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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 18, 2013

Ms. Donna Wieting, Director
Office of Protected Resources
United States Department of Commerce
National Oceanic and Atmospheric Administration
National Marine Fisheries Service
Silver Spring, MD 20910

Dear Ms. Wieting:

This letter provides both EPA's comments and a summary of public comments on the National Marine Fisheries Service's (NMFS) May 1, 2013 Draft Biological Opinion (BiOp) pertaining to the potential effects of products containing diflubenzuron, fenbutatin oxide, and propargite 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 diflubenzuron, fenbutatin oxide, and propargite. All of the public comments received on this draft BiOp are available at: http://www.regulations.gov/#!docketBrowser;rpp=25;so=DESC;sb=postedDate;po=0;dct=PS;D=EPA-HQ-OPP-2008-0654.

EPA looks forward to working collaboratively and expeditiously with NMFS, the U.S. Fish and Wildlife Service, and the U.S. Department of Agriculture to review the recent recommendations provided in the 2013 National Academy of Science (NAS) report "Assessing Risks to Endangered and Threatened Species from Pesticides" and to identify potential improvements in the current scientific procedures used in evaluating the potential impacts of pesticides to endangered and threatened species. This review is not complete, and the agencies have not yet decided on how to proceed with ongoing actions or planned future actions. As we reach mutual agreement on how to proceed and as timing allows, EPA suggests that NMFS consider advice provided in the report in the final opinion.

Potential Errors in the Draft BiOp

One public commenter noted that the figure on page 74 lists thiobencarb as a stressor of the action, which appears to be a holdover from the previous BiOp. Thiobencarb should be removed as this draft BiOp pertains to diflubenzuron, fenbutatin oxide, and propargite.

The same public commenter noted that on page 286, NMFS states that the contributing adverse effects on the environmental baseline and salmonids of chemicals evaluated in previous Opinions (2008, 2009) "continue today as the EPA has yet to implement the conservation measures (reasonable and prudent alternatives and measures) identified in the previous Opinions." It should be noted that in February of this year the Fourth Circuit Court of Appeals concluded that "the BiOp was not the product of reasoned decision-making in that the Fisheries Service failed to explain or support several assumptions critical to its opinion. To enable a renewed agency process, we vacate the BiOp and remand this case to the district court with instructions to remand it to the Fisheries Service for further proceedings consistent with this opinion." Given the status of the BiOp, NMFS should remove the reference to the 2008 BiOp from this draft BiOp.

On page 505, NMFS states that no endocrine studies have been submitted for any of the pesticides. However, a fish reproduction study that measured endocrine endpoints was provided to NMFS (York, MRID 48618906). EPA also notes that fenbutatin oxide and propagarite are on the first list of chemicals for initial Tier I testing for the Endocrine Disruptor Screening Program (http://www.epa.gov/scipoly/oscpendo/pubs/final_list_frn_041509.pdf) and the data are currently under evaluation.

The multiple references to nonylphenolics should be substantiated or removed as the registrant for diflubenzuron and propargite has informed NMFS that these compounds are not used in its formulations as documented by the Confidential Statements of Formula.

Tables 171, 172, and 173 all say "propargite" in the table even though the other chemicals (diflubenzuron, fenbutatin oxide, and propargite) are specified, respectively. This also applies for Tables 174, 175, and 176. These tables should be revised to include the appropriate chemical in each table.

Exposure Analysis (pgs. 379 – 424)

EPA commends NMFS on their effort to spatially and temporally refine the overlap between uses of diflubenzuron, fenbutatin oxide, and propargite and listed salmonid occurrence that has been made in this BiOp. Chemical-specific comments on the exposure analysis are provided below.

Diflubenzuron

Several of the diflubenzuron estimated average concentrations reported in Table 74 (page 395) exceed the cited solubility limit (0.02 mg/L) for diflubenzuron. This solubility limit is no longer considered accurate and has been updated (0.08 mg/L) in the "Registration Review: Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Diflubenzuron" document (USEPA, 2012)[1]. While most of the

[1] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0714-0005

results in Table 74 still exceed this revised solubility limit, EPA wanted to ensure NMFS was aware of this change.

Likewise, the reported log K_{ow} of 7.38 ± 0.35, as cited in Table 65 (page 374), is not correct for diflubenzuron. The log K_{ow} is 3.70, as reported in EPA's registration review problem formulation document (USEPA, 2012). EPA recommends revising the solubility and log K_{ow} values in Table 65.

