Center for Regulatory Effectiveness

March 14, 2003

Public Information and Records Integrity Branch (PIRIB)
Office of Pesticides Programs (OPP)
Environmental Protection Agency (7502C)
1200 Pennsylvania Ave., NW.
Washington, D.C. 20460-0001

Re: Docket OPP-2003-0010

Dear Sir or Madam,

The Center for Regulatory Effectiveness ("CRE") submits the following comments on the Advance Notice of Public Rulemaking published in the *Federal Register* on January 24, 2003. This ANPR focuses on regulations and policies affecting the process for consultation under the Endangered Species Act ("ESA") between EPA , the Fish and Wildlife Service ("FWS"), and the National Marine Fisheries Service ("NMFS") regarding EPA actions in its pesticide regulatory program under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). CRE's comments primarily concern the definition of "Best Scientific and Commercial Data Available." This is one of the ESA Consultation issues for which comment is expressly requested in the ANPR.

For purposes of ESA consultation, EPA cannot make an effects determination for a particular pesticide without reliable test data. Similarly, FWS and NMFS cannot issue a biological opinion without reliable test data. Tests that have not been demonstrated to be reliable should not be used in effects determinations or biological opinions. This conclusion is based on principles of sound science, and it is mandated given the requirements of the Data Quality Act, 44 U.S.C. § 3516 Statutory and Historical Notes.

The Data Quality Act imposes standards on the quality of information disseminated by most federal agencies, including EPA, FWS and NMFS. EPA, FWS and the Department of the Interior, which includes NMFS, have published their own agency-specific Data Quality Guidelines pursuant to the Act and OMB's government-wide guidelines implementing the Act. Effects determinations and biological opinions are publicly disseminated, and are therefore subject to the Data Quality Act standards.

The Act, OMB's government-wide guidelines, and the relevant agency-specific guidelines require that publicly disseminated information meet objectivity and utility standards. The Objectivity standard requires that disseminated information be accurate, reliable and unbiased. The Utility standard requires that disseminated information be useful. Influential scientific information is subject to especially stringent reproducibility and risk assessment standards.[1] ESA effects determinations and biological opinions must comply with these Data Quality standards.

CRE believes a specific example would be helpful to the agencies in understanding the new Data Quality Act requirements and their impact on the ESA consultation process. CRE and agricultural groups filed a request for correction under the Data Quality Act of EPA's FIFRA Environmental Risk Assessment for the herbicide atrazine. This Request for Correction contended that the Environmental Risk Assessment violated the Act's objectivity and utility standards because it concluded, on the basis on non-validated tests, that atrazine caused endocrine effects in various wildlife including frogs and endangered salmon. Tests that have not been validated have not been demonstrated to be accurate, reliable and useful.

EPA responded to this Request for Correction by stating in its Interim Registration Decision for atrazine:

- endocrine disruption, or potential effects on endocrine mediated pathways, cannot be regarded as an atrazine regulatory endpoint at this time; and appropriate testing protocols must be established before EPA can reach a conclusion regarding atrazine's endocrine effects.[2]

EPA also revised its atrazine Environmental Risk Assessment in response to this Request for Correction to state that atrazine should be subject to testing to determine its endocrine disruptor activity in wildlife once appropriate screening and testing protocols have been developed under EPA's Endocrine Disruptor Screening Program, which is in the process of trying to validate appropriate tests.[3]

CRE is encouraged by EPA's acknowledgment in the atrazine FIFRA review that the Data

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[1] *E.g.*, 44 U.S.C. § 3516 statutory and historical notes; http://www.epa.gov/oei/qualityguidelines/iqg-background1.htm (OMB guidelines);http://www.epa.gov/oei/qualityguidelines/EPA-OEI-IQG-FINAL-10.2.pdf (EPA guidelines); http://www.thecre.com/pdf/20021026_fws-final.pdf (FWS guidelines).

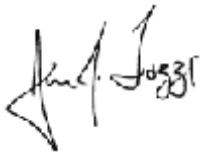
[2] http://cascade.epa.gov/RightSite/getcontent/Tempfile.pdf?DMW_OBJECTID=090007d480135dd5&DMW_FORMAT=pdf, pp. 68, 72.

[3] http://cascade.epa.gov/RightSite/dk_public_collection_item_detail.htm?ObjectType=dk_docket_item&cid=OPP-2003-0072-0010&ShowList=xreferences&Action=view, pp. 95-96.

Quality Act requires information disseminated by federal agencies to be based on tests that have been demonstrated to be accurate and reliable. This same principle applies to effects determinations and biological opinions under the ESA.

Thank you for the opportunity to submit these comments.

Sincerely,



Jim Tozzi
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