

US EPA ARCHIVE DOCUMENT

**Framework for Human Health Risk Assessment to Inform Decision Making**  
**Public and Interagency Comment Summary**  
**October 2012**

The external review draft of the *Framework for Human Health Risk Assessment to Inform Decision Making* was released for a 60-day public comment period on July 30, 2012. Public comments were received from 3M, the American Chemistry Council (ACC), the American Petroleum Institute (API), the American Water Works Association (AWWA), the Center for Regulatory Effectiveness, General Electric (GE), Jane Public, the National Fisheries Institute, the Natural Resources Defense Council (NRDC) and Syngenta. Concurrently, EPA requested comments from interagency partners and received comments from the Agency for Toxic Substances and Disease Registry and Department of Defense (sent to the public docket).

***The Department of Defense indicated that better emphasis is needed regarding the National Research Council (NRC) recommendation to include “upfront identification of risk-management options, and use of risk assessment to discriminate among these options.”***

A major focus of the Framework is an increased emphasis on the problem formulation and planning and scoping phases of risk assessment, as recommended by the NRC. The current document includes discussion regarding identification of risk management options during the early phases of the assessment, as well as utilization of this information to inform the design of the risk assessment. In addition, the Framework discusses the importance of ensuring the final product is “fit for purpose” in that the assessment addresses the needs identified during the planning process, including, for example, providing information that will be useful for risk managers in evaluating various risk management options.

***The Agency for Toxic Substances and Disease Registry’s comments focused on expanding the stakeholder discussion to distinguish between the different needs of different types of stakeholders and address the areas of genomics and genetics as they will inform future tools and approaches.***

The document has been revised in consideration of the comment submitted on addressing the needs of different types of stakeholders. The authors have made the Framework flexible to accommodate future tools and approaches without limiting the discussion to specific tools such as genomics.

***Syngenta indicated that the Agency has done an excellent job of creating the Framework as a process to better inform risk assessors and advance decision making by risk managers. It commended the Agency for its efforts to improve the risk assessment decision-making process.***

The technical panel appreciates the commenter’s interest in and encouragement of Agency risk assessment and decision making.

***The NRDC submitted comments consistent with their recent issue paper, “Strengthening Toxic Chemical Risk Assessment to Protect Human Health.” Their comments include that the term “fit for purpose” was never used in the NRC’s Science and Decisions (known as the Silver Book). Their comments also include several NRC recommendations that EPA chose not to address in this document.***

Revisions have been made to clarify use of the term “fit for purpose” as analogous to the NRC’s emphasis on improving the utility of risk assessments, as well as to clarify the NRC recommendations that the Framework is intended to address. The NRC recommendations addressed in the development of the Framework document are primarily those concerning greater emphasis on the planning and scoping phase of the risk assessment to facilitate the development of an assessment that informs the identified risk management decision. The Framework additionally was developed with consideration of NRC’s suggestions with regard to developing a framework for human health risk assessment. Other NRC recommendations are beyond the scope of this activity, as are the NRDC comments advocating changes to existing guidance and policy.

***The National Fisheries Institute’s comments supported the inclusion of the “net effect” concept in the Framework.***

Consideration of countervailing risks, as appropriate, has been added as a key consideration during the planning and scoping of the risk assessment.

***Jane Public was critical of EPA’s decision to seek an independent expert peer review and recommended that EPA only seek public input on the document.***

EPA has a longstanding commitment to and policy on external scientific peer review. The Framework document conveys the role of such review as is consistent with EPA policy. The Agency has long recognized the important role played by public input; that input, however, is not a substitute for independent expert peer review.

***GE’s comments recommended expanding the scope of the document and suggested an alternative emphasis on peer review relative to stakeholder input. GE recommends that the Framework be applicable to Integrated Risk Information System (IRIS) assessments and that the document clearly incorporates the IRIS process.***

***Several comments from GE indicated support for the draft Framework document (dated July 12, 2012):***

- ***Statements supporting the Framework concept included:***
  - ***“Framework is valuable in providing a common theme for EPA risk assessments.”***
  - ***“GE commends EPA for seeking to unify its approach to risk assessment (to the extent that is possible giving differing statutory demands).”***
- ***“GE commends the Agency for recognizing that public participation is appropriately early in the risk assessment process.”***
- ***“GE commends the Agency on its general goal of improving the utility of risk assessments and its corollary of making risk assessments ‘fit for purpose.’”***
- ***“GE also commends EPA for its discussion of economic benefits analysis in Section 2.2.1 and Text Box 2-4 of the Framework.”***
- ***“... an ancillary benefit of the document is its collection and organized reference to EPA’s numerous risk assessment guidance documents.”***

The technical panel appreciates the comments in support of the Framework document.

