



August 25, 2022

Dr. Marcia McNutt
President
National Academy of Sciences
500 Fifth St., N.W.
Washington, D.C. 20001

Dear Dr. McNutt:

The American Chemistry Council Formaldehyde Panel (“the Panel”) submits these comments on the provisional appointments to the National Academies of Sciences, Engineering and Medicine (NASEM) committee tasked with conducting a peer review of the EPA’s 2022 draft IRIS formaldehyde assessment. NASEM has long been seen as a source of non-biased, credible scientific evaluations, in large part because it guards its reputation, not only against actual bias and conflicts of interest but against the appearance of such. The current process has the potential to undermine NASEM’s carefully guarded reputation.

As discussed below, the Panel raises serious concerns with the overall process by which the provisional committee was established, the Study Director assigned to oversee and manage the committee, the overall composition and balance of the committee, and several of the provisional appointees who we believe should be disqualified because of appearance of a lack of impartiality or independence. Additionally, we are concerned with the solicitation of nominations to the committee without such solicitation being informed by EPA taking comment on the charge questions and responding to any comments. In order to fully address our concerns regarding NASEM’s failure to meet its statutory and policy obligations, we request that NASEM immediately select a new Study Director and restart the committee nomination process. As outlined below, many of the issues related to potential Federal Advisory Committee Act (FACA) violations and the appearance or lack of impartiality are the result of a Study Director who, as an EPA scientist, was significantly involved in drafting earlier versions of the IRIS formaldehyde assessment to be peer reviewed by the NASEM committee. We also request that NASEM provide a written response to the issues raised in this letter. Such a written response is needed to provide transparency and document the scientific integrity of the process, and without such a response, questions will likely persist over the credibility and objectivity of the process.

EPA contracted with NASEM to conduct an independent peer review of the 2022 draft IRIS formaldehyde assessment. Thus, the peer review is subject to the requirements related to expertise, independence, impartiality, bias, balance, diversity, and conflicts of interest under several authorities, including: 1) FACA; 2) NASEM’s Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations; 3) the White House Office of Management and Budget’s Final Information Quality Bulletin for Peer Review; and 4) EPA’s Peer Review Handbook.¹



The Committee Selection Process Violated FACA

For decades, NASEM committees have been subject to section 15 of FACA. Failure to substantially comply with FACA section 15 requirements prevents any federal agency from using “any advice or recommendation provided to an agency” by a NASEM committee.² To avoid this outcome, NASEM must certify that the “The committee was not subject to **any** actual management or control by an agency or officer of the Federal Government.”³ But in soliciting nominees from EPA staff with whom she had worked, and, in at least one instance, revealing details of committee membership, the Study Director (also referred to as the Responsible Staff Officer) effectively ceded some control over the committee to EPA.⁴ Thus, the Panel contends that NASEM cannot demonstrate that it has substantially complied with FACA section 15.

While under the agreement with NASEM EPA may offer suggestions of potential committee members during the public nomination process, EPA may not do so in a manner that violates FACA or other applicable requirements. FACA does not permit NASEM to actively solicit individual nominees from the sponsoring agency, in this case, EPA.⁵ As described in NASEM’s response to EPA’s request for NASEM to conduct a peer review of the draft IRIS formaldehyde assessment, “The EPA may offer suggestions of potential committee members to be considered by the National Academies during its nomination process. EPA may also comment on the proposed committee membership during the 20-day comment period following announcement of the provisional committee.”⁶

NASEM Should Select a New Study Director

On August 19, 2021, NASEM submitted a proposal to conduct the external peer review of the 2022 draft IRIS formaldehyde assessment. NASEM also certified to EPA that “to the best of our knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to the referenced task order exist.”⁷ We find this statement difficult to reconcile with the fact that the NASEM Study Director was previously an EPA career scientist within the IRIS Program during which time she was actively engaged in developing and reviewing earlier drafts of the formaldehyde assessment in response to the 2011 NASEM peer review of the 2010 draft IRIS formaldehyde assessment. Indeed, she served as a “disciplinary workgroup co-chair⁸” during an intra-agency review of an earlier draft. The short bio on the NASEM Study Director posted on the NASEM website, along with the bios of the provisional committee members, fails to disclose the Study Director’s substantive, years long involvement with the draft formaldehyde assessment. At a minimum, this prior involvement creates concerns about conflicts of interest and the appearance of a lack of impartiality as the Study Director’s prior work will necessarily be reviewed and the Study Director may have preconceived views on the state of the science regarding formaldehyde.

Although the Study Director is not a member of the NASEM peer review committee *per se*, the Study Director, nonetheless, plays an active and substantive role throughout the peer review process, working closely with the chair of the peer review committee:

The chair serves as the study director’s partner in managing the study – identifying problems, developing strategies to resolve



them, and cooperating to keep the committee on schedule. The study director works with the chair to develop agendas for committee meetings, prepare background materials, write or edit portions of the consensus study report, and stay in regular contact with members of the committee.⁹

Given the important role of the Study Director, their prior involvement in developing the material under review will necessarily raise questions about the impartiality of the review. The duties noted above are not mere ministerial tasks without influence on the nature or outcome of the peer review. For example, how background materials are developed has the potential to influence how peer reviewers view the scientific issues. It is also hard to see how past involvement with the issues would not influence the development of draft portions of the consensus study report. At a minimum, it raises significant questions about whether the peer review is being conducted without the appearance of lack of impartiality.

