NMFS Biological Opinion: EPA Registration of Chlorpyrifos, Diazinon, and Malathion

Protected Resources Pesticide Team

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Background

- Jan 2001- Lawsuit filed against EPA to consult on Effects of 54 active ingredients on listed Pacific Salmonids
- 2002 through 2004- EPA transmitted biological evaluations on 54 active ingredients with determinations of “may affect” on 37 active ingredients.
- Nov 2007 – Legal complaint filed against NMFS for unreasonable delay in completing consultations.
- July 2008- Settlement Agreement to complete consultation on 37 active ingredients by Feb 2012

Consultation History for chlorpyrifos, diazinon, and malathion

- May 2002- EPA transmitted malathion evaluation with determinations of may affect for 22 ESUs.
- Nov 2002- EPA transmitted diazinon evaluation with determinations of may affect for 22 ESUs.
- April 2003- EPA transmitted chlorpyrifos evaluation with determinations of may affect for 19 ESUs.
- Nov 2008- NMFS did not concur with EPAs NLAA determinations. This Opinion evaluates impacts on all 26 ESUs, plus 2 new ESUs.

How does NMFS reach conclusions in a biological opinion?

- Our process is defined in the USFWS/NMFS Consultation Handbook (1998)
- Major Components:

Status of Species	Baseline	Effects of Action	Cumulative Effects

What is the Federal “Action” ?

- “any action authorized, carried out, or funded”
- Defining the federal action is an important step during the risk assessment planning phase

Federal Action

"Authorization for use or uses described in labeling of a pesticide product containing a particular pesticide active ingredient."

Understandings reached NMFS-USFWS-USEPA meeting 12/12/2007

Deconstruction of the Action

- Stressors associated with action based on review of EPA authorized labels
  - Active ingredient
    - Metabolites and degradates
  - Other ingredients
  - Recommended tank mixtures
  - Adjuvants
  - Application restrictions/ methods

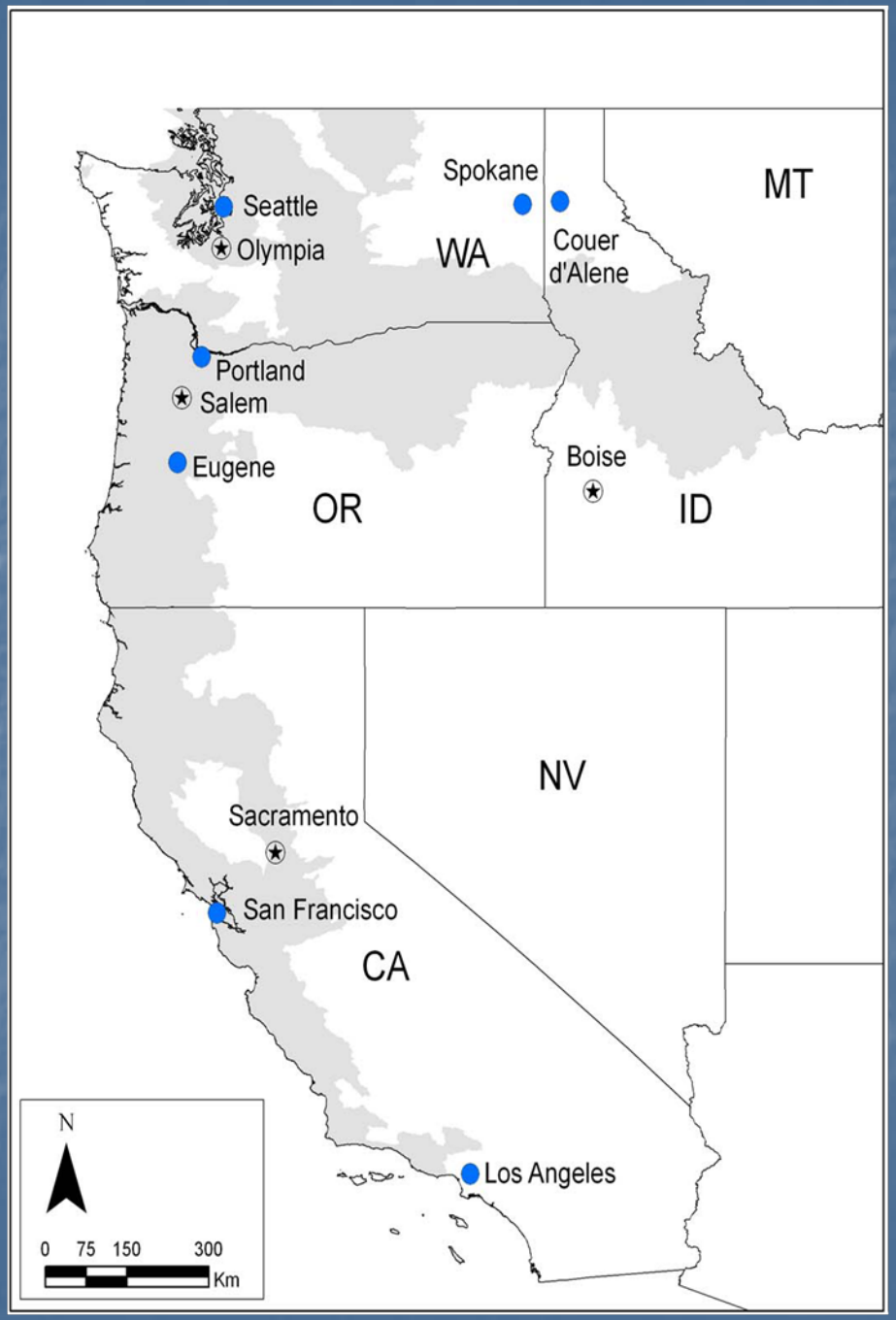
Uncertainty Regarding Action

- We did not receive all labels
  - Prefer to receive a comprehensive summary of all label restrictions (Master Label)
- Changes to labels since we received EPA's original determinations
- Continued use of existing stocks once labels have been modified
  - How much is out there and how long will it be used?

Action Area

- All areas affected directly or indirectly by the federal action, not merely the area involved in the action (50 CFR §402.02).
- The action area for EPA's national authorization of pesticides would encompass the entire U.S. and its territories and any affected waters.
- Action area is used to define what species may be affected by the action.
- However, this opinion is specific to listed Pacific salmonids

- Map indicates inland distribution of listed pacific salmonids.
- NMFS evaluated effects to these species in freshwater, estuarine, marine habitats associated with the use of pesticides in WA, OR, CA, and ID.



Status of the Species

- Contains the Ecological Information Relevant to the Opinion
  - Species life history description
  - Population size, variability, stability
  - Status and distribution
    - Reasons for listing
    - Trends
    - Threats

Chinook (9)

Steelhead (11)

Coho (4)

Sockeye (2)

Chum (2)

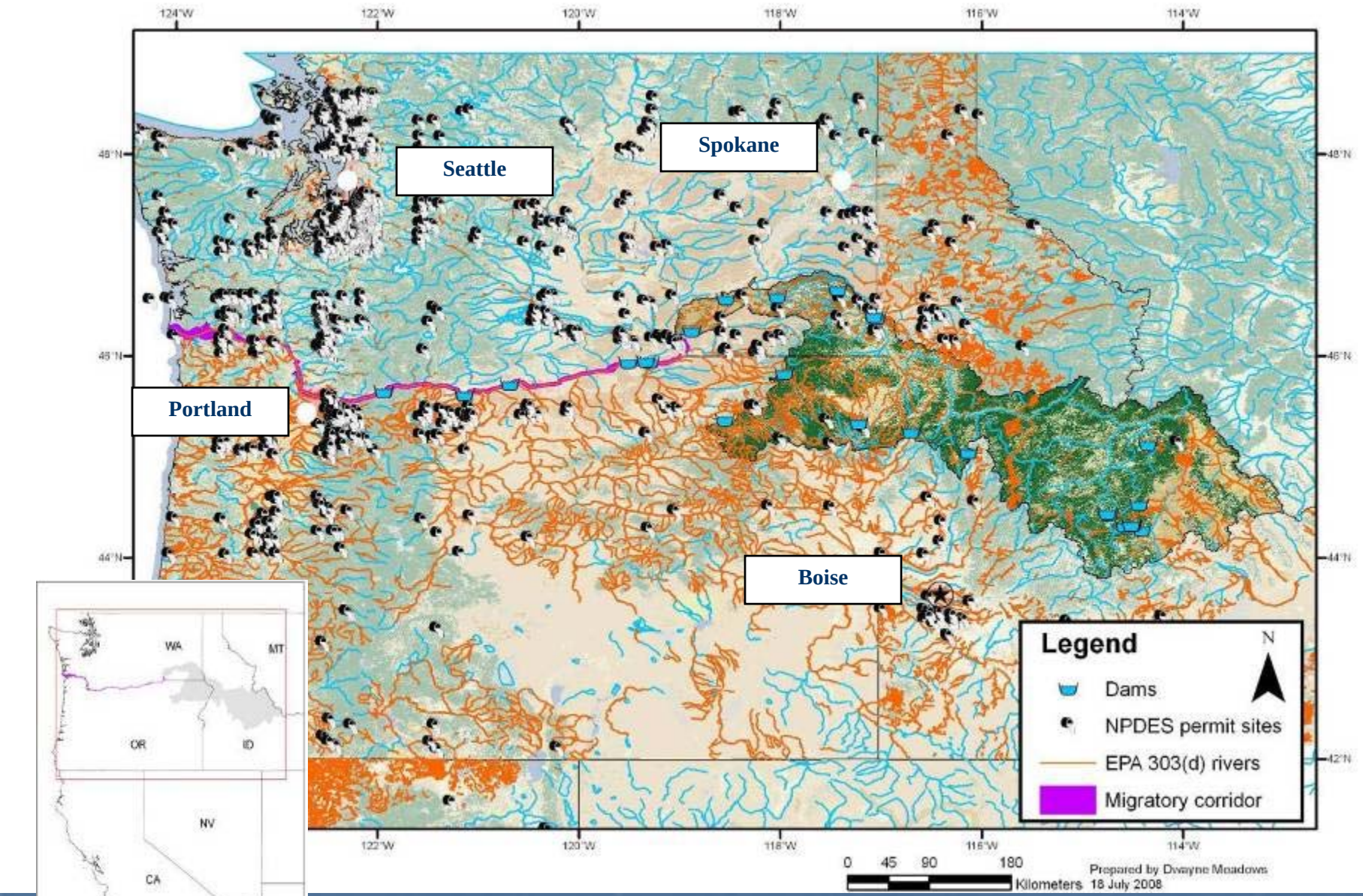
Species	Fresh water residency (yrs)[1]	Spawning Age (yrs)[1]	Evolutionarily Significant Unit	Listing Status	Year listed
Chinook *Oncorhynchus tshawytscha*	Ocean type <1 Stream type 1-2	1-6 2-6			
			Snake River fall-run	T	1992
			Snake River Spring/ Summer-run	T	1992
			Upper Columbia River Spring-run	E	1999
			Puget Sound	T	1999
			Lower Columbia River	T	1999
			Upper Willamette River	T	1999
			California Coastal	T	1999
			Sacramento River Winter-run	E	1994
			Central Valley Spring-run	T	1999
Steelhead *Oncorhynchus mykiss*	<1-3	2-5			
			Snake River	T	1997
			Upper Columbia River	E	1997
			Middle Columbia River	T	1999
			Lower Columbia River	T	1998
			Upper Willamette River	T	1999
			Northern California	T	2000
			Central California Coast	T	1997
			South-Central California	T	1997
			Southern California	E	1997
			California Central Valley	T	1998
Coho *Oncorhynchus kisutch*	1-2	1-3			
			Lower Columbia River	T	2005
			Southern Oregon/ Northern California Coasts	T	1998
			Central California	T	1996
Sockeye *Oncorhynchus nerka*	Lake type <1-3 River type <1-2	1-4 1-4			
			Snake River	E	1991
			Ozette Lake	T	1999
Chum *Oncorhynchus keta*	< 1	1-4			
			Hood Canal Summer-run	T	1999
			Lower Columbia River	T	1999