***GE recommends that problem formulation must come first similar to the methodology used by the Guidelines for Ecological Risk Assessment, concluding that “[i]t seems clear that planning and scoping a risk assessment must come after the problem is determined.”***

The text in the sections on problem formulation and planning and scoping was modified to indicate that both steps are complementary. Section 1.3 emphasizes the importance of involving risk managers early in the process to identify the questions to be addressed in the risk assessment. This emphasis addresses the questions raised by the commenter.

***GE recommends the importance of coordinating with experts in the Agency, with other federal agencies and relevant state agencies.***

The technical panel also recognizes the important role of such experts. The Framework document in Section 2.1.3 (*Responsibilities, Resources and Timeline*) states, “Depending on the context and process in which the risk assessment is conducted, specific expertise may be needed to develop particular tools, data or analyses. Coordination with other federal, tribal and state agencies and with other stakeholders also may be appropriate,

depending on the type of assessment being conducted.” The level of detail provided in this text is consistent with the overall goals of the Framework.

***GE emphasized the importance of applying the Framework to the IRIS Program, EPA’s database of health effects information for chemicals in the environment, which includes toxicity values for individual chemicals that are then used as part of the overall risk assessment process. The specific comments include:***

- ***“EPA should document the process of problem formulation, planning and scoping in the Effects Assessment.”***
- ***“EPA should involve public participation at every stage of a risk assessment and during the earliest stage of the IRIS assessment emphasizing the importance of involving problem formulation at every subsequent stage of a risk assessment.”***
- ***“EPA should not discount public input to the system.”***
- ***EPA should “stress the importance of truly independent peer review.”***

Although the technical panel agrees that stakeholder and public participation is important, the level of detail requested by the commenter is beyond the scope of the Framework document. EPA’s Risk Assessment Forum will share these comments with the IRIS Program. In a separate effort, however, EPA and the IRIS Program are addressing recommendations provided by the NRC for improving the development of IRIS assessments. Information on these activities is provided on EPA’s IRIS Web page (<http://www.epa.gov/IRIS/iris-nrc.htm>). For the status of the implementation of the NRC recommendations for the IRIS program, see the recent materials that the IRIS Program provided to the NRC,<sup>1</sup> which include the following statement:

Because of the importance of considering the scope of an IRIS assessment, the IRIS Program is developing a new initiative to include a “scoping” process as an early step in developing IRIS assessments. The scoping process involves consultation with clients in EPA’s program and regional offices. This early consultation provides an opportunity to identify key questions for framing various analyses and helps ensure that the assessment meets the needs and critical timelines of Agency decision-makers.

Appendix E (*Scoping to Inform the Development of IRIS Assessments*) provides greater details about this.

For the IRIS Program, as well as other health and risk assessments, the Framework document has cited the third edition of the Agency’s *Peer Review Handbook* as a resource for risk assessors and risk managers and others involved in the process. In addition, EPA’s *Peer Review Program* Web page,<sup>2</sup> identified in the document, provides the Framework audience with additional information and updates to the Handbook. The level of detail asked for in the comments is beyond the level of detail intended for the Framework document.

***GE provides specific recommendations regarding the evaluation risk drivers at Superfund sites, including recommendations for modifying the Superfund process.***

The level of detail provided in this comment is beyond the scope of a Framework document, which is not designed to provide program-specific guidance.

***GE emphasizes the importance of determining the likely period of exposure and that the level of exposure also is essential for an economic benefits analysis.***

The technical panel notes that this concept is addressed in Section 1.3 *Fit for Purpose*.

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<sup>1</sup> [http://www.epa.gov/IRIS/pdfs/IRIS%20Program%20Materials%20to%20NRC\\_Part%201.pdf](http://www.epa.gov/IRIS/pdfs/IRIS%20Program%20Materials%20to%20NRC_Part%201.pdf).

<sup>2</sup> <http://www.epa.gov/peerreview/>.