The August NASEM certification did not reference any specific NASEM conflict of interest policy applicable to NASEM staff.¹⁰ Nonetheless, the same principles underlying NASEM's policy that applies to members of NASEM committees, should apply equally to the NASEM staff who work closely with those committee members. The same concerns that motivated NASEM's conflict of interest policy - especially regarding information that "could have a significant impact on public perception of the objectivity and value of the committee's work" - apply equally to the Study Director.

Moreover, the Study Director's dual role clearly contravenes the spirit, if not the letter, of OMB and EPA peer review guidance and the 2003 NASEM Policy, given the Study Director is directly engaged in the peer review of work that they had substantive involvement in authoring and reviewing earlier drafts of the work product subject to NASEM review. Particularly relevant excerpts include the following:

OMB, 2004 "In its narrowest sense, independence in a reviewer means that the reviewer was not involved in producing the draft document to be reviewed. However, for peer review of some documents, a broader view of independence is necessary to **assure credibility of the process**. Reviewers are generally not employed by the agency or office producing the document. As the National Academy of Sciences has stated, 'external experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns..... In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency.'¹¹

NASEM, 2003: "[A]n individual should not serve as a member of a committee with respect to an activity in which a critical review and evaluation of the individual's own work... is the central purpose of the activity, because that would constitute a conflict of interest, although such an individual may provide relevant information to the program activity."¹²

EPA, 2015: EPA's Peer Review Handbook defines peer review as being "... conducted by qualified individuals (or organizations) who are independent of those who performed the work...."¹³ Section americanchemistry.com[®]

2.3 of EPA's Peer Review Handbook ensures "greater independence and transparency of peer reviews," through separating "the responsibilities for developing work products from conducting the peer review."¹⁴

EPA, 2015: "Can Someone Who Provided Peer Input Become an Independent Peer Reviewer for the Same Work Product Later in the Process? Generally, the answer is no, because that expert is no longer independent but rather is a contributor to the work product."¹⁵

In addition, the Bipartisan Policy Center echoed these principles for the peer review process, arguing that: "Agencies should be alert to their own biases in selecting advisory committee members. For example, staff who work on an issue to be reviewed by an advisory committee should not select members of that committee.... And agencies should periodically turn over the staff that is assigned to select panelists."¹⁶

Members of Congress have also raised concerns about the lack of independence and impartiality of the Study Director. Senator John Kennedy of Louisiana sent a letter in March 2022, prior to the release of the draft IRIS formaldehyde assessment, raising concerns about her work on the formaldehyde assessment and inability to "balance" the study director's perspective.¹⁷ As noted above, NASEM's own guidelines for committee members¹⁸ and chairs¹⁹ underscore the importance of the study director role.

In sum, the Panel recommends that NASEM promptly select a new Study Director without any "actual, apparent, or potential organizational or individual conflicts of interest related to the referenced task order" and prohibit any participation by the current Study Director in the current review²⁰

The Provisional Committee Reflects Significant Impermissible "Recycling" of Appointees²¹

In the 2021 contract between EPA and NASEM, EPA instructed NASEM to establish a committee of up to 12 experts. During one email exchange between the Study Director and an EPA colleague from whom she solicited a recommendation for a neurotoxicologist to serve on the committee, she notes, "There will be 'recycling' from the prior committee."²² Recycling of appointees, however, runs counter to OMB and EPA peer review guidance, both of which inform the NASEM peer review of the 2022 draft IRIS formaldehyde assessment because EPA has contracted with NASEM to conduct the review.

OMB Peer Review Guidance cautions agencies, including EPA, to "avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere."²³ "Furthermore, if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects.... In general, agencies shall make an effort to rotate peer review responsibilities across the available pool of qualified reviewers."²⁴

EPA's Peer Review Handbook uses similar language: "The principle is to avoid the repeated use of the same reviewer on multiple assessments unless his/her participation is essential and the



expertise cannot be obtained elsewhere.”²⁵ Elsewhere, the Handbook notes that “It is preferable... to use different individuals each time the product is sent back to peer review to provide a broader perspective. It is particularly important to rotate peer reviewers across the pool of qualified reviewers in the case of multiple HISAs [highly influential scientific assessments]. In the case of sequential reviews of one product... it may be helpful to include reviewers who were not involved in the previous review of the product to ensure that the product gets a fresh look.”²⁶ This principle is further supported by the Bipartisan Policy Center’s Science for Public Policy Project, which recommended: “[A]gencies should avoid turning repeatedly to the same scientists for service on advisory committees.”²⁷

In a number of instances, the short bios posted on the NASEM website fail to explicitly reference the other formaldehyde reviews in which provisional members participated. This omission must be corrected immediately, and the 20-day comment period restarted. Failure to disclose this information runs counter to the NASEM Policy that relevant information “must be disclosed at the time of committee formation” because such information “could have a significant impact on public perception of the objectivity and value of the committee’s work.”²⁸

Based on a review of NASEM panels related to formaldehyde or the IRIS process since 2011²⁹ as well as short bios provided by committee members:

- Six of the thirteen members served on the 2011 NASEM Review of the 2010 draft IRIS formaldehyde assessment or reviewed the 2011 NASEM report on the draft assessment.
- Six of the thirteen members have also served on subsequent NASEM panels related to IRIS or formaldehyde. In fact, several of the provisional committee members have served on multiple EPA-sponsored IRIS or formaldehyde panels over the last decade.

Based on a review of EPA’s current federal advisory committee lists as well as the General Services Administration Federal Advisory Committee Act database:³⁰

- These 13 provisional committee members have served on **over 220 federal advisory committees** at U.S. EPA and the Department of Health Human Services. This includes serving as a special government employee and consultant members. Overall, 12 of the 13 members have served on EPA or HHS advisory committees, with nine members having served on more than 10 panels.
- This includes ongoing service on major chartered EPA advisory committees with a potential role on IRIS and its uses, including the Science Advisory Board and the Clean Air Scientific Advisory Committee.

