

General Comments on the 31 July 2008 Draft BiOp

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Topics

- Use of best available data
 - How registrants can assist
 - Suggestions regarding problem formulation and analysis plan
- Long period of historical use
 - Relationship to environmental baseline
 - Trend over time
- Other ingredients
 - Consideration of inerts, adjuvants, formulations, tank mix partners
- Risk characterization
 - Desirable attributes
 - Suggested alternatives
 - Summary of NMFS quantitative risk assessment and data quality
- Recent risk mitigation measures

Use of Best Available Data (1)

- Data quality and study selection
 - A single peer-reviewed publication or finding “has limited **objectivity** depending on the level of peer review but has its **utility** defined by one circumstance and may not have been designed for purposes of risk assessment; and loses its **transparency** because methods are not documented to the degree GLPs require, loses its **quality** by its isolation and is of unknown consistency”

(Excerpt from the FIFRA Endangered Species Task Force comments submitted 10 Mar 2003 to Docket ID No. OPP-2003-0010)

Use of Best Available Data (2)

- Examples of limitations in peer-reviewed studies
 - Scholz et al. 2002:
 - Used individual fish rather than schooled fish
 - Appetites were not controlled
 - Differences in homing behavior were not significant
 - Results not reproducible (Palm and Powell SETAC 2007)
 - Moore and Waring 1996:
 - Diazinon concentrations not environmentally relevant
 - Atlantic salmon were 1 yr old – results not easily extrapolated to adult fish
 - Discounted by EPA as not relevant for risk assessment purposes.
 - Smith and Grigoropoulos 1968:
 - Malathion acute rainbow trout study
 - Study rejected on data quality grounds by EPA and DPR
 - Poorly characterized old (1960s) formulation
 - High impurity concentrations no longer allowed
 - It is inappropriate to use a submitted paper (not peer reviewed)
 - Laetz et al. describing synergy between OPs

Use of Best Available Data (3)

- Provision of all current labels
 - All labels are easily obtained electronically
<http://ppis.ceris.purdue.edu/htbin/epachem.com>
 - Labels of major manufacturers are sufficient to account for a large percentage of the total use
- Dose-response data were not obtained
 - Registrants have access to global data sets
- Current label uses ignored (focus on old uses)
 - Historical uses irrelevant to Federal Action
- New use directions and precautions not the focus of inquiry
 - Significant changes made to labels as a condition of reregistration

Use of Best Available Data (4)

- Incomplete interpretation of monitoring data
 - Recent data relevant to current uses is key, not review of historical data tied to discontinued uses
 - Regional scale assessment, not related to specific ESUs, limiting value of risk conclusions
- Did not check assumptions about inert composition and toxicity with registrants
 - All statements of formula available as confidential business information
- Exposure model inputs incorrect due to lack of information/outdated information/misinterpretation of labels
 - Historical vs. current use, interpretation of current use directions
 - Registrant expertise available

Use of Best Available Data (5)

- Context of incident reports or field studies not related to salmonid habitat
 - It is important to review quality of incident data, tie it to specific use patterns, and determine applicability to salmonid habitat
 - Field study objectives and designs influence applicability of results to other settings
- Mixture toxicity
 - In relation to particular ESUs
 - Specific mixture constituents and levels are local events controlled by overlap of use patterns, site conditions, climate, and hydrology
 - Analysis in draft BiOp has limited value for drawing risk conclusions

Use of Best Available Data (6)

- Exposure models predict frequent fish kills that do not occur (weight of evidence)
 - It is important to consider realism in model predictions, particularly when model scenarios are intentionally designed to be protective at early assessment tiers
 - Appropriate interpretation of monitoring data representative of current uses is preferable for risk characterization

Use of Best Available Data (7)

- Life-history population model runs did not use relevant environmental concentrations in particular ESUs
 - Although the model scenarios themselves are generic and do not represent specific environmental settings, the value of model predictions would increase by picking values from important points in the exposure distribution
 - This will provide a probabilistic interpretation of risk to populations

Use of Best Available Data (8)