Species Status

ESU	Historic Abundance	Most recent abundance
Snake River Spring/Summer Chinook	~1.5 million	~9,700
Columbia River Chum	>283,421	756 – 1,129
Central CA Coast Coho	200,000-500,000	6,570
Ozette Lake Sockeye	~50, 000	~3,600
Southern California Steelhead	32,000-46,000	<500

Environmental Baseline

By regulation, environmental baselines for biological opinions include the past and present **impacts of all state, Federal or private actions and other human activities in the action area**, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of state or private actions which are contemporaneous with the consultation in process (50 CFR §402.02).



Snake River Spring/Summer-run Chinook

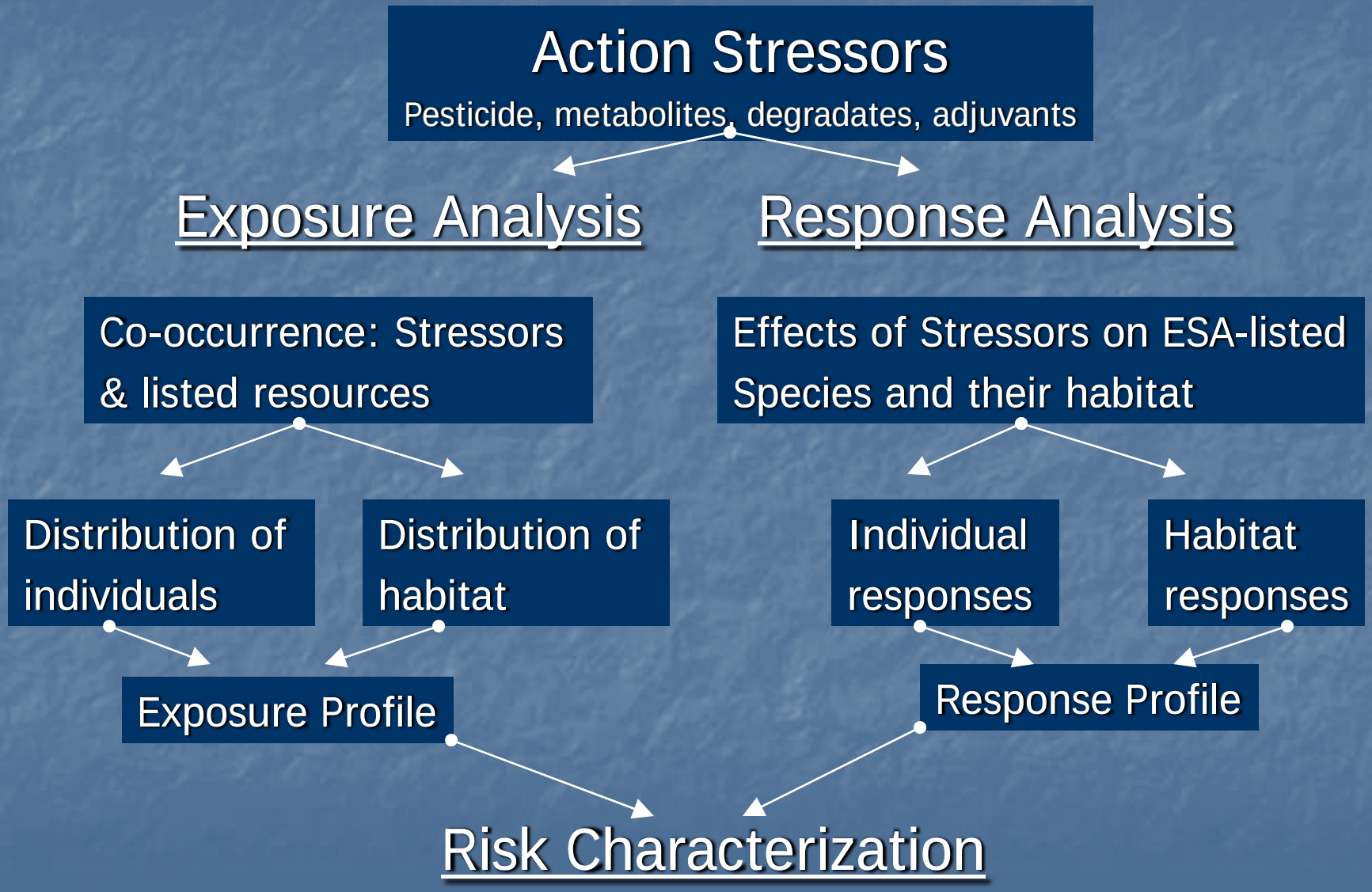
Contaminants detected in baseline habitats of Puget Sound Steelhead

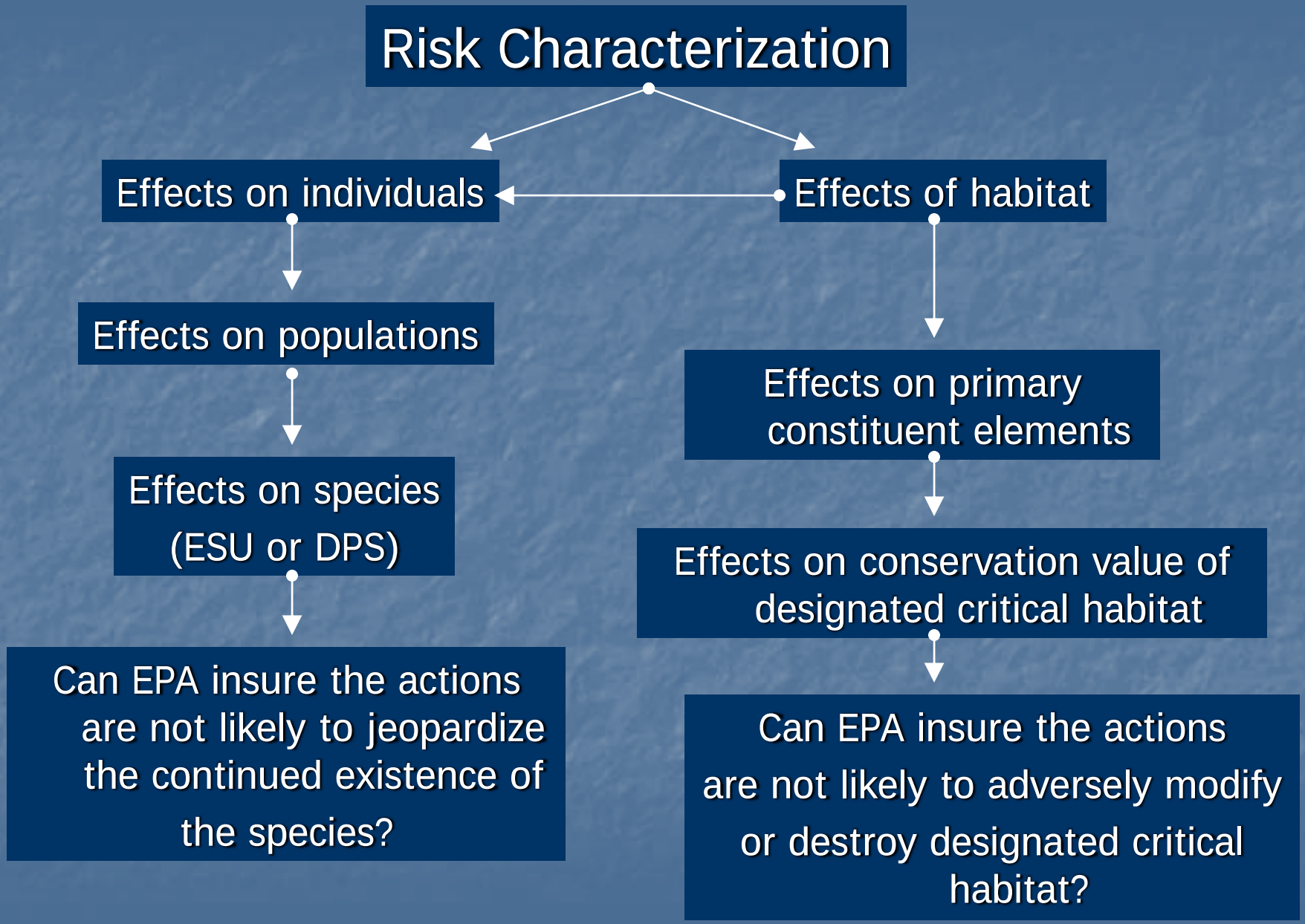
Contaminant groups	Select example(s)	Source and Use Information
Fertilizers	Phosphorus, Nitrogen	lawns, golf courses, urban landscaping
Pesticide ingredients	Chlorpyrifos, Diazinon, Carbaryl, Atrazine, Esfenvalerate, Creosote, DDT, Copper sulfate, Metalaxyl, Nonylphenol	golf courses, right of ways, lawn and plant care products, pilings, bulkheads, fences
Pharmaceuticals, personal care products	Ethinyl estradiol Nonylphenol	municipal and industrial waste discharges
PAHs	Tricylic PAHs	fossil fuel combustion, creosote treated wood
Industrial chemicals	PCBs, PBDEs, Dioxins	utility infrastructure, flame retardants, electronic equipment

