Weight-of-Evidence Pesticide Assessments for Threatened and Endangered Species to Inform Management Decisions

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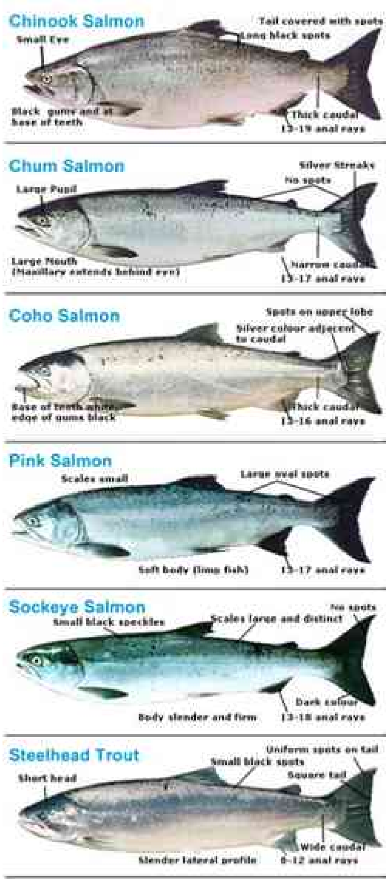
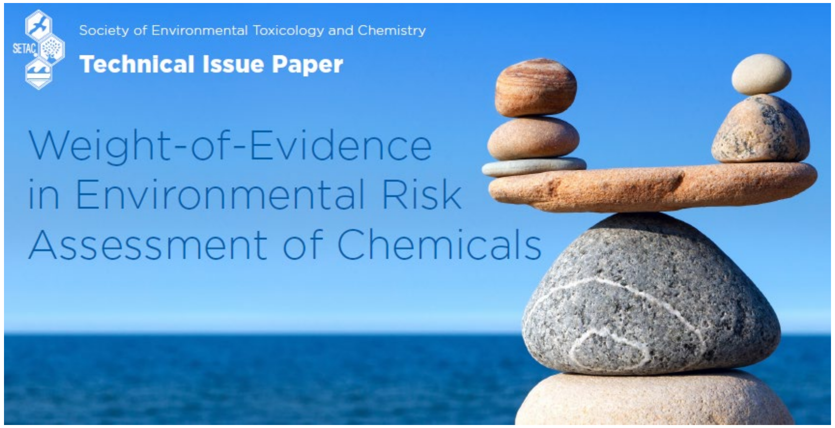
Introduction

- NMFS recently completed Biological Opinion for diazinon, chlorpyrifos and malathion
  - Based on Biological Evaluation previously prepared by US EPA
  - "Jeopardy" and "adverse modification" conclusions for 38 of 77 anadromous and marine entities and 37 critical habitats
  - FWS in process of preparing Biological Opinion for remaining listed species
- Jeopardy conclusion indicates that the action is expected to reduce appreciably the likelihood of survival and recovery of an ESA-listed species in the wild
- Adverse modification conclusion indicates that the action is expected to appreciably diminish the value of designated critical habitat for an ESA-listed species

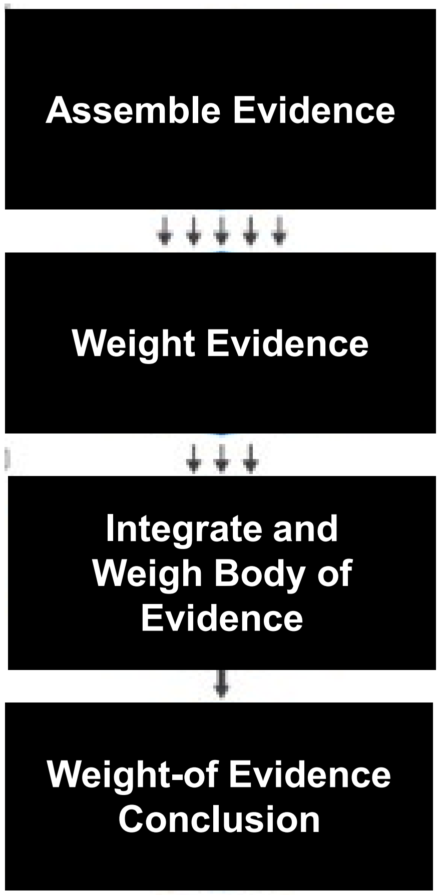


Weight-of-Evidence

- NMFS used a WoE approach to determine risk and make jeopardy calls
- WoE is the process of assembling, weighing, and evaluating evidence to come to a scientifically defensible conclusion (SETAC TIP)
- In this presentation
  - General overview of WoE framework
  - Best practices
  - NMFS WoE framework
  - Issues with NMFS framework
  - Revised approach