Fenbutatin oxide

EPA believes that it is important to characterize the modeled and measured concentrations used as exposure estimates for fenbutatin oxide. Many reported model values are above the solubility limit, which in most cases would not be expected in the natural environment. However, NMFS should clarify that in some instances the concentration of an active ingredient may exceed its solubility limit.

The following characterization was provided in EPA's 2007 "Ecological Risk Assessment for Fenbutatin-Oxide Section 3 New Use on Pistachios"[2]:

> *The solubility of fenbutatin oxide is approximately 12.7 µg/L, however, the aquatic EECs for several of the currently registered uses of fenbutatin oxide exceed the solubility limit. It is unclear if fenbutatin oxide could be present at super-saturated concentrations in water bodies immediately post application for enough time to produce acute effects in sensitive organisms. Additionally, it is unclear whether or not fenbutatin oxide that is bound in the upper soil horizons could periodically wash into surface water as soil-bound residue and cause periodic acute toxicity to organisms. To explore the risks associated with the uses that produced the highest EECs, we calculated RQs based on the solubility limit for the chemical. This resulted in a risk picture similar to the proposed pistachio use and the raspberry use (i.e., acute and chronic RQs that exceed the agency's LOCs for all aquatic animals except for the chronic RQ for the freshwater invertebrates).*
>
> *Surface water sampling in ponds and canals was conducted immediately after treatments in an aquatic residue study conducted in Florida. After peaking at less than 1µg/L in pond water in conjunction with applications, fenbutatin oxide residues declined to less than the level of quantification (LOQ) of 0.10 µg/L in 1-2 days. After peaking at typically > 10 µg/L to as much as 111 µg/L in some perimeter/lateral canal water samples in conjunction with applications, maximum fenbutatin oxide concentration typically declined to <5 µg/L within 14 days after each application, but remained above the LOQ for the 60 day post-application study period. These concentrations (>10 µg/L to as much as 111 µg/L) approached and greatly exceeded the reported solubility of the compound creating a supersaturated condition. According to the study author, the freshwater and*

[2] Panger, M., McKinnon, A. 2007. *Ecological Risk Assessment for Fenbutatin-Oxide Section 3 New Use on Pistachios*. USEPA, EFED, DP Barcode 328390. August 24, 2007

brackish water flatwood groves with shallow aquifers and extensive ditch and canal systems all had much higher levels of fenbutatin-oxide in surface water in their perimeter/lateral canals than in the ponds (MRID: 42872101 [Wallace, 1993]). It is unclear whether the compound is bioavailable for uptake by aquatic organisms during the time period between the application of fenbutatin oxide and when the compound partitions to sediment. Several issues regarding this study require further review, including: determining whether or not the analytical method used has been reviewed and accepted; determining whether or not the samples were filtered; if total suspended solids were accounted for in the water samples; and storage stability issues.

Propargite

EPA has no comments on the endpoint selection for propargite.

Public Comments on the Exposure Analysis

Modeling Issues

A public commenter indicated that watershed-scale models, such as the Soil and Water Assessment Tool (SWAT), should be used to determine the likelihood that potential concentrations of the three pesticides in intermittent streams, drainages and ditches, would threaten salmon or their critical habitat. Otherwise, protecting freshwater habitats appears to be a "no exposure" approach instead of a risk-based approach.

One public commenter indicated that the NMFS exposure assessments do not incorporate temporal fluctuations, water movement, or salmon life-stage habitat. Rather, the assessments assume that fish are exposed to stagnant, shallow 10-cm water throughout the year. These assumptions are due to the use of the AgDRIFT model rather than the more realistic PRZM/EXAMS model. NMFS should have used AGDISP which was developed specifically for forests.

One public commenter indicated that NMFS' generalized land use categories, versus specific crop uses, exaggerate the potential co-occurrence of the critical habitat of the ESU with propargite or diflubenzuron.

Lack of Inclusion of Submitted Data

A public commenter indicated that extensive information had been submitted to NMFS on diflubenzuron, specifically regarding the labels, usage, environmental fate and transport, mode of action and synergism, sublethal effects, degradate toxicity, formulation toxicity, and existing protections (Gagne 2011[3]). Although there was a citation to this paper in the NMFS BiOp, on

[3] Gagne, J.A. (2011). Diflubenzuron exposure and potential effects on threatened and endangered Pacific salmonids. Compliance Services International, Lakewood, WA; Project ID CSI 11701. MRID 48531101.

page 560, it appears that the actual reference is to Gagne et al. (2013, MRID 49094601). There is no citation to Gagne, 2011 in the References section of the draft BiOp and it does not appear that the information from this paper was used. Lastly, it is not clear how the propargite water monitoring data represent the current label and restrictions.