***GE commented that as new information is developed through the risk assessment, it is important to “continually look for opportunities to reduce risk assessment costs by eliminating tasks that are no longer necessary as understanding of the problem being investigated increases.”***

The technical panel notes that throughout the document, the Framework emphasizes the importance of ongoing communication between the risk assessor and risk manager to inform decisions regarding the project. This does not mean, however, that the risk assessment will repeat each step or task, only those that require reconsideration as a result of this communication process. The technical panel agrees that evolving understanding of problems being investigated may lead to some tasks being no longer necessary and that everyone in the process should manage costs carefully.

***GE recommends that EPA emphasize data quality throughout the process.***

The technical panel notes that in the Framework document references are provided to EPA’s quality guidelines;<sup>3</sup> EPA’s information quality guidelines;<sup>4</sup> the Office of Management and Budget’s (OMB) 2004 *Final Information Quality Bulletin for Peer Review*; and other quality-related resources.<sup>5</sup> In addition, specific programmatic information is provided. The level of detail provided is consistent with the level of detail appropriate for a Framework document.

***GE recommends additional analyses and examples to demonstrate the “residual risk after implementation of typical remedial options.”***

The technical panel concludes that this recommended addition to the document is beyond the scope of a Framework document. The level of detail is inconsistent with other examples provided in the document.

***GE recommends that EPA specifically identify the need for a probabilistic risk assessment to inform a risk management decision for consumption of fish from a specific water body.***

The technical panel notes that the purpose of the text is to provide a range of options to inform decisions regarding fish consumption. The information presented provides a range of options to reflect the variability of data on fish consumption, size of water bodies and range of decisions under various regulatory programs. This document provides a range of options for risk assessors and risk managers to consider in all steps of the process.

***GE recommends a range of approaches for assessing the toxicity of chemicals under the IRIS Program. GE states that many of the recommended approaches are emerging and have limitations associated with the access to the data.***

The technical panel notes that the specificity of the comment is beyond the scope of a Framework document. This comment will be provided to the IRIS Program.

***GE urges the Agency to adopt “quantitative uncertainty as the norm.”***

The technical panel notes that the goal of the Framework is to provide the risk assessor and risk manager the opportunity to evaluate the nature of the decision and determine the appropriate level of risk assessment to address the needs of the risk manager.

***GE recommends that EPA recognize that risk assessments may be performed by entities other than EPA.***

The technical panel notes that the document provides an overall framework for the development of risk assessments to support risk management decisions. The document has applicability to a range of users, including those identified in the comment.

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<sup>3</sup> [www.epa.gov/quality](http://www.epa.gov/quality).

<sup>4</sup> <http://www.epa.gov/quality/informationguidelines/>.

<sup>5</sup> [http://www.epa.gov/quality/qa\\_links.html](http://www.epa.gov/quality/qa_links.html).

*GE recommends updating existing EPA guidance and policies regarding risk assessment.*

The technical panel notes that this recommendation is beyond the scope of the Framework document. Individual program offices will determine the need to update guidance, guidelines and policies that are specific to their programs.

*GE indicates that "... risk assessors and risk managers, both within and outside the Agency, will benefit from EPA's compilation of these documents."*

The technical panel appreciates this comment.

***The Center for Regulatory Effectiveness recommended that the Framework be revised to include information on EPA's Information Quality Guidelines, OMB's Updated Principles for Risk Analysis, and the EPA Council for Regulatory Environmental Modeling's (CREM) Guidance on the Development, Evaluation, and Application of Environmental Models.***

In response, we have added references to the *Information Quality Guidelines* and the CREM guidance on environmental models in the section on data quality. The Framework does not include detailed treatment of the contents of those documents because this would be beyond the scope of the Framework. Any updating of the *Risk Assessment Portal* and EPA's *Risk Assessment Guidance and Tools* website also is beyond the scope of the Framework document.

*The AWWA's comments indicate that it is not clear how risk assessment processes at the Agency actually will be modified to accomplish the objectives described in the Framework. They also ask that EPA reexamine its stakeholder engagement processes and focus on involving interested stakeholders early and often, as well as provide a thorough review of data and viewpoints provided by stakeholders.*

The Framework intentionally does not include the level of detail requested by the AWWA. EPA is a regulatory agency operating under a variety of statutes and laws. It is important that the Framework remain flexible enough to accommodate both the range of assessments conducted across the Agency and changes in the science of risk assessment. As stated in the Framework, "The level and amount of detail in each product will vary according to the level and amount of detail of the risk assessment that is being characterized. Statutory or regulatory requirements and restrictions, including those established by states and tribal nations, may limit risk assessment options. In addition, court precedents can affect how EPA considers assessments of risk. The statutory or regulatory requirements often specify additional factors for consideration in the risk management decision."

