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a nonprofit corporation dedicated to the best use of toxicity data for risk values

Using Expert Peer Involvement in Risk Assessment

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Peer Involvement in Risk Assessments

- The basic principles of a quality peer review -- independence, robust scientific process, inclusion of appropriate expertise, and transparency, can be extended to insure that other types of peer involvement contribute to the development of high quality risk assessment work products.
- Peer involvement can be formal or informal, and engage those within and outside the authoring organization.
- Three types of involvement: peer input, peer consultation, and peer review used at various stages of development of risk assessment products

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Peer Review

- Gain agreement from external expert peers on conclusions and scientific basis
- Intended final work product
- Emphasis on agreement on the approach and conclusions. Consensus among the experts desirable additional support and defensibility of the results
- Formal meeting or letter review
- External experts
- Independent of authors and reviewers free of conflicts of interest
- Stakeholder involvement limited

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Peer Input

- Soliciting information, data, or opinion from scientific peers
- Generally at an early stage
- Emphasis on appropriate focus, data acquisition, and identification of issues.
- Formal or informal
- Internal or external experts
- May or may not be independent of the authors
- Stakeholders may be involved

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Peer Consultation

- Gather independent expert peer opinion and advice on a work product during its development
- Most helpful when the document is complete enough to benefit from a review, but the analysis may still be in flux, allowing the experts' comments to be readily considered and influence future direction
- Consultation on an entire work product or on specific issues or analyses
- Emphasis on scientific expert opinion and advice, rather than data acquisition
- Formal or informal
- Internal, external, or both
- Independence - transparency and disclosure

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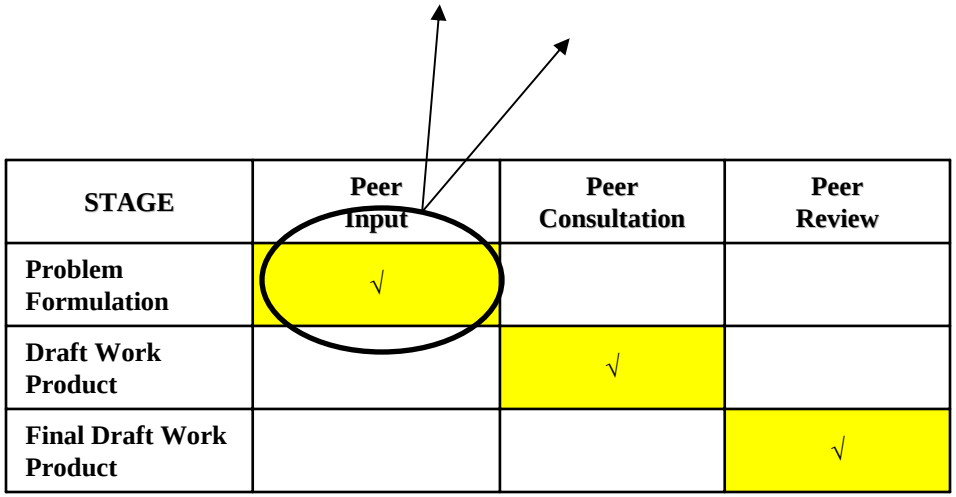
Stages of Risk Assessment Development – Opportunities for Involving Experts

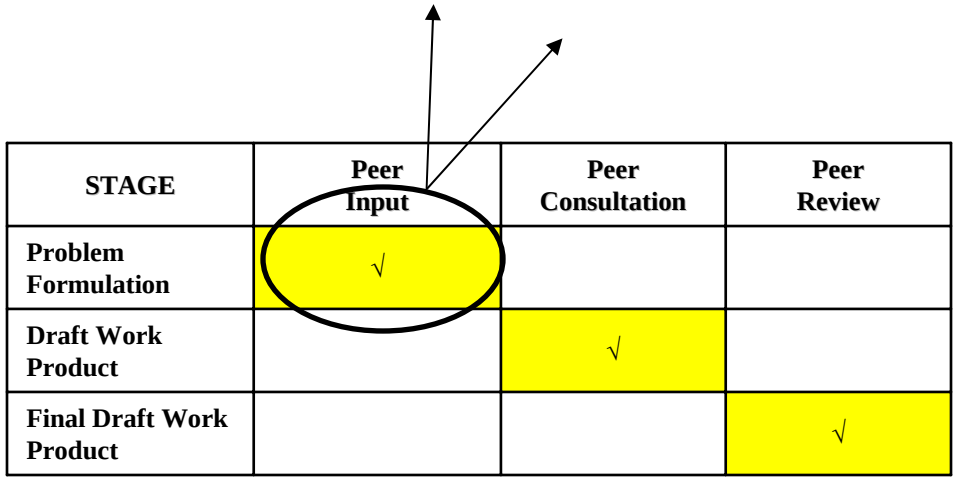
STAGE	Peer Input	Peer Consultation	Peer Review
Problem Formulation/ Scoping	√		
Draft Work Product		√	
Final Draft Work Product			√