In light of these statistics, has NASEM fully and adequately established that each of the 13 provisional members has not been improperly “recycled”? If NASEM believes so it must provide a written and transparent and robust evaluation of any members it is “recycling”.

Other Concerns Regarding Independence from the Sponsoring Agency

Additional concerns about independence, impartiality, and organizational conflicts are raised by recent EPA grants to a number of these panel members on topic relevant to this review. Based on a review of one EPA Office of Research and Development grantee database:³¹

- Provisional panel members have served as principal investigators for roughly \$100 million in grants from U.S. EPA. This includes more than 30 grants with some projects related to this review running through 2023.
- Current, ongoing EPA funding for work on chemical toxicokinetics raises questions about (at the very least the appearance of) a lack of independence and impartiality. Related issues will be central to this peer review.

At a minimum a written evaluation as to why these relationships are not disqualifying should be provided.

The Provisional Committee Lacks the Requisite Balance

Ensuring appropriate member balance and composition are fundamental to the work of the peer review committee. “Differing and new perspectives on an issue, shaped by individual knowledge and experience, can be vital to achieving an informed, comprehensive, and authoritative understanding and analysis of a problem and potential solutions.”³² Importantly, the D.C. Circuit underscored FACA’s legislative history in deciphering the “fairly balanced” requirement:

The legislative history makes clear, the ‘fairly balanced’ **requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some presentation on the committee.**³³

NASEM Policy requires that the committee be composed of experts who have “an appropriate range of perspectives on the issues to be addressed by the committee”³⁴ which raises the question as to whether NASEM has adequately addressed this need to have balanced scientific perspectives. As noted previously by NASEM, “The membership of the committee should reflect the diversity of the communities of scientists, engineers, health professionals and other experts from which the committee members are drawn, and of the communities that have a stake in the outcome of the committee’s work.”³⁵ As described in the 2003 policy:

The assessment of the necessary perspectives required for a particular study committee may also involve considerations that go beyond specific disciplinary scientific or technical concerns. For some studies, for example, it may be important to have an "industrial" perspective or an "environmental" perspective. This is not because such individuals are "representatives" of industrial or environmental interests, because no one is appointed by the institution to a study committee to represent a particular point of view or special interest. Rather it is because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee.”³⁶

Unfortunately, the provisional committee lacks the requisite balance – it lacks a sufficient representation of scientists with backgrounds and expertise in private sector industrial toxicology and industrial epidemiology.



In addition, given prior involvement with formaldehyde, and related issues, NASEM needs to evaluate if each of the panel members, “can be objective and open-minded?” As noted by NASEM

Consideration should be given to whether the committee membership can be objective and open-minded in addressing the issues before it. For example, an 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.

Appointment to the committee is not appropriate if an individual is not open to any new learning or discussion that could change his/her views on an issued being addressed by the committee.³⁷

We request that NASEM provide its analysis demonstrating why it believes that the provisional panel membership meets this requirement.

NASEM Must Ensure that Prior Disqualifications have Been Resolved

Under certain circumstances, individuals that are part of organizations with memoranda of understanding with EPA, especially the Office of Research and Development (ORD), on issues related to human health assessment or IRIS and the chemical under review should be excluded due to lack of independence and appearance of a lack of impartiality. NASEM has previously recognized this conflict and removed a 2011 provisional panel member because of an MOU between the California state health agency and ORD. NASEM should ensure that this conflict has been resolved and that there are not similar agreements that would impact the ability of members to “be objective and open-minded in addressing the issues before [the committee].”³⁸

EPA Failed to Solicit Public Comment on the Committee Charge

By accepting public comments **before** selection of peer reviewers, “the Agency can consider public comments on the scope of the charge before the selection of peer reviewers so that appropriate expertise is included to address all charge questions.”³⁹ In this case, however, rather than comport with requisite peer review guidelines, EPA never requested public comment on the charge questions in the Federal Register notice that solicited public comment on the 2022 draft IRIS formaldehyde assessment.⁴⁰ Instead, EPA only indicated that it would take comment on the charge questions when it was denying requests for extension of the comment period. EPA’s last-minute indication that commenters can provide comment on the charge questions does not address the lack of public engagement on development of the charge questions.

Even if EPA had solicited comments on the charge questions from the start, the solicitation of committee nominees took place four months **prior to** public release of the charge questions. Thus, the public was denied an opportunity to help shape the charge questions and, importantly, comment on how those charge questions should influence the composition of the committee, undermining the peer review process. To address this concern, at a minimum NASEM should pause its process,

await EPA's response to the comments on the charge questions, and then reopen nominations to solicit appropriate expertise.

As reflected above, NASEM has some options to address some of the specific concerns raised by the Panel. However, in order to fully address the Panel's concerns regarding NASEM's shortcomings in meeting its statutory and policy obligations and remove the strong appearance of lack of balanced perspectives and resulting impartiality, we request that NASEM immediately select a new Study Director, ask EPA to specifically solicit comment on the charge questions and respond to such comments, and then restart the committee nomination process. We also request that NASEM provide a written response to the issues raised in this letter.

