to revise the formaldehyde toxicity values reached by IRIS.” <https://www.regulations.gov/document/EPA-HQ-OPPT-2023-0613-0298> at p. 32.
- “Many members expressed reservations about the specifics surrounding the value of using the unedited 2022 Draft IRIS document since it is not final and the comments from NASEM review have not yet been incorporated. The Committee also suggested that the current authors revising the IRIS document take the SACC's comments into consideration.” *Id.*
- “The Committee recognized the Environmental Protection Agency (EPA) used the *Draft Integrated Risk Information System (IRIS)* values, which were extensively commented on by the National Academy of Science, Engineering and Medicine (NASEM) (NRC, 2011) and the Human Studies Review Board (HSRB) (HSRB 2023a), but the current draft does not yet reflect these comments.” *Id.* at 24.

Clearly, EPA will require additional time, beyond the Proposed Consent Decree's impending December 31, 2024 deadline, to adequately address the Differing Scientific Opinion and Recommended Path Forward set forth in Mr. McClellan's comment letter, as well as the many other SACC peer reviewers' critical comments set forth above.

B. Interagency Comments on Draft IRIS Formaldehyde Review.

In addition, written comments from other federal agencies were posted on the June 2024 Draft IRIS Toxicological Review of Formaldehyde—Inhalation which raise concerns about the Agency’s rushed process and failure to resolve key peer review, interagency, and public comments. https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549600

The U.S. Department of Agriculture (USDA) noted the following:

- “Given the significance and ubiquity of formaldehyde in commerce and in production, and the sheer volume of information contained in this review, USDA would note that the time provided for review was very short. USDA requests a more formal process to address issues related to this chemical.” *Id.* at 1.
- “USDA also requests additional interagency conversations to discuss potential implications of this draft toxicological review on future regulatory actions for formaldehyde.” *Id.*
- “USDA notes that formaldehyde is both directly and indirectly very important in agriculture, including in applications that themselves impact human and environmental health (positively). If those uses are threatened due to an overly conservative toxicological assessment of formaldehyde, that assessment could have a net adverse impact on human health and the environment.” *Id.*

And the Agency for Toxic Substances and Disease Registry, part of the Centers for Disease Control, commented as follows:

- ATSDR “disagrees with the lack of response to these other bullets (e.g., failing to incorporate relevant literature, use of uncertainty factors, lack of transparency) as they do impact the formaldehyde specific assessment.... This issue could detract f[ro]m the confidence in the entire ToxReview.” https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=549598 at p. 3.
- “It is suggested that EPA convene discussions from the larger scientific community (such as scientific international workshops, panels, or other non-governmental panels/reports) regarding the issue of mode of action and the impact that it could have on evidence findings in systematic review.” *Id.* at 4.

- “It is recommended that EPA allow for another round of interagency, peer review, and public commenting on this ToxReview to provide the scientific community time to assess whether they agree with this methodology This sentiment is echoed by public commenters.” *Id.* at 5 (citations omitted).

C. Hexion’s Standing.

“Although intervenors of right are obligated to demonstrate standing, it is unclear in this Circuit whether standing is also required for permissive intervention.” *In re Endangered Species Act Section 4 Deadline Litig.*, 270 F.R.D. 1, 5 (D. D.C. 2010) (citing *In re Vitamin Antitrust Class Actions*, 215 F.3d 26, 31-32 (D.C. Cir. 2000)). As the D.C. Circuit noted in *In re Vitamin Antitrust Class Actions*:

there is uncertainty over whether standing is necessary for permissive intervention. *Compare EEOC v. National Children’s Ctr., Inc.*, 146 F.3d 1042, 1045-46 (D.C. Cir. 1998) (recounting that Rule 24(b) requires would-be intervenors to have “an independent ground for subject matter jurisdiction” on a claim or defense that shares a common question with the claims of the original parties), and *Diamond v. Charles*, 476 U.S. 54, 76 (1986) (O’Connor, J., concurring) (“The words ‘claim or defense’ manifestly refer to the kinds of claims or defenses that can be raised in courts of law as part of an actual or impending lawsuit”); with *National Children’s Ctr.*, 146 F.3d at 1045-46 (noting that our circuit precedent avoids “strict readings of the phrase ‘claim or defense,’ allowing intervention even in ‘situations where the existence of any nominate ‘claim’ or ‘defense’ is difficult to find.”) (quoting *Nuesse*, 385 F.2d at 704)).

