

Center for Regulatory Effectiveness

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May 18, 2012

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Committee on Ecological Risk Assessment under FIFRA and ESA
Board on Environmental Sciences and Toxicology
Division of Earth and Life Sciences
National Academy of Sciences
500 – 5th Street, N.W.
Washington, D.C. 20001

Re: Briefing on the Government-Wide Data Quality Protocols and Standards that EPA, NMFS and FWS Must Meet During Pesticide ESA Consultations

Dear Committee on Ecological Risk Assessment under FIFRA and ESA:

The Center for Regulatory Effectiveness (“CRE”) submits this White Paper for the Committee’s review because EPA, NMFS and FWS have not adequately briefed the Committee on the Government-wide data quality protocols and standards that govern their ecological risk assessments under FIFRA and the ESA. CRE has long been a proponent of these protocols and standards, and helped establish some of them.

These data quality protocols and standards include:

- The Office of Management and Budget’s (“OMB”) Government-wide Data Quality Act (“DQA”) Guidelines;¹
- EPA’s, NMFS’ and FWS’ own DQA Guidelines;²

¹ OMB’s DQA Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies are available online at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf> . The terms “DQA” (short for Data Quality Act), and “IQA” (short for Information Quality Act, another name for the same statute), will be used interchangeably in this paper.

² EPA’s DQA Guidelines are available online at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf .

The Center for Regulatory Effectiveness

- OMB’s Peer Review Bulletin;³ and
- The Council for Regulatory Environmental Modeling’s (“CREM”) Guidance for the development, validation and application of computer models.⁴

The above-referenced government documents are relevant to the issues being considered by the Committee in its review of ESA Section 7 pesticide consultations. For example, EPA, NMFS and FWS explain in a written submission to the NRC that

*“The two Services and EPA approach the identification of ‘best available scientific information’ (BASDI) using a variety of differing protocols pertaining to the type and character of scientific information that may be appropriate for these evaluations. Some of these approaches pertain to the character of the information as consensus information, peer-reviewed information or published and unpublished information. **The NRC will evaluate those protocols with respect to validity, availability, consistency, clarity, and utility.**”*

“Given the ESA’s requirement to base section consultations on the best scientific and commercial data available, the Service would like the Panel to consider under what circumstances should data be excluded from the assessment of pesticide risk to listed species? **We would also like the panel to comment on what data quality standards should be applied to information that helps inform the risk assessment process.**”⁵

The NRC Committee cannot “evaluate those protocols” unless the agencies or someone else identifies them for NRC review.

The NRC Committee cannot “comment on what data quality standards should be applied” unless the agencies or someone else identifies the data quality standards that apply to all federal agencies, including EPA, NMFs and FWS.

NMFS’ DQA Guidelines are available online at *Policy Directive on Policy on the Data Quality Act*, <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/policies/04-108.pdf>. FWS’ DQA Guidelines are available online at <http://www.fws.gov/informationquality/>.

³ OMB’s Peer Review Bulletin is available online at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>.

⁴ The CREM Models Guidance is available online at <http://www.epa.gov/crem/cremlib.html#guidance> . This EPA website also provides links to “other relevant EPA Guidance/ Publications,” including EPA’s DQA Guidelines.

⁵ *Scientific Issues in Conducting Ecological Risk Assessments for ESA Section 7 FIFRA Consultations (Oct. 31, 2011)*, page 2 (italics in the original)(bolding added), available online at <http://www.thecre.com/pdf/esanrcjointissues.pdf>.

The agencies for whatever reason have not adequately informed the NRC Committee. Consequently, CRE will try in this paper to introduce the Committee to the protocols and data quality standards that govern all FIFRA registrations and all ESA pesticide consultations. We hope that our submission will assist the Committee's review. We believe that our submission is consistent with OMB's guidance to EPA in another peer review proceeding:

“Since the development of Agency Information Quality (IQ) guidelines required by statute, many agencies have been using [peer review] charge language that tracks with the standards of their own IQ guidelines. For example, such language often focuses on whether or not the information in question is accurate, clear, complete, transparently and objectively described, and scientifically justified. We believe it may be useful for EPA to follow a similar approach and incorporate some of the language from your IQ guidelines into the formulation of the [peer review] charge questions.”⁶

As discussed in detail below, there shouldn't be significantly “differing protocols” among the agencies during ESA pesticides consultations because EPA, NMFs and FWS all have to comply with OMB's Government-wide DQA Guidelines. NMFS' biological opinions for pesticides apparently violate both these OMB Guidelines and NMFS' own DQA Guidelines. All of the agencies should peer review computer models they use in order to determine their compliance with the CREM Guidance, and all peer reviews should comply with OMB's Peer Review Bulletin.

