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Environmental Protection Agency
Environmental Fate and Effects Division
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Ms. Angela Somma
National Marine Fisheries Service Office
Office of Protected Resources
1315 East-West Highway
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Dear Ms. Williams and Ms. Somma,

Re: CropLife America's Comments on the National Marine Fisheries Draft Biological Opinion on The Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon and Malathion September 15, 2008:

CropLife America (CLA) appreciates the opportunity to offer comments in response to the first NMFS Biological opinion issued as a result of the stipulated agreement and proposed order of dismissal in the NCAP v. NMFS litigation seeking a judgment on NMFS' failure to complete consultation on 37 pesticides in a timely manner.

CLA is the national trade association representing developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

Overview

By National Marine Fisheries Service's ("NMFS" or "the Service") almost complete dismissal of the Environmental Protection Agency's ("EPA") effects determinations on listed salmon species in the Pacific Northwest and its not allowing affected registrants to comment on this draft before it became publicly available, NMFS jumps to unfounded conclusions, makes leaps in logic and draws inappropriate comparisons and extrapolations resulting in a seriously false portrayal of supposed "risk." While the present draft Biological Opinion ("BiOp") addresses only three active ingredients, NMFS is under court order to issue similar reports for 34 other active ingredients

over the next four years. As a result, how the conclusions of the existing draft BiOp are resolved will set important precedents for regulatory policy for improved integration of the ESA and pesticide registration. CropLife America ("CLA") members are registrants of products involved in many ESA cases other than the three presented in this first draft BiOp. Most importantly, they are "applicants" for ESA purposes and need to be extended the rights due applicants under the statute and the Service's regulations.

The huge effort and major changes brought about by EPA's Reregistration program through Reregistration Eligibility Determinations ("REDs") are discounted by NMFS because "NMFS was unable to verify actual implementation and completion of these activities." (p. 19) These changes have reduced environmental loading, introduced additional mitigations, and strengthened the protective nature of application practices. As a result of these changes, water monitoring data demonstrate significant reductions in both the frequency and level of detections. Additionally, California's Pesticide Use Reporting data show dramatic reduction in total use of these three pesticides. NMFS's total failure to understand the reregistration process or give any credence to changes that have been made as a result of it, and its resulting treatment of historic data as meaningful when they clearly are not, renders the draft BiOp irrelevant to today's uses and labeling. For example, the maximum, minimum and arithmetic mean of water concentrations in Table 39 are calculated from 1992-2006 data. It would be more accurate to examine frequencies and concentrations in later years that are more reflective of current uses. The same is true for California data from 1990-2005 presented in Table 40.

NMFS claims that modeled concentrations are comparable to monitored concentrations in their summary discussion on pages 237-238 and states that chlorpyrifos, diazinon and malathion have been detected at 486, 67 and over 1000 ug/l, respectively. These values are not relevant to an assessment of today's uses. The value of 486 ug/l is associated with chlorpyrifos runoff measured in a citrus field study wherein a pond was incorrectly directly oversprayed; 67 ug/l is associated with the finding of diazinon in an agricultural drain; and 1000 ul/l is associated with a malathion use no longer permitted or supported by the registrant. Considerable monitoring data from the Sacramento River and from other watersheds, as well as extensive reviews of state and federal data, have been ignored by NMFS. These data consistently show substantial declines in both detects and magnitude of detects since label mitigations have been in effect. The NMFS draft BiOp incorrectly represents data by looking at an historical picture of use that was greatly different than today's situation. The NMFS draft BiOp should be a *forward looking* assessment of risk to salmonids based on reduced use and relevant monitoring data.

Fortunately, there is a wealth of data describing the toxicity and exposure of chlorpyrifos, diazinon and malathion. Unfortunately, NMFS selectively highlights fringe data to support inferences about the toxicity of chlorpyrifos, diazinon and malathion, and makes assumptions about exposure that are illogical when agronomic practices are understood. NMFS never considers the actual interface of toxicity with exposure. The interface between toxicity and exposure defines any potential risk presented to listed salmon populations in the Northwest. Because this interface is missing in the draft BiOp, any potential risk is not put into the context of current labeling and use. Symptomatic of this lack of a foundation in good science are a paucity of factual deductions that are instead substituted by *inferences* (in 9 instances); missing conclusions that are instead expressed as *expectations* (in 125 instances); and disconnected leaps in logic that are explained as *translations* (in 14 instances).

NMFS's requirements for data quality clearly are not met, because these introduced assumptions do not reach accepted data quality expectations, which are generally described as an analysis requiring sufficient transparency about data and methodology so that an independent reanalysis can be undertaken by a qualified member of the public, resulting in substantially the same results. The widely divergent conclusions drawn by NMFS's scientists, who are only remotely familiar with pesticide use and agricultural practice, and by a large group of EPA OPP scientists and registrants, who are intimately familiar with pesticide evaluation, speak to the unacceptable state of this draft BiOp.