215 F.3d at 31-32.

Even if it is required to show standing, Hexion can show “procedural” and “informational” injuries as a basis for its standing. “It is clear that an individual can enforce procedural rights, provided that the procedures sought to be enforced are designed to protect his interest.” *Murray Energy Corp., et al., v. McCarthy*, No. 5:14-cv-00039 (N.D. W.V. Mem. Op. and Order Granting Summ. Jdgmt. for Pltfs. Oct. 17, 2016) (ECF No. 293, PageID 15337) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 n. 8 (1992)(emphasis added); *Massachusetts v. EPA*, 549 U.S. 497 (2007) (“a litigant to whom Congress has accorded a procedural right to

protect his concrete interests,—here, the right to challenge agency action unlawfully withheld—can assert that right without meeting all the normal standards for redressability and immediacy. When a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.”).

The Court noted that the Fourth Circuit has held that “plaintiffs need not show that the result of the agency’s deliberations will be different if the statutory procedure is followed.” *Id.*, PageID 15341 (quoting *Pye v. United States*, 269 F.3d 459, 472 (4th Cir. 2001), citing *Federal Election Com’n. v. Akins*, 524 U.S. 11, 25 (1998)).

In addition, “[t]he Supreme Court consistently has held that a plaintiff suffers an Article III injury when he is denied information that must be disclosed pursuant to a statute, notwithstanding ‘[t]he fact that other citizens or groups of citizens might make the same complaint after unsuccessfully demanding disclosure.’” *Id.* (citing *Pub. Citizen v. U.S. Dep’t of Justice*, 491 U.S. 440, 449-50 (1989); *see also Akins*, 524 U.S. at 21-25; *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 373-74 (1982)).

These procedural and/or informational injuries suffered by Hexion include all of the following:

- a. The Administrator’s failure to make decisions under section 2605 of TSCA based on the “weight of the scientific evidence”, as required by 15 U.S.C. § 2625(i);
- b. The Administrator’s failure to describe the “weight of the scientific evidence” for the identified hazard and exposure as required by 15 U.S.C. § 2605(b)(4)(F)(ii);
- c. The Administrator’s failure to accurately integrate and assess available information on hazards and exposures for the conditions of use of formaldehyde in conducting his risk evaluation, as required by 15 U.S.C. § 2605(b)(4)(F)(i);

- d. The Administrator’s failure to make available to the public a list of the studies (and their results) considered by the Administrator in carrying out the risk evaluation for formaldehyde, as required by 15 U.S.C. § 2625(j)(4);
- e. The Administrator’s failure to use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the “best available science”, in conducting its risk evaluation for formaldehyde, as required by 15 U.S.C. § 2625(h);
- f. The Administrator’s failure to adequately consider all relevant aspects of the risks associated with formaldehyde and to compare the estimated costs and efficiencies of such a TSCA evaluation to an action under another law administered in whole or in part by the Administrator (such as the Clean Air Act), as required by 15 U.S.C. § 2608(b)(2); and
- g. The Administrator’s failure to adequately consult and coordinate with the Secretary of Health and Human Services and the heads of any other appropriate Federal executive department or agency for the purpose of imposing the least burdens of duplicative requirements on those subject to the TSCA evaluation, as required by 15 U.S.C. § 2608(d).

Thus, Hexion clearly has a sufficient basis for procedural and/or informational standing.

D. Hexion’s Intervention Will Not Unduly Delay or Prejudice the Adjudication of the Original Parties’ Rights.

Hexion’s permissive intervention for the limited purpose of objecting to the Proposed Consent Decree’s December 31, 2024 deadline for EPA to issue its final TSCA risk evaluation for formaldehyde will not unduly delay or prejudice the adjudication of the original parties’ rights. *Cf.* Rule 24(b)(3). There have been minimal proceedings in this case to date. The EPA Defendants have not yet answered the Complaints filed by the CIDA Plaintiffs or by ACC. By minute order issued on July 11, 2024, this Court granted Defendants’ Unopposed Motion for Extension of Time to Answer or Respond to Both Complaints until August 16, 2024. Nor have the Parties yet moved for entry of the Proposed Consent Decree.

