



# PPC

**PESTICIDE POLICY COALITION**  
A Coalition Working for Sound Pest Management Policies

[www.pesticidepolicy.org](http://www.pesticidepolicy.org)

April 12, 2011

Office of Pesticide Programs (OPP)  
Regulatory Public Docket (7502P)  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW  
Washington, DC 20460-0001

**Re: Comments of the Pesticide Policy Coalition Regarding the National Marine Fisheries Service Draft Biological Opinion for Six Pesticides [EPA-HQ-OPP-2008-0654-0167].**

Ladies and Gentlemen:

The Pesticide Policy Coalition (“PPC” or the “Coalition”) is pleased to submit comments to the U.S. Environmental Protection Agency (“EPA” or the “Agency”) regarding the National Marine Fisheries Service (“NMFS”) draft biological opinion evaluating the potential for six pesticide active ingredients to affect endangered Pacific salmonid species in the states of California, Idaho, Oregon and Washington.

PPC is an organization that represents food, agriculture, pest management and related organizations that support transparent, fair and science-based regulation of pest management. PPC members include: nationwide and regional farm, commodity, specialty crop, and silviculture organizations, cooperatives, food processors and marketers; pesticide manufacturers, formulators and distributors; pest- and vector-control operators; research organizations; and other interested parties. PPC serves as a forum for the review, discussion, development, and advocacy of pest management policies and issues important to its members.

## **Preliminary Observations**

The draft biological opinion suffers from both procedural and substantive deficiencies. Some of the more egregious aspects of the draft biological opinion include:

- Stakeholders have been denied the opportunity to provide meaningful comments on the document in a reasonable time-frame. Given the unreasonably short comment period, it was not possible for the Coalition to conduct a detailed review of all of the information that NMFS relied on to assess risk in the draft biological opinion. However, our preliminary review indicates that NMFS did little more than conduct a rudimentary and scientifically flawed “hazard assessment,” then layer assumption upon assumption, and finally, package these together as if the information presented portrayed an accurate characterization of potential risk to listed salmonids.
- Crucial portions of the draft biological opinion supporting jeopardy and adverse modification determinations are missing from the document. Instead, NMFS states, “We will be providing additional information that details specific consideration for each decision.” (p. 619) The lack of transparency relating to jeopardy and adverse modification determinations is astounding.
- The draft biological opinion fails to properly consider the most relevant and current best available scientific data previously submitted for consideration, in violation of the applicable statutory and regulatory requirements.

The PPC also notes that it is clear that NMFS and EPA still have not found a way to work together on consultation in a cooperative manner to meet the standards of both the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) and the Endangered Species Act (“ESA”) as mandated by Congress.<sup>1</sup> If NMFS and EPA continue on this course of action, they will create a disastrous situation in which American growers will suffer the consequences. This situation is clearly inconsistent with Congressional intent and is a waste of tax payer resources.

In January 2004, Steve Williams, Director, US Fish and Wildlife Service, and William Hogarth, Assistant Administrator, NMFS, endorsed EPA’s approach for conducting ecological risk assessments for the purposes of ESA consultations:

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<sup>1</sup> See Public Law 100–478. In 1988, Congress addressed the relationship between ESA and EPA’s pesticide labeling program in section 1010 of Public Law 100–478 (October 7, 1988), which required EPA to conduct a study, and to provide Congress with a report of the results, on ways to implement EPA’s endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber commodities. This law provided a clear sense that Congress desires that EPA and the Services should fulfill obligations to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users.

