Message from the EPA IRIS Program

September 2024

On August 19, 2024, EPA publicly released the final IRIS formaldehyde (inhalation) assessment. This final posting marks the last step of EPA's established 7-step process to develop IRIS human health toxicity assessments. All EPA IRIS assessments are developed in accordance with EPA policies and procedures, including EPA's human health assessment guidelines, EPA's Scientific Integrity Policy, and EPA's Peer Review Handbook.

During development, draft IRIS toxicological reviews undergo two rounds of 4-week review by EPA program and regional offices (at Steps 2 and 6 of the IRIS Process). Draft IRIS assessments are also shared for two rounds of 4-week interagency consultation and discussion with representatives from other federal agencies, departments, and the Executive Office of the President (at Steps 3 and 6 of the IRIS Process). Step 3 and Step 6 interagency comments are posted on the IRIS website and in the assessment-specific docket. The IRIS formaldehyde (inhalation) assessment docket is EPA-HQ-ORD-2010-0396.

This message from the IRIS Program references a request from the U.S. Department of Defense (DoD) to extend the Step 6 interagency science discussion period (Attachment 1) and EPA's rationale for denying that request (Attachment 2). In this message from the IRIS Program, EPA is providing additional information regarding this request for extension.

In their request, DoD indicated that an extension was needed to allow for interagency reviewers to consider comments from EPA's Science Advisory Committee on Chemicals (SACC), an independent federal advisory committee that supports activities under the Toxic Substances Control Act (TSCA).[1] Per DoD, "it is important that the IRIS final assessment is reviewed in the context of both the [National Academies of Sciences, Engineering and Medicine (NASEM)] report and the SACC report" because (1) EPA's draft scientific integrity policy[2] states that the EPA's policy is to ensure that peer review charge questions address all relevant scientific questions, including those raised in differing scientific opinions (DSOs), and are free from any interference, and (2) addressing SACC technical concerns regarding the IRIS assessment is necessary "so that the toxicity assessment of formaldehyde is deemed by the SACC to be scientifically sound and appropriate for evaluating risk in the TSCA context and development of existing chemical exposure limits that will determine unreasonable risk from use of mission critical products that support defense and U.S. critical infrastructure."

DoD's request incorrectly implies that the peer review charge questions were insufficient, either because they did not address all relevant scientific questions or because there was inappropriate interference[3] in

[1] During the time of the interagency consultation on the draft IRIS formaldehyde assessment, the SACC was preparing a report on its review of the draft TSCA risk evaluation for formaldehyde.

[2] EPA is in the process of revising the Agency's Scientific Integrity Policy. In January 2024, EPA released a draft policy for public review and comment (see docket: https://www.regulations.gov/docket/EPA-HQ-ORD-2023-0240/document).

[3] The draft EPA scientific integrity policy defines interference as: "inappropriate, scientifically unjustified intervention in the conduct, management, communication, or use of science. It includes censorship, suppression, or distortion of scientific or technological findings, data, environmental information, or conclusions; inhibiting scientific independence during clearance and review; scientifically unjustified intervention in research and data collection; and/or inappropriate engagement or participation in the peer review process or on Federal advisory committees."

the development of the questions. The charge questions were not interfered with or limited in scope. The peer review charge questions delivered to NASEM as part of the independent, external peer review for the IRIS formaldehyde (inhalation) assessment were developed by EPA with opportunities for input during Steps 1-4 of the IRIS process, ensuring that these questions addressed all relevant scientific questions. The NASEM peer review was charged to consider whether EPA's conclusions presented in the draft assessment were clearly presented and scientifically supported. EPA's 10-pages of charge questions to NASEM were extensive, outlining and requesting specific peer review input on over 25 foundational scientific conclusions presented in the IRIS formaldehyde (inhalation) assessment. The charge questions posed by EPA to NASEM were consistent with charge questions used for other IRIS assessments. EPA notes that DoD did not raise concerns about the charge questions during Step 3 (see DoD comments on EPA Docket EPA-HQ-ORD-2010-0396), nor did DoD raise significant scientific points on the draft assessment at any point.

Moreover, DoD's reference to EPA's DSO approaches in the context of the IRIS assessment and the SACC review of the TSCA risk evaluation is misapplied. EPA's draft scientific integrity policy defines DSOs[4] as: "A differing opinion of an EPA scientist who is or was substantively engaged in the science that may inform an EPA decision… Substantively engaged in the science refers to having contributed scientific expertise in an official capacity as a co-author or subject matter expert in the development of a scientific product." This definition is consistent with that provided in the final EPA policy document, "EPA's Approaches for Expressing and Resolving Differing Scientific Opinions." [5] Thus, scientific opinions raised by members of the SACC during its review of the TSCA risk evaluation are not "differing scientific opinions."

As noted in EPA's denial of a request for extension, the SACC panel that conducted the peer review of the TSCA formaldehyde risk evaluation was not charged with reviewing the IRIS formaldehyde (inhalation) assessment, and that panel was not convened and balanced for the purpose of reviewing the scientific content in the IRIS assessment. Statements made by some members of the SACC and by the public commenters during the SACC meeting with respect to the draft IRIS assessment are not new. These statements relate to topics raised or considered by the NASEM committee, including topics raised by public commenters during Step 4 of the IRIS Process (Public Comment & External Peer Review), and the NASEM peer review report includes reference to or recommendations on many of these topics. Thus, these topics have been thoroughly considered by EPA in the final IRIS formaldehyde (inhalation) assessment revised in response to the Step 4 recommendations received, as documented in Appendix F.

Lastly, at the end of their request, DoD stated: "In addition, per GAO-08-440 summary of EPA implemented responses to the 2008 GAO Report on *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, DoD requests that the interagency review process allow 45 days (after the final SACC report is published) to review the final IRIS assessment. See Chemical Assessments: Low Productivity and New

[4] A DSO is defined in the EPA draft scientific integrity policy as: "A differing opinion of an EPA scientist who is or was substantively engaged in the science that may inform an EPA decision. It generally contrasts with a prevailing staff opinion included in a scientific product under development. The differing opinion must concern scientific data, analysis, interpretations, or conclusions, not policy options or decisions. Substantively engaged in the science refers to having contributed scientific expertise in an official capacity as a co-author or subject matter expert in the development of a scientific product ... A differing scientific opinion does not include personal opinions about scientific issues that are not accompanied by scientific arguments."

[5] https://www.epa.gov/scientific-integrity/approaches-expressing-and-resolving-differing-scientific-opinions

Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System | U.S. GAO."

EPA would like to clarify the reference to the Government Accountability Office's (GAO) 2008 report. This report outlined GAO's concerns regarding the impact of interagency review on the timeliness of developing IRIS assessments and the hindrance of EPA's ability to manage the process, ensuring its integrity. In addition, the 45-day Interagency Science Discussion review refers to the 2009 IRIS 7-Step Process. This 45-day timeframe indicated in the GAO report covered the entirety of Step 6, including both the review by other Federal agencies (which was 4 weeks for formaldehyde) as well as EPA's revision of the Step 6 draft prior to final posting.