



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

James H. Lecky
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:

Through this letter we are relaying US Environmental Protection Agency, Office of Pesticide Programs' (OPP) comments on the National Marine Fisheries Service (NMFS) March 18, 2009, Draft Biological Opinion (the "Draft") relative to the potential effects of pesticides containing **carbaryl, carbofuran or methomyl**, to federally listed threatened or endangered Pacific salmon and steelhead and their critical habitat, if designated. EPA initiated consultation relative to carbaryl and methomyl on April 1, 2003, and initiated consultation relative to carbofuran on December 1, 2004. Given the short time frame NMFS has provided for OPP to comment, our comments do not contain a detailed point-by-point review of the Draft. Nonetheless we are providing comments that address both scientific and process/policy issues related specifically to the Draft but that also may apply to future development of other biological opinions by NMFS.

It appears that several generic issues we raised relative to a previous NMFS opinion (July 31, 2008, draft biological opinion re: three organophosphate pesticides) were not addressed in this Draft relative to the three carbamate pesticides: carbaryl, carbofuran and methomyl. As a result, our comments reiterate some points made in response to the previous draft opinion in addition to providing input specific to this Draft. For example, OPP continues to have comments regarding transparency relative to how jeopardy determinations were made, how NMFS determined to use some information but not other information, and how specific analyses were undertaken.

In Angela Somma's email of March 18, 2009 to Arty Williams, by which she transmitted the Draft inclusive of draft Reasonable and Prudent Alternatives (RPAs) and Measures (RPMs), Ms. Somma indicated that NMFS would "like to work with EPA and the applicants on developing the RPA." We very much appreciate NMFS' desire to do so and to that end, OPP had a limited discussion with the applicants and Ms. Somma and her staff on April 7, 2009. While we provided some general input at that meeting and are providing our initial thoughts relative to the RPAs and RPMs in this correspondence, the process through which these RPAs and RPMs are being developed makes it difficult to ensure broad input, and collaboration among our staff. First, in order to have a meaningful discussion around steps that would mitigate the potential for jeopardy, it is helpful to understand at what exposure levels jeopardy is deemed to occur for each of the three pesticides. Such understanding was not possible from reading the Draft. Secondly, in order to develop meaningful RPAs and RPMs that can practically be implemented we will need adequate

time to discuss such measures with the agricultural and other pesticide user communities. Even if we were able to understand the “standard” for precluding jeopardy, a time frame of less than one month is not adequate to review a draft of over 600 pages in length, understand the basis for the RPAs and RPMs, discuss those RPAs and RPMs and alternatives with user communities, and provide meaningful input back to NMFS.

Given these broad concerns relative to the Draft, and our more specific input noted below, it is our expectation that NMFS will provide an additional review opportunity on a revised Draft Biological Opinion prior to issuance of a final Biological Opinion.

- **Lack of transparency**

The draft biological opinion lacks a level of transparency necessary for EPA to understand NMFS’ rationale for its opinion that the use of these pesticides will jeopardize the continued existence of some of the evolutionarily significant units (ESUs) of the listed salmonid species that are of concern in this Draft. It is generally not transparent as to what methodology NMFS employed to collect information beyond that which was provided by EPA in the consultation packages nor is it clear how NMFS selected some available information for use in its assessment to the exclusion of other available data. It is also unclear how NMFS undertook specific analyses and how NMFS integrated or reconciled apparently conflicting information.

- **Seemingly conflicting approaches**

Although NMFS acknowledges its biological opinion is ultimately a qualitative assessment that draws on a variety of quantitative and qualitative tools and measures, the rationale for the extent to which it utilizes some tools and dismisses others is not apparent. According to NMFS, a determination of jeopardy depends in part on the viability, i.e., the probabilities of extinction or persistence, of the species and of the populations that comprise the species. However, the Draft indicated that limitations associated with how data are collected, lack of data, non-normal distributions of data and quality assurance/quality control coupled with the inherent complexity of the proposed action, introduce an unquantifiable amount of uncertainty that undermines confidence in probabilistically derived risk assessments. With that said it appears that NMFS then proceeds to rely on that same methodology to evaluate potential risks to the salmonid forage base. Further, although the Draft acknowledges that the data are non-normally distributed, it frequently relies on parametric summary statistics to describe those data.

