



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 11, 2012

Dr. Helen Golde, Acting Director  
Office of Protected Resources  
United States Department of Commerce  
National Oceanic and Atmospheric Administration  
National Marine Fisheries Service  
Silver Spring, MD 20910

Dear Dr. Golde:

This letter provides EPA's comments on the National Marine Fisheries Service (NMFS) March 30, 2012 Draft Biological Opinion (BiOp), Reasonable and Potential Alternatives (RPAs), Reasonable and Potential Measures (RPMs) and Terms and Conditions relative to the potential effects of products containing any of three dinitroaniline herbicides including oryzalin, pendimethalin, and trifluralin 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 oryzalin, pendimethalin, and trifluralin. Several issues from the current and past BiOps warrant reiteration as follows:

- EPA remains concerned with the definition of salmonid habitat being employed. The definition has changed with each successive salmonid BiOp. For the purpose of developing county bulletins to implement the RPAs and RPMs, it is vital to have unambiguous maps (GIS shape files) to define where RPAs and RPMs apply.
- EPA continues to question why NMFS would seemingly provide flexibility to EPA to develop mitigation measures intended to ensure pesticides do not reach the stated target concentrations, only then to specifically direct EPA's choice of the suite of mitigations it elects to use. In particular, EPA can find no relationship between the target concentrations to be achieved, and the requirement for a 300-foot aerial spray buffer.
- EPA is concerned with RPAs (soil incorporation and watering-in) that are not feasible given the use pattern (for example, in orchards) or growers' access to water. Flexibility in achieving these RPAs is needed, such as an alternative requirement that application be timed to follow a predicted rainfall within a specified time period.
- EPA is also concerned with multiple conservative assumptions in exposure modeling leading to physically impossible results, such as NMFS's floodplain exposure results that

exceeded chemical solubility limits. EPA maintains that our PRZM-EXAMS modeling provides appropriately conservative exposure modeling results.

EPA's comments, which are provided below, cover the areas of spatial and temporal analysis, the basis of exposure limits, floodplain exposure analysis, review of toxicity data, reasonable and prudent alternatives (RPAs), reasonable and prudent measures (RPMs), and conservation recommendations.

## **Draft Biological Opinion**

### Spatial and Temporal Analysis (pp. 693 – 759)

EPA believes that the spatial and temporal relevance of individual use patterns is vital to making spatially explicit risk decisions that protect listed and endangered species, provide growers and other pesticide users with effective management tools and reflect current agricultural practice. NMFS' enhanced use of spatial and temporal analysis incorporating specific use patterns in this BiOp is a methodological improvement in determining whether specific evolutionarily significant units/distinct population segments (ESUs/DPSs) have the potential to be exposed to levels of concern for a given pesticide. EPA hopes to see this approach incorporated and utilized in future BiOps.

One step toward more routine use of such analyses would be for NMFS to develop and make available geospatial maps (*i.e.*, GIS shape files) that explicitly show the water bodies ("salmon bearing waters") important to each species, and the function of such water bodies in the life cycle of the species. The definition of "salmon-bearing waters" has evolved over the course of the first 5 salmonid BiOps, yet we are no closer to having shape files that define the areas to be protected, and when they are occupied by particular salmonid life stages, than the general ESU/DPS limits NMFS has already supplied.

### Basis of Exposure Limits (pp. 483 – 475)

EPA notes that the target exposure limits (10 ppb for oryzalin and 1 ppb for both pendimethalin and trifluralin) appear to be based on the lowest no-observed-adverse-effect-concentration (NOAEC) for the most sensitive aquatic taxon, whether it be for direct effects to fish (trifluralin) or indirect effects via effects on aquatic plants (oryzalin and pendimethalin). EPA requests that NMFS provide further information regarding the level of direct and/or indirect effects (*i.e.*, specified exposure concentration above the NOAEC value) that would avoid a jeopardy determination.

