Report of the NJDEP Science Advisory Board

Prepared by the Science Advisory Board
Public Health Standing Committee

Review of Options for Peer Review of DSREH Human Health Risk Assessments

Approved by the
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October 5, 2017

The following report has been issued by the Science Advisory Board to the Commissioner of the New Jersey Department of Environmental Protection

Response to the Charge Questions regarding:

Review of Options for Peer Review of DSREH Human Health Risk Assessments

This report was prepared by the Public Health Standing Committee and sent to the Science Advisory Board for review and approval. The Science Advisory Board based this final report on those recommendations from the Public Health Standing Committee.

Members of the Public Health Standing Committee include:

Mark Robson, Ph.D., M.P.H., Chairperson
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NJDEP-SAB, Public Health Standing Committee
Review of Options for Peer Review of DSREH Human Health Risk Assessments

Introduction

In 2015, the Public Health Standing Committee (PHSC) of the NJDEP-Science Advisory Board was tasked with reviewing and commenting on the Draft Guidance for the Development and Review of Human Health Risk Assessment Documents prepared by the NJDEP Division of Science Research and Environmental Health (DSREH). That document initially contained a stand-alone section that provided suggested options for peer-review of risk assessments prepared by the DSREH. With the approval of the NJDEP, the PHSC separated their assignment into two separate tasks: the review of the risk assessment guidance and the review of the options for peer-review. The PHSC's review of the risk assessment guidance was completed in 2016. This report contains the PHSC's review and response to charge questions relating to the options for peer-review.

Response of PHSC/SAB on Peer-Review of RAs

Charge Question #1 - *Please comment on whether the guidance document, in general, provides clear, reproducible, appropriate and transparent options for the peer review of Division of Science, Research and Environmental Health human health risk assessments.*

The Public Health Committee (Committee) finds that the document under review is clear, reproducible, appropriate and transparent as far as laying out the options for peer review of DSREH assessments. The Committee recommends that if management of the peer review process is to be conducted by an academic or a for-profit consulting concern, the umbrella management process should be put into place prior to, and in anticipation of, any risk assessments that would be designated for peer-review via those processes.

The Committee notes that under the revised guidance document Option 2 (a university administers peer review) includes the possibility of recruitment of peer reviewers beyond those associated with the specific university with which DEP would contract for that work.

A member of the full SAB noted the need for a strong conflict of interest statement for the peer reviewers, and a strong freedom-from-coercion policy for those orchestrating the peer review process. In addition, the SAB member noted that a key to a credible process is to ask reviewers to declare their affiliations and interests when submitting their reviews, and to ensure that the orchestrator of the peer review process seeks a balance of interests across the reviews

Charge Question #2 - *Please comment on whether the options for the peer review process provide appropriate flexibility considering the types of risk assessments that the Division of Science, Research and Environmental Health develops.*

In general, the Committee agrees that the document provides appropriate flexibility for options for peer-review of DSREH assessments. However, in order for options 2 and 3 to actually provide the intended flexibility, funding would have to be available *a priori.* It is not clear to the Committee that

such funding has been committed or would necessarily be available. The Committee recommends that if Option 2 is to be utilized, DEP/DSREH should first set up an umbrella contract with a university that would provide a mechanism for the university to manage peer-reviews whether or not the university is called on to manage such peer-reviews during the life of the contract. Presumably, such a contract with a university could be set up without cost until the actual review work were needed. However, for Option 3, a similar contract and mechanism would need to be set up in advance with a private contractor, and it is assumed that a cost to DEP would be incurred for that activity alone.

A member of the full SAB suggested that the efficiency of the peer-review process could be increased by pre-approving members of a potential peer-review pool.

Charge Question #3 - *Given the differences in cost and timing for the different review options, from a technical perspective please comment on whether there is a clear hierarchy for which option(s) should be applied to which type of risk assessment document to be peer reviewed.*

The Committee is not recommending a clear hierarchy of peer review options because it believes that DSREH is in the best position to identify the most appropriate option for the specific instances as they occur in the future. Some issues which the Committee anticipates would affect option selection are availability of funding for contracted reviewers (Options 2 and 3) and timely availability of university faculty (Option 2). Overall, the Committee suggests that the simplest options appropriate be utilized, beginning with a default use of Option 1 whenever it is appropriate and feasible for DSREH to identify and select volunteer reviewers.

Addendum[1]

Peer review options

Preamble

External peer review of Office of Science (OS) human health risk-based criteria and guidance is herein defined as the selection of available and qualified individuals to provide comments on a draft document prior to its finalization and application. Peer reviewer candidates can include academic investigators with relevant subject matter expertise as well as individuals with experience in the development and review of human health risk assessment documents. The peer review process is distinct from the public comment process, which is the public posting on the DEP website of certain draft risk assessment document to provide the opportunity for any interested stakeholder (e.g., non-governmental organization, consulting firm, industry, private citizen, non-NJ state agency, academia) to submit additional data and/or comments to the DEP. When external peer review is conducted, it would occur after the draft document has been revised to reflect additional information and/or comments received through the public comment process.

