



ENVIRONMENTAL PROTECTION AGENCY

[FRL- 9758-4; Docket ID No. EPA-HQ-ORD-2012-0830]

Toxicological Review of Inorganic Arsenic (Cancer and Noncancer Effects):

In Support of Summary Information on the Integrated Risk Information System (IRIS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a public stakeholder workshop to inform the development of a state of the science toxicological review of inorganic arsenic (cancer and noncancer effects) in support of the IRIS program.

SUMMARY: The inorganic arsenic (iAs) public stakeholder workshop is designed to inform the planning for EPA's toxicological review of chronic exposure to iAs (cancer and noncancer effects), which EPA intends to post in the IRIS database. Workshop participants will be asked to highlight significant new and emerging research, discuss methods for evaluating literature, identify critical research issues (including mode of action) that may impact the toxicological review, and discuss approaches for dose-response. The ultimate goals of the workshop are to ensure that while developing the toxicological review, EPA provides public stakeholders an opportunity to inform the toxicological review and transparently communicates how EPA will produce a toxicological review that meets the needs of Agency stakeholders and partners.

DATES: The public stakeholder workshop will begin at 8:00 am on January 8, 2013, and end at 5:00 pm on January 9, 2013.

ADDRESSES: The iAs public stakeholder workshop will be held at the U.S. EPA, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27711. To attend the workshop in person, register no later than 12:00 pm on January 2, 2013, by contacting Susan Blaine via e-mail: EPA_Arsenic@icfi.com or by telephone: 703-225-2471 (reference the iAs Public Stakeholder Workshop and include your name, title, affiliation, full address, and contact information). You can also register via the Internet at <http://tinyurl.com/EPA-Arsenic-2013>. Space is limited, and reservations will be accepted on a first-come, first-served basis.

To attend the workshop via webinar/video conference, register no later than 12:00 pm on January 7, 2013, by contacting Susan Blaine via e-mail: EPA_Arsenic@icfi.com or by phone: 703-225-2471 (reference the “iAs Public Stakeholder Workshop” and include your name, title, affiliation, full address, and contact information). You can also register via the Internet at <http://tinyurl.com/EPA-Arsenic-2013>. During the meeting, webinar attendees and individuals attending the iAs public stakeholder workshop in person are welcome to make comments or ask questions of presenters. All attendees may submit materials via <http://www.regulations.gov> (Docket ID No. **EPA-HQ-ORD-2012-0830**). All materials submitted before 12:00 pm on January 2, 2013, will be included for consideration during the iAs public workshop. However, there will be multiple opportunities for public input to inform the EPA’s toxicological review of chronic exposure to iAs (cancer and noncancer effects).

Information on Services for Individuals with Disabilities: EPA welcomes public

attendance at the iAs public stakeholder workshop and will make every effort to accommodate persons with disabilities. For information on access or services for individuals with disabilities, contact Susan Blaine by telephone: 703-225-2471, by facsimile: 703-934-3740 (reference the iAs public stakeholder workshop and include your name and contact information), or by e-mail: EPA_Arsenic@icfi.com (reference the iAs public stakeholder workshop and include your name and contact information).

ADDITIONAL INFORMATION:

Workshop participants will be encouraged to think broadly about the body of iAs scientific evidence and how it can be best used to generate a toxicological review for iAs. They will be invited to participate in an open dialogue regarding ways in which this evidence could most effectively be used in the toxicological review that will serve as the scientific and technical foundations for the Agency's decisions. Specifically, workshop discussions will provide important input as EPA considers the appropriate design, scope, and methods used in the toxicological review of iAs and participants may provide individual advice to EPA. This toxicological review, in turn, will inform risk management decisions by Agency stakeholders and partners. Panelists participating in the workshop will represent a wide range of external experts, as well as EPA staff, with various areas of expertise (e.g., epidemiology, human and animal toxicology, systematic review, risk assessment, dose-response, and mode of action).

In addition to the iAs public stakeholder workshop, the National Academy of Sciences (NAS) is planning to hold a public workshop on aspects of IRIS toxicological review of iAs. EPA will consider the key issues and recommendations from the NAS and stakeholders in developing a draft toxicological review of iAs. Upon completion of the draft, the public will

have an opportunity to review and provide comments and NAS will conduct an external peer review. The draft toxicological review for iAs will be revised in response to the NAS recommendations and public comments. The final toxicological review will be posted in the IRIS database.

For updated information on the iAs public stakeholder meeting, please refer to the following website: <http://www.epa.gov/iris/>. Alternatively, please contact John Cowden, Ph.D., U.S. Environmental Protection Agency, National Center for Environmental Assessment, Mail Code: B243-01, 109 T.W. Alexander Drive, Durham, NC 27711; telephone: 919-541-3667; facsimile: 919-541-0245; or e-mail: cowden.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information about IRIS

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects and cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

II. How to Submit Materials to the Docket at <http://www.regulations.gov>

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

- <http://www.regulations.gov>: Follow the online instructions for submitting materials.
- E-mail: Docket_ORD@epa.gov.
- Facsimile: 202-566-9744.
- Mail: Office of Environmental Information (OEI) Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460. The telephone number is 202-566-1752. If you provide materials by mail, please submit one unbound original with pages numbered consecutively, and three copies of the materials. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.
- Hand Delivery: The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue, N.W., Washington, D.C. The EPA Docket Center Public Reading Room is open from 8:30 am to 4:30 pm, 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 hand delivery, please submit one unbound original with pages numbered consecutively, and 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 materials to Docket ID No. **EPA-HQ-ORD-2012-0830**. Please ensure that your materials are submitted within the specified submission period. Materials 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 materials it receives in the public docket without change and to make the materials available online at <http://www.regulations.gov>, including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an "anonymous access" system, which means that EPA will not know your identity or contact information unless you provide it in the body of your materials. If you send e-mail comments directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD-ROM you submit. If EPA cannot read your materials due to technical difficulties

and cannot contact you for clarification, EPA may not be able to consider your materials.

Electronic files should avoid the use of special characters and 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 <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://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 material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: November 29, 2012.

Debra B Walsh,
Acting Director, National Center for
Environmental Assessment

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