Response Analysis (pgs. 434 – 512, pgs. 559-562)

Diflubenzuron

EPA has the following comments on the reported diflubenzuron toxicity data for invertebrates (Table 88):

(a) The reported toxicity data did not include MRID 00038612, a study on acute toxicity to grass shrimp reported in EPA's California Red-legged Frog assessment (USEPA, October 2009[4]). It is also noted that the grass shrimp data included in Table 88 (Wilson and Costlow, 1986 and 1987; Touart and Rao, 1987) were not deemed acceptable in the ECOTOX database due to a lack of controls.
(b) The ECOTOX database contains data on *Americamysis bahia* (*Mysidopsis bahia*) that may be useful in estimating the toxicity of diflubenzuron to mysids (ECOTOX #4891 and #111352).
(c) The value reported for Kasai *et al.*, 2007 is the LC_{99} as reported in the ECOTOX database. ECOTOX reports the LC_{50} = 0.55 µg/L.
(d) EPA is not certain where the reported blackfly larvae (*Simulium vittatum*) endpoint of 1.3 µg/L came from, as the provided citation "EFED database, 2000" is vague. However, there are additional data for this species reported in the ECOTOX database (LC_{50} = 6 µg/L and 330 µg/L; ECOTOX #12088).

The 10th percentile effect concentration for diflubenzuron (0.12 µg/L, Figure 77) is based on the distribution of EC_{50}s for aquatic invertebrates; therefore it should be recalculated after any changes to the dataset are made (*e.g.*, inclusion/exclusion of the data described above).

Fenbutatin oxide

EPA has no comments on the endpoint selection for fenbutatin oxide.

Propargite

EPA has no comments on the endpoint selection for propargite.

[4] http://www.epa.gov/oppfead1/endanger/litstatus/effects/redleg-frog/index.html#diflubenzuron

Public Comments on the Response Analysis

Toxicity Data, Quality Rankings

Several public commenters noted that data and information reviewed for each assessment endpoint were assigned a qualitative ranking of either "low," "moderate," or "high." It is good that some assessment of the quality of the data used in the BiOp is made. However, the basis for ranking and criteria for scoring should be available. On page 509, NMFS lays out the criteria for the qualitative assignment. These criteria include the following. The test species should be a listed species or "appropriate surrogate" which is undefined. The experiment should be "well conducted" which is undefined, and done with stressors of the action or "relevant chemical surrogates" which are also undefined. It is not possible to evaluate how NMFS actually selected studies to use in its assessment. Tables 92-94 show that the categories of low, moderate, and high actually reflect NMFS' degree of confidence in the effects, and are not a study classification as such. Furthermore, the tables are structured so that it is not readily apparent which studies NMFS is relying on.

Diflubenzuron Toxicity Data

A public commenter noted that the mode of action of diflubenzuron is clearly different from the modes of action for fenbutatin oxide and propargite. However, NMFS uses the growth model for all three compounds. The growth model is particularly important because it is an important line of evidence for determining indirect effects and adverse habitat modification for diflubenzuron.

One public commenter indicated that NMFS used a single daphnid EC_{50}, which suggests a 48-hr exposure. There is no explanation for why this interval is justified for propargite, but a different interval is justified for diflubenzuron, especially when NMFS used the growth model for both compounds.

RPAs (pgs. 699 – 714)

1. Element 1. Implementation of chemical-specific no-spray buffers

As the implementation of these buffers is for mitigation of risk to salmonids, NMFS should move beyond a screening-level approach and consider and incorporate site-specific conditions, as well as drift reduction technologies, that might reduce the "one size fits all"-type buffer presented in RPA 1.

While it is apparent that NMFS developed buffer distances for aerial and ground applications that resulted in different pesticide concentrations in receiving waters, it remains unclear as to why such buffers should be viewed equally protective in avoiding jeopardy when it is a fundamental axiom that the exposure level is an important determinant of individual organism risk. NMFS should provide a more descriptive and detailed account of how they evaluated whether buffers would protect salmon at the population level and how the resultant receiving

water concentrations expected from proscribed buffers cascade from expected effects to individuals to populations. Furthermore, the biological opinion would benefit greatly with the addition of a more thorough technical explanation as to how the population models were used to determine if the action would affect salmonids at the population level.