*After careful consideration, the Services have concluded that this approach [EPA's ecological risk assessment process], as understood and reflected in this letter, will produce effects determinations that reliably assess the effects of pesticides on endangered and threatened species (listed species) and critical habitat pursuant to section 7 of the Endangered Species Act (ESA) and implementing regulations. The Services have further concluded that the approach used by OPP should produce effects determinations that appropriately identify actions that are not likely to adversely effect listed species or critical habitat, and that are consistent with those that otherwise would be made by the Services. This approach also will produce all information necessary to initiate formal consultation where appropriate.<sup>2</sup>*

Despite this endorsement, NMFS continues to discard EPA's effects determinations and prepare its own assessments on the grounds that EPA's process is inadequate. It is important to note that EPA's Ecological Risk Assessment Guidelines have been thoroughly reviewed and evaluated, both internally by EPA scientists and by scientists external to EPA. Rather than following the EPA Guidelines, NMFS used an unvalidated, unpublished, non-peer-reviewed population model to predict population effects and relied on questionable data and obsolete pesticide labels and application practices. If NMFS chooses to deviate from established ecological risk assessment procedures and establish its own process, then that process should be subject to the same kind of extensive internal and external review that was applied to EPA's Ecological Risk Assessment Guidelines. EPA should not accept the findings of NMFS' biological opinion until the methodology and data used have been determined to represent the best available science.

### **The Information Quality Act, Scientific Integrity, and the Peer Review Bulletin**

The PPC notes that NMFS' draft biological opinion also fails to conform to requirements and directives issued under the Information Quality Act of 2000 (IQA).<sup>3</sup> The IQA was enacted to "ensure the quality, objectivity, utility, and integrity of information disseminated to the public." Consistent with these principles, President Obama also issued a Memorandum to the Executive Branch

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<sup>2</sup> <http://www.fws.gov/endangered/pdfs/consultations/Pestevaluation.pdf>

<sup>3</sup> Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515], Dec. 21, 2000 (codified at [44 U.S.C. § 3516](#) note 4(a)).

insisting on the “the highest level of integrity” in scientific matters involving the federal government.<sup>4</sup>

As part of the IQA, Congress directed the Office of Management and Budget (OMB) to issue guidelines to “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information” disseminated by federal agencies.<sup>5</sup> In response, OMB issued the “Final Information Quality Peer Review Bulletin” (the “Bulletin”) establishing government-wide guidance aimed at enhancing the quality and credibility of government science documents through the practice of peer review.<sup>6</sup>

The Bulletin establishes “that each agency ***shall conduct a peer review on all influential scientific information*** that the agency intends to disseminate.”<sup>7</sup> (emphasis added). Scientific information includes scientific assessments (such as biological opinions), defined as:

*... an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.*<sup>8</sup>

Furthermore, the Bulletin states that if a federal agency or the Administrator of the Office of Information and Regulatory Affairs determines that a scientific assessment “... (i) could have a potential impact of more than \$500 million in any year, or (ii) is novel, controversial, or precedent-setting ***or has significant interagency interest***,” the information is considered “highly influential scientific assessment” and more rigorous peer review requirements apply.<sup>9</sup>

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<sup>4</sup> Memorandum for the Heads of Executive Departments and Agencies, March 9, 2009. 74 FR 10671. March 11, 2009.

<sup>5</sup> Supra note 1.

<sup>6</sup> Final Information Quality Peer Review Bulletin, available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>

<sup>7</sup> Id. at II.1 (emphasis added).

<sup>8</sup> Id. at I.7.

<sup>9</sup> Id. at III.1 (emphasis added).

Because biological opinions can modify the actions of federal agencies and provide liability protections as a result of incidental take statements, these assessments are of “significant interagency interest.” Consequently, biological opinions should be properly considered “highly influential scientific information” as defined by the Bulletin (regardless of the estimated potential economic impact). The PPC notes that NMFS has chosen not to classify **any** biological opinions involving pesticides and salmonids as “highly influential scientific assessments” or even “influential scientific information.”<sup>10</sup>

The aforementioned procedural and substantive deficiencies encountered with the current draft biological opinion that IQA was meant to protect against are not unique. The following responses by EPA to previously issued biological opinions involving pesticides and salmonids demonstrate common concern regarding the transparency, data disclosure and scientific integrity of NMFS’s biological opinions.