Hexion brings a unique perspective to the Proposed Consent Decree,¹¹ and is seeking to avoid a situation where this Court's consent decree is used as the stick to force EPA to cut corners and take hasty and precipitous action on the Section 6 TSCA risk evaluation for formaldehyde. Hexion hopes to avoid the Court's imposition of an arbitrary deadline which makes it significantly more likely that EPA will fail to fulfill all of its non-discretionary duties in connection with its risk evaluation for formaldehyde, which could in turn give rise to a separate citizen suit under Section 20 of TSCA. Thus, Hexion's permissive intervention "will significantly contribute to ... the just and equitable adjudication of the legal question presented." *Ctr. for Biological Diversity v. United States EPA*, 274 F.R.D. 305, 313 (D. D.C. 2011) (citing *Aristotle Int'l, Inc. v. NGP Software, Inc.*, 714 F. Supp. 2d 1, 18 (D.D.C. 2010)). No other non-parties have sought to intervene in this action.

Hexion's objections to the Proposed Consent Decree can be presented to the Court in a simple brief, in opposition to the Parties' anticipated motion for entry. The Court will then decide whether or not to withhold approval of the Proposed Consent Decree based on the merits of Hexion's arguments. The Court's consideration of Hexion's arguments will not result in any undue delay or prejudice to the adjudication of the original parties' rights.

CONCLUSION

For all the foregoing reasons, Hexion respectfully requests this Court's leave to intervene in this action for the limited purpose of objecting to and opposing the Proposed Consent Decree's December 31, 2024 deadline for EPA to complete the Section 6 TSCA risk evaluation of Formaldehyde.

¹¹ ACC's involvement is presumably limited to the chemicals DIDP and DINP at issue in the consolidated case of *ACC v. EPA*, Case No. 1:23-cv-03736, and the Proposed "ACC/CIDA" Consent Decree relates to those chemicals only.

Dated: August 30, 2024

Respectfully submitted,

/s/ Jeremy W. Dutra

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of August, 2024, the foregoing was filed electronically with the Clerk of Court using the CM/ECF system, and notice of this filing will be sent to all attorneys of record by operation of the Court's electronic filing system.

/s/ Jeremy W. Dutra _____
*Attorney for Defendant Intervenor-Movant
Hexion Inc.*

INSIDE EPA'S

INSIDE TSCAExclusive news and analysis on the new
Toxic Substances Control Act

SACC Criticism Of TSCA Formaldehyde Evaluation Could Delay Final Release

May 23, 2024

Post

Science Advisory Committee on Chemicals (SACC) members peer reviewing the draft TSCA evaluation of formaldehyde are raising early critiques of both the document itself and its reliance on draft Integrated Risk Information System (IRIS) findings -- criticism that an EPA toxics official says could delay the evaluation's current Dec. 31 target.

During SACC's May 20-24 peer review meeting for the Toxic Substances Control Act (TSCA) formaldehyde draft, members of the panel questioned EPA staff multiple times on the office of Pollution Prevention and Toxics' (OPPT) decision to use a draft IRIS assessment as the basis for some of its own analyses, and the status of that review.

Udayan Apte, a professor at the University of Kansas and SACC's lead reviewer for the evaluation's section on chronic inhalation hazards, said in the May 21 session that "many members expressed reservations" about basing a TSCA document on an unfinished assessment.

In particular, he noted that while the IRIS assessment was peer reviewed by a National Academies of Science, Engineering and Medicine (NASEM) committee in 2023, EPA has yet to issue a final version showing any changes based on NASEM's recommendations. "[T]he IRIS document doesn't seem to be a final document; it's a draft and many of the NASEM comments [are] not addressed, leaving open questions," he said.

Apte asked staff about the status of the IRIS assessment again when the committee convened on May 22, calling it the "foundation of what we are doing here."

