UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 19 2010

James H. Lecky, Director
Office of Protected Resources
United States Department of Commerce
National Oceanic and Atmospheric Administration
National Marine Fisheries Service
Silver Spring, MD 20910

Dear Mr. Lecky:

This letter provides EPA's comments on the National Marine Fisheries Service (NMFS) June 16, 2010, Draft Biological Opinion (BiOp) relative to the potential effects from the application of products containing any of twelve organophosphate (OP) pesticides to federally listed threatened or endangered Pacific salmon and steelhead and their critical habitat, if designated. The Draft addresses formal consultations EPA initiated with NMFS between 2002 and 2004, based on potential risks to the subject species from the registered uses of pesticides containing any of the following active ingredients: azinphos-methyl, bensulide, dimethoate, disulfoton, ethoprop, fenamiphos, methamidophos, methidathion, methyl parathion, naled, phorate, and phosmet. EPA recognizes that NMFS' methods of determining jeopardy have evolved from earlier BiOps. Some of the changes appear to reflect comments EPA or applicants provided on earlier BiOps. EPA appreciates NMFS communication with EPA regarding this Draft BiOp and anticipates continued communication as the BiOp is finalized.

In this Draft BiOp, NMFS provided target concentrations below which jeopardy is not expected. EPA believes that this will allow a more robust application of spatially and temporally explicit methods to mitigate exposures below the levels of concern described by NMFS. This approach provides EPA with the flexibility necessary to ensure the Reasonable and Prudent Alternatives (RPA) for each pesticide are technologically feasible and can be implemented in a manner consistent with the purpose of the action, while meeting the goal of ensuring no likely jeopardy. NMFS also clearly indicated that these target concentrations are derived directly from the population modeling completed by NMFS, which provides EPA with further clarity in understanding how the determination was made. In addition, NMFS has cataloged the various uncertainties that they believe are important to the jeopardy determination and have quantified the impact of these on the final determination by assignment of a 2X uncertainty factor. This letter provides comments on the draft RPA's in the BiOp and the attachment provides additional comments and perspectives on the approaches employed in the BiOp itself.

Comments on RPA Elements

The Draft BiOp provides a draft RPA consisting of 5 elements. Below are EPA's comments on each of those elements.

- **Element 1 - This element limits applications to times when wind speeds are less than ten mph.**

  EPA does not take issue in a general sense with wind speed limitations. EPA believes this element of the RPA would be more defensible and feasible if it acknowledged that the limitation should be applied to use patterns and application methods where off-site movement is influenced by wind conditions. This element, intended to reduce the likelihood of pesticide drift, may not be relevant for certain application methods (e.g., tree, stump or pole injection, drip irrigation) nor for certain pesticide formulations (i.e., granular).

- **Element 2 – This element prohibits applications if soil moisture is at field capacity or if a storm that could result in runoff from the field is forecast.**

  EPA has no specific comment regarding this element except to note that we have received input regarding the difficulty that this may pose to enforcement personnel since they will not necessarily know what had been forecast for the date a specific application took place.

- **Element 3 – This element provides latitude for EPA to develop and implement measures intended to limit pesticide concentrations in salmonid habitat.**

  Element 3 represents target concentrations as described previously. NMFS has proposed specific concentrations below which jeopardy to the listed salmon is not expected. EPA believes that this provides flexibility to develop this RPA element in a manner that will meet the specific needs of different regions, crops, and pesticide use requirements in the four-state region.

  In addition to these concentrations, NMFS has provided a list of suggested options for achieving these goals. These suggestions include buffers, vegetated filter strips, application rate reductions, reduction in the number of applications, application method restrictions, and restrictions on use sites (e.g., swamps). EPA agrees that all of these represent options that should be considered when mitigation is deemed necessary to achieve the target concentrations provided by NMFS.

  EPA believes that these and other tools should be applied in a manner that relies on a spatial and temporal analysis of where the target concentrations are likely to be exceeded given current use patterns for each individual pesticide. EPA believes that the spatial and temporal analysis is key to implementing this RPA so that the measures that are implemented are only done when and where they are needed, are tailored to the conditions relevant to the area identified, and take into account the range of habitats the salmon will likely occupy in the identified area. EPA will consider all of the suggested measures proposed by NMFS as well as other peer reviewed tools and methods. EPA believes this will allow flexibility to spatially target mitigations that can be implemented by growers for local conditions.