In previous comments on proposed regulations, CLA developed an instructive overview of how data quality standards are applied in the generation and use of data for FIFRA-regulated products. In that review we noted:

> Although the meaning of "best scientific and commercial data available" should be well defined, its substance should not be inflexible. The term "ecological risk assessment" here refers to EPA's existing tiered process for ecological risk assessment, for which a listed species analysis is an extension providing refinement in scale. The lower tiers of the risk assessments address all non-target organisms including endangered and threatened species. The subject area of "ecological risk assessment" is a relatively new and evolving scientific discipline where the term "best … available" must require that EPA, as the "expert agency," utilize best methods, tools and supporting data/studies available. EPA, as the "expert agency" has the capability to conduct ecological risk assessments for pesticides and refine these ecological risk assessments as necessary to develop effects determinations for listed species. In an earlier analysis, CLA pointed out that the meaning of "best….available" should not require that EPA use methods that are yet to be developed and of uncertain application and interpretation."[1]

A similar quality evaluation is proposed by Klimisch *et al* in his article "A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data."[2]

CLA is the nation's largest trade organization for pest management in agriculture and other areas. We represent more than 80 developers, manufacturers, formulators and distributors of virtually all the crop protection products used by American farmers and growers. Our members manufacture, and hold EPA registrations for, the pesticides at issue in the *NCAP* and *Washington Toxics* cases. CropLife's members are deeply affected by the draft BiOp's hypothetical extrapolations that have the potential to bring unjustified adverse consequences to growers and our nation's food safety and abundance. These comments are offered to the agencies in hope that they can work together to reach a reasonable and accurate portrayal of risk, and, when and if risk occurs, a rational development of reasonable mitigations if needed. The NMFS

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[1] The suitability of regulatory studies for use in risk assessment for endangered species, Croplife America, March 10, 2003

[2] Regulatory Toxicology and Pharmacology **25,** 1–5 (1997) Article No. RT961076

draft BiOp goes so far astray that these comments can only be illustrative of some of the problems within it. We highlight the following:

Failure to acknowledge current agricultural or application practices and their role in providing mitigation ("reasonable and prudent alternatives")

- Mitigations provided by the legal requirements for application, as given by the directions for use section of product labeling, are often ignored by the draft BiOp. For example, NMFS paid no attention to the requirements for holding rice water on the field for specific intervals after treatment, a mitigation that prevents the release of waters with unacceptable levels of residue.
- NMFS completely omits the review of beneficial programs in place that provide further mitigation, on both a regulatory and volunteer basis. For example, California has regulations governing the application of dormant-season sprays, and registrants and professional organizations have extensive educational and stewardship programs.
- Due to lack of understanding of application practices, NMFS uses inputs for drift and runoff and PRZM/EXAMS and GENEEC modeling that are more conservative than necessary, resulting in outputs that are not reflective of the real world.
- In discussing the direct effect of malathion applied over water for mosquito control, NMFS overlooks the fact that this is a restricted use, that the use requires permits in most cases, and in a number of cases this use additionally has been subjected to individual state-conducted risk assessment. Further, NMFS then transfers its analysis to other products that are NOT allowed to be directly oversprayed on water, and uses obsolete high rates to do so.
- NMFS speculates that "exposure to multiple pesticide ingredients can result in additive and synergistic responses … [so] [i]t is reasonably concluded that compounds that share a common mode of action may cause cumulative effects." (p. 236) Cumulative effects as defined by the Services' regulations implementing the ESA's consultation provisions include the **"effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation."** 50 C.F.R. § 402.02. In fact, subsequent state, local and private actions are more likely to reduce exposure, and thus reduce any speculated effect, based on added layers of regulation, assessment and use limitations, rather than increase exposure. Additionally, in discussing the number of pesticides registered and the number of cholinesterase products that may be affecting salmon (discussion beginning on p. 236), NMFS completely fails to recognize that this product line is in decline.
- NMFS notes on page 16 that "the purpose of the proposed action is to provide tools for pest control that do not cause unreasonable adverse effects to the environment", and that "This consultation is intended to cover all EPA *authorized* uses of pesticide products containing chlorpyrifos, diazinon and malathion" [emphasis added]. The action is inappropriately defined. In addition, NMFS was uninformed on the status of current use sites, approved application methods, and actual product use in sensitive areas. The registrants of these products must be consulted (as the Services' regulations and Consultation Handbook provide) and can provide current label recommendations and data to better focus this and future NMFS BiOps. There are unaddressed opportunities for NMFS to better understand the measures already taken to preclude the need for additional "reasonable and prudent

alternatives." Additionally, NMFS's failure to obtain best available data and its failure to comply with ESA Section 7 regulations and the Consultation Handbook are unacceptable.

- In statements related to miscellaneous non-crop uses of these products (starting on page 210), nearly all the treatment rates quoted and uses discussed are obsolete.