On page 710, NMFS indicates the following for the no-spray buffers:

"The degree to which expected exposure to the a.i. overlaps with response endpoints varies somewhat at different buffer sizes and among the three a.i.s. This is due, in part, to qualitative considerations made in assigning the buffers and recognition of inherent uncertainty associated with these estimates. For example, AgDRIFT estimates associated with aerial application of diflubenzuron at buffers of 500-1000 ft exceed concentrations predicted to cause population level responses associated with reductions in prey. However, we considered that AgDRIFT has a tendency to overpredict drift at larger buffer distances (Bird et al. 2002). Therefore we expect the predicted concentrations at these buffer distances to occur infrequently."

NMFS should provide information on how specific buffer distances were established and clarify what qualitative considerations were made, given that the expected exposure concentrations exceed the response endpoints. As presented, the derivation of the proposed buffers is unclear and appears arbitrary. In addition, NMFS should provide further information on the extent to which the buffers may be reduced taking into account "qualitative considerations", as well situations where factors controlling spray drift (*i.e.*, droplet size, release height, and wind speed) may influence buffer sizes.

With regards to the fenbutatin oxide no-spray buffers, although EPA uses a different methodology to estimate no-spray buffers, the estimates developed by EPA, using screening-level input parameters (*e.g.*, spray droplet size distribution of very fine) are in line with those developed by NMFS.

Public Comments on RPA 1

One public commenter stated that RPA 1 specifies no-spray buffers required for each of the three active ingredients (up to 1000 ft. for aerial application and up to 500 ft. for ground application, depending on a.i.) with specified maximum application rates that cannot be exceeded. NMFS showed example graphs of effects endpoints with buffer exposure estimates but it was not clear how these buffer values were determined. This should be clearly provided, so that anyone can repeat the analysis conducted in the BiOp and understand how the conclusions were reached.

A public commenter indicated that NMFS made efforts to qualify the strength of each source in terms of its level of uncertainty and its ability to contribute to the risk assessment. However it is still unclear how NMFS specifically considered much of the qualitative evidence in the determination of jeopardy and in outlining RPA 1. It is not clear how NMFS weighted each line of qualitative evidence against another or how they were accounted for in the final determinations. It would be extremely helpful to readers of this document if NMFS went through

the lines of qualitative evidence or gave several detailed examples of how the lines of evidence were used in determining the buffers in RPA 1. Additionally, a description as to the impact they have on buffer size determination in terms of increasing or decreasing specific distances and the degree to which this could account for gains in protection would enhance support for the conclusion contained in the document.

One public commenter expressed that because drainages and ditches are required to be buffered by NMFS (not on the EPA label), these buffers (particularly in high precipitation areas) will essentially eliminate most ground applications of diflubenzuron, and aerial applications of propargite and diflubenzuron.

One public commenter indicated that NMFS must factor in both seasonal rainfall and irrigation method when proposing buffers for propargite, fenbutatin oxide, and diflubenzuron. The buffers, as currently proposed, present a one-size-fits-all approach that is unreasonable for many crops. For fenbutain oxide and propargite particularly, mite outbreaks are most severe in hot, dry, and dusty conditions; conditions that obviously exist in areas with little rainfall. Low seasonal rainfall means less chance of runoff carrying pesticides into salmon-bearing waters. Likewise in crops using drip irrigation, there is less likelihood that over irrigation will carry pesticides off site.

One public commenter feels that NMFS has not considered existing water quality programs. In places where water quality programs already exist and where it can be demonstrated that they are protective of salmon-bearing streams, the buffer requirements outlined in the BiOp should be lifted. One effective California water quality regulatory program is the Irrigated Lands Regulatory Program (ILRP) under the Central Valley Regional Water Quality Control Board (part of the State Water Resources Control Board).

One public commenter felt the buffer zones with no vegetative buffer (300 ft. for propargite) would be almost as large as the entire treated area. The buffer zones do not account for the size of fields, only the application rate. With the exception of some wastewater ways for irrigation project drainage, there are not many lands near irrigated fields that would be considered riparian. According to this public commenter, the riparian area option (Element 3 in the BiOp) is not a realistic option.