- **Element 4 – This element requires pesticide users to report to EPA any fish mortality incidents occurring within 4 days of application of one of the subject pesticides adjacent to the pesticide application area.**

  To avoid duplication of information systems, EPA recommends this element be revised to require the user to report any such incidents to the pesticide manufacturer through the phone number on the product label. By so doing, the manufacturer would then be required to report such incident information to EPA through the existing mechanisms implementing FIFRA section 6(a)(2). This methodology was described in our response to the earlier NMFS BiOps issued in July 2008 and March 2009.

- **Element 5 – This element requires EPA to develop and implement an effectiveness monitoring program for floodplain habitats.**

  EPA has commented on Element 5 in relation to previous BiOps and will continue discussions with NMFS on the purpose and design of this requirement.

As you are aware, EPA makes draft BiOps available through the EPA Web site and through a public docket for purposes of obtaining input to draft Reasonable and Prudent Measures and Alternatives. EPA has made clear on its Web site that any comments on other aspects of the draft BiOp submitted to EPA will be provided to NMFS for consideration during development of the final BiOp. I am requesting that you consider the comments EPA has received in the public docket related to this Draft BiOp. This would include all comments with a posting date since June 17, 2010 (the date on which EPA posted the Draft BiOp to the Docket). For your convenience in retrieving these public comments, the docket may be accessed at: http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2008-0654.

Thank you for providing the Draft BiOp for EPA's review and comment. While EPA believes there are additional areas that could benefit from continued scientific discussions, EPA appreciates the methodological improvements NMFS has made relative to previous BiOps. We look forward to continued collaboration with NMFS to further scientific advances made thus far. Please do not hesitate to contact me (703-305-7090) if you have any questions.

Sincerely,

Steven Bradbury, Ph.D., Director
Office of Pesticide Programs

Attachment
cc: Donald Brady
Arty Williams
Richard Keigwin
Catherine Eiden

Attachment 1. Comments on the Draft BiOp Methodology.

- **Target Concentration.**

  NMFS has proposed target concentrations for each individual pesticide considered in this Draft BiOp. EPA believes this represents a significant advancement that clarifies the magnitude of exposure expected by NMFS to result in jeopardy and provides EPA some flexibility to develop RPA elements that will meet these targets. EPA also appreciates the development of pesticide specific targets that can be tailored to the individual use patterns. Ultimately, EPA believes this approach provides clarity and a more transparent communication of the risk concerns to stakeholders and facilitates implementation of any necessary limitations on pesticide use in a more spatially-explicit manner, consistent with EPA's Bulletins Live! application.

- **Spatial Relevance.**

  In this Draft BiOp NMFS has incorporated a spatial analysis into the jeopardy determination. The BiOp differentiates each ESU by comparing species location with expected use patterns based on land cover data obtained from the National Land Cover Data (NLCD) set. NMFS seemingly determined, ESU by ESU, the percentage of general land use classes (e.g., cultivated cropland) in a zone 2.5 km wide around occupied streams assembled from the NMFS website as well as Streamnet.org and CalFish. NMFS also coupled this with a spatial analysis of United States Geological Survey surface water monitoring data relative to species locations.

  Using this analysis NMFS has ranked the relative vulnerabilities of each ESU by likelihood of adverse effects by high, medium, and low classifications. Though not completely clear how these assignments are made, it is significant for two reasons. First, this is a more spatially- explicit approach that limits jeopardy determinations to only those ESUs with significant potential for overlap between pesticide use and species location. Second, it appears that the areas utilized by NMFS in making the jeopardy determination focus on the most relevant portions of the ESU where exposures are likely to be greatest and where species are most likely to occupy. It appears that NMFS has placed increased emphasis on areas adjacent to rearing and spawning habitat and less on the migratory corridors (see page 586 in the Draft BiOp). EPA can use such information to identify areas most likely to need the broadest protections by focusing RPA elements on the areas where juvenile salmonids are most likely to be exposed to the highest predicted pesticide concentrations.

  EPA believes this spatial approach employed by NMFS defines jeopardy as potentially occurring only when use occurs in these areas and assumes that if use is outside these areas there will be no jeopardy. In other words, if an ESU has land cover associated with a particular pesticide use, but that land cover is outside the occupied streams plus the 2.5 km zone delineated by NMFS, no jeopardy would result from current uses in that ESU. EPA interprets this to mean that where jeopardy is determined for an ESU, RPAs will only need to be implemented within the zones defined by the NMFS analysis (i.e., the occupied streams plus a 2.5 km zone around such streams). EPA believes this to be an appropriate approach in

that it maximizes protections where needed and minimizes the impact on agricultural operations.