- **Status of species within ESUs**

While each ESU or distinct population segment (DPS) is listed separately with its own designation of threatened or endangered, the draft biological opinion seems to draw conclusions on a species level rather than addressing risks to specific ESUs or DPSs. Similarly, the broad conclusion in the Draft of variable local reductions in the conservation value of critical habitat does not address whether a given designated critical habitat would no longer support the recovery of a given ESU.

The conclusions in the Draft also appear to be made without regard to the status of the ESUs or DPSs. Most of the ESUs or DPSs are considered threatened and in some cases, those designations were re-confirmed as recently as 2005, during the status review. In reviewing the status and trends section in the Draft, it appears as though some ESUs or DPSs have an

increasing number of spawners rather than a decline, and others have fluctuated widely over the course of the past decade declining to low numbers and then rebounding to high numbers. Use of these pesticides has been ongoing for decades. If the threatened status of the species has not changed appreciably during this considerable period, it would appear to provide some indication that use of these pesticides are not appreciably reducing the likelihood of both survival and recovery of these ESUs and DPSs – which is the standard for jeopardy – yet the Draft does not seem to take into account this empirical evidence. Additionally, the Draft seems not to acknowledge that agricultural chemicals are secondary stressors and therefore are considered to be a minor factor in species survival relative to other factors.

- **Actions on which EPA initiated consultation**

The draft biological opinion includes jeopardy determinations for ESUs where EPA found “no effect” of the pesticides being considered. It is unclear to EPA why NMFS chose to include in the Draft an opinion relative to ESUs on which EPA did not initiate consultation. In addition, the draft biological opinion includes two ESUs listed since initiation of consultation, for which EPA has not had an opportunity to provide its assessment to NMFS and on which EPA did not initiate consultation. It is unclear to EPA why NMFS chose to include the new listings in the draft biological opinion, rather than requesting that EPA initiate consultation on these matters, as NMFS regulations contemplate. These matters are beyond the scope of NMFS litigation regarding its current consultations with EPA, so there would appear to be no compelling reason for NMFS to forego the appropriate regulatory process in this case. EPA believes the draft biological opinion should be limited to the actions on which EPA initiated consultation.

- **Assumptions made in the draft biological opinion**

There appear to be multiple assumptions throughout the Draft about the significance, or lack thereof, of a pesticide label relative to its use. For example, the draft biological opinion appears to assume that if an application scenario is not specifically excluded on the label, it should be assessed as part of the Action. OPP recognizes that NMFS applies conservative assumptions to counteract areas NMFS views as uncertain or lacking in data. However, OPP believes such conservative assumptions still should be those that are reasonably likely to occur. There seem to be numerous assumptions made in the Draft that are not reasonably likely to occur and in fact are very unlikely to occur. For example, simply because the labels of pesticides do not prohibit applying each of these three pesticides at maximum rates, the maximum allowable number of times to a single field, does not mean it is reasonable to assume that practice would take place.

- **Use of data in the draft biological opinion**

The Draft seems to draw conclusions based on a body of data that fails to include certain studies and information provided by EPA in its consultation package while including other information that was not provided by EPA. There seems to be no explanation of the criteria that were used to determine what information was included or excluded. A transparent explanation of the standards or criteria by which NMFS makes such choices would assist our understanding relative to this Draft and would also assist us in developing consultation requests in the future.

- **Modeling and monitoring of pesticide exposure concentrations**

The population models employed by NMFS examine effects to salmonid populations resulting from a range of carbamate concentrations over a 4-day averaging period. It is not clear on what NMFS is basing its assumption that these types of exposures are present for four days. It is more likely that the peak concentrations detected from monitoring decline over this period of time; however, if there are data that support the assumption, they should be provided in the draft biological opinion. If there are no such data, that too should be made clear. Furthermore, the spatial and temporal relevance of these exposure values is not explained. This is significant because the NMFS model results indicate that at the lower exposures assessed, there is no population-level effect. This raises a question about the underlying assumptions in the population modeling. It appears to be assumed that a significant number of individuals are expected to be exposed to the concentrations evaluated. This seems unreasonable, particularly at the higher exposures, given the infrequency of those concentrations in the monitoring data sets.

