

**JOINT JIFSAN/SRA/RAC SYMPOSIUM ON  
PEER REVIEW OF RISK ASSESSMENTS AND RELATED ACTIVITIES**

USDA/APHIS  
4700 River Road  
Riverdale, MD 20737  
Conference Center Rooms C&D

On Tuesday, September 30, the Joint Institute for Food Safety and Applied Nutrition, the Society for Risk Analysis<sup>1</sup>, and the Interagency Risk Assessment Consortium co-sponsored a symposium on peer review at the USDA Animal Plant Health Inspection Service Riverdale Center (APHIS). The morning session included a discussion of definitions and perspectives on peer review, the role and value of peer review, and the proposed Office of Management and Budget (OMB) peer review guidelines for regulatory scientific information. The afternoon session went on to discuss current peer review practices and procedures in various federal agencies, including the Food and Drug Administration's Center for Veterinary Medicine (FDA/CVM) and Center for Food Safety and Applied Nutrition (FDA/CFSAN), USDA's Food Safety and Inspection Service (USDA/FSIS) and Office of Risk Assessment and Cost-Benefit Analysis (USDA/ORACBA), and the Environmental Protection Agency (EPA). The symposium concluded with a diverse speaker panel, with representatives from academia, industry, and government, providing additional perspective, emphasizing the variation between agency practices and the need for informed approaches. There were about 60 participants, representing consumers, industry, academia, and government.

Dr. Robert Buchanan, FDA/CFSAN gave the opening remarks on behalf of the Interagency Risk Assessment Consortium and Dr. Elizabeth Calvey, FDA/CFSAN/JIFSAN welcomed the participants on behalf of the Joint Institute of Food Safety and Applied Nutrition. Dr. Leslie Hushka, ExxonMobil Biomedical Sciences, Inc., welcomed the participants on behalf of the Society for Risk Analysis (SRA).

Dr. Heather Douglas, University of Puget Sound, described the different types of review and what is meant by peer review of regulatory documents. She stated that different purposes of a document required different types of review processes, and showed how as the stakes get higher, the more complex a review is required. Regulatory review has the highest stakes and therefore requires a rigorous review.

Dr. Margot Schwab, OMB/Office of Information and Regulatory Affairs, introduced and explained the 2002 publicly released OMB document on "Information Quality Guidelines" and the more recently published (August 29, 2003) "Peer Review Bulletin".

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<sup>1</sup> Disclaimer: The Society for Risk Analysis believes it has a responsibility to provide an open forum for discussion of scientific and policy questions related to, and informed by, risk analysis. The positions taken by the participants in conferences and workshops hosted or co-sponsored by the Society are those of the participants themselves, and are not necessarily those of the Society.

Dr. Leslie Hushka, ExxonMobil Biomedical Sciences, Inc., discussed additional challenges raised by the proposed OMB guidelines. Her presentation asked highlighted questions as to: What does OMB / individual agencies mean by “proper goals” for peer review? (i.e., reliable; independent?); How does OMB / Agency demonstrate that their review process is transparent (including how and when)? What objective, output-based criteria will be used to judge the success of peer review? She also raised issues for Agencies to consider in selecting peer reviewers and improving Agency peer review processes.

Dr. Robert Buchanan discussed the peer review activities of CFSAN based on recommendations and the need to formalize and implement a comprehensive peer review process that encourages critical review and evaluation to assure that CFSAN’s risk assessments meet all the requirement of FDA’s newly adopted principles for the conduct of risk assessments that support regulatory programs. He described the requirements for this process. Dr. Buchanan emphasized the need for review throughout the process of a risk assessment.

Dr. Heather Douglas then presented the strengths and limitations of regulatory peer review. Her presentation included difficulties of regulatory peer review; range of reasonable expectations; and tensions in regulatory peer review, like defining conflict of interest and chasing consensus.

Dr. Dorothy Patton’s presentation focused on EPA’s experience in refreshing and broadening its peer review activities in response to 1992 recommendations from an external “blue ribbon” scientific advisory panel. Dr. Patton, a consultant and former EPA employee, emphasized three characteristics of EPA’s program to reinforce and expand peer review principles and procedures on an *agency-wide* basis. She spoke of reliance on three “R’s”: 1) **R**igor as to criteria and standards; 2) **R**egularity as to internal processes, and 3) **R**e-education to assure agency-wide attention to these peer review criteria, standards and processes. Referring to EPA’s Peer Review Handbook, issued by the EPA Science Policy Council and available on its website, she also offered several recommendations to other agencies which, like EPA in the mid-1990s, must now revitalize their peer review programs in response to external guidance, in this case, OMB. Dr. Patton also emphasized that it was important to distinguish between “peer involvement” at early stages in document development and “peer review” of the completed, more highly evolved, document used as a basis for rulemaking.

During the question and answer period, the two main questions that came up were: when is a document ready for peer review and how do you know that a review was successful? There was much discussion as to whether a document should be in its final form for review, or should be reviewed at different stages throughout the progress of the document/risk assessment. It was widely accepted that the true measure of a successful review is a better final product.