Public participation is an essential aspect of EPA's process for making decisions to achieve the Agency's mission of protecting human health and the environment. This provides EPA with the opportunity to obtain and consider a range of views on the issue being assessed, as well as on management options. Effective public involvement (including key stakeholders and/or communities) can enhance the deliberative process and improve the content of the Agency's decisions. A critical feature of the Framework is the involvement of the public, stakeholders and communities at key points in the process. The timing/frequency and level of community involvement will depend on a number of factors, including regulatory requirements, the nature of the decision and community interest.

*The API's comments indicate that the Framework does not provide concrete guidance on how risk assessment might be approached differently so as to be "fit" for different "purposes." The Framework needs more explicit guidelines regarding its implementation.*

The bulk of API's submission appears to focus on review of a specific Agency risk assessment activity and suggestions for revisions to the products developed in that activity. The API comments that pertain to the Framework document specify a need for the addition of more explicit guidance. As clarified in the introduction of the final document, however, the Framework is not intended to establish new guidance. Instead, it is intended to serve as a useful resource for existing guidance and emphasize the importance of the planning and scoping phase to facilitate the development of an assessment that informs the identified risk management decision.

*The ACC provided recommendations for improvement of the Framework and strongly encouraged EPA to implement and utilize all components of the Framework consistently across its program offices. The ACC offered the following comment:*

*EPA noted that 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 its decision-making. Unfortunately, processes used by EPA for assessing risks to the environment and human health have often lacked a consistent, coherent, science-based framework. It is clear that EPA's risk assessment activities have not been adequately or consistently coordinated within the Agency and this lack of coordination creates the potential for incomplete assessments, duplication of effort and inconsistent findings.*

The Framework provides a general outline for risk assessment rather than prescriptive guidance. Development of such a Framework document is expected to alleviate any discrepancies among programs such as those mentioned by the commenter.

*The ACC strongly encourages EPA to develop a plan for the timely and effective implementation of the Framework in its risk assessment process.*

The Risk Assessment Forum is committed to timely completion and dissemination of the Framework document to facilitate implementation.

*The ACC agrees that early engagement and an enhanced dialogue between risk assessors and risk managers will help ensure that the purpose and scope of the assessment are appropriate for the risk manager's needs.*

The technical panel appreciates this comment.

*The ACC commented, "For particularly challenging assessments, EPA should consider having the risk assessment protocol or plan subjected to both public review and independent peer review. Additionally, the plan should be continuously reviewed and revised as needed, throughout the risk assessment to ensure that the assessment remains 'fit for purpose.'"*

The Framework specifies adherence to the Agency's *Peer Review Handbook* and also recognizes the need to continually consider the needs of the assessment to ensure that the resultant products are fit for their purpose.

*The ACC commented, "The Agency should further expand its Framework to ensure that there is adequate transparency in the risk assessment process. This should include: (1) documentation that consistent, scientifically objective data evaluation protocols are used to evaluate studies—so that the same procedures are used irrespective of who conducted the study, where it was conducted, or who funded it; (2) a description of the key decision points and assumptions employed; (3) clear documentation of the underlying criteria and methods used in assessing weight of evidence and characterizing uncertainty; and (4) clear documentation of the rationale that lead [sic] to the final risk characterization. For assessments beyond screening level determinations, the characterization must provide a full picture—not just a worst case or upper bound estimate, or an estimate based on one set of default or conservative assumptions."*

Consistent with the commenter's interest, the Framework, as well as the Agency's *Risk Characterization Policy*, encourages transparency. The *Risk Characterization Policy* and *Peer Review Handbook* include just such specific examples as those raised by the commenter.

*The ACC commented that it is "generally encouraged by EPA's commitment to stakeholder engagement as described in the Framework and recommends that EPA also include a plan to engage the public earlier in the risk assessment process and ensure that peer review recommendations are adequately addressed before a risk assessment is finalized."*

The Framework encourages stakeholder engagement, recognizing that the approach employed in the context of each Agency action will vary with the nature of the regulatory decision and associated policies and guidance.

*3M requested that the Framework elaborate on the importance of considering “mode of action” in risk assessments.*

The technical panel agrees with the commenter that mode of action determination is key to risk assessment. We felt that the inclusion of the text box on mode of action and similar concepts emphasized this point. As there are multiple documents by EPA and others referenced in the Framework, we felt that further elaboration was not needed.