The new description of small vulnerable habitats, which is the foundation of NMFS population modeling, also has implications for spatial analysis with "Floodplain Habitat" being the description of vulnerable habitat for juvenile rearing. EPA believes this ultimately could allow for mapping vulnerable habitats. In addition, floodplain habitats by their nature require a connection with flowing water, which limits the amount of time that a vulnerable habitat is likely to remain static. Also, a potentially important ramification of this could be that floodplain habitats need flow to refresh and maintain satisfactory conditions (e.g., oxygen levels and temperature) for salmonids, which could influence how these habitats should be assessed. EPA believes this refined description of vulnerable habitat is an important advancement that can be further developed by EPA and NMFS.

- **Uncertainty.**

NMFS has accounted for uncertainties in the Draft BiOp by establishment of an "uncertainty factor". While NMFS had previously identified sources of uncertainty, this BiOp quantifies the potential impact of uncertainties on the jeopardy determination. To account for these uncertainties, it appears that NMFS applied a 2X uncertainty factor to the outputs obtained from the NMFS population model runs with the lowest predicted pesticide water concentrations, e.g., the concentrations obtained from the population model were reduced by a factor of 2X.

EPA appreciates the efforts by NMFS to quantify the impact of the multiple uncertainties described in the Draft BiOp. This leads to a clearer description of these factors in the overall determination. In particular the summary provided in Table 198 is very useful. This type of characterization provides a roadmap to reduce uncertainty and we look forward to continued collaboration on these issues. Continued collaboration could include evaluating how the approach employed in this Draft BiOp can be applied in future draft BiOps and how EPA can provide additional information on those areas of uncertainty that are most critical to the final determination.

Areas for Continued Attention.

- **Population Model Assumptions and Uncertainties.**

This current Draft BiOp provides a clearer description of the critical role the population model plays in the final jeopardy determinations. 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 BiOps.

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 assumptions inherent in

NMFS' assessment impact model results. EPA believes three critical steps should be undertaken relative to this 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 were 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 current data sources would provide EPA, NMFS, and the broader scientific community, with 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, to facilitate the advancement of population modeling research generally as well as application of such models in regulatory decision makings. EPA could help facilitate, with NMFS, a broader review of the model by the scientific community and help focus options for its further refinement.

Additional Considerations:

1. *Percent Population Exposed.* The population model incorporates an analysis of variability in lethality and growth predictions based on different assumptions of the percent of population exposed in small vulnerable habitats. From the limited documentation provided it appears that if less than 25% of a population relies on these vulnerable habitats no jeopardy is predicted to occur. It is unclear, however, what type of analysis was conducted to establish the 25% level and how this level influences the final jeopardy determination, particularly for species with limited utilization of small habitats.

2. *Baseline Assumptions.* EPA now has a better understanding of the importance of the population model to the jeopardy determinations and believes that understanding underlying assumptions is critical to further the model's development. The inclusion of baseline growth and reproduction rates in the model that include data from periods when the OPs (and carbamates) were present in these waters appears to be a very important component to the model's algorithms. These previous baseline states of the populations were at a time when pesticide concentrations were likely higher than current levels. This is a key issue of model parameterization that is worth further collaboration in characterizing the model.

3. *Prey Base Assumptions.* Another important model assumption is that drift of invertebrates into the small habitat will prevent the overall prey base from dropping below 20% of the system's normal level. We request that NMFS clarify how 20% was selected, and how different assumptions might alter the jeopardy determination. In previous discussions on this issue, NMFS indicated that the model was sensitive to this parameter, but it would be helpful to make clear whether the sensitivity of the model to this assumption has been evaluated.

The areas noted above represent examples of the types of issues that remain to be discussed so that EPA has a better understanding of the sensitivity of the model to the assumptions made by NMFS and how those assumptions relate to data that might inform the selection of each assumption.

- **Availability of Data and Methods.**

  As with the population model, some specific data are critical elements for NMFS assessment methods. For example, data from the un-published article summarized in Table 3 of Appendix A (source: NOAA, 2009, *Toxicity of twelve organophosphate pesticides to juvenile coho salmon*, NOAA Northwest Fisheries Science Center) appear to relate acetylcholinesterase (AChE) inhibition to synergy and is incorporated in the population model. Availability and publication in the peer-reviewed literature of unpublished studies would facilitate further clarification of the methods employed in the jeopardy determinations and also would be of great interest to the scientific community generally.

- **Miss-interpretation of EPA Modeling.**

  The exposure sections in the Draft BiOp repeatedly state that EPA's EECs from GENEEC and PRZM/EXAMS are 24-hour averages. The GENEEC and PRZM/EXAMS models provide instantaneous (peak) concentrations.