EPA, NMF and FWS Have To Comply With OMB's Government-wide DQA Guidelines

A federal statute called the Data Quality Act (“DQA”) requires that most federal government agencies meet specified quality standards before they make scientific or other information publicly available. This statutory requirement means that federal government agencies must ensure that all scientific information they use or rely on meets the DQA standards. These quality standards are implemented first by Government-wide guidelines developed and published by OMB. The DQA requires that the other federal government agencies develop and publish their own, agency-specify quality guidelines. The agency-specific guidelines must be approved by OMB and must be consistent with OMB's Government-wide guidelines.⁷

As EPA explains in its DQA Guidelines:

“Developed in response to guidelines issued by the Office of Management and Budget (OMB) under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554;

⁶ OMB document available online at <http://www.thecre.com/pdf/ombiqacomments.pdf>

⁷ Supporting citations for this discussion, and a more detailed discussion, are available beginning at page 4 of the document at <http://thecre.com/pdf/20051228.pdf>.

H.R. 5658), the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency (the Guidelines) contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information we disseminate. The Guidelines also outline administrative mechanisms for EPA pre-dissemination review of information products and describe some new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB guidelines.”

“EPA's Guidelines are intended to carry out OMB's government-wide policy regarding information we disseminate to the public.”⁸

OMB's Government-wide DQA Guidelines direct Federal agencies

“to develop information resources management procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality (including the objectivity, utility, and integrity) of information before it is disseminated. In addition, agencies are to establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of information disseminated by the agency that does not comply with the OMB or agency guidelines. Agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated, and incorporate them into existing agency information resources management and administrative practices.”⁹

OMB's Government-wide DQA Guidelines define “quality” as the encompassing term, of which “utility,” “objectivity,” and “integrity” are the constituents. “Utility” refers to the usefulness of the information to the intended users. “Objectivity” focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. “Integrity” refers to security – the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. “Dissemination” is defined to mean “agency initiated or sponsored distribution of information to the public.”¹⁰

OMB explains that “if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information,

⁸ EPA DQA Guidelines, section 1, available online at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf .

⁹ Supporting citations for this discussion, and a more detailed discussion, are available in the document online at http://www.thecre.com/misc/20040606_worms.htm .

¹⁰ *Id.*

The Center for Regulatory Effectiveness

this appearance of having the information represent agency views makes agency dissemination of the information subject to these [DQA] guidelines.”¹¹

Several months later, in reviewing agency-specific DQA guidelines, OMB further explained how the DQA guidelines covered outside or "third party" information relied upon by an agency in a rulemaking. OMB used the draft Department of Transportation ("DOT") DQA guidelines as an example:

“DOT incorporated these principles from the OMB guidelines by stating that an agency disseminates information if it relies on information in support of a rulemaking. ‘If the Department is to rely on technical, scientific, or economic information submitted by, for example, a commenter to a proposed rule, that information would need to meet appropriate standards of objectivity and utility’ (DOT, 3). ‘The standards of these guidelines apply not only to information that DOT generates, but also to information that other parties provide to DOT, if the other parties seek to have the Department rely upon or disseminate this information or the Department decides to do so.’ (DOT, 8). . . . Other agencies, particularly those likely to be involved with using and/or disseminating ‘influential’ information, must include similar provisions in their guidelines.”¹²

In correspondence with CRE, NMFS acknowledges that both the OMB Government-wide and NMFS’ own DQA guidelines apply to outside or third-party information if NMFS uses or relies on that information.¹³

This outside or third party issue is further addressed in a recent report by NOAA’s Science Advisory Board. This NOAA SAB “report, ‘Assessing the Use of Data from non-NOAA Sources’, provides guidelines for developing a NOAA policy on the use of environmental data from external sources for various mission purposes. It aims to provide the basis for creating a NOAA policy that can aid in deciding whether or not to acquire data from non-NOAA sources and proposes standards to be applied to such acquisitions. Though NOAA has used data from external sources throughout its history, the DAARWG found such use has often been on an *ad hoc* basis. The intent of this document is to inform a potential NOAA policy that would apply particularly when external data are relied upon for operational purposes or decision-making.”¹⁴

¹¹ Page 8454 of OMB’s Federal Register notice available online at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf>.

¹² *Memorandum for the President's Management Council*, June 10, 2002, on "Agency Draft Information Quality Guidelines," from John D. Graham, Administrator of OMB's Office of Information and Regulatory Affairs, at 6-7 of Attachment, available online at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/iqg_comments.pdf.