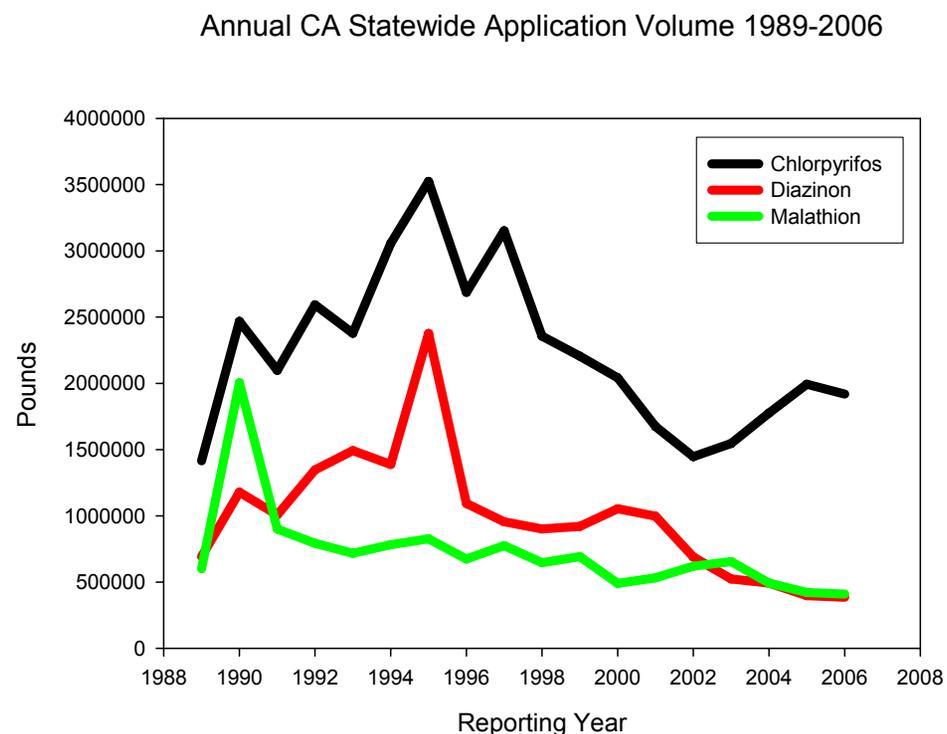
- Stewardship and water quality implementation programs ignored
 - Registrants can provide detailed information on partnerships with stewardship organizations and interactions with grower coalitions dealing with BMP education in water bodies designated as having impaired water quality

Use of Best Available Data (9)

- Did not consider long period of historical use as a component of environmental baseline
 - The environmental baseline in the document was qualitative
 - Given all of the more important stressors generally agreed to have contributed to salmonid decline, how is the baseline incrementally moved by pesticide residues that constitute a minor component of water quality, itself a minor stressor

Long Period of Historical Use

- Represented by California PUR data, available at <http://www.cdpr.ca.gov/docs/pur/purmain.htm>
- Inconsistent with general conclusion in draft BiOp implying Federal Action for three OPs will have in the future a severe impact on existing populations (would have already occurred)
- Note general trend for decreased use



Source: Cal/EPA DPR Pesticide Use Reports

Other Ingredients

- Inerts generally are much less toxic than the a.i.
 - Can work with registrants under confidentiality agreement to determine actual product composition, as does EPA under statute for CBI
- Adjuvants are added to tank mixes in small amounts
- Nonylphenol or other non-ionic alkylphenol polyethoxylates are used in much higher volumes in other industries that contribute most of the environmental load
- Formulated products generally have the same biological activity as the a.i. in non-target toxicity tests

Risk Characterization (1)

- A useful risk characterization integrates and evaluates exposure and effects information to provide risk managers:
 - Some indication of the greatest risks
 - Ability to ask “what if” questions regarding the consequences of potential management actions
- Generally, when sufficient data exist to make quantitative risk statements, the risk characterization is best expressed in terms of probabilities of effect

Risk Characterization (2)

- The draft BiOp integration and evaluation of exposure and effect information is given in Figures 39, 40, and 41
 - Ranges of generalized exposure information are compared to ranges of toxicity information

