

PPC

PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

www.pesticidepolicy.org

**Statement of the Pesticide Policy Coalition
to the
House Committee on Agriculture and House Committee on Natural Resources
Joint Public Hearing to Review the Costs of Federal Regulatory Dysfunction to
American Jobs, Agriculture, Health and Species**

May 3, 2011

The Pesticide Policy Coalition (“PPC”) respectfully submits the following statement for the record on matters pertaining to the *Joint Public Hearing to Review the Costs of Federal Regulatory Dysfunction to American Jobs, Agriculture, Health and Species*.

PPC is a coalition of 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.

The PPC recognizes that the Endangered Species Act (“ESA”) section (7)(a)(2) imposes a duty on federal agencies, including the Environmental Protection Agency (“EPA”), to ensure that actions carried out by agencies are “not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat of such species...”. 16 USC Section 1536(a)(2). This duty applies to the registration of pesticide products by EPA. The PPC also understands that this may, in some circumstances, result in additional restrictions on pesticide use by growers, pesticide applicators, and other end users in limited geographical areas. The PPC stands by, and supports, *science-based* regulation.

With respect to the regulation of pesticides, however, the implementation of the consultation process established under ESA section 7(a)(2) is completely dysfunctional. The PPC has submitted public comments to specific draft biological opinions pertaining to pesticides as well as comments responding to various Federal Register Notices addressing ESA-related policy issues. We have attached several examples of comments previously submitted to Federal agencies to provide context and supporting evidence for the following observations:

- Under the Federal Insecticide, Fungicide and Rodenticide Act, pesticides are thoroughly tested, examined, and regularly re-examined to identify potential adverse effects on fish,

wildlife and non-target plant species. EPA's processes and assessments are relatively transparent and undergo regular independent review.

- In contrast, the development of biological opinions and related assessments by the Services lack transparency and scientific integrity. The Services appear to do little more than conduct rudimentary and scientifically flawed *hazard assessments*, then layer assumption upon assumption, and finally, package these together as if the information presented portrayed an accurate characterization of potential risk to listed species from pesticides.
- Biological opinions fail to conform to requirements and directives for peer review issued by the Office of Management and Budget under the Peer Review Bulletin.
- EPA and the Services do not agree on fundamental scientific issues at the heart of pesticide consultations. Until this is resolved, no progress can be made.
- Stakeholders have been denied the opportunity to provide meaningful comments on any of the draft biological opinions issued to date, despite a Congressional directive to ensure that ESA compliance for the pesticide regulatory program be designed "to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators."
- Implementation of grossly flawed biological opinions will lead to unwarranted restrictions on pesticides critical to protect public health and agricultural productivity with no measurable benefit to threatened and endangered species.
- The current ESA consultation process is dysfunctional and an unnecessary duplication of government resources. Consequently, the Administration should immediately suspend implementation or further development of biological opinions until these issues are resolved and a workable process is developed (seeking Court approval to do so, if necessary).

Respectfully Submitted,



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PPC

PESTICIDE POLICY COALITION
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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.¹ 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:

¹ 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.²

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).³ 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

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

³ 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.⁴

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.⁵ 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.⁶

The Bulletin establishes “that each agency ***shall conduct a peer review on all influential scientific information*** that the agency intends to disseminate.”⁷ (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.*⁸

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.⁹

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

⁵ Supra note 1.

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

⁷ Id. at II.1 (emphasis added).

⁸ Id. at I.7.

⁹ 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.”¹⁰

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, 2008.¹¹

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

¹⁰ See National Oceanic and Atmospheric Administration Peer Review Plans. Available at http://www.cio.noaa.gov/Policy_Programs/prplans/PRsummaries.html.

¹¹ *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.*¹²

Example 2: EPA's response to the draft biological opinion involving three carbamate insecticides issued on March 18, 2009.¹³

*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.*¹⁴

¹² 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>.