One public commenter recommends that NMFS factor use patterns into the buffers proposed in the draft BiOp. Low use equals low risk and a reduced need to create buffers. The public commenter also indicated that if the buffers proposed for fenbutatin oxide are applied to irrigation canals, they are unworkable. It is not clear (without appropriate data) how applications near non-salmon bearing water affect salmonids, especially given the possible large spatial separation between application site and the salmon-bearing water.

2. Element 2. Application of reduced no-spray buffers with a maintained vegetated filter strip ≥ 30 feet.

On page 430 of the Draft BiOp, NMFS states "We also consider runoff a likely pathway of exposure although environmental fate characteristics suggest it may be less important than drift as none of the three a.i.s are particularly mobile in soil." Given the relatively low solubility of the three pesticides (0.013-0.6 mg/L) along with the low potential for mobility (K_{oc} values ranging from 2,000 to 320,000 L/kg_{oc}), EPA believes that the majority of runoff from fields treated with these pesticides would be bound to eroded soil rather than mixed with water. While vegetative buffers have the potential to mitigate pesticide movement due to soil erosion, EPA questions the validity of the use of a vegetative filter strip as means to mitigate exposure in aquatic habitats via runoff when spray drift is the primary route of exposure. Additionally, no rationale is provided regarding the extent to which a vegetative filter strip would result in a reduction of the no-spray buffer distances by up to 25%. Generally, when EPA considers the impact of spray drift buffers and vegetative filter-strips, the analysis is done independently, since the transport routes are separate and mitigation of one route does not impact the other route. NMFS should clarify exactly how the no-spray buffer would be reduced with a maintained vegetated filter strip, how one would determine the reduction in the no-spray buffer, and how one will one ensure that the vegetated filter strips will be "maintained".

Public Comments on RPA 2

Several public commenters indicated that it was unclear whether the no-spray buffers distances prescribed in RPA 2 begin from the edge of field, and therefore include the >30ft vegetated filter strip, or whether no-spray buffers start at the inner edge of the >30ft vegetated filter strip.

Furthermore, it is unclear what criteria was used to define 30 feet as the minimum distance or why further reductions in no-spray buffer distances were not considered if larger vegetated filter strips were in place. The public commenter also noted that the BiOp did not mention other specifications or give directions to technical guidance as to how filter strips should be created or maintained. The BiOp also did not explain if the potential benefit of having a vegetated filter strip was evaluated and whether a quantitative method (similar to Element 1) was used to determine the reduction in no-spray buffer size for RPA 2. Perhaps NMFS could describe this in more detail or illustrate this with figures similar to those used in RPA 1 (Figures 85, 86, and 87).

NMFS did not provide a rationale for why reductions in no-spray buffer distances were considered for the >30 ft vegetated filter strip but not for other types of conservation buffers (*i.e.*, vegetative barriers, herbaceous wind barriers, riparian forest buffers, etc.). These other conservation buffers would similarly provide potential reductions in pesticide drift and reduced runoff of the chemicals included in the current action as well as other pesticides and adjuvants that may degrade water quality and potentially pose a threat to salmonids and their habitat. NMFS should consider applying the same reduction to no-spray buffers considered for >30 ft vegetated filter strips to other types of USDA NRCS recognized conservation buffers which is in part suggested in RPA 3 of the BiOp.

NMFS is proposing the use of vegetative buffer strips. In growing regions where there is low rainfall, maintaining these buffer strips would require the application of irrigation water. One public commenter is concerned that this additional water requirement might not, in and of itself, be protective of salmonids. Increasing the demand for irrigation water seems counterproductive to protecting salmon populations. Pressure currently exists to reduce the amount of water used for irrigation to protect salmon populations by increasing the flows in salmon-bearing waters. While vegetative buffer strips might be relatively easily established and maintained during the winter months in the Sacramento Valley (where there is on average more than 25 inches of rainfall), irrigation would be necessary to maintain buffer strips during the summer months. The further south in the San Joaquin Valley, the less likely it is that vegetative buffer strips could be maintained as there is insufficient rainfall even in the winter months.

A public commenter asked why NMFS did not consider low-drift application methods for RPAs 1 and 2. A public commenter also suggested that landowners' current stewardship efforts should also be taken into account for RPA 2.