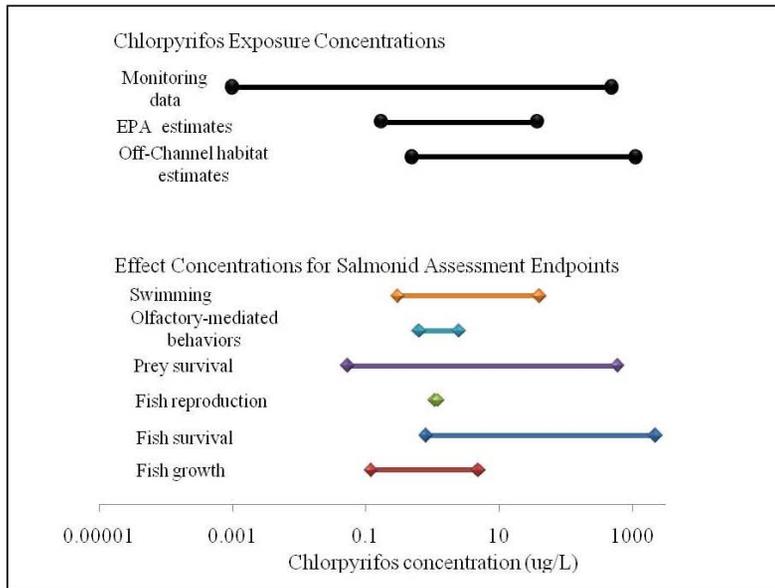


Figure 39. Chlorpyrifos exposure concentrations and salmonid assessment endpoints' effect concentrations in ug/L.

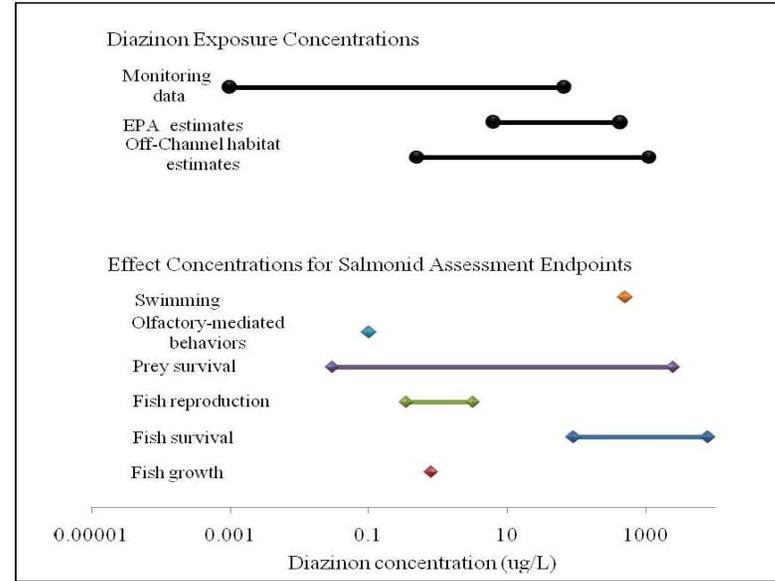


Figure 40. Diazinon exposure concentrations and salmonid assessment endpoints' effect concentrations in ug/L.

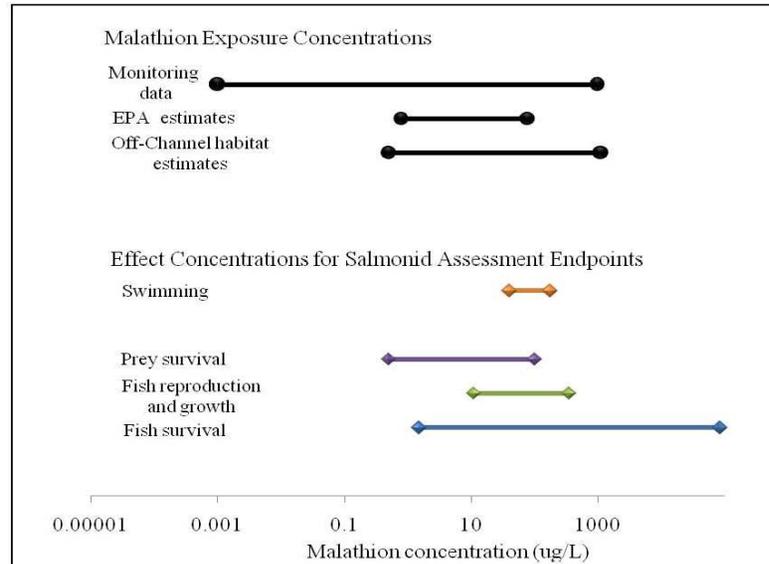


Figure 41. Malathion exposure concentrations and salmonid assessment endpoints' effect concentrations in ug/L.