Weight-of-Evidence: General Approach



Identify, filter and summarize available lines of evidence

Assign each piece of evidence a weight based on the evidence's strength, relevance and reliability

Evaluate the lines of evidence together and assess consistency to identify the appropriate conclusion

SETAC Technical Information Paper

Suter II, GW and SM Cormier. 2011. Science of the Total Environment 409:1406–1417.

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Best Practices

- Derive WoE framework *a priori*, ensure that it is broadly reviewed
- Derive risk questions or hypotheses during problem formulation
- Specify inclusion/exclusion criteria for pieces of evidence
- Do not exclude pieces of information that have null findings or are not supportive of favored risk hypotheses
- Do not exclude potentially important lines of evidence because they have limitations (all lines of evidence have limitations)
- Be transparent
  - Identify sources of information, provide study reviews and scores
  - Provide criteria for weighting of pieces of information and lines of evidence
  - Describe process of weighing body of evidence and arriving at risk conclusions
  - Document sources of uncertainty, specify potential impacts on risk conclusions
- Be objective, do not bias towards worst case, avoid logical inconsistencies
- Document and explain ambiguities and discrepancies

Adapted from Hall et al.. 2017. Integrated Environmental Assessment and Management 13:573–579.
Rhomberg et al. 2013. Critical Reviews in Toxicology 43:753–784.

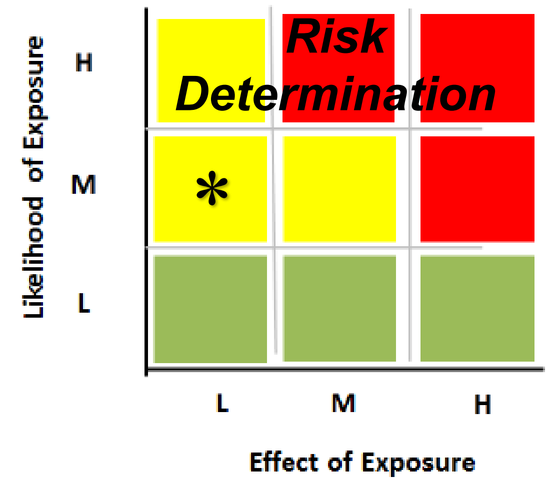
NMFS Risk Hypotheses

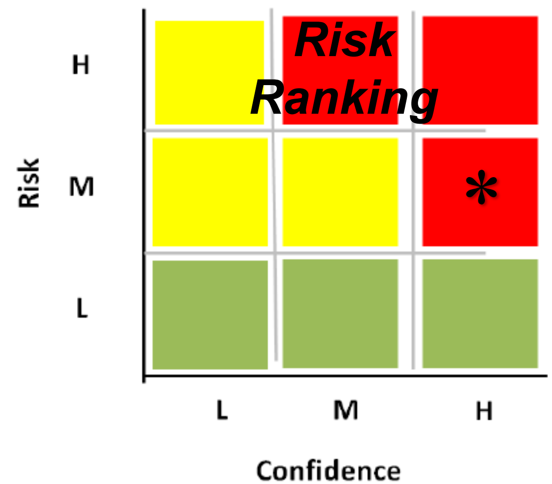
Risk Hypotheses for Adults:
Exposure to chlorpyrifos is sufficient to reduce adult abundance via direct exposure (mortality)
Exposure to chlorpyrifos is sufficient to reduce adult productivity via impairments to reproduction (reproduction)
Exposure to chlorpyrifos is sufficient to reduce adult abundance and productivity via impairments to ecologically significant behaviors. (behavior; sensory)
Exposure to chlorpyrifos is sufficient to reduce cholinesterase activity; the identified mechanism of toxicity (enzyme).
Mixtures: Formulated products and tank mixtures containing chlorpyrifos are anticipated to increase risk to direct and indirect effects to fish in freshwater habitats
Abiotic Stressors: Exposure to elevated temperatures enhances the toxicity of the stressors of the action.
Risk hypotheses for designated critical habitat:
1. Exposure to the stressors of the action is sufficient to reduce the conservation value via reductions in prey in rearing sites.
2. Exposure to the stressors of the action is sufficient to reduce the conservation value via degradation of water quality in migration, spawning, and rearing sites.

