IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CHEMISTRY COUNCIL, INC.,
Plaintiff,

v.

NATIONAL ACADEMY OF SCIENCES;

U.S. ENVIRONMENTAL PROTECTION AGENCY;

MICHAEL S. REGAN, in his official capacity as Administrator of U.S. Environmental Protection Agency,

Defendants.

Case: No. 23-cv-2113

PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION AND RESPONSE TO MOTION TO DISMISS

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INTRODUCTION

In their combined Responses to the American Chemistry Council's ("ACC's") Motion for Preliminary or Permanent Injunctive Relief ("PI Mot.") and Motions to Dismiss, Defendants NAS and EPA barely address the merits of ACC's FACA claims. There is a reason for that: there are so many evident flaws in NAS's review of EPA's 2022 draft formaldehyde IRIS assessment ("Assessment") that it is hard for Defendants to argue that they comply with FACA standards for independence, transparency, and balance. From EPA's narrow formulation of the scope of NAS's review to its non-public proposal of Committee members, to NAS's failure to disclose (or justify) conflicts of interest and publish substantive summaries of closed-door meetings, the NAS review process was designed and conducted to exclude a meaningful review of the science. Indeed, the declaration NAS relies on to support its brief confirms the superficiality of NAS's review, admitting that EPA barred NAS from reviewing the substance of or science behind the Assessment. *See* NAS Mem., Symmes Dec. ¶ 15. This is exactly what Congress, understanding the power of NAS imprimatur of agency action, intended to prevent when it prohibited agency control of NAS reviews and imposed specific procedural requirements on NAS committees.

Instead of defending ACC's claims on their merits, Defendants try to avoid their adjudication. EPA contests ACC's standing, and each Defendant argues that the Court lacks jurisdiction to adjudicate the FACA claims against it and cannot provide any remedy, now or later. If correct, this view of FACA would render a significant part of that Act dead letter, making FACA's very specific requirements for NAS advisory committees purely guidance, and FACA's provision stating that agencies "may not use" NAS reviews that violate FACA (5 U.S.C. § 1014(a)) an empty mandate. Defendants' shell game also would incentivize EPA to outsource statutorily required peer reviews to NAS without any meaningful accountability for either body, despite Congress's enactment of specific requirements for such collaboration.

Fortunately, this is not the law. Rather, this court regularly adjudicates FACA-based claims, and has remedied FACA violations under both the Mandamus Act and the APA, as it did in *NAACP Legal Defense and Education Fund, Inc. v. Barr*, 496 F. Supp. 3d 116, 144-45 (D.D.C. 2020) (finding FACA violations and holding "the APA is an appropriate vehicle for [plaintiff's] claims against [the agency]" while "mandamus relief is the appropriate vehicle" for claims "against non-agency defendants"). There is no legal or logical reason why those bases for jurisdiction would be unavailable to address FACA violations by a NAS advisory committee and EPA. FACA does not exclude NAS committees from its scope; to the contrary, it imposes specific requirements on NAS committees, including those funded with taxpayer dollars and carrying out statutorily mandated peer reviews of agency regulatory science, and it forbids agencies from using work by a committee that violated those requirements. 5 U.S.C. § 1014(a).

Here, EPA is already using NAS's Report to assert that its formaldehyde assessment—including its conclusion that formaldehyde poses health risks at low levels—is sound, and to move the Assessment to the next step in the IRIS process. These unlawful uses of a NAS work product generated in violation of FACA are already causing reputational and business harm to ACC members who produce and use formaldehyde. That harm will only increase as EPA takes planned further steps to incorporate the Assessment into its regulatory agenda—as EPA's brief confirms the agency intends to do, and do quickly. ACC's members should not have to wait for such further action to seek the relief promised by FACA: a prohibition on use of a NAS report that results from unlawful process. That is particularly true since EPA has taken the view that, once it undertakes rulemaking using a peer-reviewed IRIS assessment, it is too late to challenge that assessment. Defendants' view, then, is that there is no right time to challenge a NAS review of an EPA assessment under FACA. Before NAS's report is used is too early; after is too late.

That misguided view of FACA would render it toothless—at least in regard to NAS reviews of agency regulatory science. That is not what Congress intended. *See NAACP*, 495 F. Supp. 3d at 135 ("[I]t is implausible to conclude that Congress simultaneously passed a law designed to constrain executive discretion and ensure Executive Branch accountability, while also wholly precluding judicial review of advisory committee [ ] decisions.") (quoting *Nat. Res. Def. Council v. Dep't of Interior*, 410 F. Supp. 3d 582, 604 (S.D.N.Y. 2019)). The Court should decline to adopt an interpretation of the FACA provision addressing NAS committees that renders NAS's and EPA's statutory obligations purely optional. Rather, as in prior FACA cases, this Court should hold the Committee and EPA to the specific obligations Congress imposed, and provide the remedy that Congress prescribed by barring EPA from using the unlawful NAS report.

ARGUMENT

I. The Court should grant injunctive relief because ACC's claims are likely to succeed.

Defendants spend notably little of their briefs on the merits of ACC's FACA claims, barely attempting to rebut them.[1] This silence on the merits betrays the weakness of Defendants' position.

No reasonable person could look at how the Committee proceeded and think it was consistent with Congress's intent or FACA's specific requirements that NAS advisory committees act free from any agency control; issue reports that are the result of their independent judgment;

[1] EPA instead argues that injunctive relief should not issue because ACC waited too long to file its PI motion. Hardly. ACC filed its PI motion on October 13, 2023, less than a month after filing its Amended Complaint (Sept. 15)—which ACC had to file after NAS rushed to complete the Report shortly after ACC filed its original complaint. ACC moved as expeditiously as it could to amend the complaint and complete the PI motion, while still thoughtfully briefing the merits of its claims and the PI factors. And contrary to EPA's suggestion (EPA Mem. at 32), ACC's diligent attempts to first try to address the FACA violations through comments, letters, and other engagement with Defendants only supports the timing of their request for judicial relief. *See Texas Children's Hosp. v. Burwell,* 76 F. Supp. 3d 224, 244-45 (D.D.C. 2014) (finding that plaintiffs had a reasonable explanation for delay in seeking a PI where they demonstrated a "diligent pursuit of a variety of avenues for reversing [agency] policy" first).

be fairly balanced and free from unjustified conflicts; and publicly disclose the substance of their closed-door discussions, the information they considered, and information about proposed committee members. If the violations ACC has alleged do not collectively show NAS's failure to comply with FACA, the Act's requirements for NAS committees have no meaning.

But this Court need only agree that NAS or EPA violated FACA in one of the myriad ways identified in ACC's opening brief and discussed further below for injunctive relief to be warranted. The Act plainly states that an agency "may not use" a NAS report produced in violation of FACA. 5 U.S.C. § 1014(a). The question then is not, as Defendants suggest, whether ACC is likely to succeed on *all* of its FACA claims, but simply whether it is likely to succeed in regard to even *one*. If so, an injunction should issue to fulfill Congress's mandate that an agency is barred from using the work product of a NAS Committee that proceeded in violation of FACA.[2] That mandate has no meaning if injunctive relief—either preliminary or permanent—is not available to bar agency use of an unlawful NAS Report *before* EPA uses that Report.

A. Defendants' filings confirm that EPA improperly controlled the Committee.

Defendants briefly assert—with minimal supporting argument—that EPA did not control the Committee in violation of FACA's prohibition on "*any* actual management or control" by the referring agency. 5 U.S.C. § 1014(a)(1) (emphasis added). But their filings indicate otherwise and, together with the evidence cited in ACC's PI Motion, show that ACC has not only stated a claim based on improper management or control, but is likely to succeed on that claim. Furthermore,

[2] *See NAACP*, 496 F. Supp. 3d at 116, 145 (prohibiting defendants from future "submi[ssion], public[cation], or rel[iance] on any report or recommendations produced by the Commission until the requirements of FACA are satisfied"); *Alabama-Tombigbee Rivers Coal. v. Fish & Wildlife Serv. of U.S. Dep't of Interior*, Civ A. No. 93-AR-2322-S, 1993 WL 646409, at *2–*4 (N.D. Ala. Nov. 9, 1993) (finding "plaintiffs will suffer severe and irreparable harm" from use of the report and enjoining such use, even though the government argued they "can seek and obtain any necessary corrective action within the rule-making process").

EPA and NAS ignore that, in describing the requirements for Section 15(a), Congress directs that "the final report of the Academy will be the result of the Academy's independent judgment," a standard that is plainly not met here. 5 U.S.C. § 15(b)(1)(C).

For example, NAS relied on the declaration of Gregory Symmes, who explained that EPA "limited" "the scope of the formaldehyde committee's review … to … whether EPA adequately evaluated scientific literature and methodologies to support its formaldehyde response analysis." NAS Mem., Symmes Dec. ¶ 15. Effectively, NAS was only permitted to say whether EPA presented a methodology and literature citation list that, when taken alone without alternative views, would "support [EPA's] formaldehyde response analysis." *Id*. This is not a true peer review, and does not allow the Committee to conduct full and meaningful deliberations. To make sure that the Committee did not critique the Assessment or how it was generated (as NAS did in response to the 2010 Assessment), EPA "provided further that the Academy would not assess the human health effects of formaldehyde separately from the EPA's IRIS assessment." *Id*. Mr. Symmes thus confirms that EPA limited the Committee's review to ensure that it did not consider or dispute EPA's key substantive and scientific conclusions. This narrow review stands in stark contrast to NAS's 2011 review of the 2010 formaldehyde assessment. There, the committee explained that, to "address [its] charge," it had to "consider[] the methods … of the document as a whole" and assess the "processes underlying the development of the draft," which is how the Committee found "recurring methodological problems."[3] EPA prohibited such review here.

[3] *EPA's IRIS Program: Evaluating the Science and Process Behind Chemical Risk Assessment*, Hearing for the Subcommittee on Investigations and Oversight, Committee on Science, Space and Technology (July 14, 2011) at 41, https://www.govinfo.gov/content/pkg/CHRG-112hhrg67255/pdf/CHRG-112hhrg67255.pdf.

Defendants are correct that an agency can decide which questions to ask of NAS, but that does not mean that an agency can design the scope and questions in such a constrained way that it controls NAS's work and inherently violates the FACA requirement that NAS's review be free from agency control. For example, by Defendants' logic, NASA could contract with NAS to advise on the shape of the Earth, but limit NAS to reviewing "flat Earther" literature, establish charge questions and a scope of review that limits criticism, and prohibit it from independently reviewing NASA's scientific conclusions. By any reasonable definition, however, such limitations do not permit an independent review, and show at least *some* "actual management or control by [the] agency." 5 U.S.C. § 1014(a)(1).

The same logic applies here, where EPA solicited NAS's "comment on whether the" Assessment's use of evidence was "scientifically justified"[4]—but then mandated that NAS "shall not conduct an independent assessment separately from the IRIS document" and that "[c]omments provided by the NAS committee shall be limited to responding to the materials provided by the EPA," ignoring any otherwise available information. Pl.'s Mem., Ex. C at 2. NAS could not "comment on other interpretations of scientific information relevant to the hazards and risks of formaldehyde[.]" Pl.'s Mem., Ex. R at 2. EPA even dictated the length of the Committee's public peer review meetings, Pl.'s Mem., Ex. C at 3, and thereby limited the Committee's opportunity to hear and consider alternative interpretations and information disregarded by EPA. That cannot be squared with the regulations implementing FACA, which make clear that where an agency contracts with NAS for an advisory report, the agency may only use the report if "the committee's

[4] Final External Peer Review Charge Questions for the IRIS Toxicological Review of Formaldehyde—Inhalation (June 2022), https://www.regulations.gov/document/EPA-HQ-ORD-2010-0396-0104.

meetings, deliberations, and the preparation of reports *are all controlled by the academy*." 41 C.F.R. Pt. 102-3, Subpt. E, App. A (emphasis added).

Thus, by severely limiting the substance of the Committee's deliberations, dictating the length of the Committee's public meetings, and constraining the information the Committee could consider so as to effectively dictate the outcome of the Committee's process, EPA impermissibly managed and controlled the Committee in violation of FACA's requirement that a NAS review proceed free from "any" such "management or control." 5 U.S.C. § 1014(a)(1).

