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

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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) March 1, 2011 Draft Biological Opinion (Draft BiOp) relative to the potential effects of products containing any of four herbicides and two fungicides to federally listed threatened or endangered Pacific salmon and steelhead and their critical habitat, if designated. The Draft BiOp 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: 2,4-D, triclopyr butoxy ethyl ester (BEE), diuron, linuron, captan, and chlorothalonil. EPA appreciates NMFS' communication with EPA regarding this Draft BiOp and anticipates continued communication as the BiOp is finalized.

In this Draft BiOp, NMFS determined that three pesticides do not pose likely jeopardy (linuron, captan and triclopyr BEE) and that three others do pose likely jeopardy (2,4-D, diuron and chlorothalonil). NMFS provided target concentrations below which jeopardy to salmonids is not expected for two of the three pesticides determined to jeopardize salmonids (2,4-D and diuron), providing EPA with the opportunity to craft specific Reasonable and Prudent Alternative (RPA) elements that will ensure these target concentrations are not exceeded. This approach provides EPA with the flexibility necessary to work with applicants, state regulatory agencies and growers to develop specific RPA elements that are technologically feasible and can be implemented in a manner consistent with the purpose of the action (control of the target pests), while meeting the Endangered Species Act goal of ensuring no likely jeopardy. However, NMFS has neither proposed a target concentration nor proposed any other chlorothalonil-specific elements of an RPA to preclude jeopardy likely to result from the use of chlorothalonil. While it is unclear from the discussion in the Draft BiOp why this difference occurs, it is EPA's understanding based on discussions with NMFS staff that time did not permit development of a substantive chemical-specific RPA for this pesticide. Finally, although the Draft BiOp concludes that no likely jeopardy exists from the current uses of linuron, captan and triclopyr BEE, it includes proposed Terms and Conditions as part of the Reasonable and Prudent Measures (RPM) to minimize take, which are very similar to the non chemical-specific elements of the RPAs (e.g., wind speed, soil moisture, rain event, incident reporting, and effectiveness monitoring) for 2,4-D, diuron and chlorothalonil, which were determined to cause jeopardy.

Below are our more specific comments on the Draft RPAs and RPMs. Additionally, we have included comments addressing other aspects of the Draft BiOp in the Technical Appendix included as an enclosure to this letter.

Comments on RPA Elements

The Draft BiOp provides a draft RPA consisting of seven elements. Below are EPA's comments on each of those elements. Where appropriate, we have also included information from the public docket relative to input on the draft RPAs and RPMs. In addition to the RPA/RPM specific comments, EPA is concerned generally about whether each element is implementable and enforceable.

- **Element 1 - Do not apply pesticide products containing 2,4-D, diuron, or chlorothalonil when wind speeds are greater than or equal to 10 mph.**

  EPA does not take issue in general with wind speed limitations as restrictions for pesticide applications to reduce drift. EPA believes this element of the RPA would be more appropriate and feasible if it acknowledged that it 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 or drip irrigation) nor for certain pesticide formulations (e.g., granular).

  In discussions between EPA and NMFS staff, NMFS indicated they may modify this element in the final biological opinion so that wind only needs to be considered if the application of the pesticide is occurring within 1000 feet of salmonid habitat. NMFS further indicated it was considering a modification to this element that would prohibit application unless the wind was blowing away from the habitat regardless of wind speed. NMFS also indicated it is considering further limitations on pesticide applications by introducing the term "wind currents" and stating that the pesticides cannot be applied if wind currents could move the pesticide into the habitat. It is EPA's understanding that NMFS intends this term to include natural "currents" as well as those that are the result of wing tip vortices or are rotor induced during pesticide application and are spatially and temporally limited.

  EPA supports minimizing limitations based on wind direction and believes if the winds are blowing away from the habitat, application could be permitted regardless of wind velocity. EPA is concerned with the concept of limiting use if any "wind currents" might move the pesticide toward the habitat. EPA believes this approach is overly broad and that we would have difficulty explaining and enforcing such a requirement. Finally, EPA remains concerned with the definition of salmonid habitat being employed by NMFS as it applies to this element as well as the RPAs and RPMs throughout the Draft BiOp.

