



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2012-0830; FRL-9994-24-ORD]

Availability of the Updated Problem Formulation and Protocol for the Inorganic Arsenic IRIS Assessment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period associated with the release of the Updated Problem Formulation and Protocol for the Inorganic Arsenic IRIS Assessment. This document summarizes the Agency needs for the assessment and presents the refined focus based on problem formulation activities conducted since the last assessment plan released to the National Academy of Sciences, Engineering, and Medicine (NAS) in 2015. EPA is releasing this document for public comment in advance of an NAS public meeting on July 16, 2019.

DATES: The 30-day public comment period begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] and ends [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The Updated Problem Formulation and Protocol document will be available via the Internet on IRIS' website at https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?&substance_nmbr=278 and in the public docket at <https://www.regulations.gov>, Docket ID: **EPA-HQ-ORD-2012-0830**.

FOR FURTHER INFORMATION CONTACT: For information on the docket, contact the ORD Docket at the EPA Headquarters Docket Center; telephone: 202-566-1752; facsimile: 202-566-9744; or e-mail: Docket_ORD@epa.gov.

For technical information on the protocol, contact Dr. James Avery, NCEA; telephone: 202-564-1494; or email: avery.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information on the IRIS Program and Systematic Review Protocols

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA strives to provide high quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health.

The IRIS Program is developing an updated Toxicological Review of Inorganic Arsenic. Given the size and complexity of the evidence base for this chemical, input on the scope of this assessment has been sought from the National Academy of Sciences, Engineering, and Medicine (NAS), EPA Program and Regional Offices, other federal agencies, and public stakeholders to help focus the objectives of the assessment and ensure it is transparently conducted. The Updated Problem Formulation and Protocol summarizes the Agency's need for the assessment and presents the refined focus based on problem formulation activities conducted since the last assessment plan released to the NAS in 2015. In July 2019, an NAS ad hoc committee will conduct a peer review of the revised scope of the assessment and determine whether the proposed methods are appropriate to synthesize the scientific evidence and develop conclusions. The peer review charge questions will be available in the docket prior to the NAS meeting.

II. How to Submit Technical Comments to the Docket at <https://www.regulations.gov>

Submit your comments, identified by Docket ID No. **EPA-HQ-ORD-2012-0830** for Inorganic Arsenic, by one of the following methods:

- *https://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *E-mail*: Docket_ORD@epa.gov.
- *Fax*: 202-566-9744.
- *Mail*: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. The phone number is 202-566-1752.
- *Hand Delivery*: The ORD Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004.

The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. **EPA-HQ-ORD-2012-0830** for Inorganic Arsenic. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only

be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <https://www.regulations.gov>, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through <https://www.regulations.gov> or e-mail that you consider to be CBI or otherwise protected. The <https://www.regulations.gov> website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <https://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>.

Docket: Documents in the docket are listed in the <https://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other

information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in <https://www.regulations.gov> or hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated: May 16, 2019.

Tina Bahadori,
Director, National Center for Environmental
Assessment.

[FR Doc. 2019-11072 Filed: 5/24/2019 8:45 am; Publication Date: 5/28/2019]