Defendants also have no response to the hard evidence of further EPA control discussed in and attached to ACC's PI motion: emails between EPA and NAS, outside the normal nomination solicitation process, regarding who should be appointed to the Committee. EPA admits "that an EPA staff member provided suggestions" for appointments. EPA Mem. at 25. EPA tries to brush aside that correspondence as a normal way of soliciting arms-length input. It was not.

In fact, EPA has a policy in its Peer Review Handbook addressing how it can suggest reviewers. Specifically, if EPA suggests any peer reviewers, it should provide "a pool of qualified peer reviewers … in alphabetical order"; the proposal "should include more individuals than the number required for the review"; and EPA should specifically note "that it is a suggested list and other qualified candidates may exist who are not on the list."[5] EPA did not follow this policy here, instead telling NAS who specifically should review the Assessment, providing very few names and not noting that they were just suggestions and NAS could also choose from other candidates.[6] EPA argues that the Handbook did not apply because it was "a single employee" (Stan Barone)

[5] EPA, Science and Technology Policy Council, *Peer Review Handbook* 59 (4th ed., Oct. 2015) ("EPA Peer Review Handbook"), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf.

[6] Pl.'s Mem., Ex. D at 1-2.

directing NAS's selection process, not the agency. But Mr. Barone was acting in his official capacity, on his official EPA email account, during work hours. *See id*.

What's more, EPA views these emails regarding Committee appointments as relating to an official agency decision; it redacted the names of its proposed Committee members, citing the "[d]eliberative [p]rocess." *See id*. That means EPA views its "suggestions" to NAS regarding Committee members as relating to *EPA's own decision-making process*.[7] If emails regarding the choice of Committee members relate to EPA's decision, not that of NAS, then EPA believes it, not NAS, was deciding the Committee's composition.

EPA attempts to argue (EPA Mem. at 25-26) that its deliberative process claim does not show that the agency views the choice of Committee members as an *EPA* decision. EPA cites *100Reporters LLC v. U.S. Dept. of Justice*, 248 F. Supp. 3d 115, 147-49 (D.D.C. 2017), as confirming that there can be protected communications between an agency and a contractor. This is true, but EPA ignores that the test set forth in that case asks whether there actually was an applicable privilege, such as the deliberative process privilege. 248 F.Supp.3d at 145-49. And the court explained that to claim "'a document as predecisional," the agency must connect it to "'an agency decision or policy to which the document contributed.'" *Id*.at 151 (quoting *Senate of P.R. v. DOJ*, 823 F.2d 574, 585 (D.C. Cir. 1987)). EPA cannot explain how its emails about the choice of Committee members simultaneously contribute to "an agency decision" while also leaving the decision to pick Committee members entirely up to NAS, as required by FACA.

Even setting that aside, the facts remain that an EPA employee, acting in their official capacity as part of an EPA decision-making process, told NAS that they should reuse members

[7] *See* DOJ Guide to [FOIA], Exemption 5 at 9-10 ("documents conveying advice from an agency to" a decisionmaker that "is not itself an 'agency' under FOIA" would not be protected as deliberative), https://www.justice.gov/d9/pages/attachments/2023/03/13/exemption_5_final.pdf.

from the 2010 committee, and identified specific people who should be on the committee, with no hint that these were simply suggestions rather than instructions. Pl.'s Mem., Ex. D at 1-2. That is not arms-length input that any interested person might make; it is agency "management and control." 5 U.S.C. § 1014(a)(1). NAS asserts that such input is "routine[]" (NAS Mem. at 26), but even if that were true, it does not make it a lawful practice. NAS also asserts that it regularly "asks … for input on committee memberships" from "stakeholders," (NAS Mem. at 26), but, there is no evidence that NAS directly contacted or reached out to any other stakeholders to solicit their suggestions for committee members. NAS certainly did not seek the input of ACC or any of the ACC Formaldehyde Panel members, who had to monitor NAS's website to find the general, open comment period. Only EPA had a direct line to the study director. Additionally, NAS appears in these emails to have disclosed the names of some intended members of the Committee to EPA, weeks before the public deadline for nominations, six months before the public release of the draft assessment, and 10 months before the public release of the Committee to the public.[8]

EPA seems to argue that, even if it told NAS who to appoint, that would not equate to management or control of the review process. EPA Mem. at 25. In support, EPA points to a case brought under a different section of FACA that does not even use the term "control" (instead, referring to whether an agency utilizes the committee), and that does not concern who chose the Committee. *See* EPA Mem. at 25 (citing *Washington Legal Found. v. U.S. Sent'g Comm'n*, 17 F.3d 1446, 1450 (D.C. Cir. 1994)). But the regulations implementing the relevant section of FACA clarify that NAS is subject to "actual management or control" "if the members of the committee are" selected by the agency instead of the academy. 41 C.F.R. Pt. 102-3, Subpt. E, App. A. That is precisely what happened here—as EPA's emails with NAS make clear.

[8] Pl.'s Mem., Ex. D at 1.

EPA limited the scope of the review to prohibit NAS from substantively reviewing EPA's assessment of the science or its conclusions, and then EPA played a lead role in selecting the Committee members to undertake this limited review. If such circumstances do not equate to at least *some* actual management or control of a NAS review (in violation of FACA's prohibition on "any" actual management or control, 5 U.S.C. § 1014(a)(1)), it is unclear what would.

B. Defendants' filings confirm that the Committee was not fairly balanced.

NAS's proposed interpretation of FACA's "fairly balanced" requirement would not just "give[] the Academy lots of leeway" in appointing committee members (NAS Mem. at 18), it would eliminate all meaning from the statutory text. In response to the documented fact that ACC *repeatedly* approached NAS, both before and after NAS formed the Committee, to explain the myriad ways in which the proposed and then final Committee lacked balance, NAS answers that it must have used its best efforts to satisfy the "fairly balanced" requirement because it has a policy requiring balance. NAS Mem. at 18. The superficiality of that response alone indicates that ACC is likely to succeed on this FACA claim.

NAS has not attempted to provide any reason for appointing a Committee of which more than half the members are academic epidemiologists, and which lacks expertise in occupational epidemiology, pharmacokinetic modeling, hematology, and reproductive effects—all of which are areas that the EPA task order expressly recommended be represented. Pl.'s Mem., Ex. C at 2-3. In response, NAS can say no more than that it has a policy designed to ensure balance. But simply *having* policies requiring compliance with FACA's fair balance requirement cannot be sufficient to defeat a FACA fair balance claim. That is particularly true where the basic facts regarding the Committee's makeup—that the Committee is mostly comprised of members from one particular discipline—facially indicate a lack of balance. And the panel's preponderance of epidemiologists without experience in *occupational* epidemiology is a critical deficiency, particularly because EPA

relies upon occupational cohorts in its draft 2022 IRIS formaldehyde assessment to draw carcinogenicity conclusions.[9] The Report reflects this disciplinary bias; contrary to other peer review bodies, the Committee, dominated by epidemiologists, endorsed the use of low-quality epidemiological studies over controlled human exposure studies.[10]

In response to ACC's point that NAS did not appoint any members with an industry viewpoint, NAS does not argue that it has balanced opposing interests, merely that it does not need to think about such things because it only conducted a "'scientific peer review'" that was "'politically neutral and technocratic.'" NAS Mem. at 19-20.[11] Although that may be true if NAS had selected unbiased Committee members and the Committee limited itself to addressing purely scientific and technical issues, that is certainly not true here, where the Committee represented one point of view—and then, despite its narrow charge, strayed into policy by recommending that EPA move quickly to finalize the Assessment in order to fulfill EPA's policy-making mission. Where, as here, a committee includes representatives with particular biases or offers non-scientific

[9] *See, e.g.,* EPA, *Toxicological Review of Formaldehyde—Inhalation, CASRN 50-00-0* (the Assessment), at xxix (Apr. 2022), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=544587.

[10] *See* Draft Report of the EPA Human Subjects Review Board at 9-10 ("the controlled chamber studies . . . have preferred study design and greater scientific rigor than the observational studies . . . HSRB recommends that EPA use exposure levels from chamber studies rather than observational studies"), https://www.epa.gov/system/files/documents/2023-10/july-2023-hsrb-report-woe-formaldehyde.pdf; Pl.'s Mem. at 22.

[11] NAS also argues that it is not required to consider viewpoint balance at all because it is only subject to FACA section 15, but this argument ignores the broad wording of FACA section 15, which specifically requires that NAS "committee membership is fairly balanced." 5 U.S.C. § 1014(b)(1)(B). Unlike the portion of FACA requiring other advisory committees to be "balanced in terms of the points of view represented and the functions to be performed," (5 U.S.C. § 1004(b)(2)) the provision applicable to NAS groups together balance of viewpoint and balance of function into one broad term "fairly balanced." This broader term does not require viewpoint balance to be individually named in order to be required of NAS.

opinions, it must have representation from balancing viewpoints, such as that of industry. This is true for several reasons.

First, an industrial perspective is necessary from a functional, not just viewpoint, perspective, for an evaluation and interpretation of exposures in various workplace epidemiology studies. Pl.'s Mem. at 23. The IRIS Assessment used "observational epidemiological studies" of workers and attempted to extrapolate from these studies "exposure measurements [from] within occupational settings," similar to the workplaces of ACC's members.[12] It is thus only logical to have at least one person on the Committee personally familiar with the industrial and occupational uses of formaldehyde and the science on occupational exposure to formaldehyde.

Second, NAS points to *Cargill Inc. v. United States*, 173 F.3d 323 (5th Cir. 1999), for its position that viewpoints are irrelevant, but the Fifth Circuit did not, as NAS suggests, stop its inquiry at whether the advisory committee was assigned a technocratic task.[13] The court also looked to whether there was evidence that "membership is somehow biased toward one particular point of view," and whether there was a "*prima facie* showing that the membership of the committee is biased in its point of view." *Cargill*, 173 F.3d at 338. Unlike in *Cargill*, there is such evidence here. ACC explained that four Committee members plus the Study Director[14] have clear

[12] The Assessment at xxvii-xxix.

[13] Despite relying on *Cargill*, NAS noted that it addresses the fair balance provisions applicable to other advisory committees under other sections of FACA, not to NAS under section 15. NAS Mem. at 19. As discussed in footnote 11, *supra,* NAS argues that it is not required to consider viewpoint balance at all, but this ignores the broad wording of FACA section 15, which is unique in that it broadly requires committees be "fairly balanced." 5 U.S.C. § 1014(b)(1)(B). This necessarily includes at least some viewpoint balance.

[14] Although the Study Director is not a "member" of the Committee, they are a key contributor to its work, frequently writing sections. Here, Dr. Guyton was the staff lead in charge of the section of the Report related to cancer assessment. *See* Ex. A, April 13 through 15, 2023 Committee emails at 2. As a result, the Study Director's biases shape the outcome of the Committee's work, and must be balanced in the same manner as Members in order for the Committee to be "fairly balanced." Unrefuted in EPA and NASEM's reply is the extensive documentation of Guyton's

biases in favor of the Assessment itself and/or significant connection to the IRIS Program that authored it. *See* Pl.'s Mem. at 10-13, 23-24, 26-30. Perhaps most notably, both Dr. Samet, the Chair, and Committee member Dr. Ivan Rusyn have repeatedly conveyed their beliefs—articulated before the Committee began its supposedly objective review of the Assessment—that the IRIS Program is functioning appropriately and conducted the Assessment correctly, and that the Assessment should be quickly finalized and used as the basis for regulation.

For example, in 2019, three years before the Committee began its work, Dr. Rusyn testified before Congress regarding EPA's IRIS Program, characterizing the formaldehyde assessment as one of the "high-quality comprehensive assessments that are ready for completion under the IRIS process" and noting that "delays in completing the evaluation of [formaldehyde] are unacceptable."[15] Notably, the Preface to the Report directly echoes this opinion, suggesting that this preexisting viewpoint influenced the Pl.'s Mem., Ex. A at xi-xii. Dr. Rusyn has also had significant involvement with EPA's IRIS Program. In his own words, Dr. Rusyn has noted that he "interacted with IRIS staff on a variety of scientific and methodological issues directly relevant to implementation of the advice from the National Academies."[16] In addition to serving on the 2011 NAS committee that reviewed the 2010 draft IRIS formaldehyde assessment, he chaired a NAS Committee that hosted workshops to "support development of EPA's IRIS Toxicological

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prior employment and direct involvement in developing the Assessment, as well as her work history with EPA's IRIS program and IARC.