Other questions that came up and were also discussed at length include:

*What is the value of OMB’s involvement in reviewing agencies’ peer review process?  
What exactly is meant by peer review outside of data, i.e. opinion, models, etc.?*

The afternoon session focused mainly on agency experiences and needs for peer review of risk assessments by the different agencies mentioned above, as well as benefits of economic review.

Dr. Jim Schaub, USDA/ORACBA provided some background on ORACBA and gave an overview of federal peer review for risk analysis. He described the provisions of the ORACBA statute with regard to the risk assessment and cost benefit analysis process, expectations, and ensuring that regulatory analysis is performed consistently and using reasonable data.

Dr. Jeff Morris, EPA/ORD complemented Dr. Patton's presentation by describing EPA's current practices and the evolution of their Peer Review Program. He stated that EPA has begun to involve more scientists and engineers in their decision process. Dr. Morris also explained EPA's interpretation of the OMB "influential information" phrase and described what documents should be subject to peer review in line with OMB guidelines.

Dr. Carol Maczka, USDA/FSIS, provided an overview of the FSIS risk assessments reviewed and type of review they received. These included reviews by contract with an independent body outside of government, such as the National Academy of Science (NAS); National Advisory Committee for Microbiological Criteria for Food (NACMCF); the Interagency Risk Assessment Consortium (RAC), as well as by a consortium of universities. She described the current review process of FSIS and the criteria used for a "good" peer review. Dr. Maczka discussed the needs and challenges FSIS is faced with in conducting peer review. Advantages and disadvantages of hiring outside contractors were discussed in depth during the question and answer period. She also added that agencies need to develop standard operating procedures for doing peer reviews, and develop an expert registry.

Dr. Barry Hooberman, FDA/CVM, followed on after Dr. Maczka and he described the role of the RAC in the peer review of CVM's risk assessments, in a "peer consultation" capacity. Dr. Hooberman also discussed the differences in peer review needs between USDA/FSIS, FDA/CFSAN, and FDA/CVM and effectively demonstrated the difference between microbial risk assessments and antimicrobial resistance risk assessments. His presentation also described CVM's options for peer review, which have included the judicial system, and CVM's past experiences, with emphasis on "lessons learned".

Dr. Richard Williams, FDA/CFSAN completed the presentation session of the symposium with his presentation on the economic benefits of economic peer review. The recently formed Inter-Agency Economic Peer Review (IEPR) group was formed to work on peer review of cost benefit analyses. Dr. Williams described several factors that should be considered in a cost/benefit analysis. These include issues such as the expertise of the economists conducting the analysis; the expertise of the reviewers; probability of errors being detected and being corrected and the impact on regulation and policy.

During the question and answer period, several questions were asked of the afternoon speakers and discussed. These included:

*Is there any benefit to identifying the weakest link in a risk assessment?*

*How long does peer review take?*

*How does public comment fit into the peer review process?*

*What should the public's expectations be of the quality of data in risk assessments?*

*How do agencies deal with conflict of interest with independent contractors?*

During the panel discussion the panel moderator, Mohammad Modarres, UMD, asked the panel members to address certain questions:

*What does (regulatory) 'peer' review really mean in a practical sense?*

*What are the key components of a peer review process?*

*How should peer review be conducted?*

The panel members included representatives from government, industry, academia, private, and consumers: Carol Maczka, USDA/FSIS; Leslie Hushka, ExxonMobil; Philip DeShong, UMD; Dorothy Patton, consultant; Caroline Smith DeWaal, Consumer Science in the Public Interest. Panel members agreed peer review is a process that should be seen as a means to improve the quality of the work effort but also expressed concerns that it may not be the means of choice in some instances, that reviewers need to be experienced in risk assessment as well as in their own fields, that reviews are often conducted only at the end of a risk assessment's development even though peer review might be constructive at an earlier stage, and that reviews are costly in both time and money. Key components of a peer review process identified by the panel were: a product ready to be peer reviewed, the peer reviewers themselves and a clear charge to them, time for the reviewers to conduct their reviews, and openness about the process that permits both the reviewers' evaluations and the agency's responses to them to be known. There was general recognition by the panel that how peer reviews should be conducted will vary with circumstances.

Dr. Donald Schaffner, Rutgers University, provided the closing comments. He reminded the audience that our understanding of peer review of risk assessments is still in its infancy. Our knowledge of the peer review process for research publications or grants is of some value, but does not take us as far as we need to go. Dr. Schaffner specifically mentioned the importance of auditing of the computer model as part of the review process.

Specific suggestions that Dr. Schaffner noted from the days presentations included the importance of matching the peer review scope with the needs of the agency. He suggested requesting an analysis with as much specificity as practicable, noting that the more you ask of reviewers, the trickier it becomes, and that resources may be consumed that are inversely proportional to risk. Dr. Schaffner suggested that it might be possible to design an algorithm which would provide guidance on when and how much peer review is required in a particular situation.

Finally, Dr. Schaffner concluded that in working with peer review panels, agencies should be aware of the importance of the specific charge to peer-reviewers, noting that panels may waste time chasing consensus or setting policy (which may be beyond the scope of the charge). Dr. Schaffner noted that the panel manager is of key importance and must have must have the knowledge, skill and attitude to keep the panel focused within the stated scope of the review.