Flawed assessment of "Other Stressors"

- Figure 1 (p. 17) identifies as stressors many components evaluated in other ways by EPA that are in some cases insignificant in their environmental release (metabolites, degradates, "other ingredients," tank mixes, adjuvants/surfactants added to formulations).
- In discussing "other ingredients" (p. 18 and elsewhere), there is no recognition of EPA's tiered review of toxicity testing for active ingredients and formulated products. Additionally, one example of a formulation additive is given (nonylphenol) without regard to its actual use in the formulation of the three products under consultation, and without recognition of other common additives or carriers, such as clay or water. Registrants are required to submit confidential statements of formula identifying these ingredients in their formulations and EPA must review those statements in making registration or reregistration decisions.
- Based on the review and assessment of thousands of pesticide uses and the refinement of a tiered toxicological assessment process, EPA has developed a reliable method to demonstrate whether or not the use of a product presents risk. One aspect of this process is how metabolites, degradates and formulation additives are handled. NMFS greatly overstates the potential for these entities to occur in the environment, let alone present an impact or potential exposure. The standard of "reasonably likely to occur" has not been met.
- NMFS questions the impact of formulation additives such as nonylphenol but fails to relate this back to pesticide formulation testing. NMFS uses water monitoring data and nonylphenol concentrations as a "reason" for concern with the pesticidal use of formulation ingredients. However, NMFS does not put this information in context by noting that approximately 80% of the use of nonylphenols is in industrial and institutional surfactants, 10% in rubber and plastic antioxidants, and 10% in miscellaneous uses (primarily in lube oil additives; see http://www.the-innovation-group.com/ChemProfiles/Nonylphenol.htm). Potentially, the exposure of aquatic systems to nonylphenol from its use in pesticides is negligible to non-existent when put in context with other uses.
- NMFS claims nonylphenol in insecticide formulations was linked to Atlantic salmon "population crashes" in Canada. (p 280) The referenced article's conclusions were in fact based on a temporal correlation and not on established cause and effect. Declines in catches could obviously be due to a wide variety of factors. Nothing in the article supported cause-and-effect population "crashes."
- Further, NMFS repeatedly complains about the 4,000 inerts "used in pesticides" and in one case cites xylene as an example. (p. 234) Xylene may not be used as a formulation additive unless its presence is declared on the pesticide label, and it has in fact been dropped from virtually all pesticide formulations. In speculating on the role of formulation additives, NMFS is again operating with and utilizing outdated, incomplete, and inaccurate information which leads to the erroneous conclusions.
- In referring to specific products this 4,000 number is used repeatedly as if inerts are added willy-nilly to end use products without consideration of circumstances. For example, an end use formulation must be safe for use on the target crop. NMFS cites the carrier used for

Lorsban 15G as 82.5% of the formulation by weight, as if that contribution should produce some alarm – not recognizing through experience that most granular formulation carriers are inert clay that ultimately is subsumed by the soil to which it is applied, without toxic effect.

Mischaracterization of tank and environmental mixtures

- In its Overview Document, EPA notes that it does not regulate based on mixtures. Therefore there is no "action" in this regard for NMFS to evaluate. The requirements of FIFRA are directed to the evaluation of an individual pesticide product. EPA notes that: "The Agency does not routinely include in its screening level assessments, an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of product formulations of active ingredients, each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site."[3]
- Monitoring data presented by EPA and registrants do not support NMFS's assumption of the co-occurrence of these products in waters used by salmon as habitat.
- Misinterpretation of risk at the individual level is grossly magnified by subsequent population modeling of questionable validity.
- NMFS presents a supposed risk from an example of a fly spray with the addition of piperonyl butoxide. (p 253 and following) NMFS does not address important factors such as whether or not the use is still legal; what is the size of the package; where the product is allowed to be used; or how the use presents possible exposure.
- In constructing its "mixture scenario" (p. 275), NMFS assumed maximum rates and maximum numbers of applications for all three products would be used. The total that NMFS calculates as applied is 14.75 lbs, with the statement that these are "common use rates." Such assumptions demonstrate a lack of understanding of agronomic needs, economics, and pest control practice. Additionally, NMFS fails to utilize available data that more accurately describe use rates, application methods, areas treated, and limits on total active ingredient allowed per season, total number of applications, intervals required between applications, and maximum allowable single rates of application.

Erroneous and exaggerated calculations and methodologies

- NMFS recalculates exposure incorrectly. For example, in calculating pesticide drift (Table 31, p. 209), NMFS finds that the total drift is in excess of the amount of material applied. By adding the percentages predicted at various distances, the total drift predicted by NMFS is 105% of the amount applied for the fine-medium droplet size and 155% of the amount applied for the very fine-to-fine droplet size. NMFS provides no data, experience or scientific modeling to support such a claim. Drift of more material than applied is of course impossible.
- There are persistent misconceptions about the effects of these products on salmon olfactory response and behavior, and these are the responses that drive the draft BiOp's findings on an

[3] Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations. USEPA Office of Pesticide Programs, Washington, D.C. January 23, 2004 ("Overview Document")

individual and population level. Independent studies challenge the findings on which NMFS's draft BiOp is based. Issues of data quality and extrapolation further compromise the use of these data to establish valid endpoints of concern.