[15] *EPA's IRIS Program: Reviewing Its Progress And Roadblocks Ahead*, Hearing Before the Subcomm. on Investigations and Oversight, 116th Cong. 2, Statement of Dr. Ivan Rusyn ("Statement of Dr. Ivan Rusyn"), at 10 (Mar. 27, 2019), https://republicans-science.house.gov/_cache/files/a/2/a2e745af-d8e1-4ec8-8ad2-b911a9ab43e3/BA4E9317509D052F516127CA4CF5F256.2019-03-27-testimony-rusyn.pdf.

[16] Statement of Dr. Ivan Rusyn at 2.

Reviews."[17] EPA and OMB have acknowledged that repeatedly turning to the same peer reviewers, or allowing a reviewer to conduct a peer review of work on which they previously consulted, is prohibited (unless unavoidable) because "they may lose their impartiality."[18] Even if such a bias is not disqualifying as a conflict, *see* Section I.D, *infra,* it must be balanced by countervailing views to avoid an imbalance on the Committee. The Committee was not so balanced here, where no contrary viewpoints, more inclined to question EPA's IRIS process and the Assessment, were reflected in the makeup of the Committee.

Committee chair (and member) Dr. Samet also has strongly held views on the IRIS program. The week after the Committee began deliberations, Dr. Samet published a blog post in which he stated that the IRIS Program's methods and causal judgments since 2011 "have proved to be effective and have supported many measures that have advanced public health."[19] Whether the IRIS Program used methods and made causal judgments that were effective and supported was one of the few issues on which the Committee opined. Thus, Dr. Samet's statement on that point, made before reviewing the Assessment, reflects a biased view that the IRIS Program and its Assessment were reliable. Moreover, his position that IRIS assessments "support[] many measures that have advanced public health," is a policy view that the IRIS Program generally produces useful

[17] NAS, Workshops to Support Development of EPA's IRIS Toxicological Reviews, https://www.nationalacademies.org/our-work/workshops-to-support-development-of-epas-iris-toxicological-reviews.

[18] *EPA Peer Review Handbook* at 70, 73, https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf; *see also* Office of Management and Budget, *Final Information Quality Bulletin for Peer Review* at 18 (Dec. 16, 2004), https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf.

[19] Jonathan Samet, *The COVID-19 Pandemic & More: Colorado's plateau continues …*, Colo. Sch. of Pub. Health, Dean's Notes (Oct. 18, 2022), https://coloradosph.cuanschutz.edu/news-and-events/newsroom/deans-notes/public-health-main-site-news/the-covid-19-pandemic-more-colorado-s-plateau-continues-and-causation-and-its-consequences.

assessments. Dr. Samet's predetermined view that EPA's IRIS assessments are effective and reliable[20] was not balanced on the Committee—whether by a member with industrial or occupational epidemiological expertise, or by persons concerned that the IRIS Program may still have significant methodological issues.[21]

NAS's own Policy, on which it relies in its brief (NAS Mem. at 18), shows the importance of countering such viewpoint biases. The Policy states:

> [A]n individual may have strongly held views or biases, or may be closely associated with a group that has taken a strong position, on an issue before the committee. This does not preclude appointment to the committee as long as the individual remains open to new learning that could change his/her views. However, *it may be necessary to include on the committee other members with contrasting views* to maintain balance.

NAS Mem., Symmes Dec., Ex. A at 2. Yet NAS did not include such contrasting views on the Committee here.

NAS's Policy also defines as "Relevant" (*id*. at 5) the public statements made by Dr. Rusyn and Dr. Samet, as well as Dr. Samet's work for IARC, "an entity that has taken a public position on an issue that is central to the work of the committee." *Id.* at 4. NAS's Policy requires disclosure

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[20] Dr. Samet also has admitted to having "potential biases" in favor of International Agency for Research on Cancer ("IARC") analyses because of his "more than three decades" of chairing and participating in IARC groups. Dr. Samet's biased point of view towards IARC is relevant due to the Committee's reliance on IARC as a means to support EPA's conclusions regarding carcinogenicity. *See, e.g.*, Pl.'s Mem., Ex. A at 39. Again, NAS has not provided any evidence that it tried to balance an admitted bias in favor of IARC analyses with any opposing viewpoint.

[21] NAS also failed to address concerns that those in the agricultural sector, particularly agricultural scientists, should have been represented on the Committee. Rep. Sanford Bishop, then-Chair of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, flagged these imbalance concerns to EPA in June 2022, explaining that, "formaldehyde is a building block chemical used in a wide variety of agricultural settings" and, "[g]iven the substantial impact of this assessment on the agricultural sector and the requirement that the scientific review process be balanced and geographically diverse, EPA should also ensure that at least 2 of the 12 peer reviewers for this assessment have a background in an agriculture-related science." Letter from S. Bishop to M. Regan, June 7, 2022, https://downloads.regulations.gov/EPA-HQ-ORD-2010-0396-0066/attachment_1.pdf.

of these relevant statements and relationship both "at the time of committee formation and in any report of the committee." *Id* at 3. NAS failed to disclose such statements and work, and NAS's failure to follow its own Policy on balance not only demonstrates its failure to comply with the corresponding FACA requirement, but also undermines NAS's defense that it must have complied with FACA's fair balance requirement because it has a policy directing it to do so.

Even if the Committee members did not have such obvious inherent biases as to require countervailing perspectives, the Committee's decision to go beyond its limited mandate from EPA by weighing in on the political issue of whether EPA should finalize and use the Assessment makes it clear that NAS is obligated to ensure balanced perspectives. The D.C. Circuit has explained that, where the facts show "that the Committee had broadly interpreted its mandate and was considering substantive changes in federal policies and programs" instead of merely conducting a technical analysis, the court should assess whether there was a balance of viewpoints. *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Priv. Sector Surv. on Cost Control*, 711 F.2d 1071, 1074 (D.C. Cir. 1983). In the very first pages of the Report, the Committee asserts that the Assessment "needs to be completed to support EPA in accomplishing this mission" "to protect human health" (even though the Committee was told by EPA *not* to review EPA's substantive conclusions regarding human health impacts) and "urges closure on the Draft Assessment." Pl.'s Mem., Ex. A at xi-xii. EPA never asked NAS to opine on whether the Assessment should be completed because that is a political question, involving Agency resources and priorities, not a question for scientists. The Committee's decision to focus on EPA's "mission" and urge certain policy decisions removes the Committee from the technocratic sphere and thus, under *National Anti-Hunger Coalition*, 711 F.2d at 1074, requires a consideration of the lack of balance in their viewpoints. This is another reason that ACC's "fair balance" claim is likely to succeed.

EPA and NAS's attempts to defend ACC's FACA Section 15 fair balance claim beg the question of what that statutory provision *does* require of NAS. Defendants do not attempt to explain how the Committee, despite being comprised almost entirely of persons from one discipline and representing one point of view (academics in favor of finalizing the Assessment) could be considered "fairly balanced." The implication of their arguments is that Section 15's fair balance requirement is essentially non-justiciable. But that line of argument was squarely rejected by this Court in *NAACP*, where it held that courts can assess whether a committee has sufficient diversity in personnel from different backgrounds and perspectives—and found fair balance lacking where all committee members hailed from a law enforcement background and shared a pro-police perspective. 496 F.Supp.3d at 132-36, 143-44 (noting that the committee did not include "a single member" representing communities or those subject to policing). While the topic of this review process may be more scientific, the flaws in its makeup are essentially the same; the Committee does not include a single member with the expertise and perspective of an occupational epidemiologist, representing the views of those subject to regulation of formaldehyde production and use, or even simply more inclined to be critical of EPA's IRIS process or Assessment. As it did in *NAACP*, the Court therefore should enter "injunctive relief requiring defendant [ ] to ensure the Commission has a fairly balanced membership." *Id*. at 145.

C. Defendants' filings confirm that the Committee failed to disclose required information to the public.

ACC's "public disclosure" FACA claim is also likely to succeed. The attachments to NAS's own brief show that NAS failed to disclose meeting summaries, written materials submitted to the Committee, and meaningful biographies of members, all of which are required by FACA.

Mr. Symmes attaches to his declaration the so-called meeting "summary" (NAS Mem, Symmes Dec., Ex. C) that NAS generated in order to comply with FACA's requirement that "[t]he

Academy shall make available to the public … a brief summary of any [closed] committee meeting." 5 U.S.C. § 1014(b)(4). This document cannot reasonably be called a summary in any usual sense of that word. A summary is "a short, clear description that gives the main facts or ideas about something."[22] NAS's document gives no "description" of, nor any "facts" about, the meeting it supposedly summarizes, noting only that the Committee discussed "Composition, balance, and conflict of interest." These words do not describe the "main facts" or "ideas" discussed; they do not even identify the precise topics (e.g. what particular potential or actual conflicts of interest were discussed). And they provide absolutely no information about the conclusions the Committee reached about the conflicts discussed. NAS points to language in the Act specifically requiring summaries to provide certain information (such as which committee members attended and which materials were made available to them), but the Act's direction to that end does not obviate the broader textual obligation to provide a "summary" of the meeting content.

NAS also failed to disclose all "written materials presented to the committee." 5 U.S.C. § 1014(b)(3). Here, NAS again relies on its policy of creating a public access file (PAF) with relevant materials, and then points to its policy not to disclose comments regarding committee composition. NAS. Mem, Symmes Dec. at ¶¶ 26-27. ACC disagrees with the notion that comments regarding committee composition, even when submitted after the Committee is formed and while the Committee is holding discussions about "Composition, balance, and conflict of interest" (NAS. Mem, Symmes Dec., Ex. C), are only for use of NAS, not the Committee, and therefore need not be disclosed to the public. Even if that were the case, NAS still has completely failed to address ACC communications to the Committee itself, which were not on the PAF. *See* Pl.'s Mem., Ex. B

[22] Cambridge Online Dictionary, *Summary*, at https://dictionary.cambridge.org/us/dictionary/english/summary.

¶12 ("NAS has not disclosed that ACC sent the Committee a copy of the complaint in this case to make all Committee members aware of ACC's concerns and the basis therefore, nor did NAS post ACC's August 7, 2023 letter to the Committee regarding an alternative EPA review of formaldehyde"). Knowing that NAS has failed to post at least two communications from ACC to the Committee itself, one cannot credit Mr. Symmes' position that, because NAS creates a PAF with communications, it must have complied with its FACA disclosure obligations.

Finally, NAS argues that it provided sufficient "brief biographies" of proposed Committee members (NAS Mem. at 22), but those biographies omit key information that NAS itself has defined as "relevant" and in need of disclosure. *See* § I.B, *supra* (discussing NAS's Policy defining relevant publications and prior work requiring disclosure). NAS has not disclosed members' publications that are relevant to the Committee's work[23] or ties to organizations with strong opinions on the risks of formaldehyde,[24] which is the bare minimum that must be disclosed—even under NAS's own Policy. Multiple ACC letters in August and September 2022 outlined that biographical information on provisional committee members was "inaccurate and/or missing critical information regarding potential bias and conflict of interest," including inaccurate and insufficient information regarding participation on formaldehyde-related NAS and EPA peer review bodies.[25] And yet NAS has never included that information in its Committee biographies.

ACC is thus likely to succeed in showing that NAS violated FACA by failing to disclose at least some materials that FACA requires be provided for public review.

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[23] For example, Dr. Samet's blog post lauding the IRIS Program's methodology and judgment and noting the need for IRIS assessments to support public health, and Dr. Rusyn's statement to Congress that the formaldehyde Assessment was high quality and should be finalized quickly.

[24] For example, Dr. Samet's work with IARC, which he admitted creates a bias and potential conflict of interest.

[25] Pl.'s Mem., Ex. L at 2; Pl.'s Mem., Ex. F at 5-6.