Respectfully,



Lynn Dekleva Ph.D.
Senior Director
Chemical Products & Technology Division
American Chemistry Council
On Behalf of the ACC Formaldehyde Panel

cc: Ms. Audrey Mosley
Dr. Clifford Duke
Dr. Elizabeth Eide

¹ EPA recently confirmed that its external "fit-for-purpose peer review[s]" are "conducted in accordance with the EPA Peer Review Handbook."
https://sab.epa.gov/ords/sab/sab_apex/r/files/static/v403/Science%20Supporting%20EPA%20Decisions.pdf

² 41 C.F.R. §102-3.185(a).

³ 41 C.F.R. §102-3.185(a)(2) (emphasis added).

⁴ EPA's Peer Review Handbook also restricts EPA's role in identifying potential panel members and explains how inappropriate involvement can constitute "direct subcontracting" in violation of acquisition regulations:

When a contractor is managing a peer review (either by panel or letter) for the Agency, the prime contractor is responsible for selecting who will perform the peer review.



Interfering in this process may be a violation of federal and Agency acquisition regulations. Specifically, it may constitute directed subcontracting.

The EPA can establish qualifications for peer reviewers. The Agency should not be involved, however, in the selection of individual peer reviewers and should avoid commenting on the contractor's selection of peer reviewers other than to determine whether the reviewers, once selected, meet the qualifications established, including compliance with contract requirements pertaining to COI. The EPA may identify, however, a pool of qualified peer reviewers for the prime contractor to consider. The candidates should be listed in alphabetical order and, to avoid directed subcontracting issues, the list generally should include more individuals than the number required for the review.

U.S. Environmental Protection Agency, Science and Technology Policy Council, Peer Review Handbook, 4th Edition, Oct. 2015, 4.6.3. (hereinafter, "Peer Review Handbook").

⁵ 41 C.F.R. §102-3.185(b). As shown in this document

(https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000023.pdf/12670242-7f5b-47b7-9878-ddff1ea79191?x-csrf-token=dee585d6-b8ec-4441-8ee4-afc99d6d621c)

the Study Director not only made several general solicitations of nominees from EPA staff but also asked EPA to identify an expert in a specific area and informed EPA that it intended to recycle experts from prior work. (https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000125.pdf/a2e0ef78-2b13-4cc3-893d-4718f9bace52?x-csrf-token=dee585d6-b8ec-4441-8ee4-afc99d6d621c)

. Given the redactions, however, it is difficult to fully assess these communications, but in at least one instance it appears that the Study Director revealed the name of a provisional committee member to an EPA employee many weeks before this information was publicly disclosed. Moreover, we do not know who EPA staff may have nominated in response to these solicitations or whether NASEM selected any of these nominees. Additionally, given the limitations on EPA involvement in the nomination process noted in fn 4, supra, NASEM must examine all EPA communication and submittals to ensure that EPA complied with its Peer Review Handbook.

⁶ [Letter from Elizabeth Eide to Vicki Soto, Re: RFP NO. PR-ORD-21-01009, Proposal No. 10005571, August 19, 2021.](#)

https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006791_00010434.pdf/5d94b0d9-050a-47db-95b3-2bd24b2ecee2?x-csrf-token=ae8b37d2-290b-4eee-97c0-9778ea241b9d

⁷ [Conflict of Interest Certification](#)

https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000180.pdf/939c7bb1-e9eb-43a3-b5ea-da32955df9c0?x-csrf-token=ae8b37d2-290b-4eee-97c0-9778ea241b9d.

⁸ [Disciplinary Workgroup](#)

https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006791_00010434.pdf/5d94b0d9-050a-47db-95b3-2bd24b2ecee2?x-csrf-token=ae8b37d2-290b-4eee-97c0-9778ea241b9d

⁹ The Consensus Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Members, p. 7, (hereinafter, "Guide for Members").

¹⁰ [Conflict of Interest Certification](#)

https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000180.pdf/939c7bb1-e9eb-43a3-b5ea-da32955df9c0?x-csrf-token=ae8b37d2-290b-4eee-97c0-9778ea241b9d

¹¹ Final Information Quality Bulletin for Peer Review, Executive Office of the President, Office of Management and Budget, Dec. 2004, at 17-18 (emphasis added). (hereinafter, "Peer Review Bulletin").

¹² The National Academies, Policy on Committee Composition and Balance and Conflicts of Interest, for Committees Used in the Development of Reports, May, 2003. While NASEM has indicated that the 2021

policy governs this review, it has provided no indication as to why the concerns related to being involved in the review of one's own work do not continue to apply.

¹³ Peer Review Handbook, at 20.

¹⁴ *Id.* at 32.

¹⁵ *Id.* at 73.

¹⁶ <https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2019/03/BPC-Science-Report-fnl.pdf> (pg. 19).

¹⁷ <https://www.kennedy.senate.gov/public/cache/files/6/7/67e204ad-9069-47bc-8098-47a14557f1a5/A73E19D30A589AD639C424A15AD0F876.sen.-kennedy-letter-to-dr.-clifford-duke-re-iris-3.2.22.pdf>.

¹⁸ Guide for Members

¹⁹ The Study Process of the National Academies of Sciences, Engineering, and Medicine, A Guide for Committee Chairs.

²⁰ [Conflict of Interest Certification](#).

https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000180.pdf/939c7bb1-e9eb-43a3-b5ea-da32955df9c0?x-csrf-token=ae8b37d2-290b-4eee-97c0-9778ea241b9d

²¹ The follow issues, as well as others, related to the composition are presented in more detail in a companion letter also delivered today.

²² [Recycling](#)

https://foiaonline.gov/foiaonline/api/request/downloadFile/ED_006489_00000125.pdf/a2e0ef78-2b13-4cc3-893d-4718f9bace52?x-csrf-token=ae8b37d2-290b-4eee-97c0-9778ea241b9d

²³ Peer Review Bulletin at 40.

