

ENVIRONMENTAL PROTECTION AGENCY

[FRL-xxxx-xx-ORD; Docket ID No. EPA-HQ-ORD-2018-0654]

Availability of the ORD Staff Handbook for Developing IRIS Assessments.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 90-day public comment period associated with release of the ORD Staff Handbook for Developing Integrated Risk Information System (IRIS) Assessments, or IRIS Handbook. The IRIS Handbook provides operating procedures for developing assessments including problem formulation approaches and methods for conducting systematic review, dose response analysis, and developing toxicity values. EPA is releasing this document and the charge questions for public comment in advance of a National Academy of Sciences, Engineering, and Medicine (NASEM) peer review. Comments received will be summarized and provided to the committee conducting the peer

review. This document was prepared by the Center for Public Health and Environmental Assessment (CPHEA) within EPA's Office of Research and Development (ORD).

DATES: The 90-day public comment period begins [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], and ends [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The IRIS Handbook will be available via the Internet on the [IRIS](https://www.epa.gov/iris) website at <https://www.epa.gov/iris> and in the public docket at <http://www.regulations.gov>, Docket ID: EPA-HQ-ORD-2018-0654.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, 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 IRIS Handbook, contact Dr. James Avery, CPHEA; telephone: 202-564-1494; or email: avery.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information on the IRIS Handbook

The "ORD Staff Handbook for Developing IRIS Assessments," or "IRIS Handbook," provides operating procedures for developing assessments to the scientists in the IRIS Program.

The IRIS Handbook implements recommendations and input from the National Academy of Sciences, Engineering and Medicine (NASEM), EPA Agency reviewers, other Federal Agencies, EPA's Science Advisory Board, and workshops involving input from experts in systematic review. The steps in the overall IRIS process have not changed (<https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process>). The IRIS Handbook is designed so that it can be updated, as needed, to allow for incorporation of method refinements, advances in assessment science, and any updates in EPA guidance (see <https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/df0f42c34645448685258570005adfff!OpenDocument&TableRow=2.3#2>).

II. Information Regarding the Peer Review

EPA is announcing that NASEM will conduct an external peer review of the IRIS Handbook. Information regarding this peer review will be provided through the IRIS website (<https://www.epa.gov/iris>) and via EPA's IRIS listserv. To register for the IRIS listserv, visit the IRIS website (<https://www.epa.gov/iris>) or <https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-system#connect>.

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

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2018-0654 for the IRIS Handbook, 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. Due to COVID-19, there may be a delay in processing comments submitted by fax.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The phone number is 202-566-1752. Due to COVID-19, there may be a delay in processing comments submitted by mail.

Note: The EPA Docket Center and Reading Room is currently closed to public visitors to reduce the risk of transmitting COVID-19. Docket Center staff will continue to provide remote customer service via email, phone, and webform. The public can submit comments via www.regulations.gov or e-mail. No hand deliveries are currently being accepted.

Instructions: Direct your comments to docket number EPA-HQ-ORD-2018-0654 for the IRIS Handbook. 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 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 www.regulations.gov or e-mail that you consider to be CBI or otherwise protected. The 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 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 www.epa.gov/epahome/dockets.htm.

Docket: Documents in the docket are listed in the 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 www.regulations.gov or in hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Dated:

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Assessment.