  Commenters note that many existing labels, some examples of which EPA has provided to NMFS, contain limitations relative to wind, to reduce drift. They believe current language should be retained rather than adopting new wind limitation language as part of the RPA. In part this is recommended to ensure the issues of variable wind direction and high inversion potential under conditions of very low wind are addressed in any wind limitations adopted.

- **Element 2 – Do not apply pesticide products containing 2,4-D, diuron, or chlorothalonil when soil moisture is at field capacity, or when a storm event likely to produce runoff from the treated area is forecasted to occur within 48 hours following application by NOAA/NWS (National Weather Service) or other similar forecasting service.**

  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. This concern is based on how one would definitively determine what the weather forecast had been prior to the date/time of application and, if a storm had been predicted, whether that storm could be expected to result in runoff. NMFS has been requested to include in this RPA element a limiting factor in terms of the forecasting of a storm event. That is, to indicate that if there is less than an X% chance of rain, this element would not be required. Another approach might be to simply prohibit application when the forecast for the next 24 or 48 hours includes the prediction of rain at greater than X%. Should NMFS choose to adopt recommendations such as these, EPA would have no objection.

  Additionally, similar to EPA's comment on the applicability of wind to certain application methods, commenters stated that methods that limit application areas - such as individual plant treatment, low volume basal or cut-stump/surface applications - should not be limited relative to predicted rain events.

- **Element 3 – 2,4-D specific requirements**

  Element 3 represents several limitations on the use of 2,4-D including establishing target concentrations for 2,4-D below which jeopardy to the listed salmon is not expected; limiting direct applications of 2,4-D BEE to water; and limiting applications adjacent to certain riparian areas. It appears to EPA that the 2,4-D threshold value of 10 ug/L was derived from a single secondary citation of a study involving two species of prairie pothole plants. The Agency is unsure why more relevant aquatic community effects studies from the same publication which might have been more appropriate for salmonid environments were not used.

  Public comments indicate that the maximum concentration levels in water are unreasonably restrictive, and that the level for 2,4-D is seven-fold lower than the MCL for drinking water (70 ppb). The comments indicate that the rationale to support the need for a seven-fold reduction in allowable levels is not well established. Commenters also state that it appears that the RPAs do not take into account existing state laws and federal programs, including those administered by the USDA/NRCS, which promote and fund the development of Best Management Practices (BMPs) including buffer strips along riparian zones. They believe RPAs should be developed that leverage existing programs that focus on implementing BMPs tailored to site-specific conditions.

  EPA believes as a generic matter, that setting target concentrations provides some flexibility to EPA to develop RPA elements in a manner that will allow the specific needs of growers in different regions of the four-state area to be taken into account. NMFS has provided a list of suggested options for achieving these goals including use of buffers and vegetated filter strips (VFS), reduction in application rates and numbers of applications, and restrictions on application methods and use sites (e.g. swamps). EPA agrees that all of these represent options that should be considered when mitigations are deemed necessary to achieve the target concentrations provided by NMFS. Further, EPA believes 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 will consider all of the suggested measures proposed by NMFS as well as other tools and methods. However, it is unclear why NMFS would subsequently retain any approval authority over EPA's choice of the suite of mitigations it elects to use to remain below the target concentrations.

While this element includes information that use should be restricted based on timing windows identified by NMFS, the specific windows are not clear. However, some states have indicated they use timing windows to reduce potential effects to aquatic species. EPA will discuss this concept further with its state regulatory partners. Finally, limitations applicable within the geography of certain of the salmon and steelhead, to ensure shading, bank stability and erosion control are expected to be difficult to implement in the field. Public comments indicate that 2,4-D is occasionally applied to non-native or invasive weeds in riparian zones and ditch banks to promote the growth of native vegetation but that the RPA does not allow for this level of flexibility. Further commenters state a concern that RPA elements such as this will impact their ability to control invasive species near aquatic habitat, as required by some state laws.

Please see the technical appendix enclosed with this letter for further input on the provisions in this element.

- **Element 4 – Diuron-specific requirements**

Element 4 proposes that EPA implement risk reduction measures to ensure that drift of diuron does not exceed 0.05 lbs/A in riparian habitat and where a riparian area is not present to ensure maximum concentrations in salmonid habitat do not exceed 2.9 ug/L. As with element #3, EPA appreciates the establishment of quantitative thresholds. However it is unclear how these thresholds were derived. EPA believes that the general description of riparian habitat provided in the footnote associated with this element of the RPA is complex and will make identifying such habitat difficult for pesticide users. Consequently, enforcement of this RPA element will be difficult.