STAGE	Type of Peer Involvement	Considerations
Problem Formulation /Scoping /Data Gathering	**Peer Input** • Data requests • Workshops • Meetings, informal or formal • Informal discussions • Expert Elicitation and Expert Judgement to fill data gaps or address uncertainties	• Is there an accepted standard approach available? • Are there previous relevant examples to follow? • Are there data or analytical tools to suggest? • Do outside parties have additional data/information? • Are there outstanding science or science policy issues that must be resolved or addressed? • Should additional studies be conducted or data collected? • What is the available budget and timeline?



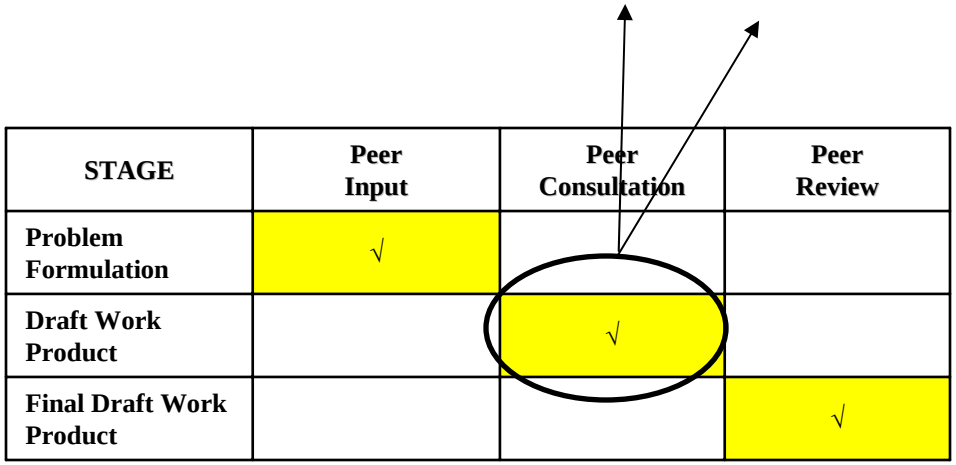
STAGE	Peer Input	Peer Consultation	Peer Review
Problem Formulation	√		
Draft Work Product		√	
Final Draft Work Product			√

STAGE	Type of Peer Involvement	Considerations
Problem Formulation /Scoping /Data Gathering	**Peer Input** • Data requests • Workshops • Meetings , informal or formal • Informal discussions • Expert Elicitation to fill data gaps or address uncertainties	• Is there an accepted standard approach available? • Do outside parties have additional data/information? • Should additional studies be conducted or data collected? • Are there approaches or analytical tools to suggest? • Are there outstanding science or science policy issues that must be resolved or addressed? • What is the available budget and timeline?



STAGE	Peer Input	Peer Consultation	Peer Review
Problem Formulation	√		
Draft Work Product		√	
Final Draft Work Product			√

STAGE	Type of Peer Involvement	Questions to Cover
Draft Work Product	**Peer Consultation** • Requests for written comments or review • Panel meetings or conference calls • On single issues or entire work product	• Were all the appropriate data identified? • Were the data interpreted correctly and presented in sufficient detail? • Are there alternative approaches that should be considered? • How can the work be strengthened and improved?