²⁴ *Id.* at 18.

²⁵ Peer Review Handbook at 70.

²⁶ *Id.* at 73.

²⁷ <https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2019/03/BPC-Science-Report-fnl.pdf> (pg. 19).

²⁸ The NASEM Policy at 5.

²⁹ <https://www.nationalacademies.org/our-work/review-of-epas-draft-iris-assessment-of-formaldehyde>; <https://www.nationalacademies.org/our-work/review-of-advances-made-to-the-iris-process>; <https://www.epa.gov/iris/iris-and-national-academies-sciences-nas>; <https://www.nationalacademies.org/our-work/review-of-epas-iris-assessment-handbook>; <https://www.nationalacademies.org/our-work/review-of-the-formaldehyde-assessment-in-the-national-toxicology-program-12th-report-on-carcinogens>; <https://www.nationalacademies.org/our-work/review-of-advances-made-to-the-iris-process>; <https://www.nationalacademies.org/our-work/workshops-to-support-development-of-epas-iris-toxicological-reviews>; <https://www.nationalacademies.org/our-work/review-of-epas-tsca-systematic-review-guidance-document>.

³⁰ <https://www.facadatabase.gov/FACA/FACAPublicPage>.

³¹ https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/search.welcome.

³² The NASEM Policy at 1-2.

³³ *Nat'l Anti-Hunger Coal. v. Exec. Comm. of President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074, n.2 (D.C. Cir. 1983). (emphasis added; internal citations omitted).

³⁴ National Academies of Science, Engineering and Medicine, Policy on Composition and Balance, Conflicts of Interest, and Independence for Committees Used in the Development of Findings, Conclusions, and Recommendations, at 1 (2021)



³⁵ *Id.* at 2.

³⁶ 2003 Policy at 3.

³⁷ The NASEM Policy at 2. (emphasis added).

³⁸ The NASEM Policy at 2.

³⁹ EPA's Peer Review Handbook at 86.

⁴⁰ 87 Fed. Reg. 22208 (April 14, 2022).

Message

From: Kraft, Andrew [Kraft.Andrew@epa.gov]
Sent: 10/14/2021 4:11:07 PM
To: Guyton, Kathryn [KGuyton@nas.edu]; Soto, Vicki [Soto.Vicki@epa.gov]; Shams, Dahnish [Shams.Dahnish@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]
CC: Ray Wassel [rwassel@nas.edu]
Subject: RE: Formaldehyde study

Okay, thank you, good information to have for our Agency review meeting on formaldehyde in an hour😊! -Andrew

From: Guyton, Kathryn <KGuyton@nas.edu>
Sent: Thursday, October 14, 2021 12:03 PM
To: Soto, Vicki <Soto.Vicki@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>
Cc: Ray Wassel <rwassel@nas.edu>
Subject: Re: Formaldehyde study

Dear all,

Please note that, based on feedback from stakeholders, we have extended the deadline for the call for nominations for the formaldehyde study to October 29, 2021. The new deadline is noted on the [project page](#) and the [nominations portal](#). We will inform subscribers via the BEST Listserv later today.

We welcome any suggestions you may have, and will be happy to keep you informed.

All best wishes,
Kate

From: "Guyton, Kathryn" <KGuyton@nas.edu>
Date: Monday, September 27, 2021 at 3:35 PM
To: "Soto, Vicki" <Soto.Vicki@epa.gov>, "Shams, Dahnish" <Shams.Dahnish@epa.gov>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>
Cc: "Wassel, Ray" <RWassel@nas.edu>
Subject: Re: Formaldehyde study

Dear all,

I'm happy to share that the call for nominations for the formaldehyde study is now available online at the following link: <https://survey.alchemer.com/s3/6542334/Call-for-Nominations-Review-of-EPA-s-2021-Draft-Formaldehyde-Assessment>.

As noted, the National Academies encourage the nomination of volunteers who reflect the populations we serve and also welcome in particular nominations of candidates from underrepresented racial and ethnic groups, women, and early- and mid-career professionals.

With best wishes,
Kate

From: "Soto, Vicki" <Soto.Vicki@epa.gov>
Date: Thursday, September 23, 2021 at 6:33 PM
To: "Guyton, Kathryn" <KGuyton@nas.edu>, "Shams, Dahnish" <Shams.Dahnish@epa.gov>, "Kraft, Andrew" <Kraft.Andrew@epa.gov>, "Glenn, Barbara" <Glenn.Barbara@epa.gov>
Cc: "Wassel, Ray" <RWassel@nas.edu>
Subject: RE: Formaldehyde study

Thank you Kate,
Vicki

From: Guyton, Kathryn <KGuyton@nas.edu>
Sent: Thursday, September 23, 2021 6:21 PM
To: Soto, Vicki <Soto.Vicki@epa.gov>; Shams, Dahnish <Shams.Dahnish@epa.gov>; Kraft, Andrew <Kraft.Andrew@epa.gov>; Glenn, Barbara <Glenn.Barbara@epa.gov>
Cc: Ray Wassel <rwassel@nas.edu>
Subject: Formaldehyde study

Dear all,

Please be aware that we have announced the formaldehyde project on our webpage:
<https://www.nationalacademies.org/our-work/review-of-epas-2021-draft-formaldehyde-assessment>

The call for nominations will open soon, for ~3 weeks. I'll be happy to keep you informed.