Approach to the Assessment

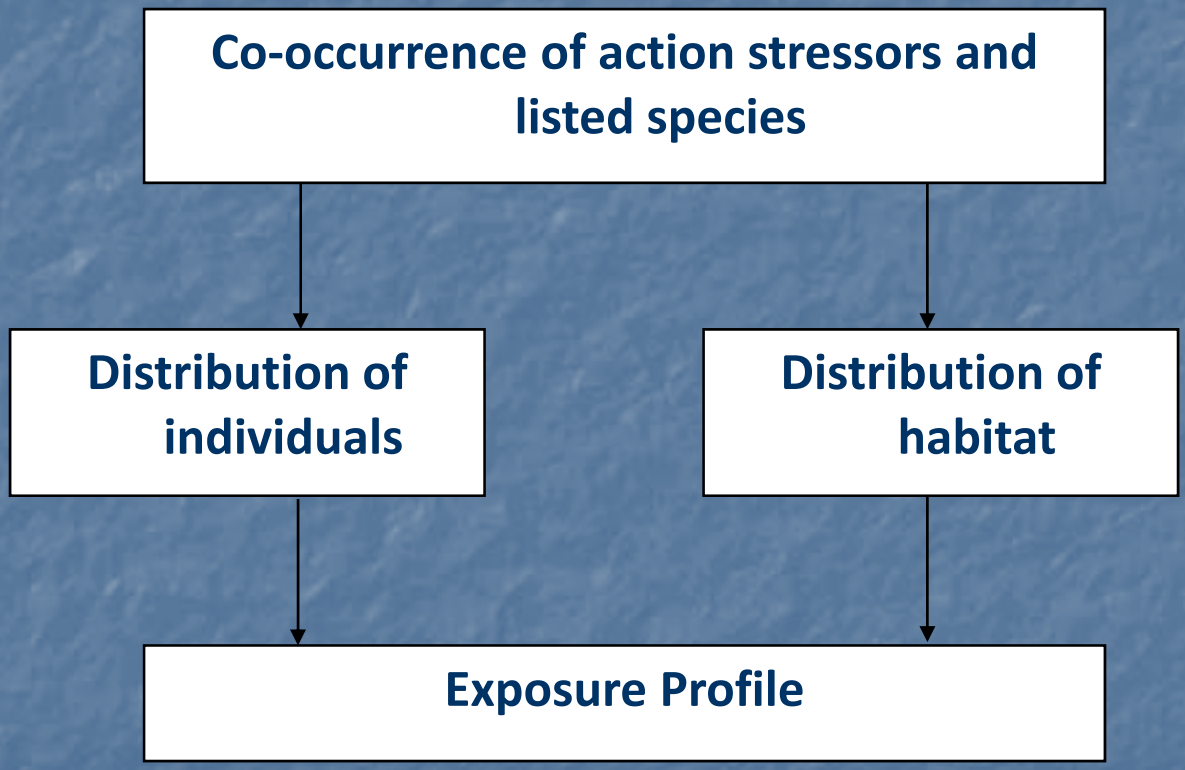
- Identify stressors that may have direct and indirect effects on environment
- Characterize exposure to individuals and designated critical habitat
- Identify risk at the individual level
- Evaluate population level consequences
- Evaluate risk to species (considering effects of action, condition of environmental baseline, status of the species, and cumulative effects)

Risk Framework

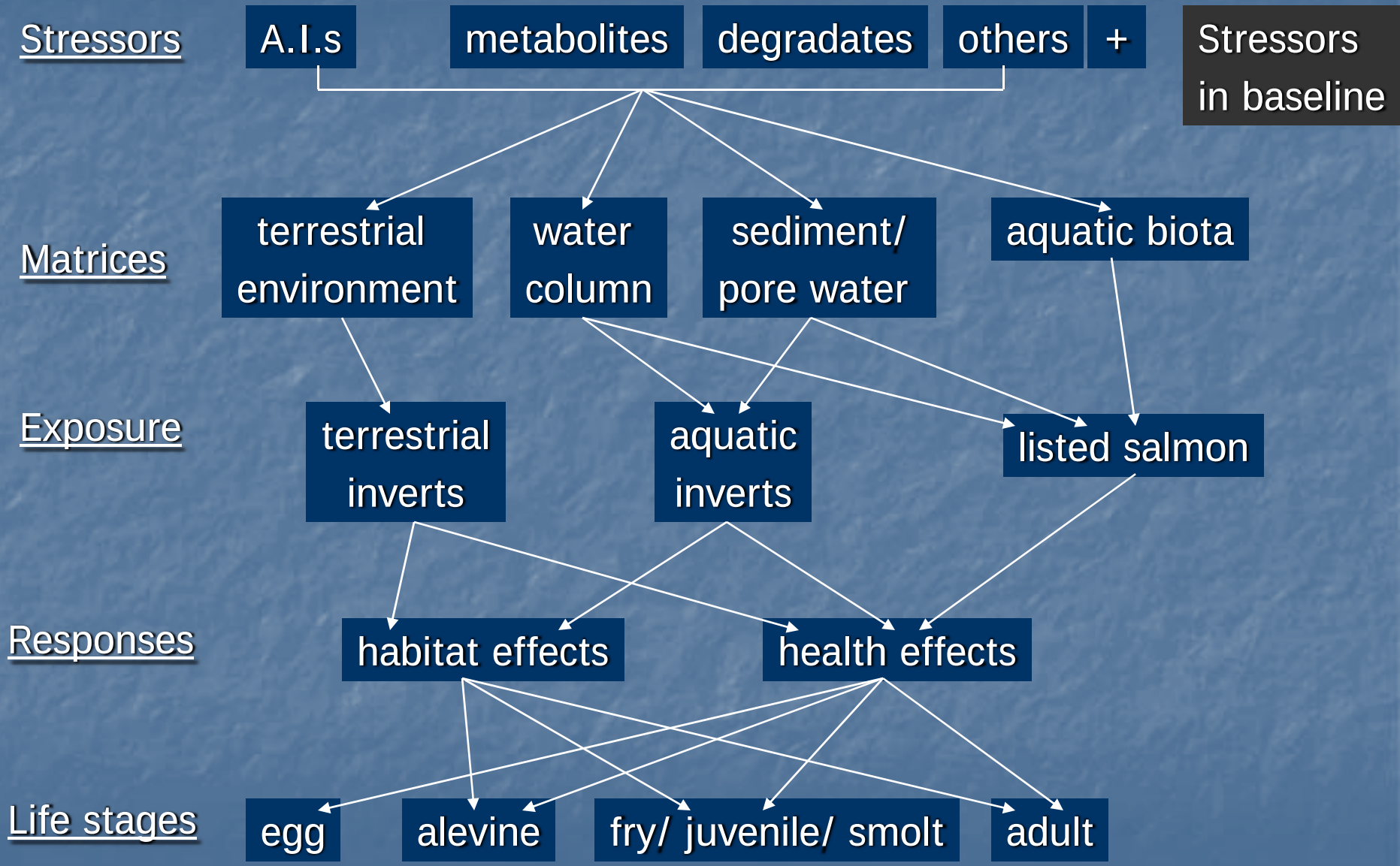



Risk Characterization
Effects on individuals
Effects of habitat
Effects on populations
Effects on species (ESU or DPS)
Can EPA insure the actions are not likely to jeopardize the continued existence of the species?
Effects on primary constituent elements
Effects on conservation value of designated critical habitat
Can EPA insure the actions are not likely to adversely modify or destroy designated critical habitat?

Exposure Analysis



Distribution of Stressors



Distribution of Listed Species (life history considerations)

Species	Spawning	FW Rearing
Chinook (9)	4 distinct runs- spring, fall, summer, winter	Ocean type <1yr Stream type 2 yrs+
Coho (4)	Small coastal tributaries	~ 1.5 years
Chum (2)	Lower reaches of rivers and tributaries	Estuaries & nearshore environments
Sockeye (2)	Lakeshores, inlets/outlets to lakes	intermediate feeding areas along bank, nursery lakes 1-3 yrs
Steelhead (11)	Repeat spawners, in riffle above pools	Variety of habitats, usually 2-3yrs

Product Uses

- Agricultural crops (row crops, orchards)
- Public health (mosquito, fly)
- Indoor and outdoor residential
- Commercially grown ornamentals
- Structural pest control (wood treatments)
- Animal treatments

Exposure Information Evaluated

- EPA estimates of exposure from BE
- NMFS estimates for off-channel habitats and mixtures
- Monitoring data

PRZM-EXAMS Estimates for EPA

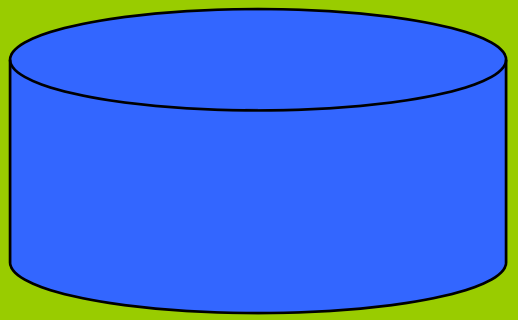
AI	Acute EECs (ppb)	60-day Avg EEC (ppb)
Chlorpyrifos	0.61-9.8	0.17-4.7
Diazinon	8.9-75	6.4-45
Malathion	7.8-77	0.8-13

PRZM-EXAMS

- Characterized as high end screening
- Predictive capability depends on site specific conditions
- Does not represent worst case
  - model inputs
  - 90^{th} percentile output
  - monitoring exceeding modeling predictions