Risk Characterization (3)

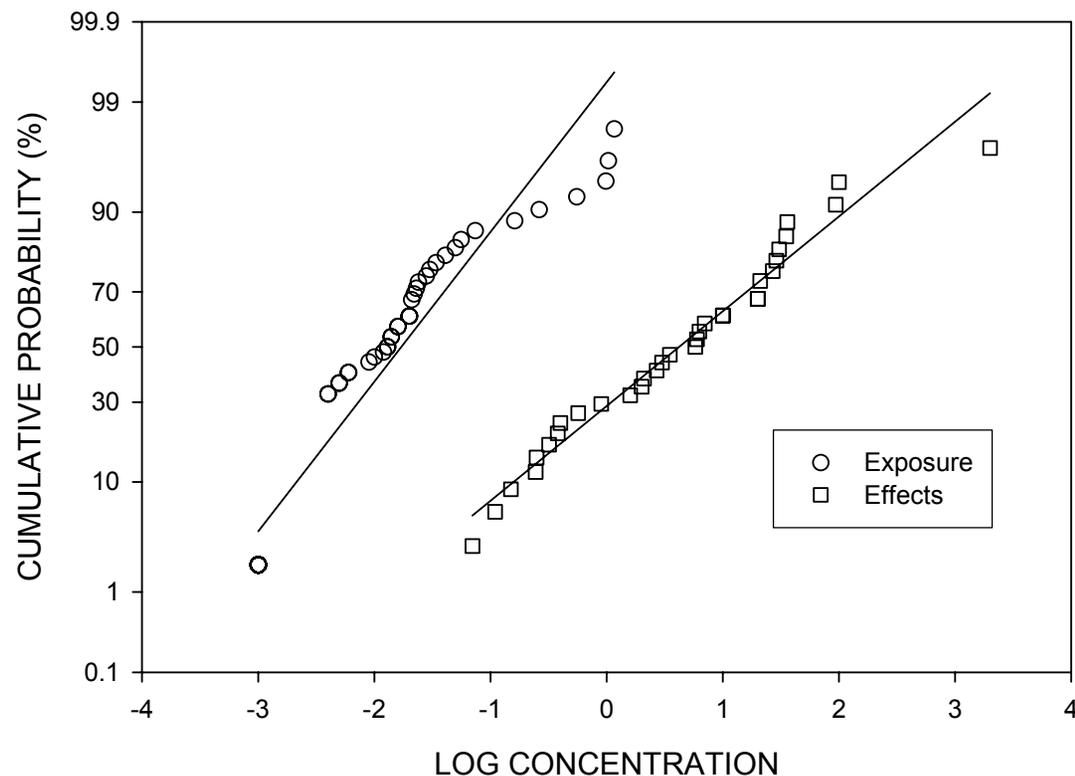
- These risk characterizations are inadequate and misleading
 - Information related to exposure and effects distributions omitted
 - All toxicity endpoints are given equal weight
 - No probability statements of risk are possible
 - No statements of risk in specific ESUs are possible
 - “What if” questions regarding RPMorAs are not possible

Risk Characterization (4)

- National Oceanic and Atmospheric Administration Information Quality Guidelines (November 6, 2006)
 - Analysis of Risks to Human Health, Safety and the Environment
 - When NOAA performs and disseminates influential risk assessments that are quantitative in nature, in addition to applying the two objectivity standards above, risk assessment documents made available to the public shall specify, to the extent practicable, the following information, adapted from the SDWA principles:
 - each ecosystem component, including **population**, addressed by any estimate of applicable risk effects;
 - the **expected or central estimate of risk** for the specific ecosystem component, including population, affected;
 - each appropriate **upper-bound and/or lower-bound estimate of risk**;
 - data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the uncertainties; and
 - additional studies known to the agency and not used in the risk estimate that support or fail to support the findings of the assessment and the rationale of why they were not used.