- Very poor logic seems to prevail in many of NMFS's associations, one of which is: "Given the [*assumed*] effects of the other two OPs, we *expect* that malathion can impair olfaction, *but have no information on its potency*" [emphasis added]. (p 273) Recent work has in fact cast great doubt on the validity of the findings on which NMFS assumptions about an olfactory response are based.
- In discussing cholinesterase inhibition for mixtures, predicted responses were so variable as to be meaningless: prediction of inhibition ranged from 20 to 78% and mortality from 8 to 99% (p 274) - all based on hypothetical data with no validation of such findings in the lab or the field.
- NMFS presents as "quantitative" its method to predict potential population-level effects (discussion beginning on p 281, and elsewhere). The unvalidated population models are applied using qualitative assumptions and incorrect interpretation of existing data. The models use "generalized populations" (which, in its species review, NMFS admits are not understood anyway), and an assumption about first year juvenile salmon survival, and an assumed intrinsic growth rate, and an assumed domino effect. None of these assumptions is supported by the presentation of data. The model assesses growth effects over more than 140 days in fresh water and exaggerates both the concentration and length of exposures. NMFS discounts huge standard deviations in its unexposed modeled population, a signal in scientific endeavor that an underlying premise is flawed. NMFS notes it selected the lowest reported LC50 value to "ensure that risk is not underestimated, however if this is an outlier then it will over-predict mortality." (p 283) This "however" is dismissed in further discussions.[4] Slight changes in the outcome (as little as 3%) portray large impact. The results are presented with the caveat "if the juvenile life stages are exposed." (p 289) Even with these faults, the population model shows little if any effect on salmonid populations, when realistic peak concentration values, reflective of today's labeling, are used.
- NMFS quotes Woods and Figueroa 2007 (p 298) in reviewing cumulative effects, and uses an upward economic trend (and ignores a downward employment trend) to infer that a commensurate increase in water diversions will occur. Economic trend analysis and water use estimates are not compatible and should not be interchanged in predicting an effect. NMFS also predicts increased water diversion when other published references note that expansion of water irrigation will not occur. For example in the Columbia Basin, the Columbia Basin Project is not operating at full capacity but is not predicted to increase. The project irrigation facilities were planned to deliver a full water supply to about 1.1 million acres of land previously used only for dry farming or grazing. About 671,000 acres are currently irrigated and further development is not anticipated (http://www.usbr.gov/dataweb/html/columbia.html).
- In portraying monitoring data, in one case NMFS uses "mean values [that] represent the average concentration detected at a single site during 2002." (p 276) This represents a total of

[4] The term "however" is used, following a statement of fact or series of facts, 180 times in the draft BiOp. The overuse of the term "however" is symptomatic of an argument that attempts to make the hypothetical real. http://ucrel.lancs.ac.uk/publications/CL2003/papers/neff.pdf

5 samples. Why are 5 samples, in one year, representative of 177 samples collected from 9 sites over a two year period? The relevance of this site to the watershed and habitable salmon waters is not explained and selective use of data seems designed to give the desired outcome.

- NMFS claims long term exposure will result in impact to growth but does not present evidence that concentrations of the products are truly present at the required level for the periods of duration that match cited studies (274 days). In fact, as a migratory fish, salmon move through fresh and ocean waters and pre-smolts are not in the waters used for examples (agricultural drains, etc). Despite stating that it found no quantitative relationship between growth and fish survival in the field or lab (p 277), NMFS piled assumption upon assumption to conclude that there is a relationship.
- Water monitoring data are presented in a consolidated form, not making it possible to interpret the reduction in pesticide concentrations that have resulted following rate reductions and cancellation of urban and other uses of these products. Additionally, seasonality, the fact that agricultural drains are not habitat, and other significant factors required to be considered in evaluating "exposure" based on monitoring results are simply ignored seemingly to get to the highest concentration possible without regard to its relevancy to posing actual exposure conditions.
- NMFS concludes that "Concentrations of chlorpyrifos, diazinon, and malathion can occur well over 100 ug/l and upwards of 1000 ug/l based on measured environmental concentrations and exposure models." (p 237) However, the concentrations on which NMFS bases its effects evaluation are based on canceled uses or monitoring results from historical periods that are no longer reflective of the label.
- NMFS claims that modeled concentrations compare to monitored concentrations in the summary discussion on pages 237-238 and state that chlorpyrifos, diazinon and malathion have been detected at 486, 67 and over 1000 ug/l respectively. It is not clear from the text of the draft BiOp that use of these values for exposure assessment is valid. In the text, the value of 486 ug/l for chlorpyrifos is from an experimental field study submitted by the registrant to EPA.[5] Extremely high water concentrations were attributed to misapplication of chlorpyrifos, based upon labeled procedures, where chlorpyrifos was inadvertently applied directly to the surface of the pond. The maximum value of 67 ug/l is incorrect as a basis for diazinon evaluation under current legal use patterns: it is a concentration from an agricultural ditch, not salmon habitat, that occurred before rates and restrictions now on the label were in effect. As for the value reported for malathion, the detection value occurred as a result of a USDA-sponsored program to eradicate the Med Fly in 1981. The program used an unregistered formulation containing a ULV formulation of malathion and a protein bait. The registrant does not support the use of malathion for Med Fly programs when sprayed over urban environments. For this reason, USDA reports that malathion will no longer be used in these programs.
- NMFS does not recognize the significance or balance that some other circumstances bring to the assumption of exposure. For example, the draft BiOp acknowledges Yakima River basin as "one of the most agriculturally productive areas in the US" (p 178), yet monitoring results