3. Element 3. Use of riparian areas to reduce pesticide loading negating the need for no-spray buffers.

NMFS is proposing the use of riparian areas (*e.g.*, vegetated buffer areas between treated fields and waterbodies used to filter, transform, and absorb pesticides) to reduce pesticide loading and possibly negating the need for no-spray buffers. NMFS proposes a coordinated effort between EPA, USDA's Natural Resources Conservation Services (NRCS), and others in exploring the use of riparian areas, such that qualified personnel could verify the effectiveness of riparian areas at removing pesticides, and a reduced set of no-spray buffers, or the alleviation of a no-spray buffer, would be credited to the land owner. EPA agrees that the use of riparian areas has the potential to reduce pesticide loading via runoff and spray drift and that this RPA has the potential to be an effective means at reducing pesticide loading to waterbodies. The use of this measure on a label or Endangered Species Protection Program (ESPP) Bulletin may present some challenges, given that the effects of riparian areas are pesticide-specific, site-specific, and temporally-specific, and currently, EPA does not have the means to evaluate their effectiveness. EPA is open to working with NMFS and USDA to further develop the use of riparian areas for protecting endangered species and also minimize impacts to grower operations. Alternatively, drift reduction technologies, such as low-drift nozzles, addition of adjuvants, and the use of physical drift reduction devices (*e.g.*, spray shields, cones, etc.), can be applied objectively in reducing or eliminating no-spray buffers. Additionally, EPA is currently finalizing its protocol for the evaluation of drift reduction technologies (DRTs), allowing for their implementation in an economically feasible manner.

Public Comments on RPA 3

A public commenter indicated that NMFS should change the definition for "riparian area" in RPA 3. The mention of pesticides should be deleted, as riparian areas exist in many areas without pesticide usage. Riparian areas may also contain non-native vegetation. The public commenter suggested the following: Riparian areas occur along watercourses or water bodies, and they are distinctly different from the surrounding lands because of unique soil and vegetation characteristics that are strongly influenced by unbound water in the soil.

A public commenter indicated that the use of the term "buffer" for both no-spray and riparian was confusing. NMFS should consider using "buffer" for one or the other, but not both; i.e., no-spray zone and riparian buffer or no-spray buffer and riparian area. Additionally, the more effective a riparian area is at pesticide removal, the narrower the no-spray buffer could be.

A public commenter noted that RPA 3 requires USDA's NRCS and EPA to develop a novel approach which could take years to implement. A public commenter questioned whether NMFS would permit enough time for "a novel system" to be developed. Otherwise, RPAs 1 and 2 would be the only alternative for growers who would be heavily and negatively impacted.

Terms and Conditions (pgs. 719-720)

Term and Condition 1.a *EPA shall not authorize application of pesticide products when wind speeds are greater than or equal to 10 mph.*

EPA recommends that wind direction, as well as wind speed, should be considered. NMFS should specify whether or not they would consider different buffers depending on the wind direction.

Term and Condition 1.b *EPA shall not authorize application of pesticide products when soil moisture is at field capacity, or when a storm event likely to produce runoff from the treated area is forecasted (by NOAA/National Weather Service, or other similar forecasting service) to occur within 48 hours following application.*

In EPA's responses to previous draft BiOps, EPA has stated that there is confusion surrounding the term "field capacity". EPA previously recommended that the Term and Condition be changed to indicate that applications may not be made when the "soil is saturated."

EPA also previously recommended that NMFS consider whether this Term and Condition would more appropriately limit pesticide application when soil is saturated AND when a storm event likely to produce direct runoff to salmonid-bearing water from the treated area is forecasted. It was argued that both soil saturation and a rain event is what would lead to runoff. It was further suggested that NMFS include in this Term and Condition a suitable rainfall probability to inform when rainfall is considered "likely." For example, this Term and Condition may be more meaningful if it were to specify a specific threshold probability of a storm event of a certain

magnitude, such as when the potential for a significant storm event is greater than 50% (or some other suitable rainfall probability). This would provide flexibility to continue operations when the probability of an event is low or when even though high in probability, the event itself is inconsequential such as "occasional rain" or "light drizzle" is predicted as is said to often be the case in parts of the Pacific Northwest.

EPA also questioned the need to predict rainfall events that may occur within 48 hours and asked for an explanation of why 48 hours is appropriate rather than 24 hours or some other time frame.

Terms and Condition 1.c *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 and 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 FIFRA 6(a)2 to require registrants to report all fish kills immediately, regardless of incident classification (i.e. both minor and major incidents). Within one year of receipt of this Opinion, EPA shall submit an annual report to NMFS Office of Protected Resources that identifies the total number of fish affected and incident locations.*

EPA appreciates the revision of this term, as compared to those in previous BiOps, to include the alternative for incidents to be reported as stipulated on the product label.