- NMFS used a WoE approach to assess risk hypotheses
- Risk hypotheses developed by life stage

NMFS WOE Approach

- Overall risk ranking for each species based on
  - Likelihood of exposure
  - Effect of exposure (based on risk quotient)
  - Confidence in risk determination
- Risk determination: Red=High, Yellow=Medium, Green=Low
- Risk ranking: Red=High, Yellow=Medium, Green=Low
- Driven by worst-case scenario, i.e., use pattern or habitat bin with highest likelihood of exposure and risk quotient
- Risk "modifiers" also considered (e.g., influence of rising temperatures and presence of pesticide mixtures)





NMFS WOE Approach

Likelihood of Exposure

- *Overlap of crop footprint and range*
  - *Low = <1%*
  - *Medium = 1-5%*
  - *High = >5%*
- Presence during application(s)
- Pesticide persistence
- Number of applications
- *Proximity of use sites to sensitive areas*
  - *Yes = ≤300 m*
  - *No = >300 m*
- Time in aquatic areas
- Proportion of range in US

Effect of Exposure

- Low = All EECs below lowest LOEC
- Medium = Any EEC above LOEC but below median effect level
- High = Any EEC above median effect level

Confidence

- Concordance, i.e., higher confidence with more uses and toxicity endpoints having similar findings
- Percent overlap of uses with range
- Representativeness of exposure model and toxicity information

Issues With NMFS WOE Framework

- Excluded information that indicated lower risk findings or did not corroborate modeling line of evidence
  - Actual use data far lower use than assumed by NMFS
  - Targeted monitoring data indicated much lower exposure than did models
  - Trends data for salmon abundance indicate no relationship to pesticide use
- Did not include important lines of evidence
  - Relied on lines of evidence that are highly related, i.e., exposure model results compared to various in vivo toxicity endpoints
  - Did not consider population trends, targeted monitoring data, field studies, etc
- WOE assessment biased towards worst case
  - Assumed all salmon co-occur in space and time with peak concentrations
  - Even if risk determination was low, species with >1% overlap did not have low risk rank
- Did not document and explain ambiguities and discrepancies
  - Population models predict rapid extinction for many salmon ESUs, yet higher historical use over many decades has had no discernable impact on salmon abundance

Comparison of Malathion Use Assumed in the Biological Opinion with Median 2010 - 2015 Actual Malathion Use Derived from the California PUR and AgroTrak databases

Salmonid ESU/DPS	Maximum Use Assumed in BiOp (lbs/yr)	Estimated Median Actual Use (lbs/yr)	Actual Percent of Max Use, (%)
California Coastal Chinook Salmon	1,749,306	0	**0**
Central Valley Spring-run Chinook Salmon	29,040,058	15,105	**0.05**
Lower Columbia River Chinook Salmon	896,515	4,729	**0.53**
Puget Sound Chinook Salmon	1,401,099	1,905	**0.14**
Sacramento River Winter-run Chinook Salmon	6,599,827	11,664	**0.18**
Snake River Fall-run Chinook Salmon	5,779,720	3,141	**0.05**
Snake River Spring/Summer-run Chinook Salmon	12,416,719	3,151	**0.03**
Upper Columbia River Spring-run Chinook Salmon	4,598,745	1,285	**0.03**
Upper Willamette River Chinook Salmon	3,719,303	17,612	**0.47**
Columbia River Chum Salmon	983,470	5,843	**0.59**
Hood Canal Summer-run Chum Salmon	94,253	2	**< 0.01**
Central California Coast Coho Salmon	2,475,844	1,569	**0.06**
Lower Columbia River Coho Salmon	888,414	4,729	**0.53**
Oregon Coast Coho Salmon	1,476,625	95	**0.01**
Southern OR\Northern CA Coasts Coho Salmon	2,185,608	51	**< 0.01**
Ozette Lake Sockeye Salmon	3,895	0	**0**
Snake River Sockeye Salmon	4,777,785	0	**0**
California Central Valley Steelhead	33,649,927	130,619	**0.39**
Central California Coast Steelhead	2,568,957	2,158	**0.08**
Lower Columbia River Steelhead	853,192	4,271	**0.50**
Middle Columbia River Steelhead	11,869,025	31,474	**0.27**
Northern California Steelhead	979,453	0	**0**
Puget Sound Steelhead	1,367,239	1,919	**0.14**
Snake River Basin Steelhead	12,416,719	3,628	**0.03**
South-central California Coast Steelhead	5,379,603	92,002	**1.71**
Southern California Steelhead	1,991,549	84,543	**4.25**
Upper Columbia River Steelhead	5,022,974	6,995	**0.14**
Upper Willamette River Steelhead	3,775,877	21,466	**0.57**

>5X National Annual Use!