NMFS expressed that OPPs 2003 and 2004 effects determinations “provided pesticide exposure estimates from uses in relatively few crops considering the number of registered uses of carbofuran, carbaryl, and methomyl” (p. 288). As NMFS is aware, OPP has conducted more recent effects determinations relative to the potential effects of carbaryl and methomyl on the CA red legged frog. These determinations contain EECs relevant to all currently registered uses of methomyl and carbaryl that are specific to CA, including many uses that were not modeled in the 2003 salmonid effects determinations for these pesticides. These data could be useful for characterizing exposures of salmonids to these two pesticides. These assessments and effects determinations are available online at: <http://www.epa.gov/espp/litstatus/effects/redleg-frog/index.html>.

The Draft employs a conservative assumption about concentrations of the three pesticides that will co-occur. It seems to assume that frequency of detection is an “indicator” of an issue. However, frequency of detection for multiple compounds does not mean that the three carbamates will co-occur. In addition, the assumption that the maximum peaks will co-occur in a single sample is not supported by actual monitoring data. The Draft also uses cumulative assessments conducted by OPP as precedent for these assumptions. However, those assessments used relative exposures accounting for unique compound specific timing and percent crop treated – factors that do not appear to have been considered in the Draft. Finally, using a long-term average from GENEEC is highly conservative because these values do not account for any transport out of the system, which will surely happen even in low-flow off channel habitats (they cannot be static for that long and be biologically viable).

An atrazine assessment is cited in the Draft as being the basis for the conclusion that PRZM/EXAMS EECs are exceeded by monitoring data. In that case, roughly 2 dozen samples out of 25,000 exceeded modeled EECs indicating that 99.999% of PRZM/EXAMS EECs exceeded measured atrazine concentrations. It is not clear why NMFS would draw the conclusion based on these data, that EECs modeled using PRZM/EXAMS for the carbamate pesticides in CA, OR, ID and WA will likely be exceeded by actual levels in water.

It is not clear based on the information provided in the Draft to what extent the monitoring data can be attributed to use of pesticides containing carbaryl, carbofuran or methomyl. For example, methomyl detections could be attributed in part to uses of thiodicarb, which degrades to methomyl; and detections of 1-naphthol, a degradate of carbaryl, could be in part from natural sources.

- **Characterization of effects**

The Draft does not appear to consider potential effects resulting from chronic exposures. In OPP's assessment of carbaryl relative to the CA red-legged frog, an acute to chronic ratio was used to derive a chronic endpoint that was relevant to the most sensitive test species for the acute exposure (Atlantic salmon). The resulting NOAEC was 6.8 µg/L. The methomyl CA red-legged frog assessment used a NOAEC of 12 µg /L to represent chronic effects to the frog. This value was based on an ACR-derived NOAEC for the channel catfish. Further, the assessment for carbaryl includes species sensitivity distributions for fish and aquatic invertebrates. As noted previously, this assessment can be accessed at dupr.www.epa.gov/espp/litstatus/effects/redleg-frog/index.html.

Cumulative probability distributions were used to characterize acute effects of the three carbamates to salmonid prey. The 10th percentile of each plot was used to represent the EC50 for prey exposed to the three carbamates and subsequent growth effects to salmonids. The draft biological opinion indicates that the 10th percentile was a "reasonable choice in keeping with general risk management practices of protecting the aquatic community" (p. 422). Other risk assessments that were cited include the EPA Office of Water's procedures for establishing Aquatic Life Criteria and the EPA OPP's probabilistic risk assessment of carbofuran. In both assessments, a more conservative level of effects has been employed (i.e., 5th percentile). Given that the EPA assessments were not intended to distinguish between cases of jeopardy and non-jeopardy, the 10th percentile may be appropriate. However, the rationale for selecting the 10th percentile is not clear.

- **Metabolites, degradates, and other ingredients**

The Draft uses effects data from organophosphate pesticides to draw conclusions regarding the potential of the subject carbamate pesticides to have sublethal effects on salmonids. The rationale supporting such use of the organophosphate data is not clear in the Draft. Although the mode of action is similar, the effects of each chemical are observed at chemical-specific concentrations. Perhaps the focus should, therefore, not be on whether the three carbamates have sublethal effects on salmonids but at what concentrations these effects may occur.