With best wishes,
Kate

Kate Z. Guyton, PhD DABT
Senior Program Officer
Division of Earth and Life Sciences
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kguyton@nas.edu

Message

From: Barone, Stan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4F8618ACBBA418DA24C110F3123A2AF-BARONE, STAN]
Sent: 10/14/2021 6:55:24 PM
To: Guyton, Kathryn [KGuyton@nas.edu]
Subject: RE: Nominate an Expert for Formaldehyde Assessment Science Study

Love recycling in some cases.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

When I was reviewing formaldehyde previously this was one of the key references we considered Dr Pitten

<https://www.sciencedirect.com/science/article/pii/S0344033800801004>

Human studies

<https://pubmed.ncbi.nlm.nih.gov/27796833/>

From: Guyton, Kathryn <KGuyton@nas.edu>
Sent: Thursday, October 14, 2021 12:21 PM
To: Barone, Stan <Barone.Stan@epa.gov>
Subject: Re: Nominate an Expert for Formaldehyde Assessment Science Study

Hi Stan!

Thanks for your message, and for these great suggestions. There will be "recycling" from the prior committee which included **Ex. 5 Deliberative Process (DP)**. Any thoughts for a neurotox person? We just extended the deadline to Oct 29 in case you have any ideas.

Thank you!
Kate

From: "Barone, Stan" <Barone.Stan@epa.gov>
Date: Thursday, October 14, 2021 at 9:19 AM
To: "Guyton, Kathryn" <KGuyton@nas.edu>
Subject: RE: Nominate an Expert for Formaldehyde Assessment Science Study

Kate

Glad you getting this done.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Guyton, Kathryn <KGuyton@nas.edu>
Sent: Monday, October 4, 2021 5:00 PM
To: Barone, Stan <Barone.Stan@epa.gov>
Subject: FW: Nominate an Expert for Formaldehyde Assessment Science Study

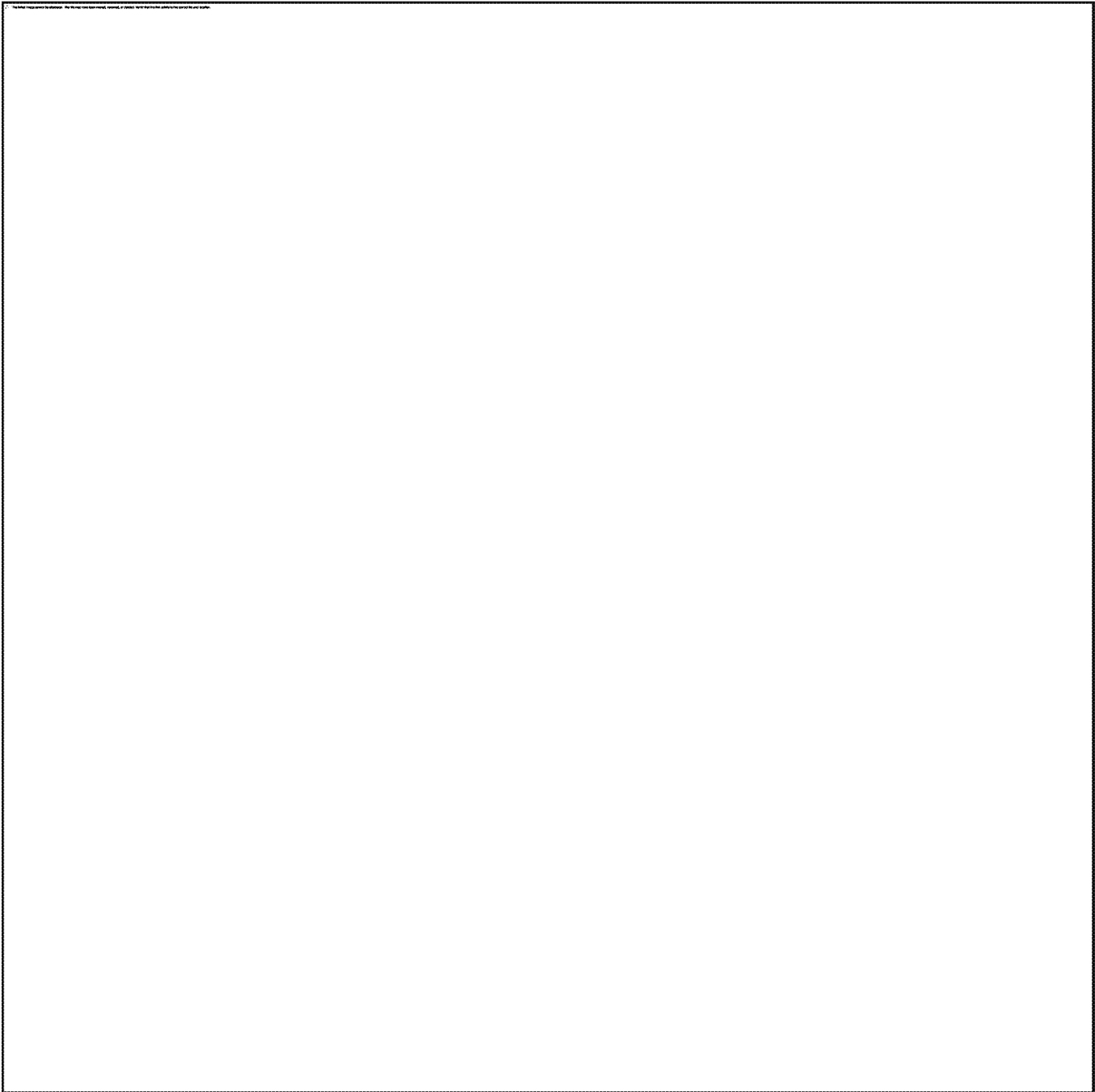
Hi Stan!