[5] Dow AgroSciences 1999. Report GH-C 4873 MRID 44736901

from that watershed do not indicate that the products assessed in the draft BiOp occur there with any frequency or at levels of concern.

Understatement or dismissal of the role that exposure plays in risk assessment

- The inclusion of Ozette Lake Sockeye as a "may affect" is unfounded in absence of an explanation for how this ESU would be exposed to pesticides (see discussion beginning on p 110) - the basis of the no effect. Ozette Lake is surrounded by National Park land, and the tributaries are all on forest land for which no use of these products has been demonstrated.
- On page 205, NMFS states: "Given that all listed Pacific salmonid ESUs utilize watersheds where the use of chlorpyrifos, diazinon, and malathion products are authorized, and these compounds are frequently detected in watersheds where they are used, we *expect* that all listed salmonid ESUs will be exposed to these compounds and other stressors of the action." This statement equates geographic registration with labeled use and is incorrect. As pointed out above, Lake Ozette, the home of one of the listed ESUs, is isolated and surrounded by forest and National Park. Sites where the products could actually be used, circumstances contributing to the containment of off-target movement, and relevant water monitoring data need to be integrated into the exposure evaluation.
- NMFS notes for oxons that "the primary data gap regarding risk to the oxons is the concentrations in the environment and the actual concentrations that lead to adverse impacts." (p 280) EPA and/or the affected registrants have considerable data evaluating degradation and metabolic pathways and these data demonstrate degradates and metabolites of these products have been adequately addressed and do not present the risk NMFS supposes.
- Species occurrence in the action area is equated with exposure. Rather than determine if (1) there is truly an exposure and (2) a subsequent measurable or identifiable risk, the analysis is based on the expected *response* to a risk, <u>whether or not that risk is presented in reality</u>. The response analysis is characterized as risk. The approach is flawed and states risk where none exists. The process is introduced (p 28) as: Step1 Identify spatial extent (action area) – Step 2 Identify listed resources in action area ("these represent our exposure analysis") – Step 3 Demonstrate how listed resources are likely to respond *given their exposure* (response analysis) – Step 4 Integrate exposure and response analysis as risk characterization. Later in the analysis, "response analysis" is interposed with "effects analysis" with the assumption that the effect is induced in the "real world" – an assumption that is made but not proven.
- In its discussion of how PRZM EXAMS represents – or does not represent – predicted water concentrations, NMFS uses the habitat of spawning salmon as an example and reports that the waters used for spawning are often shallow, of little movement and possibly isolated from the main river stem. (p 213 and following) However, in this discussion NMFS did not address the spawning destination of salmon, which is generally in topography that is remote from intensive agriculture or any significant use of these products.
- NMFS presents a hypothesis supporting maternal transfer of the products to eggs (p 276), whose only supporting data are from incident reports that are neither analyzed nor put in context of legal uses relevant to salmon habitat.

- NMFS relies heavily on a study by Cuffney to support the assumption that salmon prey are impaired in a way that will reduce salmon growth. (p 277) However, Cuffney showed in his work that the primary impact of species abundance and diversity is elevation, and that the rearing streams of the eastern Cascades are nearly pristine. NMFS admits "[w]e were unable able [sic] to locate information that attributed reduced growth in salmonids to specific insecticide exposures that reduced prey . . ."[6], yet NMFS supports its conclusions on growth being affected based on two papers that have nothing to do with pesticides as a stressor (one evaluates the impact of invading rainbow trout populations, the other compares nocturnal and diurnal feeding patterns), and ultimately claims the line of evidence is reasonable "because it is a reasonable deduction grounded in salmonid ecology and biology." (p 278)
- NMFS states that "[t]he largest concentrations detected in surface waters were consistently those associated with large scale spray programs," (p 238) but gives no substantive evidence to support this statement. NMFS piles speculative assumption upon speculative assumption. For example, in concluding the discussion on page 238 about exposure to formulation additives and degradates, not having proved these are even worthy of the qualification as "stressors," NMFS notes "Although we are *unable* to comprehensively quantify exposure to these chemical *stressors*, we are *aware* that exposure to these stressors is *likely* and we *assume* they *may* contribute to additional *risk* to listed Pacific salmonids" [emphasis added].