Intrinsik Corp and Stone Environmental Ltd. 2018. Comments on the Draft Biological Opinion for Malathion Issued by NMFS.

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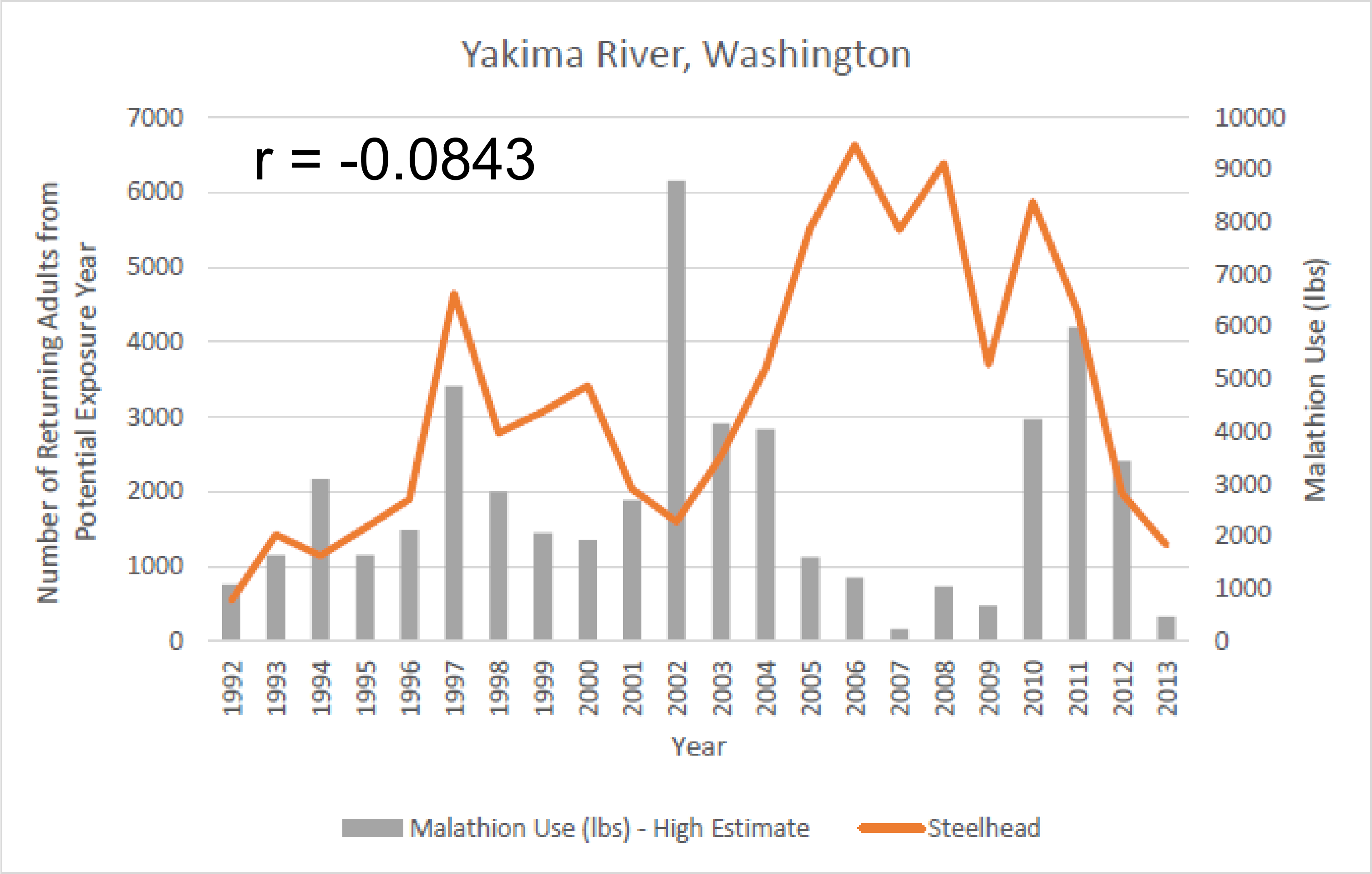


Compliance Services International. 2018. Comments on the Draft Biological Opinion for Malathion Issued by NMFS.