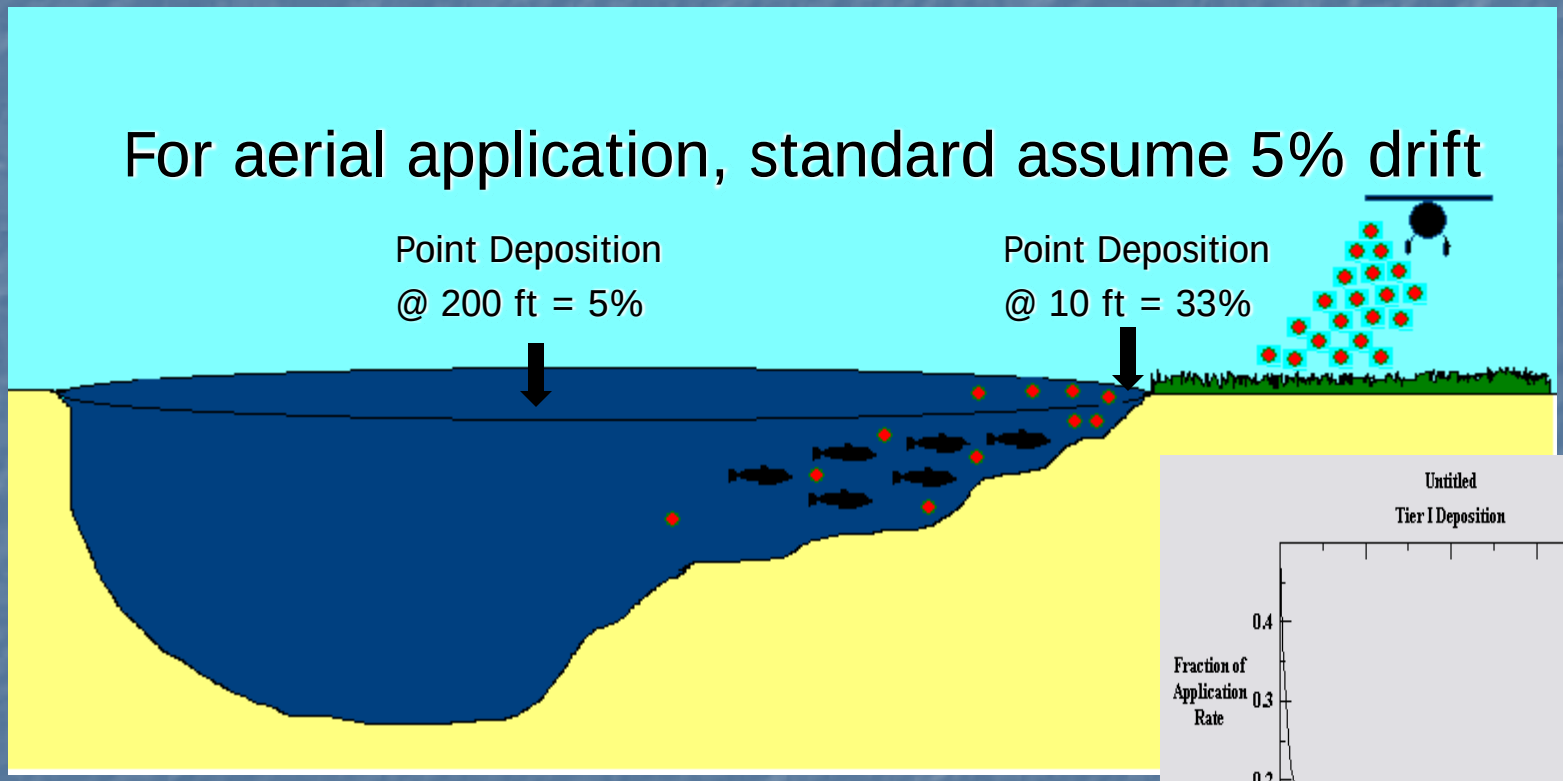
Estimated Concentrations PRZM-EXAMS

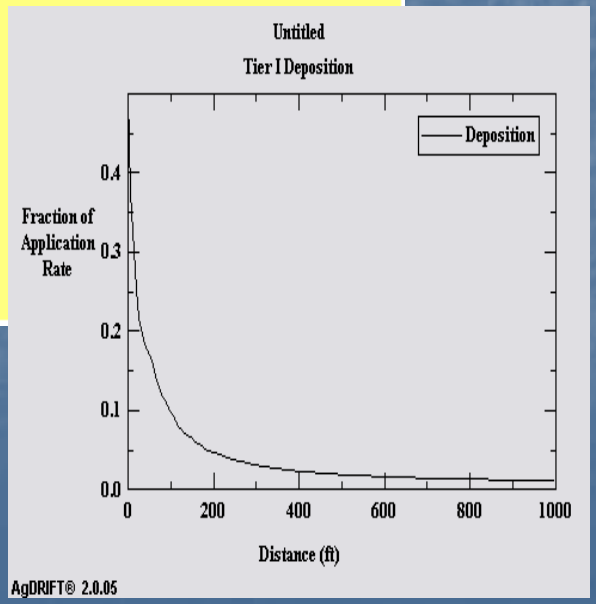
- 10 hectare watershed
- 1 hectare pond, 2 meters deep
- Static system



EPA “Farm Pond”

Assumption of Uniform Distribution





Importance of Off-Channel habitats and small streams

- habitat for rearing, spawning
- 1st yr survival=pop growth
- Restoration focus

- **Essential habitat for small fry/juveniles to rear and seek protection from high velocity flows**

What are off-channel habitats?

- Low flow, shallow environments
- may be susceptible to pesticides
- Occur in floodplains
- Spatially and temporally variable in occurrence, flow, and size.

- Examples of off-channel habitats include intermittent streams, backwaters, braids, oxbows, off-channel ponds, constructed and restored habitats.
- Where they exists, salmonid use is high

Chlorpyrifos label setbacks: What about intermittent streams?

- Permanent water such as rivers, natural ponds, lakes, steams, reservoirs, marshes, estuaries, and commercial ponds

What about water courses that are man made and used by listed species or drain into their habitat?

Off Channel Habitats estimates for direct over-sprays

Active ingredient concentration in surface water from a direct overspray at an application rate of 1 lb a.i./Ac

Water Depth (meters)	A.I. Concentration
2	56 ppb
1	112 ppb
0.5	224 ppb
0.3	374 ppb
0.1	1.1 ppm

AgDrift Estimates for Off Channel

Active ingredient concentration in surface water from application of 1 lb a.i./Ac with ASAE fine-medium droplet distribution, and other EPA defaults.

Water Depth (meters)	Buffer (setback) to aquatic habitat in feet	A.I. Concentration ppb
1	0	34
1	150	6
0.5	0	67
0.5	150	13
0.1	0	333
0.1	150	64

Pesticide Mixtures

- Two or more pesticides are detected in agricultural, urban, and mixed use watersheds more than 90% of the time*
- Monitoring in urban streams across U.S.**
  - Two or more herbicides in 85% samples
  - Two or more insecticides in 54% samples
  - Four or more herbicides were detected in 61% of the water samples.
- Monitoring by WSDA in listed salmonid habitats***
  - urban sites: Averaged 3 pesticides/sample, found up to 9 pesticides in a single sample.
  - Agricultural sites: Averaged 3-5 pesticides/sample, found up to 14 pesticides in a single sample.

Source:

*Gilliom et al. 2006. Pesticides in the nations streams and groundwater, 1991-2001. NAWQA Program Circular 1291. Unites States Geological Service.

**Hoffman et al. 2000. Environmental Toxicology and Chemistry 19:2249-2258.

***Burke et al. 2006. Surface water monitoring program for pesticides in salmonid-bearing streams, 2003-2005. WSDOE. Publication no. 06-03-036.

Pesticides commonly occur as mixtures in fish habitats

Greater than 80% of urban streams contain three or more pesticides.
(Hoffman et al., 2000, *Environ. Toxicol. Chem*. 19, 2249-2258)

More than 90% of urban, agricultural, and mixed-use streams contain 2 or more pesticides.
(Gilliom et al., 2006, *USGS Circular 1291*)

Frequency of Insecticide Detections in Surface Water

NAWQA Study Area	Diazinon	Malathion	Chlorpyrifos	Carbaryl	Carbofuran
Puget Sound	48%	D	3%	D	D
Central Columbia	4%	2%	9%	6%	5%
Yakima River	18%	D	D	90%	ND
Willamette	35%	5%	21%	18%	29%
Sacramento River	75%	33%	38%	60%	36%
San Joaquin-Tulare	71%	8%	52%	25%	5%

D= detected, frequency not reported
ND=not detected

Data from U.S. Geological Survey NAWQA Circulars 1237, 1159, 1161, 1216, 1144 and 1215

GENEEC Mixture Estimates

90-day average concentrations of chlorpyrifos, diazinon, and malathion assuming label specifications for ground applications in onions (63719-220, 5905-248, 9779-5).

Use	Rate Lbs ai / A	Apps.	Interval Days	Buffer	90-d avg ppb
Chlorpyrifos Foliar	1	2	7	25	6.77
Diazinon In-furrow	4	1	Na	0	39.37
Malathion foliar	1.25	7	14	0	4.11

Monitoring Data Considered

- NAWQA national surface water monitoring, and subset from CA (EPA's BEs)
- NMFS queries on NAWQA monitoring data streams sampled in CA, ID, OR, WA (1992-2006)
- NMFS queries of CDPR surface water database

Monitoring Data Considered (continued)

- Published studies
  - diazinon runoff, CA(Werner et al 2002, Werner et al 2004)
  - diazinon and chlorpyrifos in surface waters of northern California (Bailey 2000).
- CDPR report -chlorpyrifos and diazinon in lower Salinas Valley, CA (Kozlowski et al. 2004)
- WSDA monitoring reports 2003-2006

Monitoring Data Considered (continued)

- Reports on large scale spray operations
  - APHIS grasshopper control
  - Medfly eradication programs
  - Boll weevil eradication programs
  - Mosquito spray operations

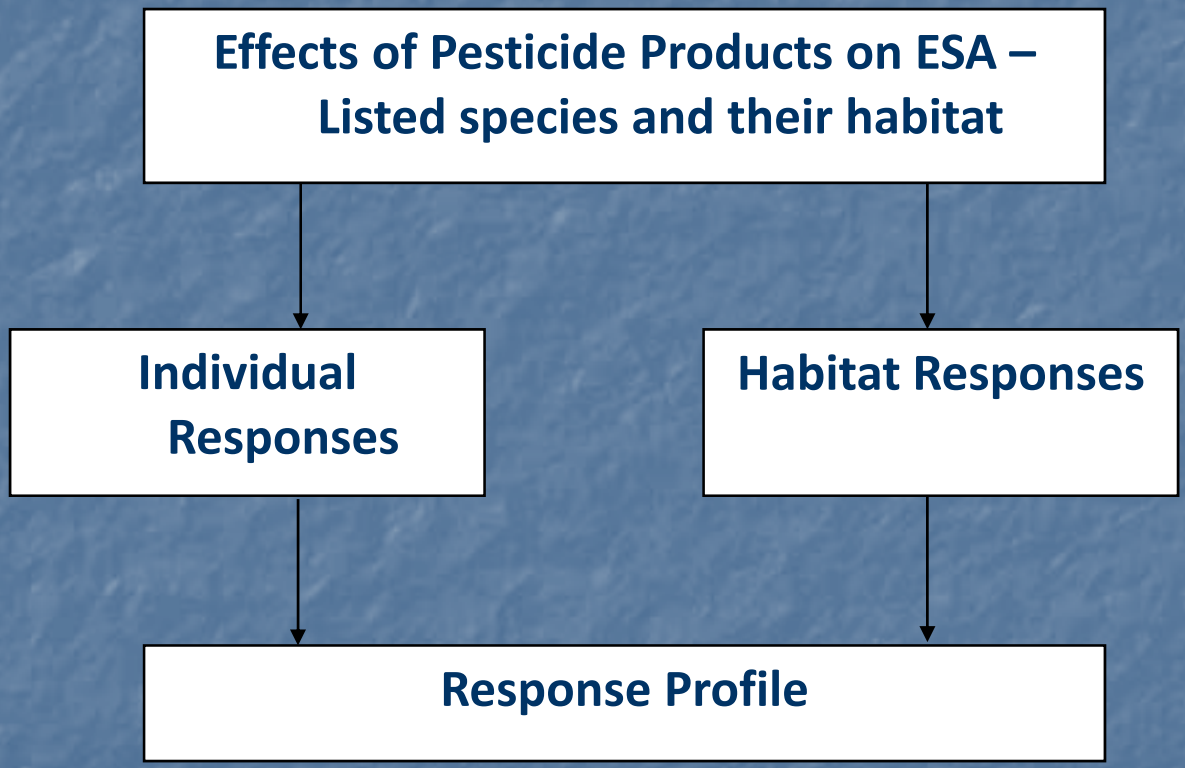
Exposure to other action stressors

- Other ingredients not identified
  - 1000's of potential "inerts"
  - Some are toxic to aquatic species (NP/ethoxylates)
- Authorized tank mixtures not defined
- Uncertainty regarding these exposure and risk is factored into the final conclusion