D. Defendants' filings confirm NAS did not disclose or justify conflicts of interest.

Whether one views the Committee members' relationships to EPA, its IRIS program, and IARC as a fair balance issue or a conflicts of interest issue, one thing is clear: many Committee members have ties that needed to be disclosed and either balanced, shown to be unavoidable, or addressed through removal of that member from the Committee. NAS did none of these things.

Most notably, Dr. Rusyn's work on the Committee resulted in him reviewing an assessment that was developed based on his own prior advice to and consultation with EPA regarding how to fix the IRIS process, including how to implement the findings from NAS's review of the 2010 formaldehyde assessment. Dr. Rusyn was a faculty fellow to the IRIS Program from 2011 to 2013, after NAS's 2011 Report on EPA's 2010 formaldehyde assessment. At that time, he worked on "scientific and methodological issues directly relevant to implementation of the advice from the National Academies," implementation of which was evaluated in the Report.[26] To claim that a person has no conflict of interest when reviewing work product developed based on their advice would defy all logic. In fact, it also defies EPA's own policy, under which peer reviewers are not "independent" if they are "associated with the generation of the specific work product, either directly by substantial contribution to its development or indirectly by significant consultation during the development of the product." EPA Peer Review Handbook at 70. Other reviewers, such

[26] Statement of Dr. Ivan Rusyn at 2. Some of Dr. Rusyn's work with the IRIS Program and its formaldehyde Assessment is documented in emails between himself and Dr. Guyton. Notably, in 2012, Dr. Guyton invited Dr. Rusyn to present within EPA on the "Roadmap for Revision" of the IRIS formaldehyde assessment (Ex. B, Jan. 23, 2012 emails between K. Guyton and I. Rusyn), and then blind copied him on comments on the draft assessment sent to senior EPA officials a year later. Ex. C, April. 23, 2013 email from K. Guyton to B. Sonawane. Dr. Guyton's incorporation of Dr. Rusyn into the IRIS review process further demonstrates both her and Dr. Rusyn's significant past involvement with the IRIS formaldehyde Assessment—and their bias in favor of bringing the process to a close.

as Dr. Sheppard, may have conflicts of interest or bias because of their repeated, extensive relationships with EPA. *See* Pl.'s Mem. at 28-31. NAS's Policy cannot save it from the fact that these relationships with the sponsoring agency are relevant according to the government's own standards, and yet NAS failed to even disclose these close connections between Committee members and EPA, the referring agency whose work the members were assessing.

Dr. Samet also has a clear conflict of interest due to his ties to IARC, with which the Report seeks to align itself on key issues. *See* Pl.'s Mem. at 30. Dr. Samet's connection to IARC is financial and ongoing,[27] yet it was not disclosed or addressed in any way, contrary to NAS's own policy. NAS entirely failed to address this additional conflict in its brief.

Defendants do not even attempt to argue that Dr. Guyton is not conflicted or demonstrably biased. Nor could they. Before joining NAS, Dr. Guyton worked on the Assessment itself.[28] While at EPA, Dr. Guyton argued against changing major conclusions of EPA's 2010 Assessment or conducting additional peer review in response to NAS's scathing 2011 report.[29] It is now Dr. Guyton who NAS has tasked with "primary responsibility" for ensuring compliance with FACA[30]--and preparation of the section of the Report related to cancer assessment. *See* Ex. A, April 13-15, 2023 Committee Emails at 2.

Individually and collectively, these conflicts—which were never disclosed let alone justified—violate FACA's prohibition on proceeding when Committee members have undisclosed

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[27] *See* Samet JM, et al., *Commentary: Role and communications of cancer hazard determinations. Carcinogenesis*, 43(2):79–81 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8947230/ (publication funded in part by IARC).

[28] Pl.'s Mem., Ex. G.

[29] Pl.'s Mem., Ex. H.

[30] *The Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Chairs*, at 5 (Feb. 2016), https://sites.nationalacademies.org/cs/groups/ssbsite/documents/webpage/ssb_173593.pdf.

and unjustified conflicts. *See* 5 U.S.C. § 1014(b)(1)(A) (conflicts must be "promptly and publicly disclosed" and NAS must explain "why the conflict is unavoidable"). Whether these conflicts are considered alone or in combination with the other FACA violations discussed above, it is clear that NAS has not complied with FACA in its review of the Assessment, and ACC's FACA claims are therefore likely to succeed on the merits, justifying early injunctive relief.

II. The Court should grant injunctive relief now because ACC's members face irreparable harm and the equities favor early injunctive relief.

A. Early injunctive relief is needed to stop and prevent irreparable harm.

ACC and its members are already suffering harm from the NAS Report, and the longer the Report stands and EPA is permitted to use it to finalize the Assessment and take various regulatory actions based on it, the greater that harm will grow.

1. ACC's members are already experiencing harm from the Report.

First—and of critical importance when determining whether ACC's members face imminent harm so as to justify injunctive relief—NAS's issuance of the Report has *already* harmed ACC's members who produce formaldehyde and products made from it. It has done so by suggesting that formaldehyde—a chemical found in a wide range of everyday products as well as the human body—is harmful to human health even in very small amounts.[31] In other words, the Report itself inflicts reputational harm on producers of formaldehyde products (which include basic construction materials, health products, and consumer items). That alone is sufficient basis for the court to issue preliminary injunctive relief. *See Everglades Harvesting and Hauling, Inc. v.*

[31] Pl.'s Mem., Ex. A, Report at xii (claiming Assessment's "findings on hazard and quantitative risk are supported by the scientific evidence identified"). The findings that NAS reviewed include that levels of formaldehyde below natural background levels—and often less than that found in human breath—are harmful to human health.

Scalia, 427 F. Supp. 3d 101, 116 (D.D.C. 2019) (granting PI on the basis of reputational harm); *Beacon Assocs., Inc. v. Apprio, Inc.*, 308 F. Supp. 3d 277, 288 (D.D.C. 2018) (same).

By publishing the Report, NAS has issued what will be seen by many as its "official determination that formaldehyde exposure causes" cancer, and this determination "cause[s] a variety of adverse impacts on industry."[32] As ACC has explained, "quasi-regulatory actions," like NAS's review of the IRIS Assessment, "have significant impacts" on ACC members, including the creation of "market distortions" due to "the stigma of a hazard determination." Pl.'s Mem., Ex. B, ACC Decl. ¶ 27. As examples, a foreign government[33] as well as Members of Congress[34] have pointed to NAS reviews of formaldehyde to make claims regarding carcinogenicity and to justify policy actions. Experts have found that "the stigma of a hazard determination, once imposed, is difficult to erase, even if the technology or substance is completely exonerated through additional research,"[35] and "ACC's experience supports this conclusion."[36] The NAS Report alone will discourage use and consumption of formaldehyde products, harming ACC members' businesses—and the effect will be even greater after EPA uses the Report to finalize the Assessment.

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[32] John D. Graham, *Testimony for the Joint Economic Committee of the U.S. Congress* at 8 (Apr. 30, 2014), https://www.jec.senate.gov/public/_cache/files/def8558f-e82d-4b94-aaecb4d40f9b0455/graham-testimony.pdf.

[33] Ex. D, *Chemical Watch, French authority concludes formaldehyde can cause leukemia: ANSES evaluation lent heavily on 2014 report by US National Research Council,* Nov. 28, 2023, https://chemicalwatch.com/903882/french-authority-concludes-formaldehyde-can-cause-leukaemia (French authority reached a carcinogenicity conclusion regarding formaldehyde based on a report by the US National Research Council, which is the operating arm of NAS).

[34] U.S.H.R. Comm. on Science, Space, & Technology, *Science Committee Leaders Applaud National Academies Decision on IRIS Assessment of Formaldehyde* (Aug. 14, 2023), https://democrats-science.house.gov/news/press-releases/science-committee-leaders-applaud-national-academies-decision-on-iris-assessment-of-formaldehyde ("[W]e join the esteemed committee in urging EPA to finalize the formaldehyde assessment so its conclusions can be utilized by public health entities to protect the health and safety of Americans").

[35] John D. Graham, Testimony for the Joint Economic Committee of the U.S. Congress at 8-9

[36] Pl.'s Mem., Ex. B, ACC Decl. ¶ 27.

EPA also is *already* actively "us[ing] the Report in violation of its FACA obligation not to use the product of a NAS review that did not comply with all applicable FACA requirements. 5 U.S.C. § 1014(a). EPA has already made public statements, after publication of the Report and relying on its substance, to claim that the Assessment can be relied upon by EPA and the public. Specifically, EPA relied on the Report to represent to the public that the Assessment's findings have NAS's imprimatur, and the Assessment need only be edited for improved clarity.[37] Such statements only worsen the reputational damage caused by the Report itself, and the harmful effect of the Report on both producers and consumers of formaldehyde products. Thus, some of the harms that ACC seeks relief from in this suit are not just imminent; they are already upon ACC and its members. And they cannot be undone—although they can be prevented from compounding if the Court enjoins EPA from further using the Report (which would include by relying on it in public statements about the Assessment and formaldehyde) and orders NAS to include a disclaimer on any publication of the Report flagging that it was produced in violation of FACA.

EPA has also already used the Report to officially and publicly change the status of the IRIS assessment of formaldehyde from step 4 ("Public Comment and External Peer Review") to step 5 ("Revise Assessment").[38] This change means that EPA has completed all steps that require it to accept comments from outside the agency, and ACC has no further opportunity to affect the Assessment before it is finalized. Moreover, this change conveys to the public (incorrectly) that the Assessment is in near-final form and can be relied upon, because it has undergone peer review.

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[37] EPA, *[NAS] Releases Peer Review Report of Draft IRIS Formaldehyde Assessment* (Aug. 9, 2023), https://www.epa.gov/newsreleases/national-academies-sciences-engineering-and-medicine-releases-peer-review-report-draft.

[38] EPA, IRIS Assessments, Formaldehyde CASRN 50-00-0, https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419 (last visited Dec. 4, 2023).

EPA also updated it October 2023 IRIS Program Outlook[39] to reflect moving forward with the IRIS assessment based on completion of NAS's review (plans that were "TBD, pending delivery of peer review report" previously.[40] Yet again, EPA is already "using" the Report in violation of FACA, and such usage is already harming ACC's members who produce and use formaldehyde.

Because the Report is already causing reputational damage to producers and consumers of formaldehyde products, the harms that ACC asks this Court to stop and prevent are not theoretical. They are already occurring, and their impact will only grow—and become irreparable—if the NAS Report remains in the public domain without a disclaimer, order prohibiting reliance on it, or at least declaratory relief stating confirming that it was produced in violation of FACA.

2. ACC's members face further irreparable harm as EPA moves forward to finalize the Assessment based on the unlawful Report.

Furthermore, as EPA proceeds to finalize the Assessment based on the Report—as it has promised it will[41]— and then uses the Assessment to take additional actions, the harms from the Report will multiply. It would be near impossible and a waste of resources for ACC and its members to attempt to challenge each instance in which EPA or some other agency relies on the Report. And EPA has suggested that, once an Assessment is finalized, it is too late. Now may be the only point in time for ACC to obtain full relief from NAS and EPA's FACA violations, and to limit and prevent harms to ACC's members. To do so, ACC needs injunctive relief now, before EPA further "uses" the report in violation of FACA. 5 U.S.C. § 1014(a).

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[39] EPA, A message from the IRIS Program: IRIS Program Outlook (Oct. 2023), https://www.epa.gov/system/files/documents/2023-10/iris_program_outlook_oct2023.pdf.

[40] EPA, A Message from the IRIS Program, IRIS Program Outlook (June 2023), https://www.epa.gov/system/files/documents/2023-06/IRIS Program Outlook_June_2023.pdf.

[41] *See, e.g.* EPA Mem. at 28 (noting that "NAS's peer review is … step four (4b) in EPA's seven-step process" and "EPA will revise its draft assessment, accounting for … the peer review" before the Assessment is finalized).