¹³ *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.

¹⁴ 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, 2010.¹⁵

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 ...¹⁶

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-

¹⁵ *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.

¹⁶ 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.”¹⁷ 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.”¹⁸ 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.

¹⁷ Final Information Quality Peer Review Bulletin at IX.2. Available at

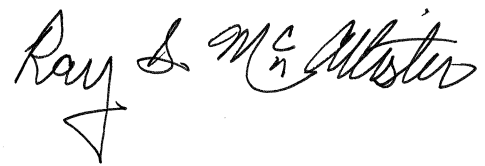
<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>

¹⁸ Id. at 33.

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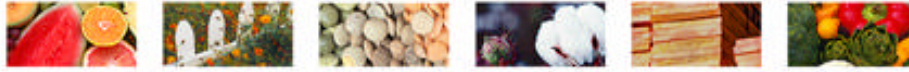
Sincerely,

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 a distinct "S" before "McAllister".

Chair, Technical Committee

Pesticide Policy Coalition

rncallister@croplifeamerica.org



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October 14, 2008

Public Comment Processing
Attn: 1018-AT50
Division of Policy and Directives Management
U.S. Fish and Wildlife Service
4401 North Fairfax Drive
Suite 222
Arlington, VA 22203

**RE: Interagency Cooperation Under the Endangered Species Act:
Proposed Rule, 73 FR 47868 (Aug. 15, 2008) Docket No. FWS-R9-ES-
2008-0093**

Ladies and Gentlemen:

The Pesticide Policy Coalition (“PPC” or the “Coalition”) is pleased to submit comments in support of the amendment of certain Endangered Species Act (“ESA”) §7 rules in 50 CFR Part 402 proposed by the U.S. Fish and Wildlife Service (“FWS”) and National Marine Fisheries Service (“NMFS”) (collectively, the “Services”).

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.

The PPC supports the prompt finalization of the proposed rule. In 2004, the Government Accountability Office (GAO) urged the Services to “resolve disagreements about when consultation is needed” – a principal purpose of this proposed rule.¹

The proposed rule attempts to reduce the workload of the Services and streamline the consultation process. The key proposed changes —

- Enhance flexibility of a federal agency proposing actions (“action agency”) in meeting requirements to prepare biological assessments by allowing the use of a document prepared for another purpose, as long as it contains the relevant analysis of whether to initiate consultation;
- Modify the definition of “cumulative effects” to clarify that it is narrower than the similar term “cumulative impacts” under the National Environmental Policy Act (with which it is frequently confused), and to limit the scope under this definition to effects that are “reasonably certain to occur” in the area subject to the “particular” action undergoing consultation—not just an amalgam of future effects;
- Modify the definition of “effects of the action” to require that, for indirect effects, an effect must be caused by the action and must be “reasonably certain to occur,” based on “clear and substantial information,” before it can be included in an effects analysis; and require a close causal connection, not just a “but for” relationship, between the proposed action and the effect being evaluated;
- Delineate instances in which no take is anticipated and ESA §7 is not applicable, including situations in which (1) there is no effect on the listed species or critical habitat; (2) the proposed action is an insignificant contributor to any observed effects; (3) any effects are not capable of being meaningfully identified, are wholly beneficial, or involve only a remote risk of jeopardy to the species or harm to critical habitat;
- Streamline informal consultation by shifting a greater portion of the “not likely to adversely effect” (NLAA) determinations from the Services to the action agency and by providing a timeline that enables the action agency to terminate the consultation without the Service’s concurrence in order to avoid unreasonable delays.

¹ Endangered Species: More Federal Management Attention Is Needed to Improve the Consultation Process, p. 59. (GAO-04-93 March 2004)
<http://www.gao.gov/new.items/d0493.pdf>

The proposed changes will help to make the ESA §7 compliance process more efficient and more manageable for action agencies, such as the Environmental Protection Agency (EPA), reduce the number of unnecessary consultations, and avoid delays that have hampered the consultation process, including litigation rooted in the language of the existing regulations.