- **Element 5 – Chlorothalonil-specific requirements**

Element 5 lacks any detail regarding the effects and concentrations which are of concern to NMFS. This lack of detail precludes EPA, applicants and stakeholders from understanding how to implement this element or provide any meaningful comment at this time.

- **Element 6 – Report all incidents of fish mortality that occur within the vicinity of the treatment area, including areas downstream and downwind, in the four days following application of any of these a.i.s to EPA OPP.**

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 comments provided in response to the three previous BiOps. As noted below, it is unclear how the applicator in the field would be able to distinguish between fish that have died from pesticide exposure and those that expired through natural or other causes.

- **Element 7 – EPA shall develop and implement a NMFS-approved effectiveness monitoring plan for floodplain habitats, and produce annual reports of the results.**

  EPA has commented on Element 7 in relation to previous BiOps and will continue discussions with NMFS on the purpose and design of this proposed 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 any draft RPAs and RPMs. EPA believes this letter and attachment capture the essence of the public comment on RPAs and RPMs EPA wishes NMFS to consider. However, since we have not reiterated specific comments in this letter EPA recommends NMFS review such comments as submitted to the Docket. EPA has made clear on its Web site that any comments on other aspects of the Draft BiOp submitted to EPA, will also be provided to NMFS for consideration during development of the final BiOp. I am requesting that you consider all of the comments EPA has received in the public docket related to this Draft BiOp. This would include all comments with a posting date since March 3, 2011 (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. EPA appreciates the methodological improvements NMFS has made relative to previous BiOps but believes there are additional areas that would benefit from further scientific review, discussion and continued collaboration between EPA and NMFS. In this regard the upcoming National Academy of Sciences review of scientific issues associated with the development of BiOps will be very informative. Please do not hesitate to contact me if you have any questions regarding our input.

Sincerely,

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

cc: Donald Brady
Arty Williams
Richard Keigwin
Jack Housenger

TECHNICAL APPENDIX
Comments on NMFS March 1, 2011 Draft BiOp

Target Concentrations and Other Limiting Factors

NMFS has proposed target concentrations for two of the three pesticides considered in this Draft BiOp to cause jeopardy to salmonids. 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. 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 specific pesticide uses in a more spatially-explicit manner, consistent with EPA's Bulletins Live! application. However, EPA is unclear why the third pesticide deemed to cause jeopardy (chlorothalonil) does not have a target concentration (or any quantifiable threshold).

For the two pesticides where target concentrations are identified, such concentrations were not derived using a population model and appear to have been selected from the toxicity data, although no direct relationship is cited. As a result, it is unclear how this target concentration was derived. Assuming these values were selected from the reviewed suite of toxicity studies, the relevance of the studies that appear to correlate with the target concentrations is unclear. For example, for both 2,4-D and diuron, an ecosystem function endpoint is presented by NMFS that is based on Brock et al. 2000. However, these endpoints are secondary citations from other papers. For 2,4-D, the other paper is not an ecosystem investigation. It is an investigation of the growth/damage response of two species of macrophytes to 2,4-D. Indeed, the lowest community function results from the Brock et al. paper are from another secondary citation (Boyle 1980) in which the NOEC was stated to be 500 mg/L and included the cascade of events from primary productivity up to salmonid surrogate equivalent of an apical teleost predator. For diuron, the endpoints are purported to be changes in redox potential, and pH in microcosms exposed to diuron. The NOEC and LOEC from this study are reflected in the Brock et al. 2000 paper. However, the original paper provides no information on the apparent effects for the LOEC nor does it provide any statistical analysis with controls to determine the NOEC and LOEC. Without such information the statistical establishment of these thresholds cannot be investigated.