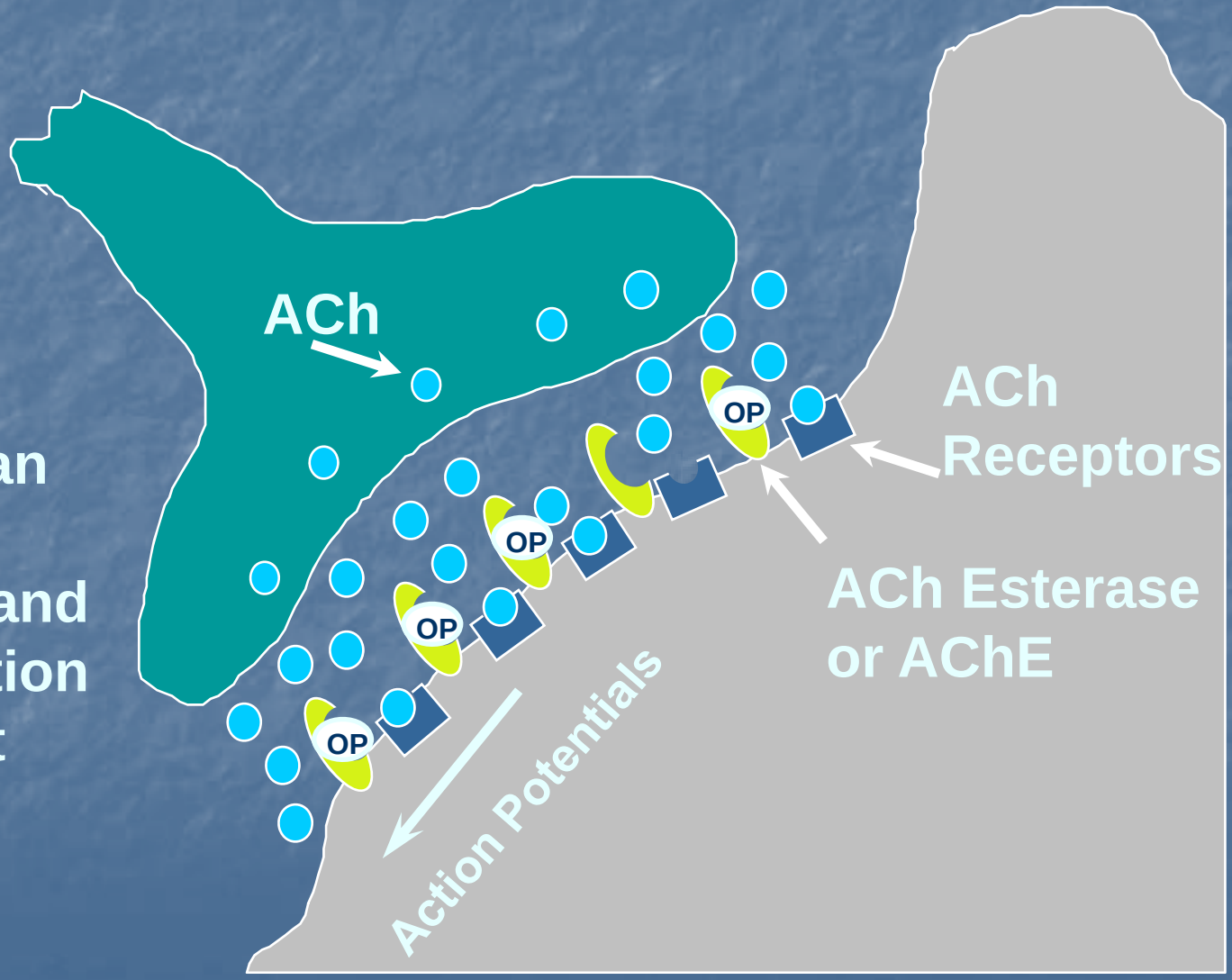
Exposure conclusions

- We expect exposure to occur in all ESUs given the species distribution and widespread use of these chemicals.
- Modeling and monitoring data represent the range of likely exposure to a.i.'s.
- There is not adequate information available to define likely exposure distributions for the active ingredients or the other action stressors.

Response Analysis

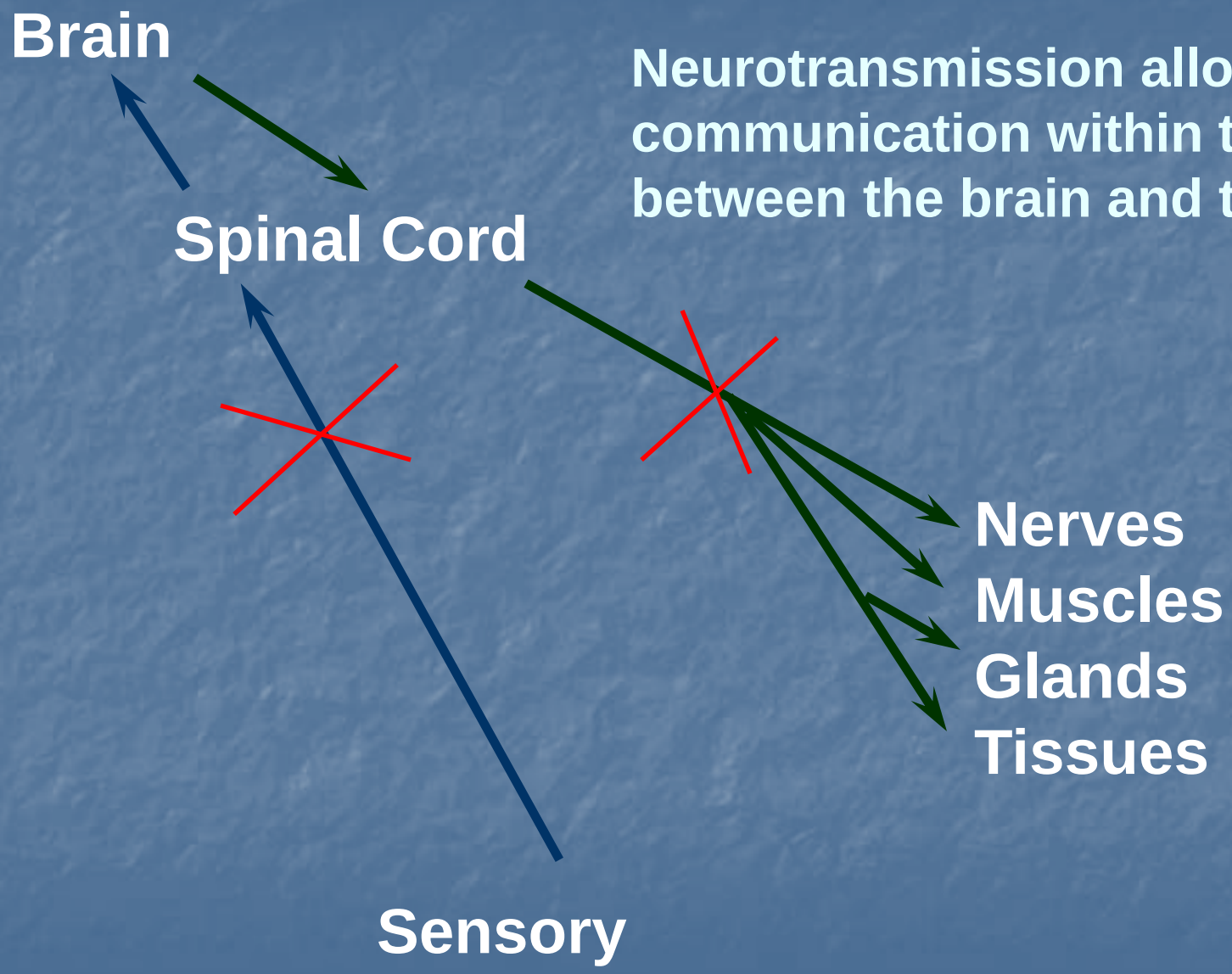


Inhibition of AChE allows the accumulation of large amounts of ACh in the synapse.



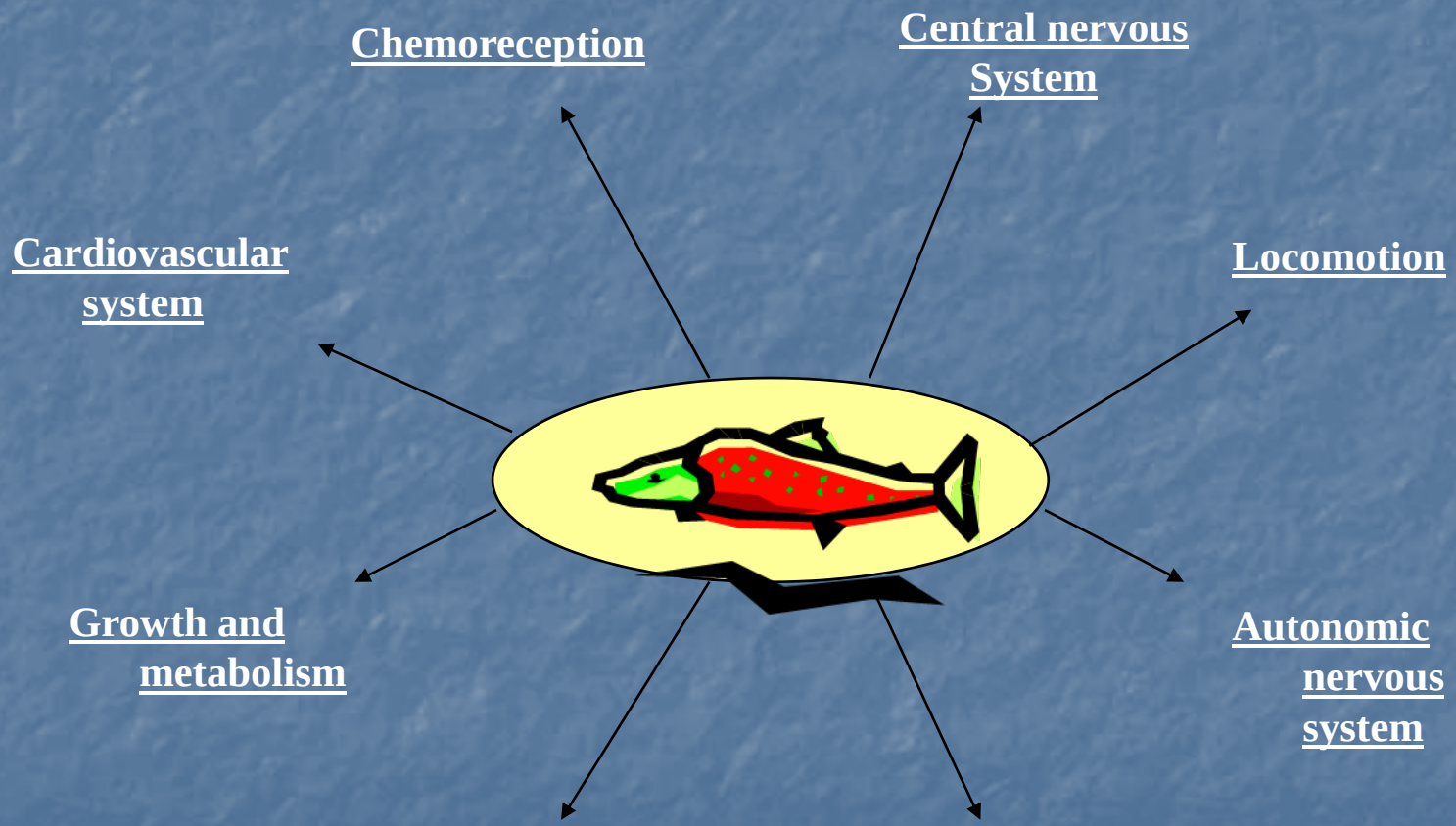
High ACh can cause high firing rates and desensitization of the target tissue.