That EPA will use the Report to finalize the Assessment and take further steps to adopt the Assessment's hazard conclusions into regulatory requirements does not mean that the harm ACC's members face from the Report is not imminent. *See Alabama-Tombigbee Rivers Coal.*, 1993 WL 646409, at *2–*4 (finding "plaintiffs will suffer severe and irreparable harm" from use of the report, even though the government argued that plaintiffs "can seek and obtain any necessary corrective action within the rule-making process," and explaining that to find otherwise would create "the potential for mischief"). ACC and its members thus are not required to wait until EPA has already used the NAS Report to propose rules (e.g., under TSCA, FIFRA, and the Clean Air Act), comment on such actions to re-explain the FACA violations, wait for EPA to finalize those actions, and then challenge each such action relying on the Report and Assessment on the same basis (i.e., violation of FACA) and same set of facts.

That would not just be difficult, costly, and impracticable for ACC and its members, it would be a waste of judicial resources. This is particularly true where EPA has taken the position that ACC cannot challenge even *final* IRIS assessments because, in EPA's view, IRIS assessments are not final agency actions that can be independently challenged.[42] That would leave only the opportunity for collateral challenges after EPA has finalized each separate rule or regulatory policy relying on the assessment, essentially forcing ACC and other stakeholders to play whack-a-mole by challenging every unlawful use of the Report. This is an impossible task from both a practical and legal perspective. Once an IRIS assessment is incorporated into a regulatory action, years will have passed since the underlying FACA violations occurred, potentially creating statute of

[42] *See* EPA Mem. at 28; EPA Answering Br., *Huntsman Petrochemical LLC v. EPA*, No. 23-1047, Doc. 202448 (D.C. Cir. October 30, 2023) ("EPA Huntsman Br.") at 42.

limitation issues—as EPA has argued in other cases.[43] EPA will then argue that the final actions are supported by a peer review,[44] are very technical and cannot reasonably be challenged,[45] and should not be enjoined because of the delay in such challenges and the Agency's investment into the Assessment.[46] EPA's own arguments, if correct, make it such that this may well be the only opportunity to obtain meaningfully judicial review of the FACA violations raised here.

Turning to the additional ways EPA has confirmed that it plans to use the Report in the future, they are certain; they are directly connected to the Report itself; and they will further harm ACC's members. Petitioner's brief outlined the many ways EPA has promised to use the Report and the Assessment. ACC Brief at 38-41.[47] EPA has been quite open about its plans to use the Report to finalize the Assessment, and then use the Assessment to adopt regulations under TSCA and FIFRA, [48] which will plainly impact ACC's members that produce and use formaldehyde.

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[43] EPA Mem. in Supp. of Mot. to Dismiss, *United States v. Denka Performance Elastomer, LLC,* No. 23-cv-00735, Doc. 57-1 at 2, 24 (E.D. La., May 9, 2023).

[44] EPA, *Reconsideration of 2020 National Emission Standards for Hazardous Air Pollutants; Misc. Organic Chemical Manuf. Residual Risk Review*, 87 Fed. Reg. 77985, 77990 (Dec. 21, 2022) (using IRIS values because they have undergone "an extensive peer and public review process that adhered to the guidelines in EPA's Peer Review Handbook"); EPA Huntsman Br. at 6 ("EPA followed … advice from external scientific peer reviewers").

[45] EPA Huntsman Br. at 14.

[46] *See* EPA Mem. at 3 (arguing that FACA violations should not "delay EPA's important ongoing work"); *id*. at 31-32 (arguing that EPA should be permitted to use the Report because of the time between which ACC first notified NAS and EPA of its concerns and the time when it brought this action, and because the government has already expended significant federal funds).

[47] ACC has also explained how other federal agencies as well as states will use the Assessment, to the detriment of ACC's members. Pl.'s Mem. at 41-42.

[48] EPA, *Memorandum of Materials for Review by HSRB for the May 16-18, 2023 Meeting* at 3 (Apr. 21, 2023), https://www.epa.gov/system/files/documents/2023-05/HSRB_transmittal_and_charge_2023_May_16-18%20FINAL.pdf ("Once [NAS] completes its review of the draft IRIS assessment for formaldehyde, [EPA's Office of Chemical Safety and Pollution Prevention] plans to rely on the chronic non-cancer inhalation reference concentration (RfC) and cancer inhalation unit risks (IUR) from IRIS" for their forthcoming human health risk evaluations of formaldehyde under TSCA and FIFRA).

This is not mere speculation; these are plans that EPA has published.[49] Any changes that EPA may make to the Assessment to address the Report will not affect its substantive conclusions because EPA has already made clear that it views the Report as ratifying the Assessment's conclusions—even though EPA specifically told NAS not to review the substance of those conclusions—and only requiring changes for clarity.[50]

Defendants argue that harm from future actions utilizing the Report is not imminent because the Report is "the first domino in a long causal chain" (NAS Mem. at 27) instead of the last step before those particular harms—but that is exactly the point. Once one knocks down the first domino in a chain, the fall of the last is a foregone conclusion. So too here. EPA itself identified the chain of events that will result if it is not immediately barred from relying on the unlawful NAS Report,[51] and it has already moved on to the next step in its process to finalize the Assessment.[52] Every single step in this chain of events is an illegal use of the Report, and every step causes some harm to ACC and its members, with the later steps of formal regulation stemming from the Report and Assessment causing the greatest harm. It is no defense that additional steps intervene before the ultimate harm occurs.[53]

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[49] *Id.*

[50] EPA, *[NAS] Releases Peer Review Report of Draft IRIS Formaldehyde Assessment* (Aug. 9, 2023), https://www.epa.gov/newsreleases/national-academies-sciences-engineering-andmedicine-releases-peer-review-report-draft.

[51] EPA, *Memo. of Materials for Review by HSRB* at 3 (Apr. 21, 2023), https://www.epa.gov/system/files/documents/202305/HSRB_transmittal_and_charge_2023_May_16-18%20FINAL.pdf.

[52] EPA, IRIS Assessments, Formaldehyde CASRN 50-00-0, https://iris.epa.gov/ChemicalLanding/&substance_nmbr=419 (last visited Dec. 4, 2023) (showing, under "Assessment Status," that EPA moved from "Public Comment and External Peer Review" to "Revise Assessment").

[53] *See Alabama-Tombigbee Rivers Coal.*, 1993 WL 646409, at *2–4.

If the Court were to deny a preliminary injunction and require ACC to wait while this case is briefed on the merits, it will be too late to avoid harm from EPA's reliance on the NAS Report. EPA's administrator has told Congress that EPA is "moving on an expedited time frame" and using all necessary resources to "move expeditiously" to finalize the Assessment.[54] In October, EPA announced that it plans to issue the final IRIS Assessment of formaldehyde less than a year from now.[55] Such speed is to be expected given that the Report urges EPA to move expeditiously to finalize the formaldehyde Assessment in order to fulfill EPA's mission. Report at xii. If the court does not issue relief in the near term, EPA will have finalized the Assessment before a decision is issued, further cementing the reputational injury to ACC's members and causing market deselection of formaldehyde due to a scientifically flawed Assessment and NAS report. Either preliminary or permanent injunctive relief is therefore needed now in order to prevent these harms.

Moreover, as discussed above, EPA has taken positions *in this very case* that, if correct, preclude any meaningful review of an IRIS value that results from a NAS peer-reviewed assessment. EPA cannot insist that there will be a later opportunity to challenge the validity of its reliance on NAS's Report when it has argued in its brief here that the time for any challenge has already passed,[56] and because NAS has completed the Report, EPA should not be stopped from finalizing the IRIS assessment and subsequent rulemaking based on it.[57] And if ACC were

[54] Hearing on Science and Technology Activities at EPA Before H.R. Comm. on Science, Space, and Technology, 118th Cong., Statement of Michael Regan at 1:48:35-1:50:04 (Sept. 27, 2023), https://www.youtube.com/watch?app=desktop&v=s9x1sxi5eO0.

[55] EPA, A message from the IRIS Program: IRIS Program Outlook (Oct. 2023) https://www.epa.gov/system/files/documents/2023-10/iris_program_outlook_oct2023.pdf at 3 (noting a final Assessment in "FY24," that is by the end of September 2024).

[56] EPA Mem. at 31.

[57] EPA Mem. at 3 (arguing that FACA violations should not "delay EPA's important ongoing work"); *id*. at 31-32 (arguing that EPA should be permitted to use the Report because the government has already expended significant federal funds, though it will expend further resources to use the Report before such time as EPA argues the case could be brought).

nonetheless forced to wait to until the final IRIS value is used in regulation before challenging the process that led to it, EPA will then argue that far too much time has passed to challenge the underlying NAS review. Indeed, EPA regularly argues that its final actions relying on assessments that were subject to peer review are supported by the scientific process and thus inherently reliable.[58] EPA also argues, in challenges to IRIS assessments, that its decisions are very technical and cannot reasonably be challenged, even where petitioners raise process concerns.[59]

Thus, EPA seeks to have its cake and eat it too, preventing review both now and later. In addition to the growing harms that ACC will endure with the passage of time, EPA's litigation positions regarding the sanctity of "peer-reviewed" IRIS assessments preclude meaningful future review of NAS's review process, such that the harms ACC's members face will be irreparable—unless prevented by this Court in the near term. Issuance of an injunction barring EPA from using the Report now is thus both appropriate and necessary.

3. Alternatively, this Court can prevent and remedy the harms ACC and its members face by issuing permanent injunctive relief.

In the alternative, if the Court agrees that ACC has demonstrated that the NAS Committee process violated FACA but is unsure whether ACC has shown imminent irreparable harm as required under the PI standard, the Court can and should simply enter summary judgment on the merits, as it has the authority and discretion to do where no further factual development is needed to show a legal violation. *See* PI Motion at 2 n. 1; *Morris v. Dist. of Columbia*, 38 F. Supp. 3d 57, 62-63 (D.D.C. 2014) (treating motion for preliminary injunction as summary judgment motion because "the Court's resolution of the legal issue . . . resolves the merits of the case. . . . Therefore,

[58] 87 Fed. Reg. at 77990; EPA Huntsman Br. at 6.

[59] EPA Huntsman Br. at 14.

the Court will decide this case on the merits."); *Ready for Ron v. FEC*, No. 22-3282, 2023 WL 3539633, at *6 (D.D.C. May 17, 2023) (treating PI motion as a motion for summary judgment).

Neither Defendant has argued against this course. In fact, EPA's position that it need not produce an administrative record and that any record would not be "germane"[60] supports converting Plaintiff's motion for a preliminary injunction to a summary judgment motion and issuing permanent injunctive relief. EPA has even explained that it cannot think "what an administrative record could even entail," and thus effectively conceded that the court has all the information it needs to decide these claims on the merits.[61] This Court should not hesitate to take EPA at its word and issue permanent injunctive relief barring EPA from using the Report, and declaring that the NAS Committee violated FACA so that other agencies and actors who might rely on it are aware of the Report's failings.

B. The equities favor the issuance of early injunctive relief.

NAS and EPA barely attempt to argue that the public interest and balance of harms do not favor injunctive relief if the Court finds a FACA violation. NAS asserts that the fact that the "Academy's reports are often seen as important scientific resources" somehow weighs against an injunction. NAS Mem. at 29. That fact—with which ACC agrees—only reinforces the need for injunctive relief that alerts agencies and the public that this NAS Report cannot be viewed as sound, but rather was produced by a process that violated FACA requirements applicable to NAS. Otherwise, NAS takes issue only with one of the particular forms of injunctive relief sought by ACC: an order requiring NAS to include, on any published version of the Report, a disclaimer that the Report was not produced in compliance with FACA. There is nothing novel or complex about

[60] EPA Mem. at 37-38

[61] EPA Mem. at 37.

this request. Indeed, that is what this Court ordered in *NAACP*.[62] And it is perhaps the least invasive form of relief for which ACC could ask; it would not require NAS to change the Report's substance—or even reconstitute the Committee (in a fairly balanced, conflict-free way) and proceed in accordance with FACA if NAS was not willing to do so. It would leave it up to NAS and EPA to determine whether and how they want proceed so that EPA can finalize the Assessment without unlawfully relying on a process that did not comply with FACA.