The Office of Science recognizes that whether a peer review and/or public comment will be conducted for all risk assessment documents, or whether the extent of review will be determined on a case-by-case basis, is ultimately a policy decision that should be addressed by DEP management. However, the Office of Science does not foresee a need for peer review for all risk-based criteria and guidance, and believes that, in certain situations, external peer review may not be necessary when a risk assessment document has been subjected to public comment. The Office of Science proposes to provide recommendations to DEP management as to which documents require and would benefit from peer review.

Several scenarios presented below in Table 1 provide recommendations for which types of Office of Science documents should be subject to peer review. Following these scenarios, we present several options in Table 2 as possible mechanisms for conducting such peer reviews. These options differ in terms of the level of administrative effort, cost, and time required. Management decisions will be necessary to determine the most appropriate options.

[1] This addendum was added in January 2024 to the 4-page "Review of Options for Peer Review of DSREH Human Health Risk Assessments" report from the NJ DEP Science Advisory Board (SAB) dated October 5, 2017, upon noticing that the referenced guidance document with the peer review options was not included. The content and context of this addendum is maintained for consistency with material supplied to the SAB.

Table 1. Types of risk assessment documents	
Document	**Need for external peer review?**
Conducted by Office of Science	
1. Ground Water Criteria	
a) Interim specific (generated from primary scientific literature by OS)	OS will provide recommendation to DEP management as to whether external peer review is needed for the risk assessment document. This OS recommendation will be based, in part, on the complexity of the risk assessment and the existence of qualitative and/or quantitative risk information available in EPA's IRIS database.
b) Interim specific based on pre-existing IRIS value	
c) Interim generic	No. There is limited information for these chemicals and default criteria values are used.
2. Soil Criteria	
a) Interim (generated from primary scientific literature by OS)	OS will provide recommendations to DEP management whether external peer review is needed for the risk assessment document. This OS recommendation will be based, in part, on the complexity of the risk assessment and the existence of qualitative and/or quantitative risk information generated by EPA's IRIS database.
b) Interim based on pre-existing IRIS value	
3. Air Criteria	The OS will provide guidance to DEP management whether external peer review is needed for the risk assessment document. This OS recommendation will be based, in part, on the complexity of the risk assessment and the existence of qualitative and/or quantitative risk information generated by EPA's IRIS database.
4. Drinking Water Guidance	No. Guidance documents have no regulatory status and are generally issued quickly to address an emergent situation for which advice is needed rapidly.
5. Technical support to soliciting programs	No. OS activities are limited to searching for pre-existing information regarding a chemical. Note: OS response is often needed rapidly.
Miscellaneous	
Drinking Water Quality Institute	No. Prior to drafting the health effects document, an opportunity is provided for information and other input from the public. If DEP accepts the MCLs recommended by the DWQI, they are proposed as regulations that are subjected to a public comment period.

Table 2. Options for external peer review			
	Option 1	**Option 2**	**Option 3**
Description	OS administers the peer review	Academic institution administers the peer view via contract with OS	Private contractor (e.g., those used by USEPA) administers peer review via contract with OS
Pros	• Offers a relatively large pool of peer reviewers from other NJ state agencies, other entities (e.g., academia), and state risk assessors from across the country (e.g., FSTRAC or State Risk Assessors group) • No need to financially compensate peer reviewers who are NJ state employees • Requests to potential peer reviewers from other states will be made on the basis of reciprocity as needed	• OS can nominate peer reviewers based on expertise • Limited time requirement from OS	• Offers a relatively large pool of peer reviewers • Limited time requirement from OS • Contractors have experience in reconciling conflict of interest and evaluating peer reviewer candidates
Cons	• Need to dedicate OS time to administering peer review and potentially to reviewing other states' risk assessments (i.e., reciprocity) • Selection of peer reviewers by OS may be perceived as biased by external stakeholders • If OS cannot provide financial compensation, reviewer candidate pool could decrease—especially with respect to non-governmental scientists • May need to reconcile conflict of interest for peer reviewers • Need to develop a mechanism for soliciting state risk assessors	• Availability of monetary resources to fund contract and compensate peer reviewers • May need to reconcile conflict of interest for certain peer reviewers	• Bidding process • Availability of monetary resources to fund contract and compensate peer reviewers
Timeframe to initiate	• Months • Contingent on OS finding individuals to participate as peer reviewers	• Months	• Months
Cost to OS	• <$10K yearly cost, if all non-governmental peer reviewers receive financial compensation[1]	• ~$30K initial contract to academic institution to administer the program • Additional yearly cost of <$10K[1]	• Cost likely equivalent to or in excess of Option 2
Footnotes: [1]Cost based on the following: estimated $700 compensation for each individual participating on a peer review panel, 3 individuals serving on a given peer review panel, estimated 4 documents to be peer reviewed per year (i.e., $700 x 3 x 4 = $8400)			