How Does the Nervous System Work?



Neurotransmission allows communication within the brain, between the brain and the body.

Physiological systems potentially affected by cholinesterase inhibition



Developed Risk Hypotheses based on available data

-Information on active ingredients:

- Salmonid lethality from acute exposure.
- Salmonid behavioral impacts (swimming, migration, spawning, predator avoidance).
- Reduction of salmonid prey.
- Impacts on salmonid growth and reproduction.
- Mixtures cause additive and synergistic responses.

-Other action stressors cause adverse effects

-Baseline stressors contribute to increased responses (temperature, other OPs/CBs)

Summarized Effects Data

- Summarized effects data from EPA's biological evaluations and open literature.
- Discussed the relevancy of the effect to our assessment endpoints (growth, survival, etc.)
- Scored the degree of confidence we had in the observed effect
  - Direct measurement of assessment endpoint
  - Appropriate surrogate for listed species
  - Well-conducted study

Chlorpyrifos

Assessment Endpoint	Concentration ranges of observed effect (ug/L)	Degree of confidence in effects
Salmonid		
Survival	0.8-2200	High
Growth	0.12-4.8	High
Reproduction	1.09-1.21	High
Swimming	0.3-40	High
Olfactory behaviors	0.625-2.5	High
Habitat		
Prey survival	0.05-600	High

Diazinon

Assessment Endpoint	Concentration ranges of observed effect (ug/L)	Degree of confidence in effects
Salmonid		
Survival	90-7800	High
Growth	0.8	High
Reproduction	0.35-3.2	High
Swimming	500	High
Olfactory behaviors	0.1-1.0	Medium
Habitat		
Prey survival	0.03-2500	High

Malathion

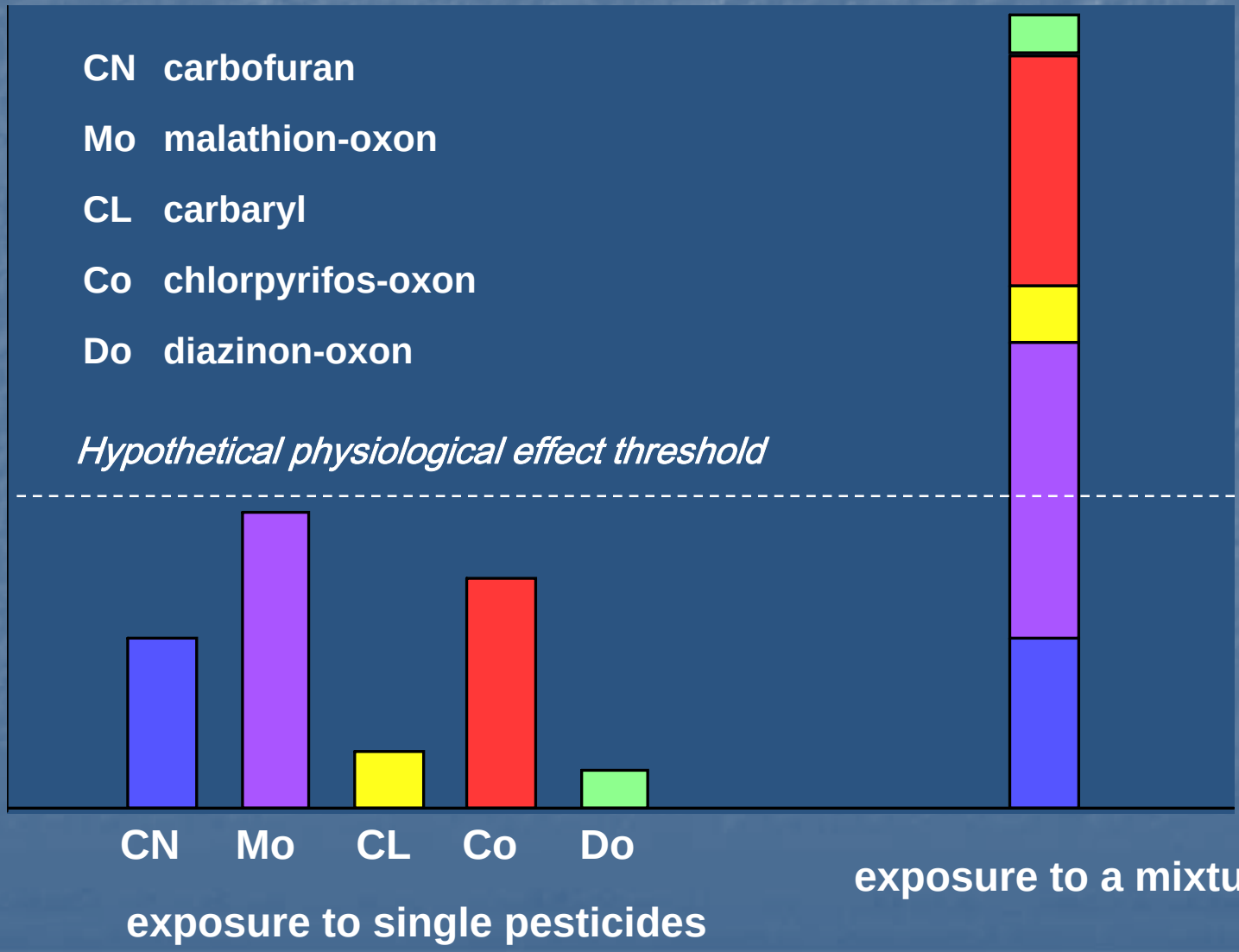
Assessment Endpoint	Concentration ranges of observed effect (ug/L)	Degree of confidence in effects
Salmonid		
Survival	4.1-174	High
Growth	NS	Low
Reproduction	NS	Low
Swimming	40-175	High
Olfactory behaviors	-	-
Habitat		
Prey survival	0.5-100	High

Nonylphenol

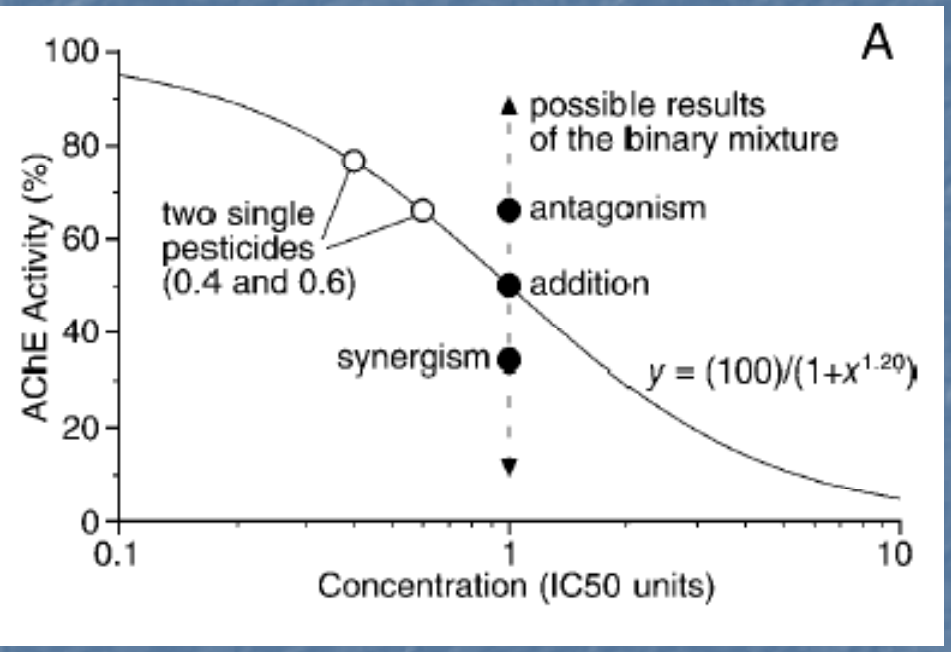
Assessment Endpoint	Concentration ranges of observed effect (ug/L)	Degree of confidence in effects
Salmonid		
Survival	130->1000	High
Reproduction	0.15-10	High
Smoltification	5-100	Medium
Endocrine disruption	5.0-100	High
Habitat		
Prey survival	1->1000	High

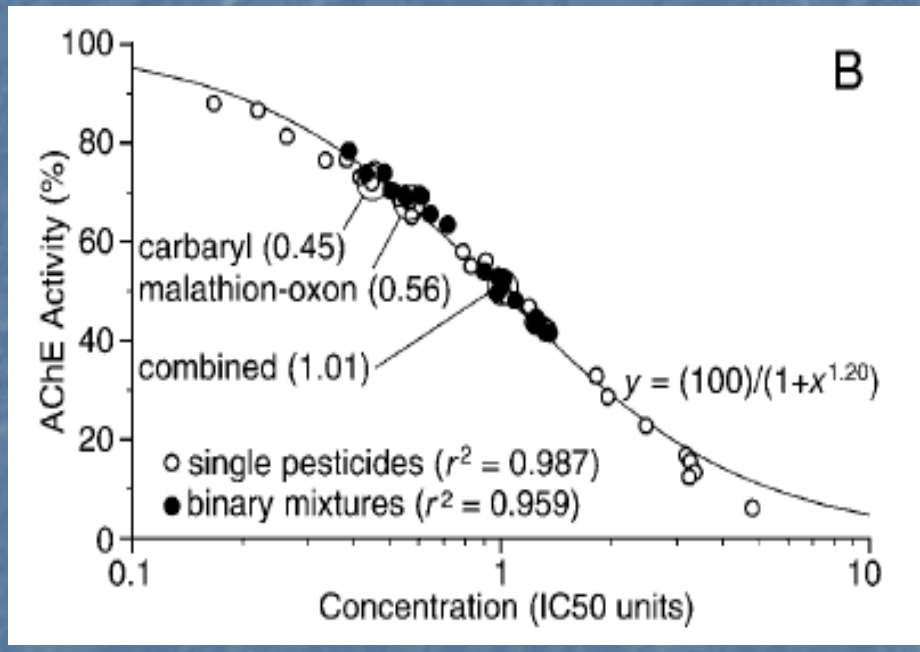
Organophosphorus Insecticide Mixtures

Potential Toxicity of Pesticides With a Similar Mode of Action



Binary combinations of organophosphates and carbamates produce additive inhibition of Chinook salmon cholinesterase





Scholz et al. 2006. Dose-additive inhibition of Chinook salmon acetylcholinesterase activity by mixture of organophosphate and carbamate insecticides. Environ. Toxicol. Chem. 25 (5): 1200-1207.