For its part, EPA argues that "significant public resources" went into development of its Assessment, and the public has an interest in EPA being allowed to complete the Assessment to "provide information about the health risks of formaldehyde, which is a high product volume chemical that is present in a wide variety of products and ubiquitous in air." EPA Mem. at 36. But again, that is precisely why injunctive relief is needed: If EPA's Assessment is not properly peer reviewed by NAS, then EPA cannot provide the public with *accurate* information about formaldehyde's health impacts. And EPA's admission that formaldehyde is widely present in everyday products and "ubiquitous in air" only cements the need to ensure that, before EPA publishes an Assessment that essentially tells the public that small amounts of formaldehyde can harm them, that Assessment be subject to a review by a fairly balanced NAS committee, comprised of scientists from a variety of backgrounds and disciplines, that is not controlled by EPA (i.e., allowed to review EPA's scientific conclusions), and that keeps the public fully informed by publishing all of the information FACA requires the Committee to disclose. In short, Defendants' assertions about the equities only demonstrate the critical need for injunctive relief.

[62] *NAACP Legal Def. & Educ. Fund, Inc. v. Barr,* No. 20-1132, 2020 WL 6392777, at *3 (D.D.C. Nov. 2, 2020) (prohibiting defendants from "releasing the Commission's report unless they either comply with FACA, or instead include a disclaimer in the report stating that the Commission violated FACA in producing the report").

III. NAS and EPA's attempts to avoid adjudication of ACC's claims fail.

Rather than attempting to show that NAS's review of the Assessment complied with FACA and the Committee was not managed or controlled by EPA, Defendants try to prevent the Court from reaching the merits of ACC's claims by raising standing, finality, and other threshold arguments. All fail, and Defendants' motions to dismiss should be denied.

A. ACC has standing.

ACC has alleged informational and representational injuries caused by both NAS and EPA, which this Court's law confirms is sufficient to demonstrate standing FACA claims.

Informational standing: As EPA admits, courts have consistently recognized that a committee's failure to disclose information as required under FACA constitutes a sufficient injury for standing. *See, e.g., Pub. Citizen v. U.S. Dep't of Just.,* 491 U.S. 440, 449-450 (1989) ("[R]efusal to permit appellants to scrutinize [a] [c]ommittee's activities to the extent FACA allows constitutes a sufficiently distinct injury to provide standing to sue."); *Am. First Legal Found. v. Cardona,* 630 F. Supp. 3d 170, 180 (D.D.C. 2022) ("It is well established that in the FACA context, an informational injury—even without an accompanying diversion of resources—is sufficient to confer Article III standing.") (citation omitted); *NAACP*, 496 F. Supp. 3d at 128. Similarly, courts have also found representational injury sufficient to show standing to bring a FACA fair balance claim where a party is denied "access to a representative voice" on the at-issue committee. *NAACP,* 496 F. Supp. 3d at 128; *see also Wash. Legal Found. v. Am. Bar Ass'n Standing Comm. on Fed. Judiciary,* 648 F. Supp. 1353, 1357-58 (D.D.C. 1986) ("When the [fair-balance] requirement is ignored . . . persons having a direct interest in the committee's purpose suffer injury-in-fact sufficient to confer standing to sue."). Neither EPA nor NAS deny that ACC has suffered cognizable injuries here, nor could they.

EPA argues, however, that ACC's alleged informational and representational injuries are not traceable to the agency because it was NAS that created the Committee and conducted the Assessment. EPA cannot so easily get away from its obligations under FACA. Courts, including this one, have found standing to sue an executive agency under FACA even when the committee was convened by a *private* entity at the government's request. *See Pub. Citizen,* 491 U.S. at 450-51 (finding plaintiff had standing to sue executive agency under FACA where alleged advisory committee, the American Bar Association, was free from agency control); *Jud. Watch, Inc. v. U.S. Dep't of Com.,* 583 F.3d 871, 873 (D.C. Cir. 2009) (finding standing to sue executive agency under FACA where at-issue committee was appointed by two private business groups and committee comprised of private-sector business leaders); *Byrd v. EPA,* 174 F.3d 239, 244 (D.C. Cir. 1999) (finding standing satisfied where committee was established by private contractor). There is no reason why that conclusion would not apply equally when courts review violations of Section 15's requirements for NAS committees—and no Court has so held. That would be illogical given that, ultimately, it is the agency that Section 15 bars from using any recommendation from an advisory committee formed in violation of FACA. And as here, it is the agency that calls for NAS's review of its work product in the first place. NAS's violations of the FACA procedural requirements specifically applicable to it thus are plainly traceable to EPA's actions.

Next, EPA argues that any injury suffered by ACC could not be redressed by injunctive relief against the agency. EPA's assertion is contradicted by controlling law. In *Public Citizen v. U.S. Department of Justice,* the Supreme Court found that plaintiff's informational injury, stemming from the committee's failure to disclose information as required under FACA, was redressable by the relief requested, which included a declaration that the committee was subject to FACA's requirements and an injunction ordering the agency to cease using the committee until it

complied with those requirements. 491 U.S. at 447, 450. The Court reasoned that "if FACA applies to the [agency's] use of the [committee]," then the committee would need to provide access to its meetings and disclose documents not otherwise exempt under FACA. *Id.* at 450; *see also Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods,* 886 F. 2d 419, 435 (D.C. Cir. 1989) ("The alleged injury from the lack of any consumer representative is easily remedied by the relief requested in Public Citizen. . . .") (per curium) (Edwards, J., concurring in part and dissenting in part). Similarly here, ACC's injuries from the unlawfully developed Report and EPA's continued use of the Report can be redressed by an injunction enjoining EPA from further accepting, using, or relying on the Report. Even if ACC may not obtain complete relief, the "potential gains" from a favorable decision are "undoubtedly sufficient to give [ACC] standing." *Pub. Citizen,* 491 U.S. at 451 (rejecting argument that plaintiff's injury was not redressable because meetings and documents plaintiff sought may be closed to the public under FACA).

Declaratory relief would also redress ACC's injuries. *Byrd,* 174 F.3d at 243-44; *NAACP,* 496 F. Supp. 3d at 131-32. A declaration that the Committee's Report was developed in violation of FACA would provide plaintiff "ammunition for [its] attack on the Committee's findings in subsequent agency proceedings that make use of the [advice or recommendation]." *Byrd,* 174 F.3d at 244. Declaratory relief "might also prompt . . . additional, FACA-compliant peer review on the issue." *Id.* Indeed, given that FACA prohibits a referring agency from using the product of a NAS review that did not comply with Section 15's requirements, 5 U.S.C. § 1014(a), declaratory relief would force EPA and the Committee to comply with their FACA obligations since EPA cannot move forward to finalize the Assessment without peer review. And while injunctive relief is also appropriate here, "ordering declaratory relief alone to redress . . . informational and representational injuries would not be unprecedented." *NAACP,* 496 F. Supp. 3d at 131-32 (citing

Nw. Forest Res. Council v. Espy, 846 F. Supp. 1009 (D.D.C. 1994) (ordering declaratory relief for FACA violations)); *see also Ctr. for Arms Control & Non-Proliferation v. Pray,* 531 F.3d 836, 839 n.1 (D.C. Cir. 2008) ("Regardless whether mandamus relief is available, a declaration of [plaintiff]'s legal right to the [withheld] materials could form the basis of an injunction against the [committee], which would redress the claimed injury").

Associational standing: ACC also has demonstrated associational standing to bring claims against NAS and EPA. Notably, EPA does not dispute that ACC has met the requirements of the associational standing test it identifies at the outset of this part of its standing argument (see EPA Mem. at 19). EPA does not argue that ACC's members declarations are factually insufficient to show that, as producers and users of formaldehyde, they have a real stake in NAS's review process.

Rather, EPA's only argument as to ACC's associational standing is that there is no imminent injury to ACC's members from EPA's actions. As discussed in Section II above, however, ACC's members face imminent and irreparable harm from EPA's ongoing and future use of the unlawful Report. And contrary to EPA's argument, courts have recognized that plaintiffs have standing to bring claims under FACA and to seek injunctive relief enjoining an agency from using a work product produced in violation of FACA *before that happens*. *See Animal Legal Def. Fund v. Shalala,* 53 F.3d 363, 366 n.4 (D.C. Cir. 1995) (remanding to district court and asserting that plaintiffs may be entitled to permanent injunction prohibiting federal defendants from publishing, employing, or relying on committee's work until FACA requirements are satisfied); *Alabama-Tombigbee Rivers Coal. v. Dep't of the Interior,* 26 F.3d 1103, 1107 (11th Cir. 1994) (court may enjoin the government's use of a product created by a committee that failed to comply with FACA requirements). Underlying these decisions is the understanding that plaintiffs do not

have to wait for an agency's actual reliance on a work product created by a committee that failed to comply with FACA before it suffers an injury sufficiently imminent for standing.

Organizational standing: Finally, ACC has shown organizational standing because it has alleged a diversion of time and resources from activities that are more than "issue advocacy."

Contrary to EPA's assertion, many of the letters and comments that ACC provided to EPA and NAS during the review process did not advocate for what ACC "wants the government to adopt as its accepted risk level for formaldehyde." EPA Mem. at 18. Rather, ACC sought in multiple communications to inform NAS and EPA of their FACA violations, and requested that they address those procedural violations. *See* Pl.'s Mem., Ex. B, ACC Decl. ¶¶ 9, 11-12. Additionally, ACC expended resources to obtain documents withheld by EPA and NAS through FOIA to evaluate the extent of EPA's involvement in the development of the Committee. *Id.* ¶ 10. These actions are distinct from the sort that courts have found to be "pure issue advocacy." *See, e.g., Env't Working Grp. v. FDA,* 301 F. Supp. 3d 165, 172 (D.D.C. 2018) (emails and letters to agency and efforts to "promote legislation in Congress" were issue advocacy); *Int'l Acad. of Oral Med. & Toxicology v. U.S. Food and Drug Admin.,* 195 F. Supp. 3d 243, 257 (D.D.C. 2016) (efforts to "alter government regulatory policy" are issue advocacy).

ACC incurred expenses to respond to EPA and NAS's failure to comply with their statutory obligations under FACA, which deprived ACC of the information to which it is entitled under the statute's disclosure requirements. As this Court has found, even where a plaintiff expended some resources on issue advocacy, it may nonetheless establish an injury sufficient for organizational standing where it also expended resources on non-advocacy activities. *Scenic Am., Inc. v. U.S. Dep't of Transp.,* 983 F. Supp. 2d 170, 178 (D.D.C. 2013). That is the case here. ACC therefore has organization standing as well as informational and associational standing to bring its claims.

B. ACC can obtain mandamus relief against NAS.

NAS makes the extreme argument that, although it has clear statutory obligations under FACA Section 15, those obligations are not judicially enforceable against NAS. There is no case so finding, and this Court should decline to be the first to construe FACA Section 15 to allow NAS to avoid its statutory obligations. As NAS admits, this Court had no problem exercising its mandamus authority in *NAACP Legal Defense & Educational Fund, Inc. v. Barr* to not only compel action by DOJ and the Attorney General, but also to compel an advisory committee comprised, in part, of non-federal employees or officers to comply with applicable FACA requirements. 496 F. Supp. 3d at 144-45. This suit is nothing new in that regard.

Mandamus is appropriate where the plaintiff has shown (1) a clear and indisputable right to relief; (2) the defendant is violating a clear duty to act; and (3) no adequate alternative remedy exists. *Am. Hosp. Ass'n v. Burwell,* 812 F.3d 183, 189 (D.C. Cir. 2016). ACC has demonstrated that these requirements have been satisfied in regard to NAS.

First, it is undisputable that Section 15(b) imposes on NAS specific, non-discretionary obligations. Nearly every provision of Section 15 prescribing NAS's statutory duties uses the word "shall." 5 U.S.C. § 1014(b)(1) (NAS "shall" provide public notice of the names and brief biographies of individuals appointed to the committee and "shall" provide a reasonable opportunity for public comment on committee appointments); *id.* § 1014(b)(1)(A)-(B) (NAS "shall make its best efforts to ensure that" the committee does not have conflicts of interest (unless they are unavoidable and publicly disclosed) and is fairly balanced); *id.* § 1014(b)(3) (NAS "shall make available to the public" written materials provided to the committee). The use of the term "shall" admits no discretion. *Mach Mining, LLC v. EEOC,* 575 U.S. 480, 486 (2015). Accordingly, "the language of [FACA] leaves no room for discretion," *Jud. Watch, Inc. v. Nat'l Energy Pol'y Dev. Grp.,* 219 F. Supp. 2d 20, 43 (D.D.C. 2002), and such "discrete, non-discretionary duties qualify

as relief in the nature of mandamus." *Jud. Watch, Inc. v. U.S. Dep't of Com.,* 736 F. Supp. 2d 24, 31 (D.D.C. 2010) (citing *Nat'l Energy Pol'y Dev. Grp.,* 219 F. Supp. 2d at 43).