**Example 1:** EPA’s response to the draft biological opinion involving three organophosphate insecticides, issued on July 31, 2008.<sup>11</sup>

*The Draft lacks a level of transparency necessary for EPA to understand NMFS’ rationale for its opinion that the use of any of the pesticides will jeopardize the continued existence of any of the species at issue. It is generally not transparent as to what methodology NMFS employed to collect information...nor is it clear how NMFS selected some available information for its use in its assessment to the exclusion of other available data. It also is unclear how NMFS undertook specific analyses and how NMFS integrated or reconciled apparently conflicting information...[W]e have serious questions and doubts about the support for NMFS’ conclusion that these pesticide jeopardize all of the species and adversely modify their critical habitat...the Draft provides no basis from which to have a meaningful discussion of the RPAs since it fails to identify a level of exposure to these pesticides that would not result, in NMFS’ opinion, in jeopardy to the species. Without a target level of*

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<sup>10</sup> See National Oceanic and Atmospheric Administration Peer Review Plans. Available at [http://www.cio.noaa.gov/Policy\\_Programs/prplans/PRsummaries.html](http://www.cio.noaa.gov/Policy_Programs/prplans/PRsummaries.html).

<sup>11</sup> *National Marine Fisheries Service Endangered Species Act Section 7 Consultation: Draft Biological Opinion on Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon, and Malathion*. Available at <http://www.regulations.gov>, ID No. EPA-HQ-OPP-2008-0654-0002.

*exposure, there could be no basis for agreement between the agencies that any alternative was either necessary or appropriate.*<sup>12</sup>

**Example 2:** EPA's response to the draft biological opinion involving three carbamate insecticides issued on March 18, 2009.<sup>13</sup>

*It appears that several generic issues we raised relative to a previous NMFS opinion ... were not addressed in this Draft ... [the Office of Pesticide Programs] continues to have comments regarding transparency relative to how jeopardy determinations were made, how NMFS determines to use some information but not other information, and how specific analyses were undertaken ... Although NMFS acknowledges its biological opinion is ultimately a qualitative assessment that draws on a variety of quantitative and qualitative tools and measures, the rationale for the extent to which it utilizes some tools and dismisses others is not apparent. According to NMFS, a determination of jeopardy depends in part on the viability ... of the population that comprise the species. However, the Draft indicated that limitations associated with how data are collected, lack of data, non-normal distributions of data and quality assurance/quality control coupled with the inherent complexity of the proposed action, introduce an unquantifiable amount of uncertainty that undermines confidence in probabilistically derived risk assessments. With that said it appears that NMFS the proceeds to rely on that same methodology to evaluate potential risks to the salmonid forage base. Further, although the Draft acknowledges that the data a non-normally distributed, it frequently relies on parametric summary statistics to describe those data.*<sup>14</sup>

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<sup>12</sup> Letter of September 15, 2008 from Debra Edwards, Director, Office of Pesticide Programs, EPA to James H. Lecky, Director, Office of Protected Resources, NMFS. Available at <http://www.epa.gov/espp/litstatus/effects/epa-to-nmfs.pdf>.

<sup>13</sup> *National Marine Fisheries Service Endangered Species Act Section 7 Consultation: Draft Biological Opinion on Environmental Protection Agency Registration of Pesticides Containing Carbaryl, Carbofuran, and Methomyl.* Available at <http://www.regulations.gov>, ID No. EPA-HQ-OPP-2008-0654-0033.

<sup>14</sup> Letter of April 10, 2009, from Debra Edwards, Director, Office of Pesticide Programs, EPA, to James H. Lecky, Director, Office of Protected Resources, NMFS. Available at <http://www.epa.gov/espp/litstatus/effects/comments-2nd-draft.pdf>.