Pesticide Consultations: Scope of the Problem

The increasing number of endangered species assessments involving plant protection chemicals confirms that the current process governing interagency cooperation needs to improve.

Since 2001, a number of citizen suits have been filed alleging that EPA failed to consult with the Services on the registration of certain pesticide active ingredients. These lawsuits involve some 193 pesticide active ingredients, 41 listed species, and 106 ecologically significant units. Over the last 6 years EPA's Office of Pesticide Programs (OPP) has completed and submitted dozens of endangered species assessments to the Services as a result of various settlement agreements. To date, however, the Services have yet to complete a single consultation.

Going forward, EPA plans to complete endangered species assessments for all registered pesticide products under its Registration Review program. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA §3(g)) requires EPA to complete endangered species assessments for an average of approximately 70 pesticide active ingredients or "cases" *per year* over the next 15 years under this program. This does not include additional assessments for new pesticide active ingredients. It does not mean that EPA must evaluate all uses of and all potentially affected species in each case for all geographic areas in the United States where those uses might occur. Although it is impossible to predict *a priori* how many of these assessments might result in requests for informal or formal consultation, it is clear that the backlog of pesticide consultations at the Services, now based primarily on single-species/single product interactions in limited geographies, will only continue to grow logarithmically. In order to avoid a train wreck for American agriculture, the current process must change.

Amended Definition of Biological Assessment (proposed 50 CFR §402.02)

The proposed change to the definition of *biological assessment* (BA) would allow other documents to serve as a formal BA, promoting efficiency and reducing burdens on action agencies. Implicit in this change is the understanding that the Service agree to rely on an action agency's assessment rather than attempting to redo assessments. The Coalition believes that the Services should accept assessments provided by action agencies and therefore we support the proposed change.

Amended Definition of Cumulative Effects (proposed 50 CFR §402.02)

The regulation now defines *cumulative effects* as “those effects of future State or private actions, not involving Federal activities, that are reasonably expected to occur within the action area.” The proposed amendment further clarifies that “Cumulative effects do not include Federal activities that are physically located within the action area of the particular Federal action under consultation.” The Coalition supports the suggested change.

Amended Definition of Effects of the Action (proposed 50 CFR §402.02)

The Services are proposing changes to the definition of “effects of the action” found in 50 CFR §402.02 that clarify the scope of analysis required during consultation under Section 7. Specifically, the proposed regulations make two changes to the definition of indirect effects and they are supported by the Coalition.

The first change would require the proposed action to be an *essential cause* of those indirect effects. The preamble explains that *essential cause* means the action is necessary for the effect to occur.² The PPC strongly supports this change. In a recent draft Biological Opinion relating to the effects of three organophosphate insecticides on salmonids,³ NMFS addressed possible stressors for salmon and steelhead, including climate change, urban growth, mining and recreation. Nonetheless, NMFS made no attempt to consider the relative effects of the various stressors or whether their effect could in any way be quantified. In commenting on that draft Biological Opinion, the Coalition questioned if NMFS purposefully overstated potential risk of these pesticides in an attempt to justify mitigation of an apparently controllable “stressor” (i.e., pesticide products registered under FIFRA) to the exclusion of other stressors that may, in fact, be more biologically relevant for these listed species but less subject to control. Such an error in judgment, played out in the establishment of mitigations for these and other pesticide products, would have devastating consequences for American food and fiber production, with little or no commensurate benefits to listed species.