Unnecessary introduction of uncertainty

- NMFS's stressors that predominantly appeared in its review of the status of the species included waterway obstructions, development (causing sedimentation, pollution run-off, habitat modification, erosion), fishing, climate change (water temperature and flow) and other impacts. None of these is put into context with the probability and magnitude expressed in EPA's findings of potential risk.
- NMFS introduces uncertainty through unfounded criticism. An example is NMFS's confusion over how drift models are applied and interpreted, by dismissing this confusion as a conclusion: "Consequently, actual concentrations in aquatic habitats adjacent to treated areas are expected to be less than or greater than the EPA estimates depending on site-specific conditions." (p. 210)
- In the section "Integration of the Environmental Baseline on Listed Resources," (p 199) huge issues exist to which the use of these insecticides pale in comparison. The assessment fails to put potential risk in context and instead positions the use of these three products as "the straw that broke the camel's back." Integration of the baseline is a tremendously complex relationship analysis, which in this draft BiOp gets only a qualitative and brief mention. In actuality, NMFS has not established a mechanism to integrate new actions in a baseline nor have they established quantifiable standards for measuring or predicting how the baseline would change with or without the presence of these three products.
- NMFS claims that an abundant evidential line supports the proposition that all swimming life stages of salmon are at risk of death, but that claim uses flawed arguments, selective data, non-relevant exposures, isolated monitoring data and exaggerated exposure calculations. Using this over-the-top approach, NMFS "therefore carry this endpoint into our population

[6] See separate compilation of how "unable" findings were converted to conclusions, Attachment 1

analysis and *translate* the reduced survival of individuals to *potential* population level consequences" [emphasis added]. (p 277)

Dismissal of peer reviewed methods and expert sources

- NMFS expressed frustration because EPA could provide no master label for the products under evaluation (p 17), but there is no mention of whether such a document was sought from the primary registrants. The registrant, as the applicant under ESA, must be consulted in the process that generated this draft BiOp.
- NMFS criticizes EPA's use of limited crop scenarios without appreciating the need to adhere to validated models. (p 211 and elsewhere) Scenarios are selected to represent the uses and regions most likely to have the highest impact or exposure to the species under assessment. Site specifics can never be addressed to the scale NMFS discusses and the models and scenarios used by EPA are meant to portray those situations that are most representative of actual or higher-end use in relevant geographies. Many of the scenarios selected or sited by NMFS for their evaluation use greater run-off predictions than that which will occur in the Pacific states.
- "Lines of evidence" (p 213) are used to undermine EPA's EEC calculations and EPA's use of PRZM-EXAMS but the replacement assumptions are based on scenarios not relevant to assessing salmon (use in Florida, for example) or water monitoring results that are presented out of context (results from non-salmon bearing waters and agricultural drains that are not habitat).
- NMFS notes that for fish, formulation toxicity information was presented but "generally not discussed or used in EPA's estimates of risk." (p 245) This understates the importance of studies required by FIFRA on fish using end use products as described by 40 CFR 158 and including OPPTS harmonized study guidelines 850.1010, -1025, -1035, -1045, -1055, and -1075. The fact of the matter is that formulated products rarely show differences in toxicity, and when they do, those differences *are* considered in risk assessment.
- Many of the stated "uncertainties" are because NMFS is not relying on a complete and relevant data set.

Incorrect associations and assumptions

- Detection of a molecule in the environment does not equate with exposure or with an ensuing effect. In discussing what "might" co-occur in the environment, levels of detection and levels inducing toxicity are not compared.
- NMFS held 2002 and 2003 risk assessments to 2008 standards, without giving EPA and the registrant an opportunity to update them using the Overview Document process that has emerged in the interim between court mandated effects determinations and this draft BiOp (4 years instead of the 90-150 day timeframe the ESA establishes unless the permit applicant consents to an extension).
- In the response analysis several theories are offered on the role of organophosphates in acetyl cholinesterase inhibition. While it is recognized that AChE depression can occur given a high enough exposure to an organophosphate, the characterization of this effect as "irreversible"

(p 240) and without a threshold level is incorrect and greatly distorts the resulting presumed effect.