WOE Approach for Pesticide ESRAs

Step 1	Formulate risk hypothesis
Step 2	Identify lines of evidence relevant to risk hypothesis
Step 3	Compile data elements for each line of evidence
Step 4	Evaluate each data element, assign scores for relevance and reliability to each data element according to pre-defined rubric
Step 5	Combine and weight scores for all data elements within each line of evidence, assign score for relevance and reliability to each line of evidence according to pre-defined rubric
Step 6	Combine and weight scores for all lines of evidence, draw conclusion relative to risk hypothesis

Risk Hypotheses and Lines of Evidence

- Example risk hypotheses
  - Acute exposure reduces adult abundance via direct mortality
  - Chronic exposure reduces productivity via reproductive impairment
  - Exposure indirectly reduces adult abundance via food web impacts
- Potential lines of evidence
  - Comparison of modeled exposure to laboratory bioassay results
  - Comparison of modeled exposure to mesocosm results
  - Comparison of targeted monitoring data to laboratory bioassay results
  - Comparison of species trends to pesticide use over time
  - Comparison of species locations to use pattern locations
  - Bioassessments
  - In situ bioassays, field studies
  - Incident reports

Evaluation of Toxicity Study Data Elements

Evaluation Scheme

- **Initially screened for relevance with 5 questions**
- **If relevant, studies rated for quality using 10 (lab) or 11 (cosm) criteria**
- **Criteria address**
  1. **Objectivity**
  2. **Clarity and transparency**
  3. **Integrity**

Scores

- **Scores range between 0 and 26 (lab) or 29 (cosm)**
- **Acceptable**
  (score = 22-26; 23-29)
- **Supplemental**
  (score = 13-21; 13-22)
- **Unacceptable**
  (score = 0-12; 0-12)

Similar evaluation schemes required for other bodies of evidence

Evaluating Relevance

	Assessment Factor	Criteria	Score
Relevance	Utility	Study community/ecosystem	YES/NO
		Single active ingredient tested	YES/NO
		Endpoints directly related to mortality, growth or reproduction	YES/NO
		Exposure route	YES/NO
		Exposure duration	YES/NO

- Bioassays only considered further if all criteria met
- Unique criteria required for each type of data element

Evaluating Data Quality

	Assessment Factor	Criteria	Score
Quality	Objectivity	Use of standard guideline/ complete description of test system and protocols	/3
	Clarity and Transparency	Identification of test substance	/3
		Consideration of imidacloprid phys-chem properties (i.e. solubility, photolysis)	/3
		Controls	/3
		Statistical procedures	/3
		Exposure concentrations	/3
		Sufficient number of samplings	/3
		Concentration-response	/1
		Test species characteristics and acclimation	/3
		Test conditions	/3
	Integrity	Good Laboratory Practices	/1

Rubric for Data Quality Criteria

Assessment Factor	Questions	Score			
		0	1	2	3
Clarity and Transparency	Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?	No information provided on test substance	Pesticide technical or formulation reported	Product identification and purity/% a.i. reported	Product, purity/% a.i. and source reported
Clarity and Transparency	Were appropriate controls included, reported and results adequate?	No controls reported	Controls used, but effects in controls not reported	Controls used, with effects in controls (e.g. mortality, immobilization) reported and within acceptable limits	Controls used, with effects in controls (e.g. mortality, immobilization) reported, within acceptable limits, and compared to treatment groups using statistical methods

Scoring Lines of Evidence

Risk Hypothesis: Use of pesticide on cotton will result in exposure that causes direct acute effects to Cape Sable seaside sparrow.
Line of Evidence: Exposure modeling versus lab bioassay results

Components of Line of Evidence	Relevance	Weighted Reliability	Comments
Model Structure, Applicability and Validity	Yes	7/10	Probabilistic, spatially-explicit species-specific model; model does not have a history of regulatory use
Lab Bioassay Results	Yes	8/10	Oral and dietary GLP studies available involving passerine test species; no sparrow studies
Overall Weight for Line of Evidence	Yes	7.5/10	Relevant and reliable line of evidence