But Anna Lowit, senior science advisor to EPA's toxics program and one of the top agency officials in attendance for the peer review, suggested that if SACC intends to recommend greater alignment between TSCA and IRIS' eventual finished products, the only way to ensure that may be to postpone release of the final TSCA evaluation.

"We have been working closely with them and our expectation, maybe up until yesterday, was that they would be finalizing that either in parallel or prior to the completion of the OPPT risk evaluation," Lowit said on May 22 -- the day after Apte's initial remarks. "But given the comments yesterday I think we are going to have to have dialogue internally on the status of that, to the extent that we have [federal advisory committee] reports that are in conflict with each other."

The TSCA formaldehyde evaluation is already long past its June 2023 statutory deadline. Moreover, EPA recently floated [a draft settlement agreement](#) with environmentalists and industry setting staggered deadlines for 22 past-due reviews that would require it to take final action on formaldehyde and four others by year's end.

However, SACC panelist Cynthia Graham, an independent toxicology consultant from Denver, questioned whether such deadlines should be EPA's priority, asking Lowit, "since each risk assessment would be important, shouldn't EPA be more concerned with an accurate risk evaluation than staying within the timeline?"

Lowit told Graham that Michal Freedhoff, the chemicals office's assistant administrator (AA), "is committed to completing a number of risk evaluations, not just formaldehyde, by December of this year. But we're looking for your feedback. And if the feedback from the panel, if it sends us in a direction we did not anticipate, we'll be assessing that. But our preference is to stay on schedule and to comply with the request of our AA."

Parallel Reviews

By contrast, EPA has largely been silent on when it expects to complete the IRIS formaldehyde assessment, which was one of many projects at that hazard analysis program that were halted during the Trump administration. Research

officials “unfroze” it early in the Biden administration, saying that the document would form the basis for the also-pending TSCA evaluation, and IRIS released a draft in 2022.

Most recently, during a May 22 NASEM event, agency research chief Chris Frey answered a committee member’s question on the status of the document by saying it is “undergoing revision in response to peer review. I don’t know when the final version will be out; it is something we are very actively working on.”

Some SACC members had raised the TSCA draft’s reliance on the IRIS assessment as a concern at their May 7 kickoff meeting. There, a few suggested they intend **to comment on their concerns**, despite the IRIS assessment being outside EPA’s formal charge questions to the committee.

EPA staff defended the decision to rely on the IRIS assessment in May 20 presentations to the SACC panel, at least to the extent it provided chronic risk values the TSCA office could use. IRIS assessments generally do not consider acute exposures or separately analyze occupational dangers, both of which are key elements in TSCA evaluations.

“OPPT has engaged in collaboration across the agency in development of the draft risk evaluation for formaldehyde,” Rochelle Bohaty, EPA’s management lead for the formaldehyde evaluation, told SACC. The agency’s TSCA, IRIS and pesticides offices have all sought to harmonize their characterizations of human health hazard from the ubiquitous chemical as they work on what will eventually be three different documents regarding it -- a TSCA evaluation, an IRIS assessment, and a pesticide registration review.

“Since IRIS had already done a substantial amount of work on hazard characterization it made sense to leverage their work and expertise; after all, we are one EPA,” she said.

Bohaty said that is why the TSCA and pesticide program’s risk analyses of formaldehyde inhalation rely on the IRIS hazard assessment for chronic cancer and noncancer hazard values. The TSCA and pesticides offices conducted their own reviews of oral, dermal, and acute inhalation effects.

Risk Analysis

In addition to broader concerns over the timelines and relationships between EPA’s multiple risk reviews of formaldehyde, SACC members offered a range of views on how the TSCA program applied the IRIS draft in its own analysis.

For instance, in a May 22 discussion of the evaluation’s chronic inhalation hazard value for non-cancer conditions, several panelists criticized the TSCA draft’s use of a point of departure (POD) -- a key element of the program’s risk analyses. The TSCA formaldehyde draft drew its chronic inhalation POD from IRIS’ work on a reference concentration (RfC), which represents an estimate of the greatest amount of the chemical a person can inhale daily over a lifetime without expected health harms.