¹³ See, e.g., NMFS’ letter to CRE available online at http://thecre.com/pdf/NOAA-IWC_Letter.pdf.

¹⁴ See letter available online at http://www.sab.noaa.gov/Reports/DAARWGtrnsmitltr_FINAL.pdf. NMFS is part of NOAA.

This NOAA SAB report on Use of Data from non-NOAA Sources acknowledges that “NOAA *Information and Quality Act [DQA]* guidelines require that original data be managed using documented processes for quality control...,”and it recommends NOAA-wide protocols for evaluating and using outside or third-party data.¹⁵

NMFS’s Pesticide Biological Opinions Apparently Violate OMB’s Government-wide and NMFS’ Own DQA Guidelines

NMFS’ *DIRECTIVE on Data and Information Management* states at page 3:

“(General Policy and Requirements A. Data are among the most valuable public assets that NMFS controls, and are an essential enabler of the NMFS mission. The data will be visible, accessible, and understandable to authorized users to support mission objectives, in compliance with OMB guidelines for implementing the ‘Information Quality Act...’”¹⁶

NMFS’ *Instruction on NMFS DATA DOCUMENTATION* states at pages 11-12 that all NMFS information disseminations must meet NMFS’ DQA Guidelines.¹⁷

NMFS must certify that information meets its DQA Guidelines requirements **BEFORE** NMFS disseminates the information to the public.¹⁸ EPA and FWS have similar DQA pre-dissemination review requirements.¹⁹

¹⁵ Page 2 of document available online at http://www.sab.noaa.gov/Reports/Assessing%20Use%20of%20Data%20from%20non-NOAA%20Sources%20Report%20to%20NOAA_January%202012%20FINAL.pdf.

¹⁶ This NMFS *Directive* is available online at <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/policies/04-111.pdf>.

¹⁷ This NMFS *Instruction* is available online at <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/procedures/04-111-01.pdf>. NMFS’ DQA guidelines are available online at *Policy Directive on Policy on the Data Quality Act*, <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/policies/04-108.pdf>. See also *NMFS INSTRUCTION on Data Quality Act, SECTION 515 PRE-DISSEMINATION REVIEW AND DOCUMENTATION GUIDELINES*, available online at <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/procedures/04-108-03.pdf>.

¹⁸ NMFS’ *Instruction on SECTION 515 PRE-DISSEMINATION REVIEW AND DOCUMENTATION FORM*, available online at <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/procedures/04-108-02.pdf>.

¹⁹ See, e.g., Section “7 Administrative Mechanism for Pre-dissemination Review,” EPA’s DQA Guidelines, available online at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

The Center for Regulatory Effectiveness

These requirements apply to biological opinions issued by NMFS during the Endangered Species Act Section 7 consultation process, including the NMFS pesticide BiOps being reviewed by this Committee. A BiOp issued by NMFS' Southwest Region demonstrates these DQA pre-dissemination review requirements.²⁰

This BiOp is dated June 4, 2009. It is issued under the Section 7 formal consultation provisions of the ESA. It addresses the proposed long-term operations of the Central Valley Project and State Water Project in the Central Valley, California, and the proposed operations' effects on listed anadromous fishes and marine mammal species. The action agency is the U.S. Bureau of Reclamation.

This NMFS BiOp includes a document entitled "Information Quality Act - Pre-Dissemination Review & Documentation Form." It contains the NMFS Region's signed and detailed certificate of compliance with NMFS' DQA pre-dissemination review procedures and requirements. NMFS explains elsewhere that the NOAA/NMFS

"Information Quality Guidelines were developed according to OMB guidance to set standards for the quality of information federal agencies disseminate to the public and to provide a mechanism through which the public may request correction of information they believe does not comply."

"Compliance with the ...Information Quality Guidelines is crucial. NOAA Fisheries [aka NMFS] has developed procedures to assist staff with the Information Quality Act pre- dissemination review process."²¹

By contrast, NMFS has issued FOUR final BiOps during consultation with EPA over pesticide effects on salmons. These pesticide BiOps are available online at:

<http://www.nmfs.noaa.gov/pr/consultation/pesticides.htm>. We cannot find a DQA pre-dissemination review certificate of compliance for any of them. We cannot find any mention of the DQA in any of them. Consequently, NMFS' pesticides BiOps appear to violate NMFS' DQA pre-dissemination review requirements and perhaps other DQA requirements.