- NMFS goes beyond the state of science by assuming synergistic behavior of the compounds. NMFS cites isolated data to support chemical synergistic effects, when the weight of evidence actually points elsewhere. EPA has determined there is no reason to believe that such effects would make any significant difference in the risks that EPA calculates. Since the time of EPA's effects determination that is the subject of this consultation, EPA has conducted additional evaluations of data related to this topic. For example, in its effect determination on atrazine, EPA followed the agreed procedures to capture the best available scientific and commercial data and surveyed the open literature for effects data addressing mixtures of atrazine and other pesticides. Based on its review of these studies, EPA concluded that claims of synergistic toxicity were questionable and could not be demonstrated because (a) the use of solvents in combination with the pesticides prevented any reasonable causal relationships and (b) the measured enzymatic endpoints could not be linked to or otherwise demonstrate any adverse effects on the assessment endpoints (i.e. survival, growth, or reproduction). Additionally and more recently, this same research group reported no synergistic and/or additive toxicity of atrazine and chlorpyrifos in fish and amphibians.[7]
- In summarizing toxicity information "from other sources" NMFS ranked the significance of data by (1) experiments using salmonids (without regard to environmental relevance, quality, repeatability, etc.), (2) measured endpoint of concern (disregarding whether the endpoint can truly be measured), (3) "relevant chemical surrogates" (an unproven association), and (4) no flaws in design. (p 255) Certainly, flaws in test design should be the first item to discount the validity of a finding. Further, with endpoints being swimming, olfaction and olfactory-mediated behaviors, toxic effects from consuming contaminated prey and other prey-related "effects", endocrine disruption, and adjuvant toxicity, it is doubtful that any of these can truly be "measured." This classification scheme essentially vacates good science. Furthermore, the endpoints in Table 50 are summarized without specification of the data used and specific references are missing.
- In "integrating" exposure and response, NMFS bases its entire argument on an untested default value, citing the Overview Document as a reference but never presenting its actual calculation. In discussing the interpretation of LC50 values, NMFS's "default slope" of 4.5 is based on EPA's presentation of such data as used to generate LOC's and safety factors (discussion beginning on page 270). But EPA is not using this number in the way that NMFS incorrectly assumes. EPA is instead demonstrating how its safety factors are protective. EPA points out that for a pesticide like carbofuran, where the range of slopes is 2 to 9, the protective factor holds even if the original calculation was with a 4.5 slope. In other words, EPA used real data to validate its assumption, and NMFS picks up the number out of context – and uses it wrongly at that. NMFS tags it as a "standard slope" while EPA used this value as a typical one for example purposes. In fact, this is one of only 5 references to the Overview Document, and none of them is in context of the document's meaning.

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[7] Wacksman M, Maul J, Lydy M. 2006. Impact of atrazine on chlorpyrifos toxicity in four aquatic vertebrates. *Arch. Environ. Contam. Toxicol.* 51:681-689

- Reliance on incorrect data is exemplified by NMFS's quoting of results from a study that purports to support "synergism" between diazinon, malathion and parathion. (p 241 and elsewhere) NMFS relies on data that simply do not pass the "best available" quality test. The article, published in 1975, is superseded by much additional, high quality research. In the cited article, chemical concentrations were not validated by analysis, nor were raw data provided to allow evaluation of what concentrations were tested, both factors that would eliminate this research from supporting a conclusion if the findings were "no effect." An unpublished study was used to corroborate these findings. The unpublished work uses questionable methods for regression analysis, presents questionable findings, and makes questionable extrapolations about cholinesterase levels.
- NMFS states that the first step in its approach to the assessment identifies "the spatial extent of these direct and indirect effects, including change in that spatial extent over time." (p 28) However, that clearly was not done.

Lack of input from varied disciplines and expert scientists

- NMFS effectively ignores EPA's conclusions that the three organophosphates will have "no effect" on certain salmon ESUs. Under the ESA and the implementing regulations, those "no effect" determinations mean that *no consultation is required*. In those situations, NMFS "lacks the authority to require the initiation of consultation" 51 Fed. Reg. 19949. Unless NMFS requests consultation on the "no effect" registrations of these pesticides, which it did not do here, NMFS must defer to EPA's "no effect" determinations and cannot override them as NMFS has done in the draft BiOp.

- Page 19-26 and repeatedly elsewhere, NMFS selectively reviews product properties, toxicity, monitoring and other data, largely disregarding important data and current uses. In fact, in entire sections there are less than a handful of references, singly introduced and not balanced by the state-of-the-art studies that support registration.
- The NMFS draft BiOp casts uncertainty on status of labeling and claims to have examined 20 labels not knowing if they were still in effect. (p 215) One label used as an example is referred to as Diazinon AG500 Insecticide, EPA reg. no. 5905-248 and is readily available on the registrant's webpage (http://www.helenachemical-west.com/data/CA%20labels/Diazinon%20AG500%20%20-%20Natl-CA.PDF). In interpreting this label, NMFS misinterpreted the seasonal limitation of 3 lbs per acre with the allowable application rate, which is ¾ lb per acre, greatly overstating use and thus expected water concentrations.

Redefinition of the metrics relevant to critical habitat evaluation

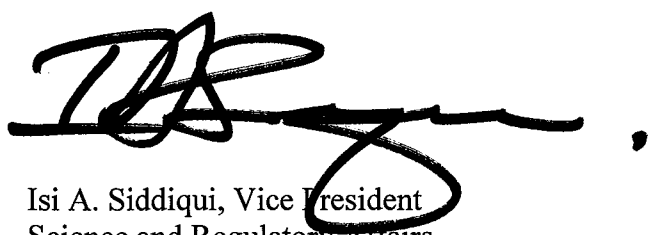
- NMFS critical habitat determinations and their justification might be helpful to establishing balance and context in this assessment (http://www.nwr.noaa.gov/Salmon-Habitat/Critical-Habitat/2005-Biological-Teams-Report.cfm). "Adverse modification or destruction of designated critical habitat" in this draft BiOp is based on the action's "effects on reductions in the conservation value of critical habitat." (p 28) More commonly the standard is "alteration that *appreciably* diminishes the conservation value" by modifying "any of those physical or biological features that were the basis for determining the habitat to be critical" [emphasis added] (50 CFR 402.02).