The second change to *indirect effects* would clarify “*reasonably certain to occur*” as follows:

Reasonably certain to occur is the standard used to determine the requisite confidence that an effect will happen. A conclusion that an

² 73 FR 47868, at 47870

³ Draft Biological Opinion for pesticides containing chlorpyrifos, diazinon, and malathion [Docket No. EPA-HQ-OPP-2008-0654].

effect is reasonably certain to occur must be based on clear and substantial information.⁴

The preamble explains that this would provide additional clarity —

... so that the effects analysis will focus on those effects that can be meaningfully considered in the context of the action under consultation. ... We propose to add the requirement that there be “clear and substantial information” that the effect will happen. Our intention is to make it clear that the effect cannot just be speculative and that it must be more than just likely to occur. We also intend to emphasize that “reasonably certain to occur” is not the equivalent of NEPA’s reasonably foreseeable standard. It is a narrower standard. We believe the proposed language to require “clear and substantial” information is within the intent of the current regulations. We note that the preamble to the current regulations discusses the difference between NEPA and the Act at length and concludes that “Congress did not intend that Federal action be precluded by such speculative actions.”⁵

The PPC supports this clarification that “reasonably certain to occur” includes elements on both the certainty of occurrence and the certainty or reliability of the information. The stringent results of ESA §7(a)(2) – that certain federal actions cannot go forward – should be imposed only where supported by sound science, and not where alleged effects are speculative or not measurable in the natural environment. Where the best available science does not provide “clear and substantial” information that an alleged indirect effect to a listed species is reasonably certain to occur, that speculative effect should not be considered by action agencies or the Services.

This reasoning is consistent with the Supreme Court’s ruling in *Bennett v. Spear*:

One obvious purpose of the requirement that each agency “use the best scientific and commercial data available” [ESA §7(a)(2)] is to ensure that the ESA is not implemented haphazardly, on the basis of speculation or surmise. While this no doubt serves to advance the ESA’s overall goal of species preservation, we think it readily apparent that another objective (if not indeed the primary one) is to avoid

⁴ 73 FR 47868, at 47874

⁵ 73 FR 47868, at 47869 - 47870

needless economic dislocation produced by agency officials zealously but unintelligently pursuing their environmental objectives.⁶

The Services should scrupulously avoid the “needless economic dislocation” that would occur if the registration of a pesticide was prohibited, revoked, or restricted needlessly based on speculative, immeasurable, and unproven effects.

The regulatory language that a “reasonable certainty” requires “clear and substantial” information also is consistent with FWS’s guidance under the Information Quality Act⁷ that “influential scientific information ... must adhere to a higher standard of quality.”⁸ The Department of the Interior’s information quality guidelines require “reliable” and “objective” information. And the Services’ ESA Consultation Handbook requires the use of “reliable” and “credible” information.⁹ Consequently, requiring that an alleged adverse effect be supported by “clear and substantial information” is consistent with the general thrust of these policies on information quality.

Amendments Related to the Applicability of the Consultation Process (proposed 50 CFR §402.03)

Under the current regulation, a Section 7 consultation is required for “all actions in which there is discretionary Federal involvement of control.”¹⁰ The proposed amendments state that no consultation is required “when the direct and indirect effects of that action are not anticipated to result in a take.”¹¹ The proposal lists five criteria to assist action agencies to identify when consultation would not apply:

- The action has no effect on a listed species or critical habitat; or
- The action is an insignificant contributor to any effects on a listed species or critical habitat; or
- The effects of an action on a listed species or critical habitat are not capable of being meaningfully identified or detected in a manner that permits evaluation; or
- The effects of an action on a listed species or critical habitat are wholly beneficial; or

⁶ *Bennett v. Spear*, 520 U.S. 154, 176-77 (1997)

⁷ 44 USC §3516 note

⁸ <http://www.fws.gov/informationquality>

⁹ *See also* the Services’ Policy for Information Standards under the ESA, 59 FR 34271 (July 1, 1994)

¹⁰ 50. CFR §402.03

¹¹ 73 FR 47868, at 47874

- The effects of an action on a listed species or critical habitat have a remote potential risk of jeopardy.