Term and Condition 1.d *EPA shall, in close coordination with NMFS Office of Protected Resources, develop and implement an effectiveness monitoring plan for floodplain habitats, and produce annual reports of the results. The plan shall identify representative floodplain habitats prone to drift and runoff of pesticides within agricultural areas. The representative floodplain habitat sampling sites shall include floodplain habitats currently used by threatened and endangered Pacific salmonids, as identified in coordination with NMFS Office of Protected Resources. Sampling sites include at least two sites for each general species (i.e., coho salmon, chum salmon, steelhead, sockeye salmon, and ocean-type Chinook and stream-type Chinook salmon). Sampling shall consist of daily collection of surface water samples for seven consecutive days during three periods of high application of these a.i.s. Collected water samples will be analyzed for the three active ingredients. A report summarizing annual monitoring data and including all raw data shall be submitted to NMFS Office of Protected Resources and will summarize annual monitoring data and provide all raw data.*

EPA has commented on this Term and Condition in relation to previous BiOps and will continue discussions with NMFS on the purpose and design of this proposed requirement. If it is determined that monitoring data are necessary, EPA can work with NMFS to design a reasonable monitoring study which will allow the federal government to determine peak concentrations of the pesticides in these vulnerable habitats and at the same time provide information and data that might allow EPA to determine the effectiveness of its modeling in determining potential exposures in such habitats. EPA would also seek the input of the U.S. Geological Survey in developing such a protocol with NMFS.

Term and Condition 2.a *EPA shall include the following instructions requiring reporting of fish kills either on the labels for all products containing diflubenzuron, fenbutatin oxide, or propargite in ESPP Bulletins:*

> *NOTICE: Incidents where salmon appear injured or killed as a result of pesticide applications shall be reported to NMFS Office of Protected Resources at 301-713-1401 and EPA's Office of Pesticide Programs. The finder should leave the fish alone, make note of any circumstances likely causing the death or injury, location and number of fish involved, and take photographs, if possible. Adult fish should generally not be disturbed unless circumstances arise where an adult fish is obviously injured or killed by pesticide exposure, or some unnatural cause. NMFS Office of Protected Resources or Office of Law Enforcement may request the finder to collect specimens or take other measures to ensure that evidence intrinsic to the specimen is preserved.*

EPA requires pesticide registrants to provide information regarding incidents to EPA through a system established under section 6(a)(2) of FIFRA. EPA would request that NMFS provide to EPA any reported incidents on listed salmonids related to diflubenzuron, fenbutatin oxide, or propargite exposure.

Public Comments, Term and Condition 2.a

One public commenter indicated that the draft BiOp does not spell out what happens if there is a fish-kill that is found to be linked to pesticide use. It does not appear that the draft BiOp currently addresses the basic, critical issues necessary to determine whether listed species - and treaty-reserved fishing rights - are being adequately protected.

One public commenter remarked that according to NMFS (page 719, Term 1c.), all incidents of fish mortality that occur within the vicinity of the treatment area need to be reported to EPA's Office of Pesticide Programs, or alternatively to the pesticide manufacturer. However in contrast, the label is required to have a statement which indicates that such incidents shall be reported to NMFS Office of Protected Resources and EPA's Office of Pesticide Programs (page 720, Term 2a.). In either case, State Lead Agencies (SLA), which are responsible for enforcing FIFRA, are not included in the notification requirements. SLAs can respond to reports of incidents in a timely manner and are experienced in conducting joint investigations with state and/or federal wildlife agencies. To prevent the loss of critical evidence due to delays, there should be an option for a "finder" to also report to a SLA, or local fish and wildlife agency.