The Draft presents stream chemical analysis data showing the presence of nonylphenol (NP) and nonylphenol ethoxylate surfactants in surface waters. It appears as though the authors are suggesting that the presence of these surfactants might be largely or solely linked to use of the pesticides in question. However, these surfactants are used for a variety of industrial, commercial, and household purposes and the omission of a meaningful discussion of these possible origins of the chemicals in water serves to overstate the role that the registrations of carbaryl, carbofuran and methomyl may play in contributing to concentrations of these surfactants in water.

- **Population models**

There are numerous areas in Appendix 1 that describe NMFS population modeling, where the methods, underlying data, assumptions and calculations are not transparent. Without such transparency it is difficult to reproduce the findings of these modeling efforts. The Office of Pesticide Programs appreciates that NMFS has agreed to provide a briefing to EPA staff regarding the population models used in the Draft. Unfortunately, that briefing is scheduled for several weeks after the date by which NMFS requested comments on the Draft and also after the time NMFS anticipates issuing a final biological opinion for the three carbamate pesticides. Hopefully, the questions and issues noted here will be answered and resolved as a result of that briefing. Until that time however, we offer the following comments and input relative to the population modeling conducted by NMFS to support this Draft.

Many of the survival and fecundity parameters of the baseline models were not adequately described within the Draft to allow for reproduction of the reported results. The mathematical model describing the link between pesticide exposure and food acquisition behavior is not provided.

The Draft did not discuss selection criteria for wild populations intended to serve as “idealized control” (p. 545 of NMFS 2008) populations for parameterization of the baseline models. In addition, the Draft did not establish that the wild populations selected were appropriate to serve as control populations. In the cases where the wild populations inhabited aquatic systems containing pesticides (e.g., in the Columbia River), effects of pesticide exposures on the survival and fecundity values of the wild populations would already be indirectly accounted for.

The baseline stream-type chinook salmon population model was parameterized based on populations from the Yakima River (p. 548). The last paragraph on p. 358 of the Draft suggests that survival and fecundity data from wild salmonid populations of the Yakima River would be representative of populations already exposed to pesticides. Therefore, the utility of the results of the stream-type chinook salmon population model in predicting effects resulting from carbaryl, methomyl and carbofuran is not apparent.

Although population models were not developed for chum salmon and steelhead, modeling results from the models for coho, sockeye and chinook salmon were used to draw conclusions for the chum salmon and steelhead ESUs. The relevance of the coho, sockeye and chinook salmon baseline models to the chum salmon and steelhead ESUs does not seem to be demonstrated within the Draft. Further information on how conclusions drawn from the coho, sockeye and chinook salmon models are transferrable to the chum salmon and steelhead would be of value.

The Draft describes the four population models as “life-history projection matrix models” (p. 544). It is not clear how the different age groups included in the four models are defined. This is especially of concern when considering the first age group, since the sensitivity analysis conducted by NMFS indicated that lambda was most sensitive to changes in the parameter representing survival of this group of individuals.

The Draft states that “The reproductive element value incorporates the proportion of females in each age, the proportion of females in the age that are sexually mature, fecundity, fertilization success, and hatch success” (p. 544). The specific data that were used to follow this method to derive fecundity values for the four models were not provided and would be useful to understanding the population modeling.

As indicated in the Draft, hatchery fish contribute to the overall abundance of many of the populations within the ESUs. Although hatchery fish released into the wild may not be included in a population, they may reproduce, thereby influencing the size of a population. In the Draft, it is not clear whether hatchery fish are considered in deriving fecundity parameter values.

Given the variability indicated in the literature used to generate survival and fecundity values, a discussion of the standard deviations associated with the values would have been informative. Although p. 546 states: “Variability was integrated by repeating the calculation of λ 2000 times selecting the values in the transition matrix from their normal distribution defined by the mean standard deviation,” the standard deviations of the survival and fecundity parameters do not seem to be provided in the Draft.