For one of the pesticides (2,4-D), the Draft BiOp proposes limiting direct applications to aquatic habitats either based on chemical form (e.g., no direct application of 2,4-D BEE to salmonid habitats) or based on timing (e.g., no application during NMFS specified timing windows). Regarding the timing windows for application, no specific windows have been proposed, although Appendix 6 of the Draft BiOp lists life history windows by Evolutionary Significant Unit (ESU)/Distinct Population Segment (DPS). The Draft BiOp indicates that NMFS reserves the right to modify the timing windows at any time. EPA requests more specificity around this potential for change to one of the RPA elements. For example, how often might such changes occur, what parameters would influence a change to this RPA element, how will that change be relayed to EPA, etc.

Finally, NMFS proposes limitations on applications for 2,4-D to riparian systems in a subset of the ESU/DPSs where applications will impact shading, bank stability, and erosion potential. EPA believes the ability of the applicators to interpret this element and to judge what is and is not

"riparian habitat", based on the NMFS definition, will prove difficult and may limit the ability of EPA to enforce such provisions. Further, it is not clear in the Draft BiOp, the degree to which a change in shading and bank stability is necessary to result in a change constituting jeopardy to the species.

Spatial Relevance

In the third BiOp, NMFS incorporated a spatial analysis into the jeopardy determination that 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 surface water monitoring data (NAWQA) relative to species locations.

That analysis seems to not be a factor in the current Draft BiOp although it is included in Appendix 5 to the current Draft BiOp. In this case, it appears that NMFS has incorporated a species-wide (rather than ESU by ESU) spatial analysis but, as with the previous BiOp, how this analysis influences the jeopardy calls is unclear.

In any case, EPA is interested in as much specificity as NMFS can provide on the use patterns of concern in the Draft BiOp. Knowing the specific use scenarios that drive the jeopardy and adverse modification determinations for each of the six pesticides covered in the BiOp will be critical in achieving appropriate, productive mitigation. Further, use of the NLCD to determine use sites for the six pesticides in the Draft BiOp coupled with the broad definition of salmonid habitat results in an overly broad approximation of the co-occurrence of salmonid exposure with pesticide use. Crop-specific use patterns based on current usage data for the six pesticides compared with realistic definitions of salmonid habitat is necessary to refine the BiOp.

Uncertainty

Unlike the third BiOp, it does not appear that NMFS has accounted for uncertainties in the Draft BiOp by establishment of an "uncertainty factor". NMFS identifies sources of uncertainty throughout the document but the impact of these on the determinations of jeopardy or the RPAs to preclude jeopardy for the three jeopardy pesticides is unclear. Further, it is unclear how the ability to quantify any one source of uncertainty would influence the jeopardy decision.

Analytical Framework of Draft BiOp

In reviewing this Draft BiOp in the context of previous BiOps, it appears that NMFS applies an "analytical" framework that consists of the following 5 steps.

- Establish a range of expected concentrations of each pesticide in surface water (both off channel and less vulnerable habitats)
- Establish a range of effects endpoints for each pesticide
- Qualitatively describe how the two previous elements overlap

- Using general land use data, species locations and timing of life history stages for each salmonid conduct a co-occurrence analysis of potential overlap of exposure with species
- Synthesize the previous steps into a qualitative ESU by ESU analysis that assigns both population and species level risk using a general classification scheme (high, medium and low value)

A similar five step approach appears to apply to evaluation of critical habitat and PCEs.

NMFS purports to use a weight-of-evidence approach combining the results of quantitative assessment with qualitative assessment to determine jeopardy for specific ESUs. However, from EPA's perspective, the process outlined by NMFS is not transparent nor is it possible for EPA to reproduce the conclusions making it difficult for EPA to both comment on and understand how jeopardy conclusions are reached. Given this, please clarify the following:

How would additional data that address the overlap analysis and conservative assumptions impact the jeopardy conclusions? Also, in several cases it appears that the Draft misstates the degree of overlap. For example, for 2,4-D, page 548 of the Draft BiOp summarizes the overlap of monitored/modeled concentrations of 2,4-D with each threshold (point or range). The table text indicates there is an overlap of floodplain and direct water 2,4-D concentrations with effects on fish reproduction. However, no such overlap exists in the tabled number values. All modeled/monitored values of 2,4-D in all scenarios were below the 2,4-D fish reproduction and growth effects range. Finally, it is unclear why there is no probability of effect analysis using the slope of the dose response from selected studies to inform the determination of "take".