Specifically, the TSCA draft’s POD is based on a 1990 study of respiratory impacts known as “Krzyzanowski et al.,” one among a small group of studies that IRIS selected to inform its RfC. The OPPT authors used an uncertainty factor (UF) of three, also in keeping with IRIS, in their calculation of a “margin of exposure” for risk calculations.

Apte said multiple “members questioned [EPA’s] sole use of the Krzyzanowski study and the UF of three,” noting that OPPT used that report alone as the basis for its risk calculation, excluding controlled “chamber” studies of human volunteers to formaldehyde, which some suggested were of higher quality. He said the panelists had concerns about the quality of its design, findings, and opaque data reporting of the Krzyzanowski study, which some suggested should have led EPA to use different data.

He noted that had IRIS staff selected another study, the RfC “would be 175-fold higher. It is just to put in perspective that depending on what studies you use, the RfCs are significantly different and without some justification, the poor quality of Krzyzanowski was so much more sensitive to effects than a set of human controlled studies, it is difficult to accept the POD provided in the document.”

Apte indicated that some members suggested that TSCA staff even change which health effect they use to calculate chronic non-cancer risks, using data on sensory irritation instead. Doing so would require selection of entirely different key studies -- a significant, and potentially time-consuming, revision.

At least two other panelists spoke up in support of the idea -- Debra Kaden, a consultant with the firm Ramboll, and Judy Strickland, a toxicologist retired from the pharmaceutical and medical testing company Inotiv. Both suggested that

the agency should target sensory irritation instead.

Another panelist, Lisa Sweeney, a toxicologist with the firm UES, also appeared to support the suggestion, but added that uncertainty over TSCA's "unreasonable risk" standard, which neither Congress nor EPA has ever defined, complicates SACC's ability to offer such recommendations.

"EPA in different programs . . . has different definitions of the type of risk," she said. "So the lack of a definition of unreasonable risk and what is unreasonable risk in the context of the TSCA program and its many, many different conditions of use kind of pervades any and all endpoints."

She added that the uncertainty applies "across the board because what's acceptable in one [program] might not in another." -- *Maria Hegstad* (mhegstad@iwpnews.com)

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August 12, 2024

Re: Differing Scientific Opinion and Recommended Path Forward—EPA Scientific Advisory Committee on Chemicals (Formaldehyde) Report

Dear Honorable Administrator Regan:

I am writing to provide you and the Agency a **Differing Scientific Opinion and Recommended Path Forward** than that related in the Final Report of the EPA Scientific Advisory Committee on Chemicals (Formaldehyde). The full title of that report is "Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2024-01, Docket ID: EPA-HQ-Oppt-2023-0613, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Peer Review of the 2024 Draft Risk Evaluation for Formaldehyde, May 20-23, 2024, Virtual Meeting via Webcast." The report was submitted by Tamue Gibson, Designated Federal Official (DFO) and Executive Secretary, Science Advisory Committee on Chemicals (SACC), through Hayley Hughes, Director, Office of Program Support to Elissa Reaves, Director, Office of Pollution Prevention and Toxics on August 1, 2024. I respectfully request that this letter be entered in the Official Public Record of the Peer Review of the EPA's 2024 Draft Risk Evaluation for Formaldehyde.

I served as a SACC ad hoc Peer Reviewer on Formaldehyde along with 9 other ad hoc Peer Reviewers appointed to complement 16 standing members of the SACC chaired by George P. Cobb, Baylor University. This is the Committee whose activities are contained in the Report noted above.

By way of background, I have over 60 years of experience as a scientist and research manager including 50 years of experience with Formaldehyde. I have served for over 35 years as Editor-in-Chief of Critical Reviews in Toxicology, a highly respected International Scientific Review Journal. I have published extensively on research conducted to evaluate the human health hazards of airborne agents. Many of my publications concern the conduct of risk assessments for these agents. A paper entitled, "Role of Science and Judgement in Setting National Ambient Air Quality Standards: How Low is Low enough?" Air Quality, Atmosphere and Health Journal 5 (2):245-258, 2012 (R.O. McClellan, 2012) is of special relevance to my "Differing Scientific Opinion and Recommended Path Forward".