Also, EPA believes that the appropriate exposure averaging period corresponding to the toxicity test on which the exposure limit is based should be used, rather than the limit being a peak exposure. Thus, for an exposure limit corresponding to a fish reproduction test, as is the case for trifluralin, the appropriate limit would be a 60-day average concentration (less than 1 ppb), rather than a one-time peak exposure (1 ppb).

### Floodplain Exposure Modeling (pp. 398 – 401)

EPA believes that that our PRZM-EXAMS modeling results represent reasonable upper-bound exposures expected from the use of these pesticides. Instead, NMFS calculated floodplain exposure based on a 2 m wide, 0.1 m deep floodplain habitat using the AgDrift model. The AgDrift Tier 1 ground aquatic exposure was calculated assuming low boom, fine to medium spray droplet size, 50th percentile deposition, and a zero-foot buffer. Based on these settings, AgDrift calculates that 16% of the application rate is deposited in the floodplain habitat. EPA does not believe that the floodplain exposures calculated by NMFS in this BiOp reflect the actual environmental partitioning behavior of the three herbicides, and thus greatly overestimate the exposure of salmonids in the water column.

The reported results exceed the solubility limit for trifluralin (2940 ppb vs. 395 ppb solubility) and for pendimethalin (1912 ppb vs. 300 ppb solubility). Results for oryzalin (1100 ppb) approach 50% of the solubility limit (2600 ppb). The former two results are obviously not possible because they exceed the solubility limit, and because the effects of sorption to sediment, metabolism, volatilization, and abiotic loss processes are neglected. These results also contradict NMFS's fugacity modeling results (p. 390, Table 76) showing that a majority of each chemical will reside in soil and sediment at equilibrium.

### Review of Toxicity Data (pp. 445- 456)

NMFS has not used sublethal effects on salmonids, either olfaction or endocrine disruption, as the basis for the jeopardy determination, but has relied on no-effect levels from studies of mortality, growth (including skeletal deformities), and reproduction. The ultimate effect of the observed skeletal deformities due to trifluralin exposure on organismal fitness is not clear; however, EPA believes this has little effect on the jeopardy determination, since the fish reproduction NOAEC was at a similar limit. EPA encourages NMFS to continue to use apical endpoints (mortality, growth, and reproduction) in its BiOps until quantitative relationships between sublethal endpoints and apical endpoints have been established. EPA requests that supporting documentation and decision rules for assignment of high, medium, and low rankings in data tables such as those on pp. 476-478 of the draft BiOp be made available for review.

### **RPA's (pp. 629-630)**

EPA understands that NMFS intends the RPA elements discussed below to be applicable to each active ingredient (a.i.), only within those ESUs/DPSs where NMFS has determined that registration of that a.i. is likely to jeopardize listed species and or adversely modify designated critical habitat. Within the geographic boundaries of those ESUs/DPSs however, EPA is unclear as to which specific waters, and when, the specified RPA's apply.

*Element 1. Concentrations of a.i. in salmon bearing waters shall at no time exceed the following thresholds: oryzalin 10 ug/L, pendimethalin 1 ug/L, trifluralin 1 ug/L.*

Based on the applicant meetings held during the week of April 9, 2012, EPA understands that other RPAs specified in the draft BiOp are intended to achieve these concentration limits. EPA may devise alternative measures that will achieve these limits.

*Element 2. Pesticide products containing pendimethalin or trifluralin shall not be applied aerially within 300 feet of salmon bearing waters. Oryzalin is not currently registered for aerial use. Should such a registration occur while this Opinion is in force, the aerial restriction will apply to oryzalin as well.*

NMFS should provide the analysis used to derive the need for a 300-foot buffer to achieve the target threshold concentrations specified in RPA#1. In addition, NMFS should provide further information on the extent to which the 300-foot aerial buffer may be reduced in situations where factors controlling spray drift (i.e., droplet size, release height, and/or wind speed) are mitigated. It is unclear to EPA why a 300-foot buffer should be required if the concentration necessary to prevent likely jeopardy has been defined.