New research with coho salmon show that binary combinations of AChE-inhibitors are even more toxic when administered in vivo

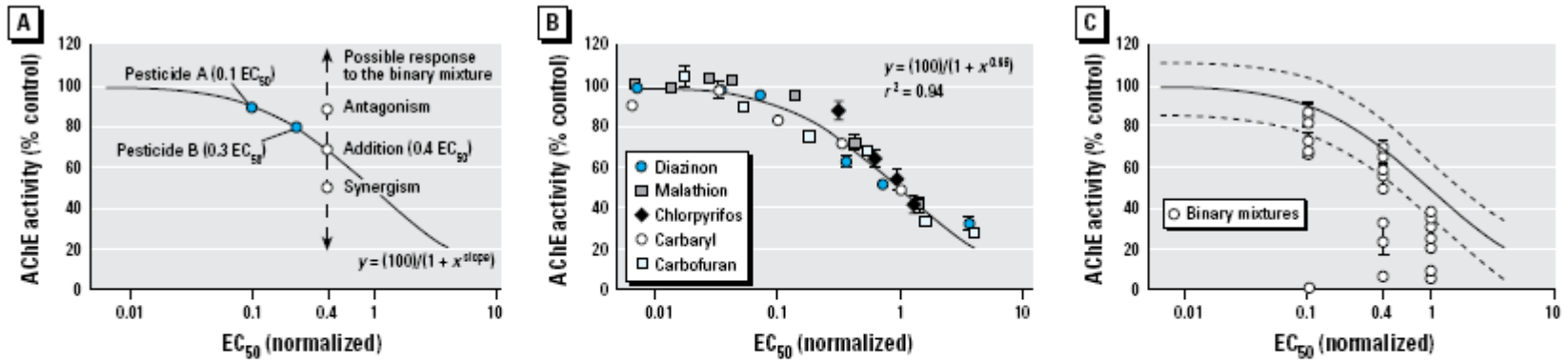
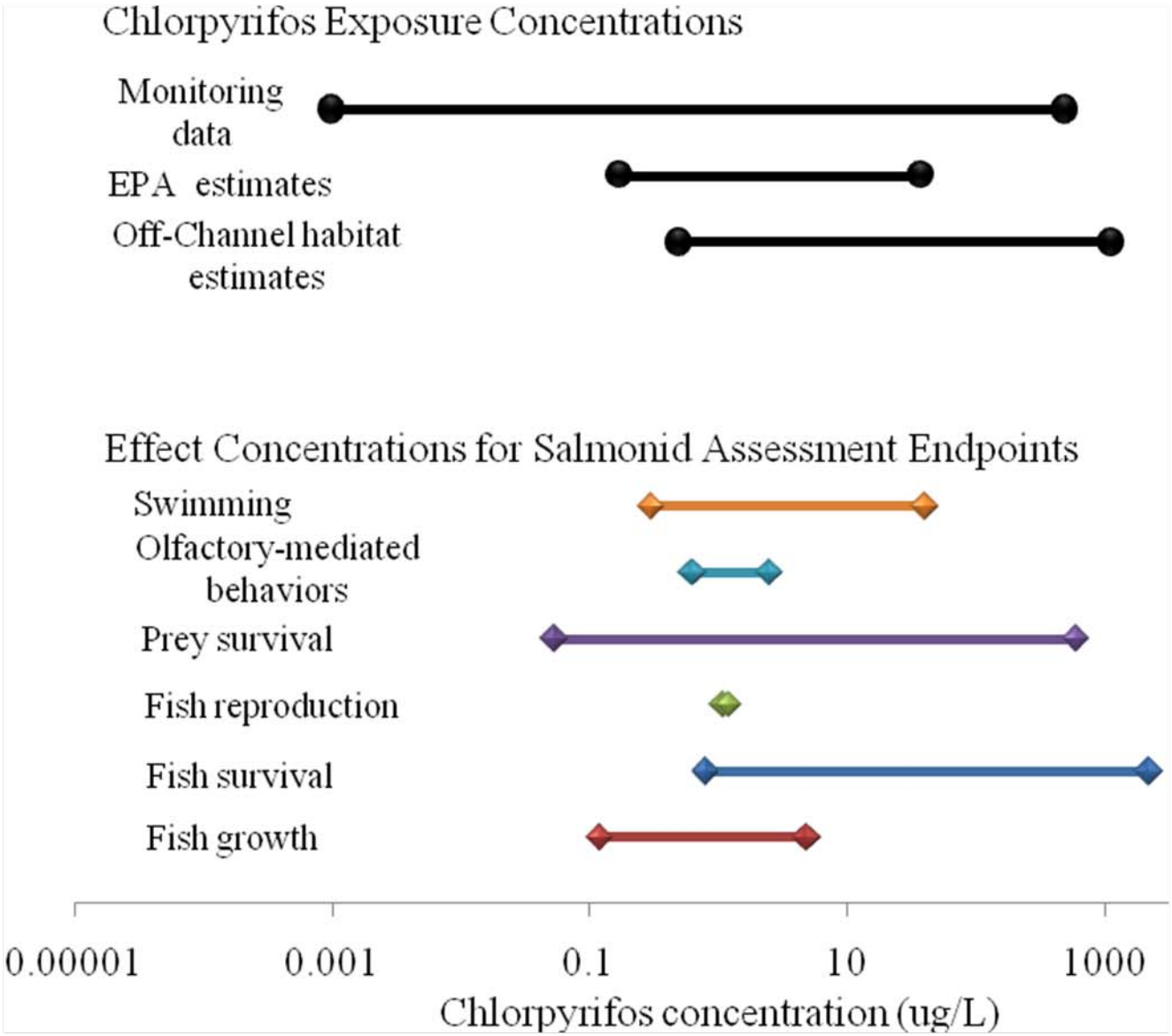
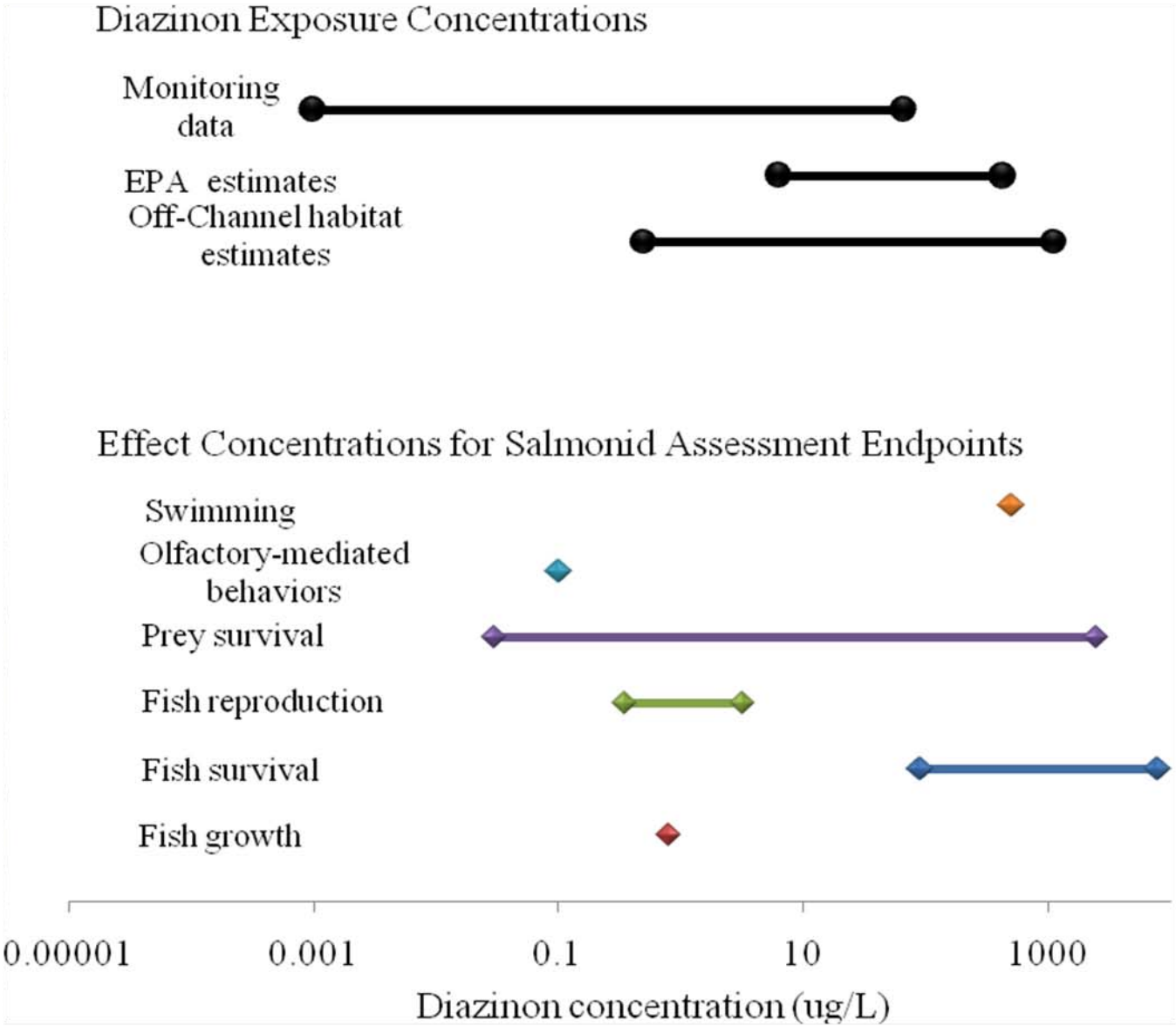
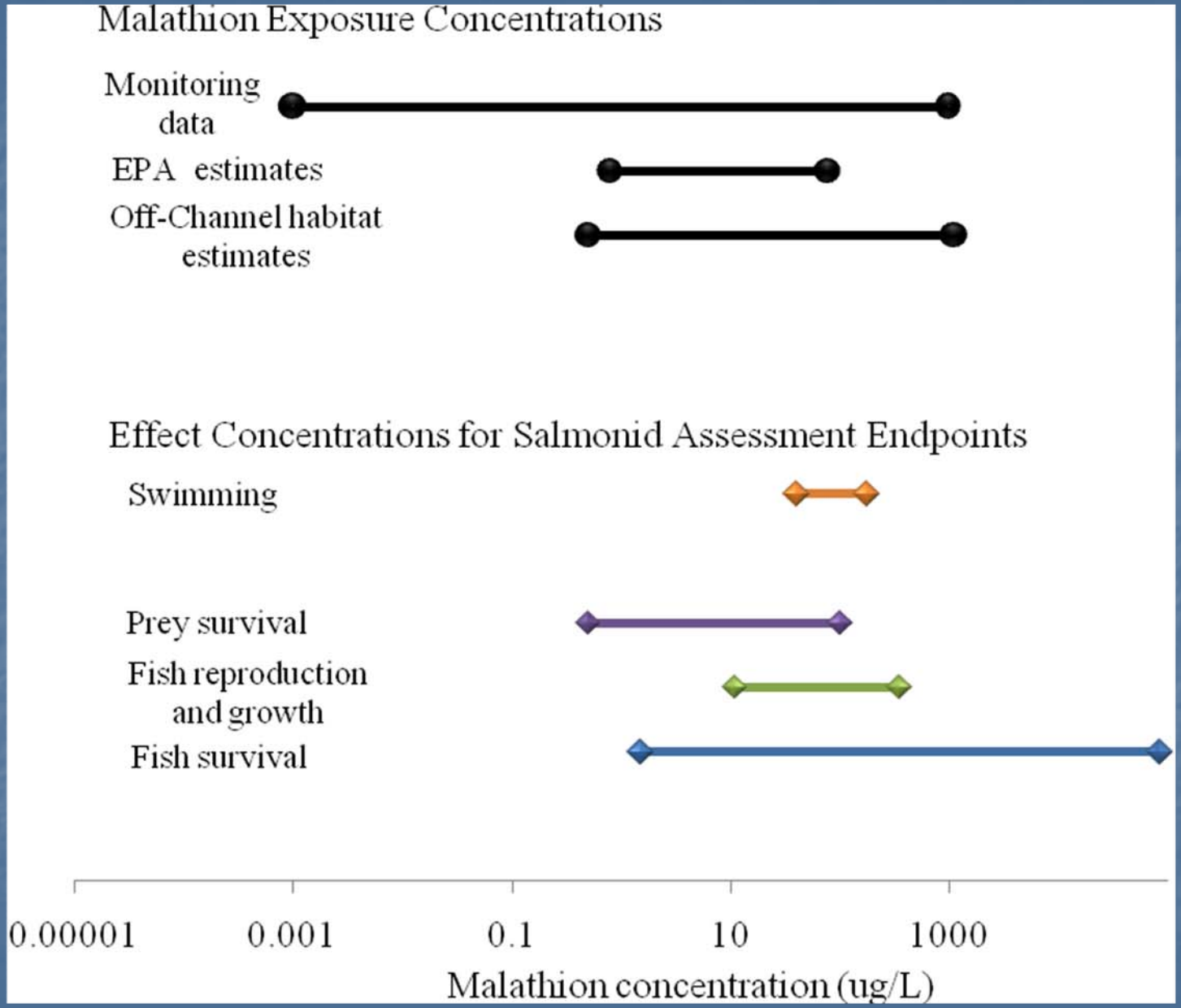