Second, NAS has violated its duty to comply with FACA. As discussed in Section I, NAS failed to disclose required information, address apparent conflicts of interest, and appointed a committee that is not fairly balanced. *See Elec. Priv. Info. Ctr. v. Nat'l Sec. Comm'n on A.I.,* 466 F. Supp. 3d 100, 123 (D.D.C. 2020) (finding plaintiff is entitled to writs of mandamus compelling advisory committee and its officer to comply with the applicable procedural requirements of FACA, including making records available for public inspection).

Third, no adequate alternative remedy exists against NAS. NAS is not an "agency" as defined under the APA. *McKinney v. Caldera,* 141 F. Supp. 2d 25, 32 (D.D.C. 2001). And Defendants are correct that FACA does not provide a private cause of action. *Nat'l Energy Pol'y Dev. Grp.,* 219 F. Supp. 2d at 34. Therefore, mandamus is the only avenue—and therefore the proper avenue—for ACC's claims against NAS. *Id.* at 41-42 (Mandamus "may provide an avenue to remedy violations of statutory duties even when the statute that creates the duty does not contain a private cause of action."). That is precisely why, in *NAACP,* this Court issued writs of mandamus compelling the advisory committee, as well as its chair and vice chair, to comply with applicable FACA requirements. *NAACP,* 496 F. Supp. 3d at 145-46 (finding mandamus "is the only vehicle" for plaintiff's claims against the committee, its chair, and vice chair and concluding plaintiff has a "judicially remediable right to have the [committee] comply with its duties under FACA" pursuant to the mandamus statute). Crucially, the court granted mandamus relief against the committee itself, even though many of its members were not federal officials or employees. *See id.* at 141 n.8.

There is no legal basis for the jurisdictional distinction that NAS attempts to draw between NAS advisory committees subject to Section 15, the provision of FACA specifically enacted for

this circumstance, and federal advisory committees subject to other provisions of the statute. To the contrary, it defies logic that federal advisory committees would be subject to judicially enforceable obligations under the statute, whereas the parallel, specific, and non-discretionary obligations imposed on NAS advisory committees are unenforceable. Under NAS's interpretation, the government could avoid obligations Congress has imposed on it by simply outsourcing its work to third-party contractors. There is no indication Congress intended to create such a loophole when it enacted specific FACA requirements applicable to NAS committees. To the contrary, when Congress amended FACA in 1997, it created Section 15 to "clarify public disclosure requirements that are applicable" to NAS. H.R. 2977, 105th Cong. (1997). Indeed, Congress explained that those amendments would "require[] *more* openness when Federal agencies utilize" NAS. 143 Cong. Rec. H10578, H10579 (Nov. 9, 1997) (statement of Rep. Steve Horn) (emphasis added); *see* 143 Cong. Rec. S12515, S2516 (Nov. 13, 1997) ("[I]f Federal funds are added to such a committee pursuant to an agreement with an agency and the respective academy, then the committee must comply with" Section 15 of FACA.) (statement of Sen. John Glenn).

Mandamus relief against NAS is also available and appropriate because courts have long recognized that NAS is a quasi-public organization. *E.g., Pub. Citizen,* 491 U.S. at 461; *Animal Legal Def. Fund, Inc.,* 53 F.3d at 429-30. The National Academies are "closely tied to" the Federal Government and "thus enjoy[] a quasi-public status." *Public Citizen*, 491 U.S. at 460-62. NAS is an "archetypal example" of a quasi-public organization because it was created and is funded by Congress. *Jud. Watch, Inc.,* 736 F. Supp. 2d at 34; *see also Animal Legal Def. Fund, Inc.,* 53 F.3d at 429 (NAS "was created by Congress to answer the government's requests for investigations, examinations, experiments, and reports, 36 U.S.C. § 253, and the government takes care of the expenses associated"). Crucially, courts have distinguished committees created by quasi-public

organizations such as NAS from those created by a "purely private" organization that merely have a contractual relationship with a federal agency. *See Pub. Citizen,* 491 U.S. at 460 (contrasting NAS from "purely private" group such as American Bar Association); *Food Chem. News v. Young,* 900 F.2d 328, 333 (D.C. Cir. 1990) (finding Federation of America Societies for Experimental Biology, a biomedical research organization, to be a "private organization and government contractor" that does not have "quasi-public status"). This Court can thus grant mandamus relief in regard to NAS, just as it has in regard to other FACA-governed advisory committees.

C. EPA's APA finality argument misses the mark, and in any event this Court can exercise its mandamus authority to order EPA to not use NAS's report.

Astoundingly, EPA argues that the Court cannot entertain ACC's FACA-based claims against that agency under either the APA or the Mandamus Act. EPA Mem. at 21 & n.6. That is plainly contrary to the law of this court, which has routinely exercised jurisdiction under both of those Acts to hold agencies to their duty to comply with FACA's clearly stated obligations.

1. The Court can hold EPA to its FACA obligations under the APA.

EPA argues that there is no cause of action against it under the APA because there is no final agency action. But as EPA admits (at 26, n.9), courts have consistently allowed plaintiffs to bring FACA claims pursuant to the APA, finding that FACA violations are final agency actions. *See e.g., Nat'l Energy Dev. Pol'y Grp.,* 219 F. Supp. 2d at 40; *Jud. Watch,,* 736 F. Supp. 2d at 30-31("[A] number of courts have allowed plaintiffs to proceed with APA actions based on alleged FACA violations . . . This court concurs with the reasoning of these decisions and concludes that the plaintiff may bring its claims pursuant to the APA."); *NAACP,* 496 F. Supp. 3d at 146.

As this Court stated twenty years ago when rebuffing an argument that FACA challenges could not proceed against an agency head under the APA because there was no final agency action: "The type of actions and inaction challenged here . . . holding meetings, refusing to disclose

documents, failure to comply with FACA's other procedural requirements, certainly fall within the broad category of "agency power" Congress intended to include in this definition of agency action. *Nat'l Energy Dev. Pol'y Grp.*, 219 F. Supp. 2d at 38 (citing FACA's legislative history). This Court held that such alleged agency actions and inactions were "final" because they "had a legal consequence—the denial of the public's right of access to that information." *Id*. at 40 (also stating: "Plaintiffs and other interested groups and citizens were prevented from enforcing their right to access information that exists pursuant to FACA. Subsequent actions taken without granting access, and the failure to grant access itself, constitute final agency action.").

EPA tries to avoid the clear precedent on this issue by arguing that the challenged failures here are attributable to NAS, not EPA. But that ignores that NAS convened the Committee *at EPA's request*, and then proceeded pursuant *to EPA's task order*. And as discussed above, EPA controlled the Committee not only by limiting its review scope but by selecting the members. NAS's violations of FACA, as it proceeded under EPA's mandate and control, are thus attributable to EPA and are final agency action that can be challenged as against the agency under the EPA. *See Nat'l Energy Dev. Pol'y Grp.,* 219 F. Supp. 2d at 36 (allowing FACA claims to proceed against agency where agency personnel "established and utilized the" committee at issue).

Furthermore, it is *EPA* that FACA specifically prohibits from using NAS's work product (the Report) if that work product resulted from a process that did not comply with FACA. 5 U.S.C. § 1014(a). As discussed in Section II above, EPA is already "using" the Report by, *inter alia,* making public statements in reliance on the Report to indicate that EPA's Assessment is sanctioned by NAS and need only be edited for improved clarity and accessibility of its methods. Therefore, EPA's direct failure to comply with *its own independent FACA obligation* is plainly a final agency

action that can be addressed by this Court under the APA. *See NAACP*, 496 F. Supp. 3d at 144 ("[T]he APA is an appropriate vehicle for LDF's claims against the [agency and agency head].").

2. Alternatively, the Court can hold EPA to its FACA obligations under the Mandamus Act.

If this Court finds that ACC is not entitled to relief under the APA, then it should enjoin EPA from using the unlawful Report under the Mandamus Act, 28 U.S.C. § 1361. *See Nat'l Energy Dev. Pol'y Grp.*, 219 F. Supp. 2d at 42; *Jud. Watch*, 736 F. Supp. 2d at 31 (holding that, in addition bringing APA claims, "plaintiff may bring his claim for alleged FACA violations under the Mandamus Act"). In that event, the analysis supporting ACC's request for mandamus against NAS similarly applies to EPA because (1) ACC has a clear right to relief; (2) EPA is violating a clear duty to act; and (3) no adequate alternative remedy exists. *See Burwell,* 812 F.3d at 189.

First, ACC has a clear and indisputable right to relief if there has been a FACA violation because FACA imposes a specific, nondiscretionary duty on EPA: EPA "*may not use* any advice or recommendation provided by the [NAS]" unless the committee has complied with the requirements in Section 15(b) of FACA and was not subject to any actual management or control by EPA. *See* 5 U.S.C. § 1014(a)(1)-(3) (emphasis added). This provision of FACA imposes on EPA a "ministerial duty" that "admits no discretion"—it plainly prohibits EPA from using the Report either if NAS has not complied with its obligations under Section 15(b) or if EPA has exercised control over the Committee. *See Swan v. Clinton,* 100 F.3d 973, (D.C. Cir. 1996); *see also Beatty v. Wash. Metro Area Transit Auth.,* 860 F. 2d 1117, 1127 (D.C. Cir. 1998) ("[A] duty is discretionary if it involves judgment, planning, or policy decisions. It is not discretionary if it involves enforcement or administration of a mandatory duty at the operational level.") (internal quotation, citation, and emphasis omitted). Indeed, when Congress amended FACA to clarify the requirements applicable to NAS under Section 15, it explained that the "burden of insuring

compliance with [FACA] falls on the agencies[,]" and agencies therefore cannot use any advice or recommendation by NAS "unless the procedural requirements set forth . . . have been followed by the Academy." 143 Cong. Rec. H10578, H10581 (Nov. 9, 1977) (statement of Rep. Waxman)

Further, as explained in Section II above, EPA has *already* used the Report, and EPA has also made very clear its intent to continue to rely on the Report. Accordingly, if relief is not available against EPA under the APA, then such relief is available under the Mandamus Act—the very point of which is to give courts an avenue to require agencies to comply with the law where they have clearly failed to do so, and no other basis for relief exists.

EPA does not seriously contend that the Mandamus Act is not an available avenue of relief for FACA claims. Rather, it argues that ACC only sought mandamus relief against NAS. Not so. ACC invoked the Mandamus Act repeatedly throughout its Complaint, including when identifying the sources of the Court's jurisdiction, and then further requested that the Court award any and all relief that is just and proper. *See* Am. Compl. at ¶¶ 31, 170 & 54. And in its PI Motion, ACC clearly requested that this Court exercise its authority to enjoin EPA from using the Report *either* under the APA or the Mandamus Act. Pl.'s Mem. at 38. There is thus no pleading deficiency here,[63] and this Court can enforce Congress's clear directive that agencies may not use a NAS report produced in violation of FACA under either the APA or the Mandamus Act.

[63] If the Court nonetheless finds that ACC did not sufficiently plead a mandamus claim against EPA, it should grant ACC leave to amend its complaint to do so. *See Foman v. Davis,* 371 U.S. 178, 182 (1962) ("If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits."); Fed. R. Civ. P. 15(a)(2) (courts should "freely give leave [to amend] when justice so requires"). But ACC submits that there is no need for it to amend the Complaint here, particularly since it asks for mandamus relief against EPA *in the alternative* to relief under the APA—as it must, given that mandamus relief is only available where no other relief lies.