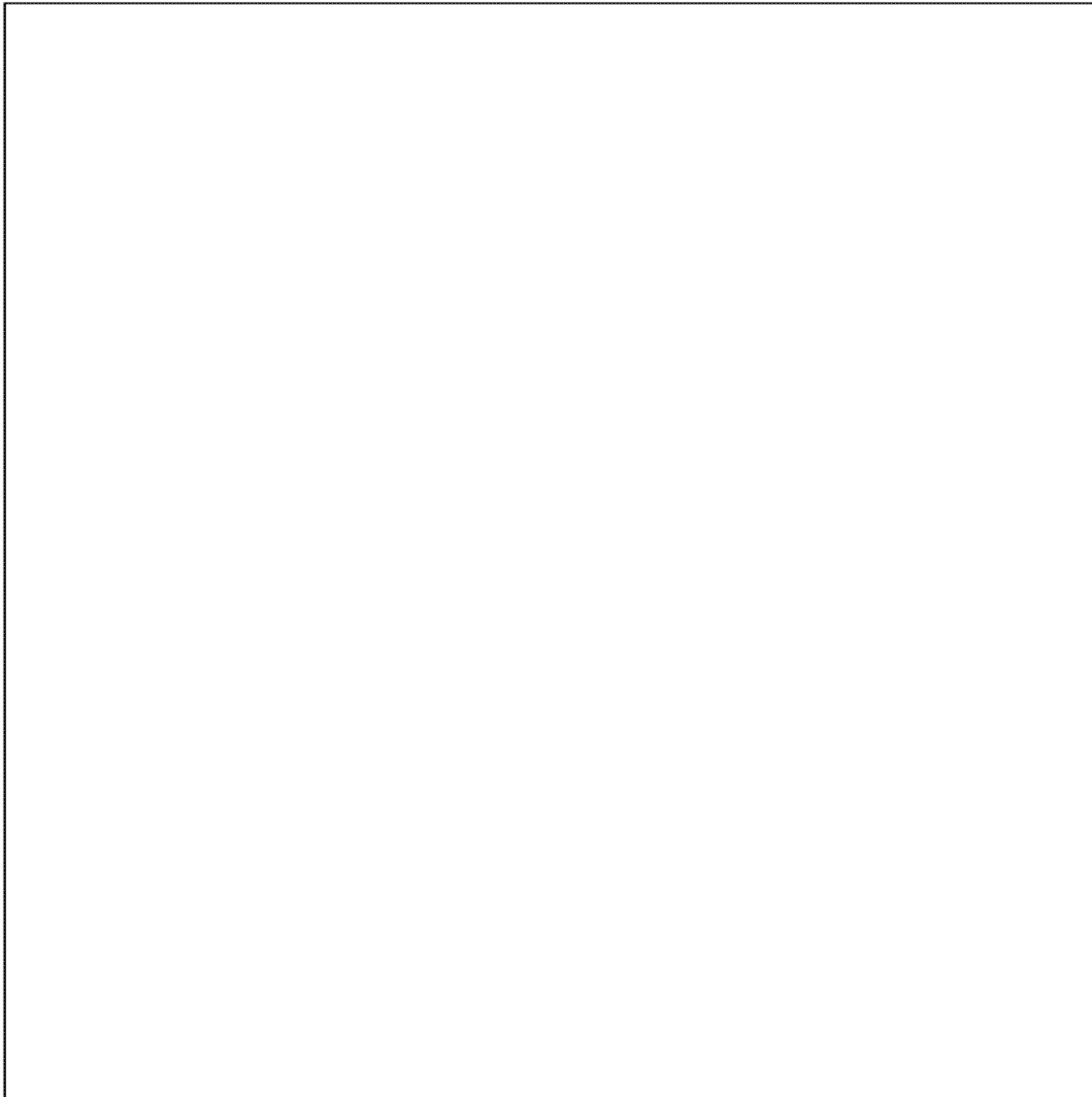
I hope this message finds you staying well. We have just launched our study on the EPA's formaldehyde assessment. I'd be grateful for any suggestions you may have for nominees, please.

All the best,
Kate

From: The National Academies Board on Environmental Studies and Toxicology <BEST@nas.edu>
Reply-To: BEST <BEST@nas.edu>
Date: Friday, October 1, 2021 at 1:00 PM
To: "Guyton, Kathryn" <KGuyton@nas.edu>
Subject: Nominate an Expert for Formaldehyde Assessment Science Study

[View this email in your browser](#)





Submit Committee Nominations:

Review of EPA's 2021 Draft Formaldehyde Assessment

Deadline: October 15, 2021

In response to a request from the Environmental Protection Agency (EPA), the National Academies of Sciences, Engineering, and Medicine invite you to nominate experts for an ad hoc committee to review the EPA's 2021 draft formaldehyde assessment. Committee meetings will begin in early 2022.

The National Academies are committed to enhancing diversity and inclusion in order to strengthen the quality of our work. We encourage the nomination of volunteers who reflect the populations we serve and also welcome nominations of candidates from underrepresented racial and ethnic groups, women, and early- and mid-career

professionals.

We invite you to submit nominations for committee members and/or reviewers by Friday, October 15, 2021.

Click Here to Submit Nominations

We are seeking approximately 12 volunteer experts with expertise in the fields of:

- Public health risk assessment,
- Systematic review methods,
- Biostatistics,
- Environmental epidemiology,
- Toxicology,
- Carcinogenesis (leukemogenesis),
- Reproductive effects,
- Developmental effects,
- Neurotoxicology,
- Respiratory effects (including asthma),
- Biological modeling,
- Exposure assessment,
- Dose-response analysis.

