

US EPA ARCHIVE DOCUMENT

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2012-0579]

**Notice of Availability of the External Review Draft of *Framework for Human Health Risk Assessment to Inform Decision Making***

**AGENCY:** U. S. Environmental Protection Agency

**ACTION:** Notice of Availability

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**SUMMARY:** The U.S. Environmental Protection Agency (EPA) Office of the Science Advisor (OSA) announces a 60-day public comment period for the external review draft of “*A Framework for Human Health Risk Assessment to Inform Decision Making*.” This document was developed as part of an agencywide program by the EPA Risk Assessment Forum. The EPA is releasing this draft document solely for the purpose of seeking public comment prior to external peer review. The document will undergo independent peer review during an expert peer review meeting that will be convened, organized, and conducted by a contractor of the EPA in 2012. The date of the external peer review meeting will be announced in a subsequent *Federal Register* notice. All comments received by the docket closing date [*insert date 60-days from the Federal Register notice issuance*], will be shared with the external peer review panel for their consideration. Comments received after the close of the comment period may be considered by the agency when it finalizes the document. This document has not been formally disseminated by the EPA. This draft document does not represent and should not be construed to represent the EPA policy, viewpoint, or determination. Members of the public may obtain the external review draft from [www.regulations.gov](http://www.regulations.gov); or [www.epa.gov/raf/FrameworkHHRA.htm](http://www.epa.gov/raf/FrameworkHHRA.htm) or from Julie Fitzpatrick via the contact information below.

This draft document describes a framework for conducting human health risk assessments that are responsive to the needs of decision making processes at the EPA. The document was developed by the EPA, to provide guidance to scientists and decision makers in the EPA.

**DATES:** All comments received by the docket closing date [*insert date 60-days from the Federal Register notice issuance*] will be shared with the external peer review panel for their consideration. Comments received beyond that time may be considered by the EPA when it finalizes the document.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2012-0579, and by one of the following methods:

- **Internet:** Follow the online instructions for submitting comments in [www.regulations.gov](http://www.regulations.gov)
- **Email:** [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov)
- **Mail:** ORD Docket, U. S. Environmental Protection Agency, Mail Code: 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460
- **Hand Delivery:** The EPA Docket Center (EPA/DC), Room 3334, EPA West Building, 1301 Constitution Avenue, NW, Washington, D.C. 20004, Attention Docket ID EPA-HQ—ORD-2012-0579. Deliveries are only accepted from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

**INSTRUCTIONS:** Direct your comments to Docket ID EPA-HQ-ORD-2012-0579. The EPA policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes 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 by statute through [www.regulations.gov](http://www.regulations.gov) or email. The [www.regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA, without going through [www.regulations.gov](http://www.regulations.gov), your email 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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the 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.

**Docket:** All documents in the docket are listed in the [www.regulations.gov](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 in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the ORD Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, DC. The 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, and the telephone number for the ORD Docket is (202) 566-1752.

**FOR FURTHER INFORMATION CONTACT:** Julie Fitzpatrick, Office of the Science Advisor, Mail Code 8105R, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-4212; fax number: (202) 564-2070, Email: [fitzpatrick.julie@epa.gov](mailto:fitzpatrick.julie@epa.gov).

**SUPPLEMENTARY INFORMATION:**

The EPA has an established history of conducting human health risk assessments. The *Framework* is intended to foster increased implementation of existing agency guidance for conducting human health risk assessments and improve the utility of risk assessment in the decision making process.

In developing the *Framework* the recommendations presented in the National Research Council's report *Science and Decisions: Advancing Risk Assessment* have been taken into consideration. Specifically, this *Framework* addresses the recommendations that the EPA formalize and implement planning, scoping and problem formulations in the risk assessment process and that the agency adopt a framework for risk-based decision making.

The *Framework* highlights the important roles of planning and scoping as well as problem formulation in designing a risk assessment. In accordance with longstanding agency policy, it also emphasizes the importance of scientific review and public involvement. The *Framework* presents the concept of "fit for purpose" to address the development of risk assessments and associated products that are suitable and useful for informing risk management decisions. This *Framework* will enhance the agency's emphasis on the importance of transparency of the human health risk assessment and decision making.

This document is not intended to supersede existing agency guidance; rather by citing and discussing existing guidance in the context of the framework it is intended to foster increased implementation of agency guidance.

Dated: July 20, 2012

  
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Science Advisor