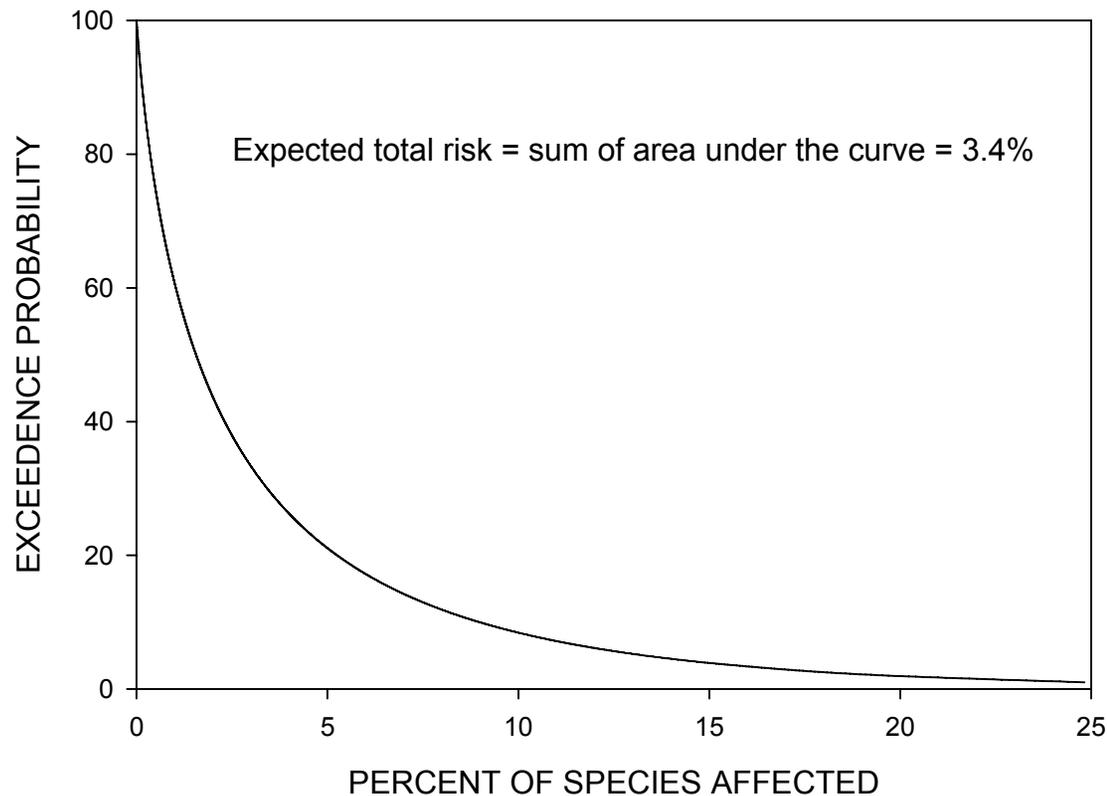
Risk Characterization (5)

- As recommended in NOAA's IQ Guidelines, it is essential to consider overlap of exposure and effect distributions to determine expected risk
 - Example: species sensitivity distribution



Risk Characterization (6)

- Or plot area under the curve for the products of cumulative probability and % spp affected



Risk Characterization (7)

- Life-history population models were used to quantitatively translate reduced survival of individuals to generalized populations of salmonids
- Following the NOAA IQ Guidelines for quantitative risk assessment, the predicted outcomes from the models suggest the expected risk at environmentally relevant concentrations is negligible (Tables 52-55)
 - For example, chlorpyrifos:
 - $\% \Delta \lambda$ always NS at 0.5 $\mu\text{g/L}$ for exposure up to 21 d, and in many cases, 60 d
 - $\% \Delta \lambda$ often NS at 1 $\mu\text{g/L}$
 - Similar profiles for diazinon and malathion

Recent Risk Mitigation Measures

- As mentioned previously the draft BiOp did not take into account revisions to product labels required as a condition for reregistration
- Numerous use restrictions were imposed
 - Spray drift management: buffer zones, best management practices
 - Specific use restrictions: total amount of a.i. applied per season, number of applications, re-treatment intervals, maximum single application rate

Product Specific Examples

- Many of the points addressed in this presentation will be illustrated in the subsequent material presented as product specific comments for chlorpyrifos, diazinon, and malathion