These other requirements may include NMFS' *Instruction* on **GUIDELINES FOR AGENCY ADMINISTRATIVE RECORDS**, which states at pages 2-3 that: "The AR [Administrative Record] first must document the process the agency used in reaching its final decision in order to show that the agency followed required procedures. For NOAA [and NMFS] actions, procedural requirements include...the Information Quality Act..."²²

²⁰ This BiOp is available online at <http://swr.nmfs.noaa.gov/ocap.htm>.

²¹ <http://www.sefsc.noaa.gov/DQA/DQA.jsp> .

²² This NMFS *Instruction* is available online at <https://reefshark.nmfs.noaa.gov/f/pds/publicsite/documents/procedures/30-123-01.pdf>.

Computer Models Should Be Peer Reviewed to Determine Their Compliance with CREM Guidance

Computer models used during ESA pesticides consultations should be peer reviewed to determine whether they meet EPA's CREM guidance. NMFS ordered such peer review for the Acoustic Integration Model in another regulatory context.²³ There should be a record for all models demonstrating their DQA compliance, and demonstrating their compliance with EPA's CREM guidance document.²⁴

EPA's CREM website explains that "The CREM developed this [guidance] document to provide a simplified, comprehensive resource for modelers across the Agency on best modeling practices. When adhered to, the guidelines will help to ensure the quality, utility and regulatory relevance of the models that EPA develops and applies and the transparency of modeling analyses and model-based decisions."²⁵

EPA produced its CREM guidance after extensive consultation with NRC.²⁶ The NRC report explained:

*"This report recommends a series of guidelines and principles that, if adopted, will improve environmental regulatory models and decisions made by the agency. Moreover, adoption of these principles **will enhance the agency's ability to respond to recent information-quality requirements** by allowing EPA to provide more informed responses to outside challenges and reduce the likelihood of erroneous data releases that can prompt challenges."*

"One laudable step has been the establishment of the Council for Regulatory Environmental Modeling (CREM) in 2000 to support modeling activities across the agency and to provide an important resource for interested parties outside of EPA. The National Research Council (NRC) convened the Committee on Models in the Regulatory Decision Process in response to a request from CREM to independently assess evolving scientific and technical issues related to the selection and use of computational and statistical models in decision-making processes at EPA."²⁷

²³ See AIM peer review at http://www.nmfs.noaa.gov/pr/pdfs/permits/lfa_aim_review.pdf.

²⁴ EPA's CREM Guidance is available online at <http://www.epa.gov/crem/cremlib.html#guidance>. This website also provides links to "other relevant EPA Guidance/ Publications," including EPA's Information Quality Guidelines.

²⁵ <http://www.epa.gov/crem/cremlib.html>.

²⁶ See, e.g., http://www.nap.edu/openbook.php?record_id=11972&page=1.

²⁷ *Id.*, pages 1 and 2 (emphasis added).

All Peer Reviews Should Comply with OMB's Peer Review Bulletin

Peer reviews conducted by NMFS or any other federal agency during pesticide consultations should comply with OMB's Final Information Quality Bulletin for Peer Review.²⁸

FWS' DQA Guidelines stress the importance of complying with OMB's Peer Review Bulletin:

"...FWS adheres to the OMB Memorandum (M-05-030) 'Final Information Quality Bulletin for Peer Review' dated December 16, 2004, to ensure that influential scientific information disseminated to the public is subject to peer review. The Bulletin directs agencies to choose an adequate peer review mechanism considering the complexity and novelty of the science, the relevance of the information to decision making, the significance of the policy decision, the extent of prior peer review and the expected benefits and costs. In addition, the agencies are directed to consider tradeoffs between depth of peer review and timeliness...."

Information types and sources, analytical methods, and assumptions will be described in administrative records for influential information."

*"If we [FWS] use peer review to help satisfy the objectivity standard, the review process employed must meet the general criteria for competent and credible peer review (OMBM-05-03, 'Final Information Quality Bulletin for Peer Review')."*²⁹

²⁸ The OMB Peer Review Bulletin is available online at <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>.

²⁹FWS' DQA Guidelines, available online at <http://www.fws.gov/informationquality/>.

Conclusion

CRE requests that the Committee consider these Government-wide data quality standards and protocols during the Committees' review of EPA's, NMFS' and FWS' pesticide consultations and risk assessments under FIFRA and the ESA.

Thank you for your time and consideration. Please contact the undersigned with any questions or if you wish further briefing on this important issue.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Jim Tozzi". The signature is stylized with a large initial "J" and a cursive "Tozzi".

Jim Tozzi

Member, CRE Board of Advisors