The PPC is encouraged that the Services wish to eliminate the need for unnecessary consultations, but we do not believe the proposal goes far enough. Federal action agencies have had decades of experience in implementing the ESA. As such, federal agencies have gained a keener understanding of the obligations and responsibilities established by the ESA and have hired staff and instituted procedures dedicated to making informed ESA decisions. The PPC agrees with the Services' statement:

The Services believe that Federal action agencies are fully qualified to make [more] determinations in the limited circumstances provided for in the proposed rule. ... We recognize that Federal action agencies have more expertise now than in 1986 and are much more aware of the consequences and significance of their findings. ... Federal action agencies understand that there are significant consequences if they were to take an action that resulted in prohibited take without an exemption through the section 7 process.¹²

The PPC that OPP has the necessary technical expertise to make NLAA determinations without being required to seek the concurrence of the Services.

It is important to note that OPP has substantial resources and expertise to conduct such evaluations that include some 700 scientists, approximately 70 of which are dedicated to the Environmental Effects and Fate Division. Moreover, the FIFRA Scientific Advisory Panel (SAP) is composed of biologists, statisticians, toxicologists and other experts who provide independent scientific advice, peer review and scientific oversight to the EPA on a wide-range of health, safety, and environmental issues related to pesticides. The expertise of the seven members¹³ of the FIFRA SAP is augmented by the Science Review Board (SRB) established by the Food Quality Protection Act¹⁴, a pool of scientists who assist in reviews conducted by the SAP. The Federal Advisory Committee Act governs the SAP, which has recently addressed (among other subjects) the following topics relevant to endangered species assessments:¹⁵

- Interpretation of the Ecological Significance of Atrazine Stream-Water Concentrations Using a Statistically-Designed Monitoring Program;
- The Potential for Atrazine to Affect Amphibian Gonadal Development;

¹² 73 FR 47868, at 47871 to 47872

¹³ <http://www.epa.gov/scipoly/sap/members.htm>

¹⁴ FIFRA §25(d)(2)

¹⁵ <http://www.epa.gov/scipoly/sap/meetings/index.htm>

- Refined (Level II) Terrestrial and Aquatic Models for Probabilistic and Ecological Assessment of Pesticides;
- Potential Developmental Effects of Atrazine on Amphibians;
- A Case Study: Advancing Ecological Risk Assessment Methods in the EPA, Office of Pesticide Programs;
- Implementing Probabilistic Ecological Assessments: A Consultation
- Insect Repellent Product Performance Testing Guideline Evaluation;
- Sediment Toxicity and Fate of Synthetic Pyrethroids;
- Methodology for Conducting Comparative Ecological Risk Assessments;
- Proposed Methods for Basin-scale Estimation of Pesticide Concentrations in Flowing Water and Reservoirs for Tolerance Reassessment; and
- Progress Report on Developing Probabilistic Risk Assessment Methodologies for Aquatic and Terrestrial Risk.

OPP can also call on additional expertise in EPA's Office of Research and Development (ORD). The Safe Pesticides/Safe Products Research Program¹⁶ in ORD is a multidisciplinary research effort that is providing the methods, models, and data needed by EPA to reduce risks presented from pesticides and other chemicals. One of the long-term goals of the program is —

... to develop the scientific underpinnings necessary to transform ecological risk assessments to a more realistic, probabilistic basis where effects can be judged by their impacts at the population level and plant community level.

Results of this research will help EPA to enhance scientifically valid approaches to extrapolate across species, biological endpoints and exposure scenarios of concern, and assess spatially-explicit population-level risks to wildlife populations and non-target plants and plant communities from pesticides, toxic chemicals and multiple stressors, while advancing the development of probabilistic risk assessment. Some of the key scientific questions being addressed include:

- What methods are needed for extrapolating toxicological data across wildlife species, media, and individual-level response endpoints?
- What methods are needed for characterizing population-level risks of toxic chemicals to aquatic life and wildlife?
- What approaches are needed for evaluating the relative risks from chemical and nonchemical stressors on spatially structured wildlife populations across large areas or regions?
- How can methods to assess direct and indirect risks to non-target plant species and plant communities from the use of chemical herbicides be improved?