**Example 3:** EPA's response to the draft biological opinion involving twelve pesticides issued on June 16, 2010.<sup>15</sup>

*Since the population model is the cornerstone of the jeopardy/no-jeopardy determinations, EPA believes it is necessary to review some of the questions and issues raised in comments on the previous [biological opinions]. Given that the target concentrations provided are directly related to the model output, a description of several key steps are needed to better understand the algorithms used in the model, the population theory embedded in the model, and how the assumption inherent in NMFS' assessment impact model results. EPA believes three critical steps should be taken relative to the model. First, the model should undergo a rigorous sensitivity analysis that identifies those inputs that "drive" the model output and those that have less significance. Second, model assumptions should be more fully defined and the rationale by which these are chosen should be clarified. For those inputs for which model results are most sensitive, a collaborative effort to further characterize the strengths and limitations of the current data sources would provide EPA, NMFS, and the broader scientific community, with the insight as to how existing data or new research could have the greatest impact in reducing uncertainty in model predictions, in this regard, EPA encourages NMFS to publicly release the model, and its code ...<sup>16</sup>*

The examples provide offer strong evidence that NMFS has failed to meet its obligations under the Bulletin as they relate to the transparency, data disclosure, scientific integrity, and peer review. It is possible that NMFS may be under the mistaken belief that because these assessments are in response to actions taken by EPA under adjudicatory processes they are exempt under section IX.2 of the Bulletin. Such an interpretation seems inconsistent under the special classification and requirements of "highly influential scientific assessments" assigned to work products with "significant interagency interest."

Moreover, the general exemption described in section IX.2 is not be applied if the assessment is "... scientifically or technically novel or likely to have a precedent-

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<sup>15</sup> *National Marine Fisheries Service Endangered Species Act Section 7 Consultation: Draft Biological Opinion on Environmental Protection Agency Registration of 12 Pesticides.* Available at <http://www.regulations.gov>, ID No. EPA-HQ-OPP-2008-0654-0103.

<sup>16</sup> Letter of August 19, 2010, from Steven Bradbury, Ph.D., Director, Office of Pesticide Programs, EPA, to James H. Lecky, Director, Office of Protected Resources, NMFS. Available at <http://www.regulations.gov>, ID No. EPA-HQ-OPP-2008-0654-0156.

setting influence on future adjudications and/or permit proceedings.”<sup>17</sup> It would be difficult, if not impossible, to argue that the biological opinions for pesticides relating to the same group of listed species are not “... likely to have a precedent-setting influence on future [registration] proceedings.” Each biological opinion issued so far by NMFS for pesticides attempts to grapple with novel science policy issues that carry over to subsequent biological opinions and associated products.

Finally, the preamble of the Bulletin states, “... agencies are encouraged to hold peer reviews of scientific assessments supporting adjudications to the same technical standards as peer reviews covered by the Bulletin, including transparency and disclosure of data and models underlying the assessments.”<sup>18</sup> NMFS attempt to exempt itself from the requirements of the Bulletin on these biological opinions is unjustified and must be corrected.

In conclusion, NMFS pattern of behavior in the development of biological opinions is appalling and suggests a willful and utter disregard for the IQA, the Bulletin, and the President’s insistence on the highest level of scientific integrity.

In summary, the PPC strongly urges that:

- EPA and NMFS resolve differences in approaches “*in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber commodities*”;
- NMFS revise the draft biological opinion (a) according to the “*best scientific data available*,” and (b) taking into account current use patterns and restrictions, as described in EPA’s reregistration eligibility decisions;
- the revised draft biological opinion be subject to independent third-party peer review, in accordance with the Peer Review Bulletin;
- stakeholders be given adequate time to review and comment on a revised draft biological opinion; and
- NMFS prepare and issue a robust response to all public comments received, prior to issuing a final biological opinion.

PPC appreciates the opportunity to comment on this draft biological opinion. If you have any questions or comments regarding this submission, please feel free to contact us.

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<sup>17</sup> Final Information Quality Peer Review Bulletin at IX.2. Available at

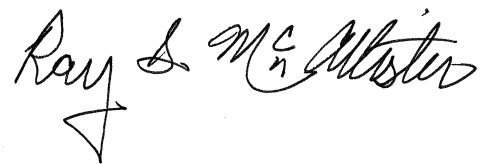
<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>

<sup>18</sup> Id. at 33.

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Sincerely,

A handwritten signature in black ink that reads "Ray S. McAllister". The signature is written in a cursive style with a large, stylized initial "R" and "M".

Chair, Technical Committee

Pesticide Policy Coalition

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