Terms and Conditions

Unlike the seven elements of the RPA, which apply only to those three chemicals for which NMFS found jeopardy or adverse habitat modification, the Terms and Conditions apply to all six pesticides. The Terms and Conditions are very similar to the non-chemical specific RPAs mentioned above (wind speed, soil moisture, incident reporting, and monitoring). It is not clear to EPA why these same RPA elements for those chemicals for which jeopardy or adverse habitat modification were found would also need to be applied to those pesticides for which no jeopardy or adverse habitat modification was found.

Modeling

It appears that population modeling based on the impacts of acetylcholinesterase inhibitors (organophosphates and carbamates) has been taken from the previous BiOps and used as a "benchmark" in this assessment. In addition to the concerns expressed in our comments on the first three NMFS BiOps relative to the population modeling employed for those assessments, the need for such a "benchmark" in this assessment is unclear since no additional modeling seems to have been conducted to determine the impacts of 2,4-D, triclopyr BEE, diuron, linuron, captan, or chlorothalonil on the salmonid populations.

This Draft BiOp emphasizes the EPA original assessments' inability to predict exposures from non-agricultural uses (rights of way are given particular emphasis). This ignores EPA's current

efforts to model and estimate exposures from non-agricultural uses. The Draft BiOp indicates that sources of information in its development included other assessments conducted by EPA on these pesticides. For example, those endangered species assessments conducted relative to the California red-legged frog. Despite this, the Draft BiOp does not consider the parts of these more recent assessments that document EPA's more current approach to assessing potential effects from non-agricultural uses of pesticides.

The Draft BiOp accounts for risks associated with activities that are not included on labels of the active ingredients included in the assessment - for example, direct application to water (see table 90) of 2,4-D. Uses that are not included on a pesticide label are illegal and not part of the federal action and therefore should not be modeled.

The Draft BiOp makes no distinction about the percentage of the population within each ESU that is likely to be exposed. It assumes that 100% of individuals within a population are exposed at the same time. Given that individual salmonids within a population are distributed throughout a river network and pesticide applications differ in space and in time, it is unlikely that all individuals of a population will be exposed at the same time and concentration. This is important since previous sensitivity analyses show that populations may not be impacted by a pesticide exposure when less than 100% of that population's individuals are exposed.

Potential Errors in the Draft BiOp

- In several places the Draft BiOp appears to misrepresent current labeled use patterns. For example:
    - On p. 418, Table 88 indicates that EPA modeled linuron at a single application rate of 1 lb/A when in fact EPA modeled this at 1 lb/A with 2 applications.
    - For captan, p.48, it is incorrectly stated within the text that active labels allow for a maximum application rate of up to 4 lbs a.i./A. The maximum single application rate as presented in Table 7 is 4.5 lbs a.i./A.
- For chlorothalonil, in Table 91 a calculation of the floodplain water concentrations for all a.i.s, a buffer of zero feet is presented. However, a water body distance from edge of field of approximately 3 feet, not zero, represents the values presented in the table.
- EPA's farm pond model has a drainage area to volume ratio of 10:1. NMFS perpetuates the assumption that smaller habitats (like the floodplain habitats) will have a greater drainage area to volume ratio than the farm pond model and thus be more likely to have higher pesticide concentrations present after a runoff event. However, it is more likely that the larger drainage areas will frequently overwhelm a smaller habitat with excess runoff and associated pesticide mass overflowing out of that habitat. It is also unclear as to how NMFS determined that the 10 to 1 ratio is not conservative as no analysis of data is provided to support the contention that these higher ratios are realistic or that they would yield higher exposures.

Other Issues Noted During Review of the Draft BiOp

- Throughout the ESU/DPS specific evaluations (pgs 618 – 659) and Critical Habitat evaluations (pgs 659 – 695), NMFS has inserted the following disclaimer: "We will be providing additional information that details specific considerations for each decision". It is unclear how EPA (and others) can interpret this determination without all information used to derive that determination.
- Incidental Take uses general fish kill observations as a measure for incidental take of salmonids. It is unclear how the applicator will know the difference between a dead fish due to natural causes and one related to one of these pesticides. If NMFS' intent is to have all observations of dead fish reported, what value will that have in determining take from use of a pesticide?
- Overall, the definitions of riparian and salmonid habitat seem overly broad.