I am proud to note my service on numerous EPA Advisory Committees under a number of EPA Administrators. My first appointment was by the late William D. Ruckelshaus to the EPA's Inaugural Science Advisory Board (SAB) Executive Committee soon after the EPA was created in December 1970. My past service included chairing the Advisory Committee that reviewed the draft Criteria Document used to set the initial National Ambient Air Quality Standard for Lead and later chairing the Clean Air Scientific Advisory Committee. Related to these EPA Advisory activities, I have been invited numerous times to testify before Congressional Committees. My testimony on November 16, 1993, before the Subcommittee of the House Committee of Science, Space and Technology focused on developments in Risk Assessment practices.

I am writing to you now to share this Differing Scientific Opinion and Path Forward Recommendation, which was not included in the Official SACC Report noted above. I do not know why my "Differing Scientific Opinion and Path Forward Recommendation" was not included in the Final SACC Report. I made my views known to both the SACC DFO and Chair in Mid-July.

The key point I would like to highlight in this Differing Scientific Opinion and Recommended Path Forward letter is that the External Scientific Advisory work of the SACC (Formaldehyde) HAS NOT BEEN COMPLETED with submission of its Meeting Minutes and Final Report based on the May 20-23, 2024, Virtual Meeting. The 150-page Report identifies numerous scientific issues that were not adequately addressed in the Draft Report. In my opinion, these issues must be addressed in a Revised Risk Evaluation for Formaldehyde. Moreover, it is crucial that the SACC (Formaldehyde) be reconvened in a **person-to-person public meeting** to ensure that the Revised Report appropriately addresses the substantial scientific recommendations made in the SACC Report just provided to the Agency. The Revised Report must provide a scientifically sound exposition of the available science on Formaldehyde's hazards to inform the Policy Judgements that must be made by Senior EPA Officials to provide Policy, Regulatory Guidance and Standards for Formaldehyde in accordance with the Toxic Substances Control Act (As amended), thereby enhancing the safe use of Formaldehyde in the future.

The Scientific Advisory process on the Formaldehyde Risk Evaluation began with the SACC, including ad hoc members, reviewing a collection of 50 EPA documents of quite variable quality. One of the most notable was the 2022 Integrated Risk and Information System (IRIS) Report that had been reviewed by the National Academies of Science, Engineering and Medicine (NASEM) 2 years previously. It is noteworthy that the 2022 IRIS Report was a successor to a 2010 IRIS Report on Formaldehyde that was never revised and finalized after review by a NASEM Committee. As a member of the National Academy of Medicine, I reviewed a draft of the NASEM review of the 2010 IRIS Documentation on Formaldehyde.

The EPA documents were complemented by many excellent public comments from 150 interested parties. Thirty five of those parties presented comments during the Virtual Meeting. It soon became apparent to me that the EPA's approach to managing the SACC was very PROCESS and CALENDAR DRIVEN. Early on I sent an e-mail to my fellow Committee members suggesting it might be useful to visit some Formaldehyde facilities to better understand its use. I was immediately reprimanded for potentially "illegally convening the SACC".

In my opinion, the EPA's approach to management of the SACC DISCOURAGED DIALOGUE AMONG COMMITTEE MEMBERS. As you know, science flourishes, including scientific reviews, when communication is encouraged between scientists with diverse backgrounds. Instead, the SACC was required to meet in Virtual Public sessions with 50 to over 80 online participants. In contrast, more than a dozen other EPA Advisory Committees met in public sessions during late 2023 and early 2024. I am compelled to ask: why EPA management did not accord this important advisory activity on Formaldehyde a higher priority and have the SACC meet in a public, in-person meeting?

Despite these substantial handicaps, the SACC (Formaldehyde) produced a credible report in a very short time. However, in my opinion some key issues were not adequately addressed in the Report. Indeed, the comments of some ad hoc SACC members were repeatedly edited, and in my opinion, this minimized the significance of their excellent comments and insights.