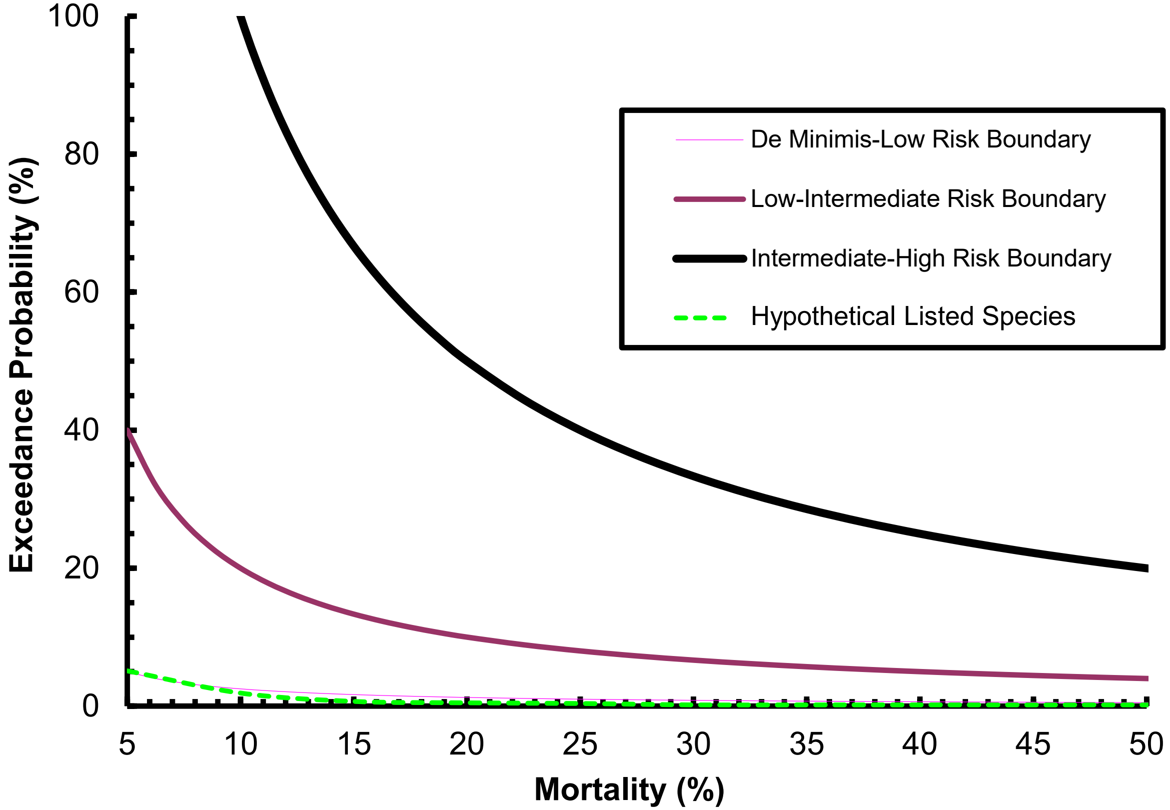
Combining Lines of Evidence

0=Negligible
0.33=Low
0.67=Intermediate
1=High

Risk Hypothesis: Use of pesticide on cotton will result in exposure that causes direct effects to Cape Sable seaside sparrow.
Line of Evidence: Exposure modeling versus lab bioassay results

Line of Evidence	Weight	Magnitude	Risk Score
Exposure Modeling vs Lab Bioassay Results	0.75	0.33	0.25
Incident Reports	0.1	0	0
Comparison of Species Trends to Pesticide Use Over Time	0.25	0.33	0.08
Field Studies	0.4	0	0
Weight of Evidence Score and Conclusion	0.33/1.5=0.22, Low Risk		

Magnitude of Risk



Conclusions

- Pesticides WoE framework for endangered species
  - Requires broader inclusion of non-modeling lines of evidence
  - Needs improved transparency, including providing sources of information, evaluations and scores for all data elements and bodies of evidence
  - Requires formal evaluation of all lines of evidence, not just modeling vs bioassay results line of evidence
- Evaluate range of scenarios from best to most likely to worst case
- Discuss and consider conflicting findings, ambiguities, sources of uncertainty
- Avoid hyperconservatism and bias, declaring most species at high risk not helpful in prioritizing species for protection actions
- Formally link WoE to decision making (e.g., determine how mitigation measures will achieve reduced risk goals)