The Draft describes the following assumptions associated with the four population models. Although these assumptions are stated within the Draft, their impacts on the certainties and uncertainties associated with the population model predictions are not made clear:

- Baseline populations had increasing population growth rates.
- Populations are independent of density effects.
- Migration does not impact population sizes.
- Ocean conditions were assumed constant.
- Freshwater habitat was assumed constant.
- Fishing pressure was assumed constant.
- Resource availability was assumed constant.

The duration of the population model simulations is unclear. It is unclear how often individuals are assumed to be exposed to the concentrations of the chemicals used in the model and whether all individuals of a population are assumed to be exposed at the concentrations used in the model. It appears that the model assumes a four-day average exposure. Is this assuming that all individuals everywhere at some point in their life cycle are exposed to a constant concentration over four days? Given the response of the model at low levels, it would be helpful if the Draft included a discussion of how an assumption of constant low-dose exposure affects the model conclusions.

- **Lack of spatial or temporal analyses**

Clearly NMFS is concerned about vulnerable habitats beyond those typically addressed in EPA’s exposure assessments. Prominent among these vulnerable habitats are what are generically described as “off-channel” habitats. The draft biological opinion provides references that indicate the importance of these habitats to salmonids, but these references in general appear to be lacking detail of the spatial and temporal relevance of these habitats. There seems to be an assumption that these habitats are more vulnerable and likely to have higher exposures than those indicated in EPA’s assessments; however, this assumption is not supported by any

data and supporting analyses. In addition to missing data regarding the spatial and temporal relevance of these habitats to individual species and populations, also missing are any monitoring data to support the contention that the exposures estimates provided for these habitats are reasonable.

The analysis for both individual effects and population level effects appear for the most part to be done generically and not on an individual ESU basis. This suggests that the jeopardy determination is based on an assumption that some significant number of individuals of a given species is subject to the various exposures evaluated in the Draft. The assumptions in the population modeling as to how many individuals are exposed, how frequently they are exposed, and what times of year they are exposed relative to pesticide use are not provided and, therefore, it is not possible to review the scientific basis of the Draft's conclusions. There is no spatial or temporal analysis that relates the exposure evaluated to the species. OPP appreciates that this Draft takes into account the lack of potential exposure to several ESUs based on lack of cultivated and urbanized land within the range of the ESUs. However, more refined spatial aspects and temporal aspects of pesticide use appear to have been discounted in the range of the other ESUs. Instead, there appear to be assumptions made that pesticide use is consistent throughout each watershed supporting these ESUs. The draft also seems to include the assumption that every water body in every watershed within the four states is a salmon-supporting water body and that use of all three pesticides around salmon-supporting waters will be the same throughout the watershed and the same throughout all the watersheds. EPA understands that substantial effort has been expended in Washington and Oregon to identify specific streams and rivers that support listed salmonids, and these specific water bodies comprise a fraction of the stream network in those states.

- **Jeopardy and non-jeopardy determinations**

OPP appreciates that NMFS considered coarse land use information and, for the Chum, life history information, in making its determinations. However, for those species for which jeopardy was found, the Draft fails to identify a level of exposure to these pesticides that would not result, in NMFS' opinion, in jeopardy. Without a target level of exposure it is difficult to determine whether a Reasonable and Prudent Alternative is necessary and if so, what scientific basis is available to support any specific Reasonable and Prudent Alternative.

- **Section 24c use of carbaryl**

Relative to the use of carbaryl to control burrowing shrimp in mud flats of Willapa Bay and Grays Harbor, WA, the Draft cites anecdotal information. While it is anticipated that carbaryl residues would be relatively high in entrained water on mud flats soon after direct treatment with carbaryl, the proximity of these tidal pools to salmonid habitat is not specified. The thousands of fish reported as killed (due to carbaryl treatments) do not appear to include salmonids but rather fish that would be likely to occupy tidal pools and/or mud flats. While the Draft is accurate in noting that the Section 24c label does not specify any label restrictions in terms of buffers, the NPDES permit does require 200-ft and 50-ft buffers from sloughs and channels for aerial and hand-sprayer applications, respectively.

Some of the monitoring data are dated and precede the implementation of the buffers currently in place on the Willapa Bay/Grays Harbor Section 24c NPDES permit. The monitoring data reported earlier in the Draft includes relatively high residues measured in Willapa Bay without adequately characterizing that the residues result from a direct application to dewatered mudflats that may not serve as suitable salmonid habitat.