To learn more about this new study, [visit our webpage](#).

Contact Us

If you have any questions, please contact Dr. Kate Guyton at kguyton@nas.edu.



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Conflict of Interest Certification

August 19, 2021

William M. Yates
Contracting Officer
US Environmental Protection Agency
Contracts Management Division
Cincinnati, OH 45268

RE: PR-ORD-21-01009 under IDIQ Contract No. 68HERC19D0011; NAS Proposal No. 10005571

Dear Mr. Yates:

I certify that, to the best of our knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to the referenced task order exist. Personnel who perform work under this task order, or relating to the task order, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this task order have been reported to the contracting officer or are attached, if applicable. We recognize the obligation to identify and report any actual or potential conflicts of interest in accordance with the contract.

If you have any questions regarding this certification, I can be reached at (202) 334-2004, or by email at rwalker@nas.edu.

Sincerely,

Russell Walker
Digitally signed by Russell Walker
DN: cn=Russell Walker,
o=National Academy of
Sciences, ou=Office of Contracts
and Grants,
email=rwalker@nas.edu, c=US
Date: 2021.08.19 15:33:39 -0400
Russell Walker
Contract Manager

500 Fifth Street, NW, Washington, DC 20001
Phone 202.334.2254 Fax 202.334.2797 www.national-academies.org

Message

From: Whalan, John [Whalan.John@epa.gov]
Sent: 7/2/2013 1:25:48 PM
To: Burgoon, Lyle [Burgoon.Lyle@epa.gov]; Davis, Allen [Davis.Allen@epa.gov]; Galizia, Audrey [Galizia.Audrey@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Jarabek, Annie [Jarabek.Annie@epa.gov]; McLanahan, Eva [McLanahan.Eva@epa.gov]; Reinhart, Paul [Reinhart.Paul@epa.gov]; Stanek, John [Stanek.John@epa.gov]; Woodall, George [Woodall.George@epa.gov]
Subject: FW: Formaldehyde assessment for review by the IRIS Disciplinary Workgroups
Attachments: FormaldehydeTRdraft070113forREVIEW.docx; Memo_HumanCancerQRA_Approaches_FormaldehydeTR.docx; Disciplinary Grps_Formaldehyde_062113.xlsx

All,

Vince Cogliano's Email (below) describes how we will proceed with disciplinary review of the draft formaldehyde assessment. I have posted the draft assessment on the O:drive as follows:

O:
Priv
NCEA_Group
Inhalation Workgroup

Ex. 5 Deliberative Process (DP)

Ex. 6 Personal Privacy (PP)

John

From: Cogliano, Vincent
Sent: Monday, July 01, 2013 6:38 PM
To: Bale, Ambuja; Ball, James; Christensen, Krista; Fox, John; Gehlhaus, Martin; Gibbons, Catherine; Guyton, Kate; Hogan, Karen; Hotchkiss, Andrew; Keshava, Nagalakshmi; Kraft, Andrew; Makris, Susan; Newhouse, Kathleen; Persad, Amanda; Schlosser, Paul; Stanek, John; Subramaniam, Ravi; Whalan, John
Cc: Glenn, Barbara; Kraft, Andrew; Burgoon, Lyle; Bussard, David; Chiu, Weihsueh; Cogliano, Vincent; DeSantis, Joe; Gatchett, Annette; Hammerstrom, Karen; Hawkins, Belinda; Perovich, Gina; Rieth, Susan; Ris, Charles; Ross, Mary; Sams, Reeder; Sonawane, Bob; Strong, Jamie; Troyer, Michael; Vandenberg, John; Walsh, Debra
Subject: Formaldehyde assessment for review by the IRIS Disciplinary Workgroups

Hello Disciplinary Workgroup Co-Chairs – Attached are the Tox Review for Formaldehyde, a memo describing approaches to the quantitative cancer assessment, and a “map” that identifies sections that pertain to each Disciplinary Workgroup. The Supplemental Information document will follow Tuesday.

We will discuss the process for reviewing this assessment at Tuesday morning’s IRIS Management Council. Then the management liaisons can discuss the review process with their respective Co-Chairs. The Co-Chairs should select primary and secondary reviewers for the sections that are pertinent to their discipline, forward the assessment to their respective Workgroups, and determine how and when their Workgroup will meet to discuss the comments that you will send to the Assessment Managers (Barbara Glenn and Andrew Kraft).

Your review should cover:

1. Are the sections you reviewed clear, convincing, and objective?
2. Are the conclusions supported by the evidence presented?
3. Are the science issues addressed effectively, with alternative perspectives discussed where appropriate?
4. Are the issues raised by the NRC review of April 2011 addressed effectively?

You need not review the original literature. Begin with the evidence tables and see whether the synthesis follows logically and clearly. If not, that is a comment to take up within the Disciplinary Workgroup.

I will also welcome your feedback about how this process worked and how we might improve it in the future.

Thank you for your assistance in simulating the SAB and public reviews of this important assessment, Vince

From: Glenn, Barbara
Sent: Monday, July 01, 2013 5:40 PM
To: Cogliano, Vincent
Cc: Bussard, David; Perovich, Gina; Sonawane, Bob; Kraft, Andrew
Subject:

The draft toxicological review for formaldehyde is attached. A file containing supplemental information will be sent later today (we have encountered problems inserting portions, complicated by the problems with Outlook that occurred today). We (the formaldehyde team) are looking forward to participating in the review process and anticipate a stronger product as a result.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Regards, Barbara and Andrew