STAGE	Peer Input	Peer Consultation	Peer Review
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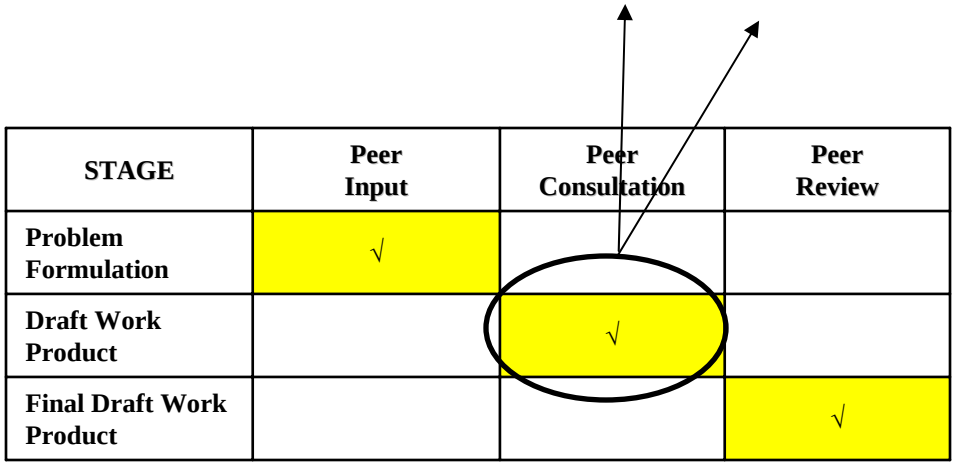
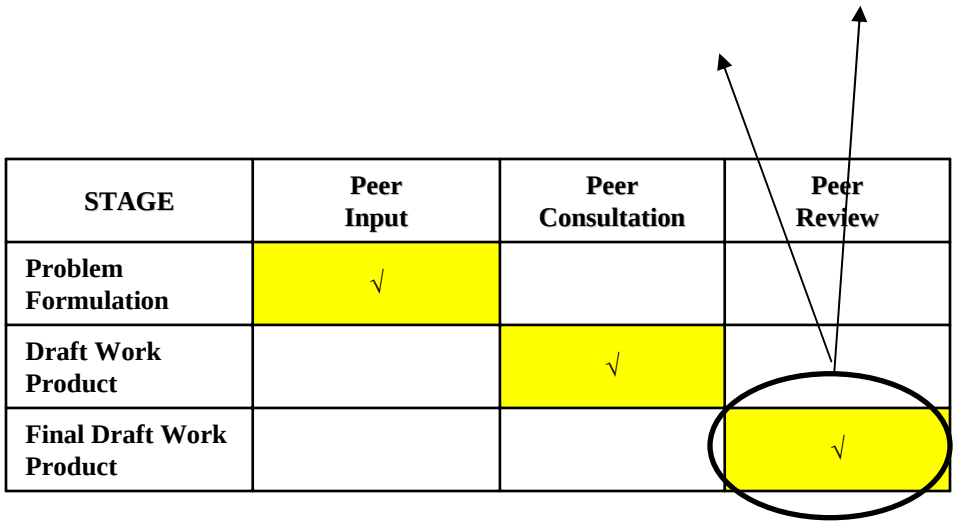


STAGE	Peer Input	Peer Consultation	Peer Review
Problem Formulation	√		
Draft Work Product		√	
Final Draft Work Product			√

STAGE	Type of Peer Involvement	Charge
Final Work Product	**Peer Review** • Written or letter review • Panel meetings or conference calls • On near final work product	• The completeness and strength of the data presented • The defensibility of the assumptions • The use of appropriate analyses and methods • The strength and defensibility of the conclusions • The strength and scientific defensibility of the rationales provided for choice of: study, effect, level, models, uncertainty factors, etc. • More specific questions regarding key specific issues



STAGE	Peer Input	Peer Consultation	Peer Review
Problem Formulation	√		
Draft Work Product		√	
Final Draft Work Product			√

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STAGE	Peer Input	Peer Consultation	Peer Review
Problem Formulation	√		
Draft Work Product		√	
Final Draft Work Product			√

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Principle -- Independence

- Independence defined as both distance from the development of the work product and freedom from institutional or ideological conflict of interest or bias.
- May not be as critical at early stages when seeking broad input from many sources
- Disclosure always a good idea
- Independence critical for peer review

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Principle -- Inclusion of Appropriate Expertise

- Success hinges on involvement of the right experts – those qualified through training and experience to offer scientific opinions on the questions and issues at hand
- Diverse scientific and institutional backgrounds contributes to balance
- Meetings allow for all experts' views to be heard

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Principle -- Transparency

- All interested persons should be able to evaluate and judge the adequacy and credibility of process and results
- Open meetings, public reports, identification of experts and credentials, disposition of comments
- Documentation made available

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Principle -- Robust Scientific Process

- Following other three principles contributes to scientifically robust process
- Focus on science, address policy and implementation in separate process
- Charge – evaluate robustness of data and analyses, and the defensibility of conclusions

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Conclusions

- Increased efficiency and effectiveness in preparing defensible risk assessments is essential to meet the demands of protecting public health
- Expert peers can identify additional data, alternate analytical approaches, and weaknesses in logic and reasoning
- Utilizing a wide range of expert peers throughout the process can minimize the need for revision and reanalysis late in the process
- Expert participation can strengthen the risk assessment and enhance the credibility and public confidence of the results.

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Thank You

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