D. EPA's sovereign immunity argument is baseless.

Finally, EPA asks this Court to dismiss ACC's claims on the basis that the United States has not waived its sovereign immunity. EPA Mem. at 29-30. But as it admits, EPA's argument hinges on the Court agreeing that ACC failed to state a viable FACA claim against that agency. *See id*. As discussed in Section I.A above, ACC's claim that EPA improperly managed or controlled the Committee not only survives a motion to dismiss, but is likely to succeed.

But even if this Court did not agree, it may still issue mandamus relief because the government waived sovereign immunity in the APA, 5 U.S.C. § 702. The APA's waiver of sovereign immunity applies to *any suit* seeking relief other than money damages, "whether under the APA or not." *Trudeau v. Fed. Trade Comm'n,* 456 F.3d 178, 186 (D.C. Cir. 2006) (quotation omitted); *see also Sea-Land Serv., Inc. v. Alaska R.R.,* 659 F.2d 243, 244 (D.C. Cir. 1981) (holding that § 702 "eliminat[es] [the] sovereign immunity defense in *all* actions for specific, nonmonetary relief against a United States agency") (emphasis in original). The D.C. Circuit also has recognized that § 702 "withdraws the defense of sovereign immunity" in actions seeking a writ of mandamus. *Hubbard v. EPA,* 949 F.2d 453, 470 (D.C. Cir. 1991). There is thus no question that the Court may issue relief against EPA, which is not immune from FACA's imperative that agencies not use the work product of a NAS advisory committee that did not comply with FACA.

CONCLUSION

The Court should deny EPA and NAS's motion to dismiss, and enter injunctive relief—whether preliminary or permanent. That relief should include both a bar on EPA's use of the NAS Report and an order that NAS include on the Report a statement that it failed to comply with FACA. If the Court enters permanent injunctive relief, it should also declare that the NAS Committee review of the Assessment violated FACA. Only that full suite of relief can prevent ACC's members from being imminently and irreparably harmed by Defendants' FACA violations.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing brief was served today via CM-ECF on counsel of record for Defendants NAS and EPA.

/s/ Amanda Shafer Berman

Dated: December 4, 2023

EXHIBIT A

To: Guyton, Kathryn[KGuyton@nas.edu]; Boyle, Elizabeth[EBoyle@nas.edu]
From: Samet, Jon[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e6b04ad8724927bd886d211d0e6eb2-Samet, Jona]
Sent: Sat 4/15/2023 3:48:25 PM (UTC-06:00)
Subject: Re: Formaldehyde Meeting Follow-Up by April 21

Hi Kate and Liz,

From Irvine to Denver to New York City—I missed yet more snow yesterday in Denver.

We had discussed making certain that there were drafts clearly labeled so as to indicate that they are the end-game versions. I don't think that has been done, certainly not for Chapter 2. At this point, we don't need version control problems.

For now, I am working on the Lange—Samet version of Chapter 2.

Jon

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From: Guyton, Kathryn <KGuyton@nas.edu>
Date: Thursday, April 13, 2023 at 10:47 PM
To: Albin, Brenna <BAlbin@nas.edu>, Boyle, Elizabeth <EBoyle@nas.edu>, DePinto, Anthony <ADePinto@nas.edu>, Gros, Darlene M <DGros@nas.edu>, Dickerson, Aisha S. <Adicke10@jhu.edu>, Olshan, Andrew F. <andy_olshan@unc.edu>, Ortega, Bobbi <BOBBI.ORTEGA@CUANSCHUTZ.EDU>, Dolinoy, Dana C. <ddolinoy@umich.edu>, Dorman, David C. <david_dorman@ncsu.edu>, Rusyn, Ivan <irusyn@tamu.edu>, Samet, Jon <JON.SAMET@CUANSCHUTZ.EDU>, Joseph Wiemels <Joseph.Wiemels@med.usc.edu>, Tsaioun, Katya <ktsaiou1@jhu.edu>, Zeise, Lauren <lauren.zeise@oehha.ca.gov>, Sheppard, Lianne <sheppard@uw.edu>, Ghosh, Rakesh <Rakesh.Ghosh@ucsf.edu>, Lange, Sabine S. <Sabine.lange@tceq.texas.gov>, Yiliang Zhu <YiZhu@salud.unm.edu>
Cc: Enriquez, Mandy <MEnriquez@nas.edu>, dcdorman@ncsu.edu <dcdorman@ncsu.edu>, Knight, William <WKnight@nas.edu>, De Castro, Katrina M.V. <KDeCastro@nas.edu>
Subject: Formaldehyde Meeting Follow-Up by April 21

[External Email - Use Caution]

Dear Committee,

THANK YOU for your excellent discussions and contributions during our meeting this week- we really appreciate it! It was our pleasure to host our travelers, and we wish you all a safe return journey.

As agreed, we will be grateful to receive any and all outstanding sections of text no later than April 21. Your fearless chapter leads will integrate these and we will provide a compiled version of all chapters for final committee review by April 28, with comments due end-of-day May 1. Details of the schedule here.

We will be following up with detailed information on each chapter, but don't hesitate to reach out in the meantime to Liz (Chapter 2), Anthony (Chapter 4) or me (Chapter 5).

Many thanks again,
Warm wishes from rainy CA,
Kate

Kate Z. Guyton PhD DABT (*she/her*)
Senior Program Officer
Division of Earth and Life Sciences
National Academies of Sciences, Engineering, and Medicine

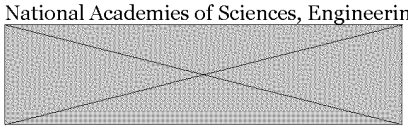

EXHIBIT B

From: Kate Guyton
To: iir@unc.edu
Subject: Formaldehyde Chapter 7
Date: 01/23/2012 04:29 PM

Hi Ivan!

Hope you are enjoying/enjoyed Michigan. :-)

Wondering if you would be willing to give our HHRA team on "Advancing hazard ID" a webinar on Formaldehyde Chapter 7...? The objective would be to give the committee's views, and (hopefully) avoid having to defend it all too heavily. If you agree, let me know if you prefer a webinar from UNC or when you are in town after your 2/15 visit.

Thanks!
Kate
----- Forwarded by Kate Guyton/DC/USEPA/US on 01/23/2012 03:00 PM -----

From: Kate Guyton/DC/USEPA/US
To: Amanda Persad/DC/USEPA/US@EPA, Ambuja Bale/DC/USEPA/US@EPA, Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Brian Pachkowski/DC/USEPA/US@EPA, Channa Keshava/RTP/USEPA/US@EPA, Connie Kang/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Miller/DC/USEPA/US@EPA, David Szabo/DC/USEPA/US@EPA, Deborah Segal/DC/USEPA/US@EPA, Gary.Ginsberg@po.state.ct.us, George Woodall/RTP/USEPA/US@EPA, Ghazi Dannan/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, iir@unc.edu, Jennifer Mall/DC/USEPA/US@EPA, Kathleen Newhouse/DC/USEPA/US@EPA, Lynn Adams/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Nina Wang/CI/USEPA/US@EPA, Raghu Nath/DC/USEPA/US@EPA, Rob Dewoskin/RTP/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Yu-Sheng Lin/DC/USEPA/US@EPA
Cc: Debra Walsh/RTP/USEPA/US@EPA, Lyle Burgoon/RTP/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA
Date: 01/23/2012 02:56 PM
Subject: Orientation for HHRA Theme 4 Project 1 Task 3

Hi everyone,

Thank you for joining our orientation meeting today. Below please find the HHRA organization chart discussed.
[attachment "Attachment B - HHRA_Program_Structure_w_20% contingency.docx" deleted by Kate Guyton/DC/USEPA/US]

Action items:
1. Winter reading list [All]; Kate will be organizing webinars on these topics:

   1) Science and Decisions: Advancing Risk Assessment [please focus on hazard identification issues]
   2) Review of EPA's Draft IRIS Assessment of Formaldehyde [Chapter 7: A Roadmap for Revision]
   3) Toxicity Testing in the 21st Century: A Vision and a Strategy

   I have posted PDFs at L:\Lab\NCEA\National Academies Press Docs; you may also

download a free PDF copy or order a book at: http://www.nap.edu/.

2. Compendium of ongoing projects-- Kate will circulate a form for you to complete

3. NCCT communities of practice website:
http://www.epa.gov/ncct/communities_of_practice.html

We will have our next meeting in approximately 2 weeks. Feel free to email me with any questions you may have about this task in the interim.

Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

EXHIBIT C

Message

From: Guyton, Kate [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=872D285E7848492CBE9AB0325C0FBADF-GUYTON, KATHRYN]
Sent: 4/23/2013 8:13:14 PM
To: Sonawane, Bob [Sonawane.Bob@epa.gov]
CC: Glenn, Barbara [Glenn.Barbara@epa.gov]; Kraft, Andrew [Kraft.Andrew@epa.gov]
BCC: iir@unc.edu
Subject: RE: Formaldehyde assessment - Hazard identification
Attachments: FA-Genetox Draft_041913 kzg.docx

Hi Bob,

Thank you for the opportunity to review the formaldehyde sections. As requested, I've appended my comments on the genotoxicity appendix.

Ex. 5 Deliberative Process (DP)

I hope these comments are helpful to you. I'd be happy to clarify when I am back in the office on Monday (note that I'll be on furlough status this week and won't be answering emails).

Thanks again,
Kate

Kate Z. Guyton, PhD DABT
Office of Research & Development, US EPA
703-347-8562 | guyton.kate@epa.gov
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FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

From: Sonawane, Bob
Sent: Monday, April 22, 2013 1:09 PM
To: Guyton, Kate
Cc: Glenn, Barbara; Kraft, Andrew
Subject: Formaldehyde assessment - Hazard identification

Hi Kate,

As discussed earlier , please review the attached draft portions of the hazard identification section and the supporting information in the appendices. Please also review the current draft version in the Response to Comments document (pages D 34-37 and D 42-48). Please let me know if you can complete review and send your comments to me in track changes by May 13, 2013. I would like you to review the Genotoxicity section first that was sent earlier today .

If you have any questions, please let me know.

Thanks,

Bob

EXHIBIT D

chemical watch news & insight

Back

French authority concludes formaldehyde can cause leukaemia

CHEMICAL WATCH NEWS

28 November 2023

ANSES evaluation lent heavily on 2014 report by US National Research Council

France | Cleaning products | Chemical industry | Built environment | Exposure scenarios | Substances of concern | EU | Federal

There is a "proven causal link" between occupational exposure to formaldehyde and myeloid leukaemia, according to an evaluation by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES).

International organisations and regional authorities had already identified the substance as carcinogenic, but disagreement remains about whether it causes leukaemia in addition to nose and throat tumours.

In 2012, the International Agency for Research on Cancer (IARC) concluded formaldehyde is a group 1 ('carcinogenic') substance under the classification system. However, its experts "were not in full agreement" on leukaemia, with a minority "viewing the evidence as limited".

ANSES reviewed the existing data, with a particular focus on a 2014 report by the US National Research Council that also concluded there is a causal association between formaldehyde exposure and myeloid leukaemia.

The result provides a strong argument for creating "occupational disease tables" for this in both the general and agricultural social security systems in France, which would allow formal recognition of leukaemia for exposed workers, ANSES said.

Tables already exist for the association between formaldehyde and other conditions, including dermatitis, eczema, rhinitis, asthma and nasopharyngeal cancer.

Formaldehyde is used in a range of professional applications, including as a preservative for biological materials, a disinfectant in hospitals and in agriculture, and a fixative in laboratories. Also, some wood, textile, rubber or resin products may release it.

Ongoing US debate

The question of this causal association is highly contentious in the US, where the EPA is currently conducting a TSCA risk evaluation that is likely to lead to future regulatory responses.

The EPA last year released a draft assessment for formaldehyde under its Integrated Risk Information System (IRIS) programme that identified "robust" human evidence that the substance causes the disease, strengthening preliminary findings from a 2010 version of the assessment. Industry groups have since filed a lawsuit challenging an external peer review of the draft, continuing a debate that has raged for more than a decade.

In the meantime, the EPA has signalled plans to rely on existing assessments in its TSCA evaluations of formaldehyde and other substances, giving rise to industry concerns that it will face stringent risk management requirements after the agency finishes its review.

The EPA said it anticipates releasing a draft TSCA evaluation for peer review next spring.