For example, in my professional opinion, there is abundant literature, developed over the last half century, that describes the unique dosimetry in laboratory animals and humans of inhaled Formaldehyde, a highly reactive gas. The dosimetry of this inhaled exogenous Formaldehyde contrasts markedly with that of the endogenous Formaldehyde found in all our bodies. The dosimetry of the inhaled Formaldehyde dictates the site of exposure-related health effects (both non-cancer effects and cancer) in the nasal tissues. In my scientific opinion, the resulting exposure–dose–response relationship has a clear threshold. This threshold relationship is unlike the non-threshold exposure–response typically assumed for many chemicals that have a very different dosimetric profile that produces very different health responses. This body of science was very well-described in many of the public comments the Agency received on Formaldehyde.

This is a topic that must be addressed in the Revised Formaldehyde Hazard Assessment that will be used to inform Policy Decisions that are required by TSCA. The situation has been further complicated by the Agency's delayed revision of the IRIS document. It is my understanding that preparation of a Revised IRIS Formaldehyde Report is complete and has been circulated to other agencies. I am compelled to ask why the Agency has not provided the revised IRIS report to the SACC?

In my opinion, the advisory tasks assigned to the SACC (Formaldehyde) are NOT COMPLETE. The Committee should be re-convened in a person-to-person Public Meeting when a revised TSAC-oriented Formaldehyde Hazard Assessment Report is available for review. This approach has been regularly used by the EPA in the past for other external scientific advisory activities, very few are treated in a "one meeting and done" fashion, let alone "one virtual meeting and done" fashion.

As mentioned, I chaired the EPA Advisory Committee that reviewed the first Criteria Document on Airborne Lead, those advisory activities took multiple meetings extending over more than a year. It took time to get the Science right on the health effects of Lead. The persistence of the Lead Advisory Committee and EPA staff was worth it. The resulting EPA regulatory action has had profound impact: I also served on the EPA's Advisory Committee on Health Effects of Diesel Engine Exhaust. That Committee met multiple times over several years and reviewed several draft Reports before a satisfactory report was recommended for approval by the Committee. The final Diesel Report and associated regulatory actions has had great impact on guiding development of a diesel technology!

I also wish to note that a major shortcoming of the final SACC Report is that the Report edited by the DFO was finalized in a manner that does not reveal the identity of the individuals (SACC members or ad hoc Reviewers) offering comments. This editorial approach substantially reduces the usefulness of the Report. As an experienced scientist, I want to be identified with my views and opinions. I expect the same of other participants. Indeed, acknowledging those who offered their opinion or viewpoint is very important. The identity of the scientists offering a particular viewpoint should also be important to the EPA Officials using the Report.

I recall my service on a CASAC that reviewed a Criteria Document on Airborne Particulate Matter (PM). The CASAC Report noted a majority of the Committee recommended reducing the National Ambient Air Quality Standard (NAAQS) expressed as an Annual Average for PM_{2.5}. The Report also noted that two members of CASAC, myself and Dr. George Wolff, did not recommend a reduction. We felt it was a Policy Judgement that should be made by the EPA Administrator. I am pleased that the Administrator elected to retain the existing NAAQS. In making that decision the EPA Administrator noted the views of the two dissenting members. I think the Administrator was

influenced by knowing Dr. Wolff and I were both experienced scientists and former Chairs of CASAC. I hope that when a Revised Risk Evaluation on Formaldehyde is reviewed by the SACC in the future, the Committee Report will have the views of individual scientists clearly identified!

As I was in the process of drafting this letter, I learned that the Science Committee on Chemical Safety apparently does not operate as part of the EPA's Science Advisory Board (SAB). As I understand, it reports directly to the Assistant Administrator for Chemical Safety and Pollution Prevention. Perhaps that explains the SACC's unusual mode of operation and the prominent role of the Designated Federal Official versus the Appointed Committee Chair.

In my opinion, the Office of Chemical Safety and Pollution Prevention personnel would learn a great deal from closer coordination with personnel staffing SAB Committees. As a scientist and U.S Citizen, I expect the EPA to have a modus operandi for obtaining and using external scientific advice in a manner that all EPA actions are based on the best available science appropriately interpreted. In my opinion, that is not happening with the SACC meeting in virtual sessions to review chemical after chemical and WITHOUT FOLLOW UP REVIEW of the Agency's revised documents.