*Element 3. Pesticide products containing pendimethalin or oryzalin shall be watered-in or soil incorporated immediately when applied to the ground within 300 feet of salmon bearing waters. Existing labels already require watering-in or soil incorporation of trifluralin.*

“Immediate” soil incorporation may be impracticable given the use pattern (orchards or post-crop emergence application). Watering-in may also be impractical when the farmer has insufficient water rights, or when natural rainfall is relied upon for activation of the herbicide. EPA suggests removing the term “immediate” and allowing for flexibility in mitigation options to achieve the desired result for use patterns where soil incorporation or watering-in are not practical and/or feasible. This might include a requirement that rainfall be forecasted within a specified time period after application.

*Element 4. A 10 ft. vegetated strip or a 20 ft no spray zone shall be maintained between any salmon-bearing waters and use sites where oryzalin, pendimethalin, or trifluralin are applied.*

NMFS should provide further supporting documentation and scientific rationale regarding the need for a 10-foot vegetated strip or 20-foot no spray buffer to achieve the target threshold concentrations specified in RPA #1. In addition, NMFS should provide further information on the extent to which the 20-foot buffer may be reduced in situations where factors controlling spray drift (i.e., droplet size, release height, and/or wind speed) are mitigated. It is unclear to EPA why a 20-foot buffer should be required if the concentration necessary to prevent likely jeopardy has been defined.

*Element 5. Report all incidents of fish mortality that occur within the vicinity of the treatment area, including any areas downstream or downwind, and in the four days following application of these a.i.s to EPA's Office of Pesticide Programs. Alternatively, these incidents may be reported to the pesticide manufacturer through the phone number on the product label once EPA modifies the FIFRA 6(a)(2) to require registrants to report all fish kills immediately, regardless of incident classification (i.e., both minor and major incidents). EPA shall submit an annual report to NMFS OPR that identifies the total number of fish affected and incident locations.*

EPA intends to require that pesticide users report such incidents. However, rather than reporting these incidents to EPA, we intend to require that they be reported to the pesticide registrant who is already required to provide information regarding incidents to EPA through a system established under section 6(a)(2) of FIFRA. By approaching incident reporting in this manner, EPA will avoid establishing a secondary system for receipt of such incidents and ensure appropriate treatment of all incidents reported.

Based on discussions with NMFS, EPA understands that RPA element 5 envisions visual inspection of adjoining water for fish mortality. A more explicit definition of “within the vicinity” is also warranted.

### **Conservation Recommendations (pp. 637)**

Element (1) recommends that mixture toxicity analysis be conducted at the screening level of analysis. This topic has been referred to the National Research Council (NRC) of the National Academy of Science (NAS). EPA will review NRC’s recommendations on mixture toxicity analysis and work with the Services to develop and adopt a scientifically sound approach. EPA will also continue to evaluate formulated product toxicity data, when submitted, to determine if observed toxic effects may be attributed to the active ingredient alone.

As you are aware, EPA makes draft BiOps related to pesticide actions available through the EPA web site and a public docket for purposes of obtaining input to any draft RPAs and RPMs in the draft. This letter transmits all public comments received by EPA for consideration by NMFS.

These comments are available at

<http://www.regulations.gov/#!/searchResults;rpp=25;so=DESC;sb=postedDate;po=0;s=EPA-HQ-OPP-2008-0654>.

EPA believes that public transparency and accountability are core values for our agencies. EPA recommends that NMFS include a section in the final BiOp that responds to all the public comments received. More specifically, NMFS should: 1) indicate for each comment accepted how that acceptance is reflected in revisions to the draft BiOp and 2) for each comment rejected, the rationale for rejecting the comment and not revising the BiOp.

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 and believes there are areas that would benefit from further scientific review, discussion and continued collaboration between EPA and NMFS. In this regard, the upcoming NRC 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 comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Bradbury", with a long horizontal flourish extending to the right.

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

Attachment

cc: Jim Jones  
Larry Elworth  
Donald Brady  
Bill Jordan  
Anita Pease  
Richard Keigwin  
Cathrine Eiden  
Mark Dyner  
Melissa Grable