Although the Draft lists several listed salmonids as frequenting the Willapa Bay/Grays Harbor area, there appears to be considerable uncertainty whether this is actually the case and even greater uncertainty whether they would be likely to encounter the elevated residues of carbaryl in and/or over directly treated mudflats.

- **Reasonable and prudent alternatives (RPAs)**

OPP appreciates having received draft RPAs and RPMs with the Draft biological opinion. As mentioned at our April 7, 2009, meeting in which we discussed RPAs relative to the subject pesticides, we are obtaining and will provide to NMFS some information we believe is critical to NMFS' consideration of whether the proposed RPAs are technologically and financially feasible. Also as noted in that meeting, however, that information is not currently assembled and will, therefore, be provided at a later date.

The Draft accounts for differing application rates leading to the need for differing buffer distances. However, the associated concentrations with each application rate/buffer width is different. It is not explained and therefore not clear, how NMFS can support different resulting concentrations. For example, for carbaryl, a 1-lb/acre application has a 200-ft buffer yielding an EEC of 2.568 ppb, while a 2-lb/acre application needs a 300-ft buffer which yields an EEC of 3.626 ppb. Both are considered to eliminate jeopardy but allow take.

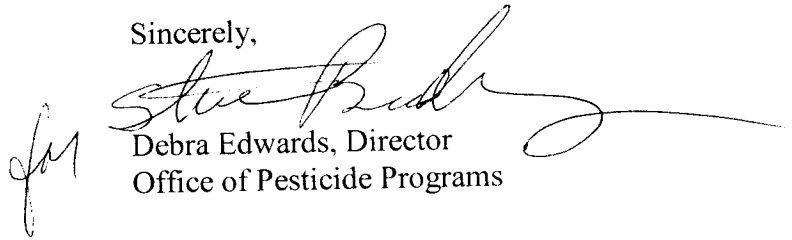
The direct overspray analysis (Table 51) and spray drift analysis (Table 52) of the Draft acknowledge a range of off-channel habitat sizes (0.1 m up to 2 m deep). However, the RPA's proposed buffers seem to be based on the most conservative assumption (0.1 m deep) of these shallow, off-channel habitats. The Draft is not clear on whether these same buffers are necessary for all salmonid habitats (i.e., main channels) to which the RPAs apply. The RPAs do not seem to provide the latitude to apply different buffer distances for these alternate habitats. Likewise the RPAs do not seem to provide the latitude to apply a combination of buffers and other technology to reduce off-site movement and therefore, reduce potential exposure to levels not resulting in jeopardy.

In the exposure and response integration, all exposure concentrations predicted for the pesticides are compared to effects endpoints to determine whether or not there will be effects to salmonids. This approach considers the chemical as a whole, not exposure concentrations resulting from individual uses. The RPAs could be more useful and practical if they accounted for specific pesticide uses. For example, the exposure and response integration could incorporate use-specific EECs to determine which uses pose a risk to salmonids

Element 7 of the RPA to require extensive monitoring of Willapa Bay relative to the Section 24c use of carbaryl suggests that the presence of listed salmonids in the estuary is an uncertainty whereas the Draft suggests that the presence of these species is well documented. Biological and chemical monitoring of the area is already conducted under the NPDES permit, and it is unclear what additional information would be obtained from this requirement.

Thank you for providing the Draft for our review and input. As our comments make clear, we do not believe the available data, as presented in the Draft, support NMFS' draft jeopardy conclusions. Given the significant nature of our comments, I request EPA be provided further opportunity to discuss the Draft with you and to review and comment on a revised Draft Biological Opinion prior to NMFS issuing its final Opinion in this matter. Please let me know if you have any questions regarding this input. I look forward to successfully concluding consultation on these three federal Actions.

Sincerely,

A handwritten signature in cursive script, appearing to read "Debra Edwards", with a long horizontal flourish extending to the right. To the left of the signature is a small, handwritten mark that looks like "for".

Debra Edwards, Director
Office of Pesticide Programs

cc: Donald Brady
Steven Bradbury
Arty Williams