- NMFS analysis of critical habitat does not rely on the regulatory definition of "adverse modification or destruction," giving it free rein to make highly speculative assumptions about what might be considered a "modification."

Being concerned about the polarity that seems to exist between NMFS and EPA, CLA recently undertook an analysis of the state of risk assessment science, the NMFS concurrence on many of the issues raised here about risk assessment, good science and data quality. This document titled "Species Assessment under the Endangered Species Act and The Federal Insecticide, Fungicide, Rodenticide Act" (Attachment 2) is attached here for further clarification of the state of the science and how good science can be applied in the pesticide endangered species assessment process.

In conclusion, pesticide registrants must have the procedural involvement that both regulations and policy provide under the ESA. With that involvement, all of the points discussed above would have been addressed and a useful draft BiOp would have been generated. In absence of applying established ESA regulation and policy, a draft BiOp has been developed in a void, resulting in an inaccurate and ineffective document.
In conclusion, pesticide registrants must have the procedural involvement that both regulations and policy provide under the ESA. With that involvement, all of the points discussed above would have been addressed and a useful draft BiOp would have been generated. In absence of applying established ESA regulation and policy, a draft BiOp has been developed in a void, resulting in an inaccurate and ineffective document.
CLA appreciates the opportunity to present the U.S. crop protection industry's views on the draft Biological Opinions on Pacific Salmon and Steelhead issued under the Endangered Species Act. If you have any questions or would like to discuss these comments further, please contact me by telephone: (202)833-4474, or via email: isiqqiqui@croplifeamerica.org; or contact Josh Saltzman by telephone: (202)872-3882 or via email: jsaltzman@croplifeamerica.org.

Sincerely,



Isi A. Siddiqui, Vice President
Science and Regulatory Affairs
CropLife America

Attachment 1:

"We were unable . . ."

To verify actual implementation and completion of these activities [mitigation by label cancellations and reduced use] (p 19)

To quantify the overall effects of wildland fire on the long-term survival (p 164)

To quantify these [habitat restoration and hydropower modification measures] potential beneficial effects (p 199)

To accurately define exposure distributions for the chemical stressors (p 237)

To comprehensively quantify exposure to these chemical stressors (p 238)

To create a predictive model of synergistic toxicity (p 243)

To locate information that attributed to reduced growth (p 278)

To locate results from field experiments for the other remaining endpoints of this hypothesis (p 278)

To make any definitive conclusions for every stressor of the action (p 280)

To accurately describe the level of risk (p 294)

There are "difficulties . . ."

In determining species viability (p 118, 124, 144, 164)

It is difficult to extrapolate the degree to which juvenile salmonids growth would be affected (p 248)

It is difficult to determine the relative toxicity of chlorpyrifos, diazinon and malathion found in contaminated insects consumed by Pacific salmonids (p 263)

It is difficult to compare these effect concentrations to OP insecticides (p 264)

These [swimming behaviors] are more difficult assessment endpoints to measure in the laboratory and particularly in the field (p 278)

It is difficult to place an exact number on the percentage of a population that is affected or how frequently a population is affected (p 291)

We find it difficult to accurately predict when these impairments and missed spawning opportunities occur (p 292)

There is difficulty in conducting field experiments with adult salmonids (p 292)

Specific populations were not modeled due to the difficulty in finding sufficient demographic and reproductive data for a single population (p 329)

Yet, "we conclude . . ."

That the effects resulting from likely exposure are [n]either discountable or insignificant (p 27)

That these hatchery programs collectively do not substantially reduce the extinction risk of the ESU [Hood Canal summer Chum ESU, p 92; MCR steelhead hatchery programs, p 134]

That compounds that share a common mode of action may cause cumulative effects (p 236)

Swimming behaviors are affected by the three insecticides (p 279)

That this hypothesis [the impact of mixtures] is well supported (p 279)

That the actual risk posed to listed salmonids and their habitat is likely greater when all ingredients are taken into account (p 281)

The likelihood of other AChE-inhibiting insecticides within aquatic habitats (p 281)

The assumption that if atrazine and possibly other triazines co-occur with one of the three insecticides then we expect enhanced toxicity to invertebrates (p 281)

These additional effects [speculated behavioral responses] cannot be dismissed (p 292)

That exposed populations are likely to have reduced abundance and productivity as a result of impaired swimming and olfactory-mediated behaviors (p 292)

That based on the expected environmental concentrations of the three insecticides, synergism is likely (p 293)

That exposed individuals are at increased risk of the suite of toxic effects expected from a particular substance (p 294)

That all populations of threatened and endangered salmonids covered by this consultation will likely show reductions in viability (p 294, 300)

Attachment 2: Species Assessment under the Endangered Species Act and the Federal Insecticide, Fungicide, Rodenticide Act