¹⁶ <http://www.epa.gov/ord/npd/safepest-intro.htm>

- What probabilistic tools can be used to characterize or predict the fate and transport of pesticides and other environmental contaminants?
- How do environmental contaminants move through environmental compartments and become available for human, aquatic, and wildlife exposures?

In 2004, OPP issued its *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs – Endangered and Threatened Species Effects Determinations* ¹⁷ to provide a detailed description of the agency's ecological risk assessment process for the evaluation of potential risk to listed species from exposure to pesticides. In their 26-page review of OPP's ecological risk assessment process, the Services stated:

After careful consideration, the Services have concluded that this approach ... 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.¹⁸

The evidence clearly demonstrates that OPP (including research support from ORD) has the resources, expertise and commitment to conduct endangered species assessments and make valid NLAA determinations without being required to seek the concurrence of the Services.

Other Amendments to the Consultations Process (proposed 50 CFR §402.13 and §402.14)

Proposed §402.13(b) states:

If the Service has not provided a written statement regarding whether it concurs with a Federal agency's determination provided for in

¹⁷ <http://www.epa.gov/espp/consultation/ecorisk-overview.pdf>

¹⁸ Letter from Steve Williams, Director, U.S. Fish and Wildlife Service, and William Hogarth, Assistant Administrator, National Marine Fisheries Service, to Susan B. Hazen, Principal Deputy Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, Environmental Protection Agency. January 26, 2004. p. 1. <http://www.fws.gov/endangered/pdfs/consultations/Pestevaluation.pdf>

paragraph (a) of this section within 60 days following the date of the Federal agency's request for concurrence, the Federal agency may, upon written notice to the Service, terminate consultation. The Service may, upon written notice to the Federal agency within the 60-day period, extend the time for informal consultation for a period no greater than an additional 60 days from the end of the 60-day period.¹⁹

Proposed §402.14 states that formal consultation would not be required if informal consultation is terminated without written concurrence from the Service.

Informal consultation was initially designed to be a quick and informal process for obtaining the Service's concurrence that a proposed action is not likely to adversely affect listed species or critical habitat and thus does not require formal consultation.²⁰ As mentioned earlier, the Services have yet to complete a single consultation (informal or formal) on the dozens of endangered species assessments submitted by EPA on listed species in the last 6 years.

Indeed, the aforementioned 2004 GAO Report stated (p. 14) that “nearly 40 percent of the 1,548 consultations completed by the Services [in the Pacific Northwest] exceeded established timeframes,” and the “Services missed established timeframes, most often for informal consultation ...” Among the principal reasons cited for delays:

- “... the Services told us that they still do not have enough resources to handle their consultation workloads ...” (p. 40);
- “Staffing level problems are exacerbated by high turnover of biologists at the Services.” (p. 42);
- “Action agency officials thought the documentation needed for the consultation process was similarly getting out of control.” (p. 50);
- “... biologists at the Services are sometimes unfamiliar with action agency programs and activities ...” which “can lengthen the consultation process.” (p. 53)

The PPC agrees that the timeframes for informal consultation have long since expanded beyond control and supports both of these amendments.

PPC appreciates the opportunity to comment on proposed revisions to ESA §7 rules. If you have any questions or comments regarding this submission, please feel free to contact us.

¹⁹ 73 FR 47868, at 47872, 47874.

²⁰ See 51 FR 19926 at 19940, 19941, 19948, 19949 (June 3, 1986).

Sincerely,

A handwritten signature in black ink, appearing to read "Beau Greenwood". The signature is written in a cursive style with a long, sweeping underline.

Beau Greenwood
Acting Chair, Pesticide Policy Coalition