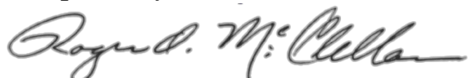
Beginning in mid-July, on multiple occasions, I informed the SACC Designated Federal Official, Tamue Gibson, and the SACC Chair, George Cobb of my "Differing Scientific Opinion" with regard to the need for the Committee to reconvene to review revised documentation when it became available. Further, I stated my desire to have my views shared with my fellow SACC (Formaldehyde) participants. I was told that could not be done; I would be violating FACA rules.

On July 25, 2024, I contacted the EPA's Inspector General "Hot Line" (888-546-8740) for assistance on this matter. Despite making numerous calls to this "Hot Line", I never received any return calls. After the SACC Report was filed on August 1, 2024, I received an E-mail from Dr. Cobb indicating that my "perspective" was reflected in the Final Report. To the contrary, I have not been able to find my "Differing Scientific Opinion" reflected in the Report. Indeed, the Report is silent with regard to any future actions reviewing a Revised Report. Apparently the past "one virtual meeting and done" SACC approach is accepted as standard practice. that should not be the case!

In closing, let me emphasize that a scientifically sound Revised Formaldehyde Risk Assessment is needed to provide you and other EPA Senior Policy makers a concise document that reviews, evaluates and synthesizes the relevant scientific information required by Senior EPA Officials to make the CRITICAL POLICY JUDGEMENTS that are needed to establish the Policies, Standards and Regulations required by the TSCA to guide the future use of Formaldehyde, a vital commodity chemical. It is important that the SACC (Formaldehyde) Committee be reconvened to conduct a thorough review of the Revised Documentation to ensure it is Scientifically Adequate. I stand ready to assist in that review.

If I can be of further assistance, please contact me.

Respectfully,



Roger O. McClellan

Member, EPA Scientific Advisory Committee on Chemicals (Formaldehyde)

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xc: Michal I. Freedhoff, Assistant Administrator-Chemical Safety and Pollution Prevention, freedhoff.michal@epa.gov

Sean ODonnell, Inspector General, ODonnell.Sean@epa.gov

George Cobb, Chair-Science Advisory Committee on Chemicals (Formaldehyde)

Tamue Gibson, Designated Federal Official, SACC, gibson.tamue@epa.gov

Members and Ad Hoc Reviewers, Science Advisory Committee on Chemicals Formaldehyde
Public Commenters on Draft Risk Evaluation for Formaldehyde

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COMMUNITY IN-POWER AND)
DEVELOPMENT ASS'N., INC., et al.,)

Plaintiffs,)

v.)

UNITED STATES ENVIRONMENTAL)
PROTECTION AGENCY, et al.,)

Defendants,)

and)

HEXION INC.)
180 East Broad Street)
Columbus, OH 43215,)

Defendant Intervenor-)
Movant.)

Case No. 1:23-cv-02715-DLF

Hon. Dabney L. Friedrich

**HEXION INC.'S DISCLOSURE OF
CORPORATE AFFILIATIONS AND
FINANCIAL INTERESTS**

In accordance with LCvR 26.1 of the Local Rules of the United States District Court for the District of Columbia, I, undersigned counsel of record for Intervenor-Movant Hexion, Inc., certify that to the best of my knowledge and belief, the following are parent companies, subsidiaries, affiliates, or companies which own at least 10% of the stock of Hexion, Inc. which have any outstanding securities in the hands of the public:

None.

These representations are made in order that judges of this Court may determine the need for recusal.

Dated: August 30, 2024

Respectfully submitted,

/s/ Jeremy W. Dutra

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Attorneys for Defendant Intervenor-Movant Hexion Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of August, 2024, the foregoing was filed electronically with the Clerk of Court using the CM/ECF system, and notice of this filing will be sent to all attorneys of record by operation of the Court's electronic filing system.

/s/ Jeremy W. Dutra _____
*Attorney for Defendant Intervenor-Movant
Hexion Inc.*