Term and Condition 2.b *EPA shall report to NMFS Office of Protected Resources any incidents regarding diflubenzuron, fenbutatin oxide, or propargite effects on aquatic ecosystems added to its incident database that EPA has classified as "probable" or "highly probable".*

While EPA will work with NMFS to develop more efficient methods for reporting incident information in a routine manner, EPA would like to better understand how NMFS intends to

utilize this information so we can optimize our reporting for their needs.Conservation Recommendations (pgs. 720-721)

Element (1) recommends that mixture toxicity analysis be conducted in screening level and endangered species biological evaluations. This topic was referred to the National Research Council (NRC) of the National Academy of Science (NAS). According to the conclusions in the NAS 2013 report "Assessing Risks to Endangered and Threatened Species from Pesticides" (page 97):

- "A quantitative mixture risk assessment requires extensive data, including data on the identity, concentration, and toxicity of mixture components. Challenges in assessing risk to listed species from pesticide-containing mixtures arise largely because of the lack of such data and the lack of understanding of the potential for interactions among mixture components."
- "In the absence of such quantitative data, the possible contribution of specific mixture components to the toxicity of a pesticide active ingredient cannot be incorporated into a quantitative risk assessment. However, the risk assessor should describe the possible effects of mixture components on the risk estimate to the decision-maker."

As the type of data identified in the NAS response is usually not available when EPA conducts a screening-level assessment, analysis of mixture toxicity is not generally conducted. However, EPA will continue to evaluate formulated product toxicity data, when submitted, to determine if observed toxic effects may be attributed to the active ingredient alone. EPA recommends that NMFS revise Element (1) in the final BiOp to integrate the approaches that are developed as part of the interagency process underway to implement the NAS recommendations relative to mixture toxicity analysis.

Element (2) recommends that EPA develop models to estimate pesticide concentrations in floodplain habitats. Models currently available to EPA are capable of simulating processes in a wide range of aquatic habitats including floodplain habitats of concern to NMFS. However, in order to make use of these modeling tools for simulating floodplain habitats, the geometry and hydrology of these systems need to be defined in a way that can be used to develop site-specific scenarios for the models. Given the wide range of floodplain habitat sizes and shapes used by Pacific salmonids, it is currently possible to assess only a small fraction of these environments, given the nature of current assessment tools. EPA has previously discussed the nature of these environments with NMFS and looks forward to further discussion on the characteristics of these waterbodies that would enable development of scenarios for floodplain habitats. Similar to the recommendation noted under Element (1) above, EPA recommends that NMFS revise Element (2) in the final BiOp to integrate the approaches that are developed as part of the interagency process underway to implement the NAS recommendations relative to exposure modeling.

Element (3) recommends that EPA develop models to estimate pesticide concentrations in aquatic habitats associated with nonagricultural applications, particularly in residential and industrial environments. EPA has developed scenarios to employ the Tier II aquatic model

currently being used (*e.g.*, PRZM/EXAMS) for residential and impervious surfaces and considers the use of these scenarios adequate for assessing runoff from these areas.

Element (4) recommends that EPA work with other appropriate federal agencies to determine efficacy of riparian area management methods in reducing pesticide loading from authorized uses especially the types of vegetation and width of riparian areas needed. As discussed in the RPA comments above, while EPA concurs that the use of riparian areas has the potential to reduce pesticide loading via runoff and spray drift, the effects of riparian areas are pesticide-specific, site-specific, and temporally-specific, and EPA does not currently have the means to evaluate their effectiveness. EPA supports collaborative efforts with NMFS and USDA to identify methods for protecting endangered species that also minimize impacts to grower operations.

As you are aware, EPA makes draft BiOps related to pesticide actions available through the EPA website[5] and a public docket[6] for purposes of obtaining input on any draft RPAs, RPMs, terms and conditions, as well as provide an opportunity to propose alternate risk reduction measures that accomplish the same protection goals but may be easier/less costly to implement. As previously noted, these comments are available at: http://www.regulations.gov/#!docketBrowser;rpp=25;so=DESC;sb=postedDate;po=0;dct=PS;D=EPA-HQ-OPP-2008-0654. EPA has made clear 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. EPA requests 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 May 2, 2013 (the date on which EPA posted the Draft BiOp to the Docket).

EPA believes that public transparency and accountability are core values for our agencies. EPA recommends that NMFS prepare a document for inclusion in the administrative record that addresses how comments were considered and, if appropriate, how the final BiOp will be modified to address the comments. EPA anticipates working with NMFS to finalize this BiOp and appropriate RPMs.

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 cooperation between EPA and NMFS.

[5] http://www.epa.gov/oppfead1/endanger
[6] http://www.regulations.gov/search/Regslhome.html#docketDetail?R=EPA-HQ-OPP-2008-0654

Please do not hesitate to contact me if you have any questions regarding our comments.

Sincerely,

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

cc: Jim Jones
Sarah Bittleman
Bill Jordan
Donald Brady
Richard Keigwin
Helen Golde
Anita Pease
Cathrine Eiden
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