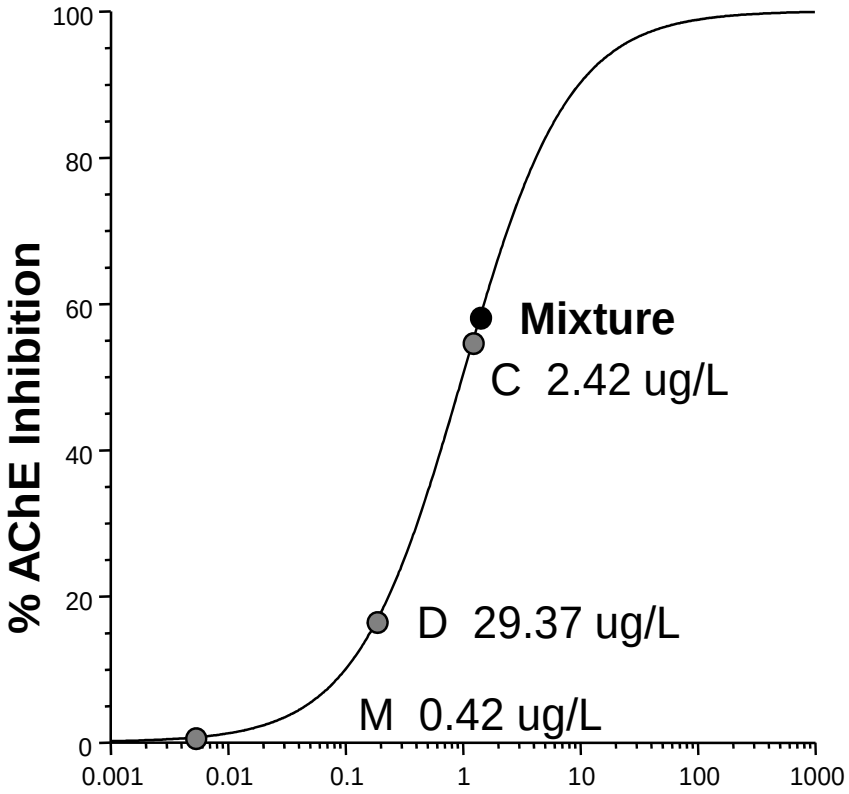
Figure 2. Binary pesticide mixtures cause additive or synergistic AChE inhibition. (*A*) Hypothetical plot describing the three possible toxicologic responses after exposure to a binary mixture of anticholinesterase pesticides. The curve represents a single regression fit to the EC_{50}-normalized data from single pesticide exposures. (*B*) Plot of the concentration–response data from five single pesticide exposures after normalization to their respective EC_{50} concentrations and collectively fitting with a nonlinear regression. This curve was used to evaluate the toxicologic response of subsequent binary mixtures (*C*). Values are mean ± 1 SE ($n = 8$). (*C*) Plot of the brain AChE activities of fish exposed to the five pesticides in all possible binary combinations. Based on a default assumption of concentration addition, the pairings were predicted to yield AChE inhibitions of 10% (0.1 EC_{50}), 29% (0.4 EC_{50}), and 50% (1.0 EC_{50}). Values are mean and SE ($n = 8$); dashed lines indicate the 95% prediction band (where 95% of the data should fall based on the regression).

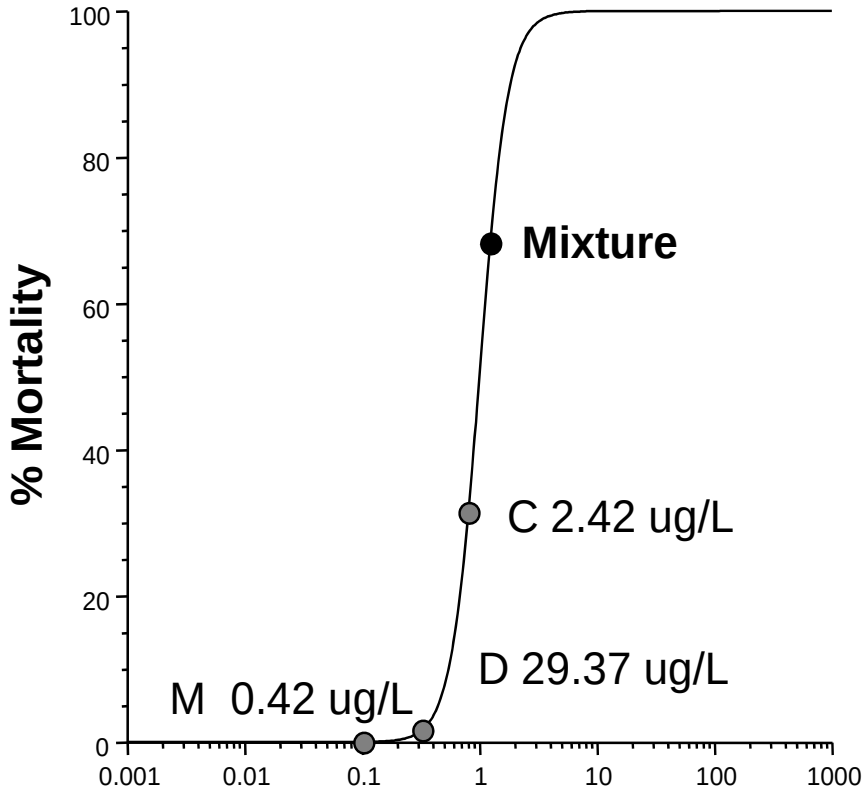
Laetz et al. 2009. The synergistic toxicity of pesticide mixtures: Implications for risk assessment and The conservation of endangered Pacific salmon. Environ. Health Perspectives 111(3):348-353.


Chlorpyrifos Exposure Concentrations
Monitoring data
EPA estimates
Off-Channel habitat estimates
Effect Concentrations for Salmonid Assessment Endpoints
Swimming
Olfactory-mediated behaviors
Prey survival
Fish reproduction
Fish survival
Fish growth
0.00001
0.001
0.1
10
1000
Chlorpyrifos concentration (ug/L)


Diazinon Exposure Concentrations
Monitoring data
EPA estimates
Off-Channel habitat estimates
Effect Concentrations for Salmonid Assessment Endpoints
Swimming
Olfactory-mediated behaviors
Prey survival
Fish reproduction
Fish survival
Fish growth
0.00001
0.001
0.1
10
1000
Diazinon concentration (ug/L)


Malathion Exposure Concentrations
Monitoring data
EPA estimates
Off-Channel habitat estimates
Effect Concentrations for Salmonid Assessment Endpoints
Swimming
Prey survival
Fish reproduction and growth
Fish survival
0.00001
0.001
0.1
10
1000
Malathion concentration (ug/L)



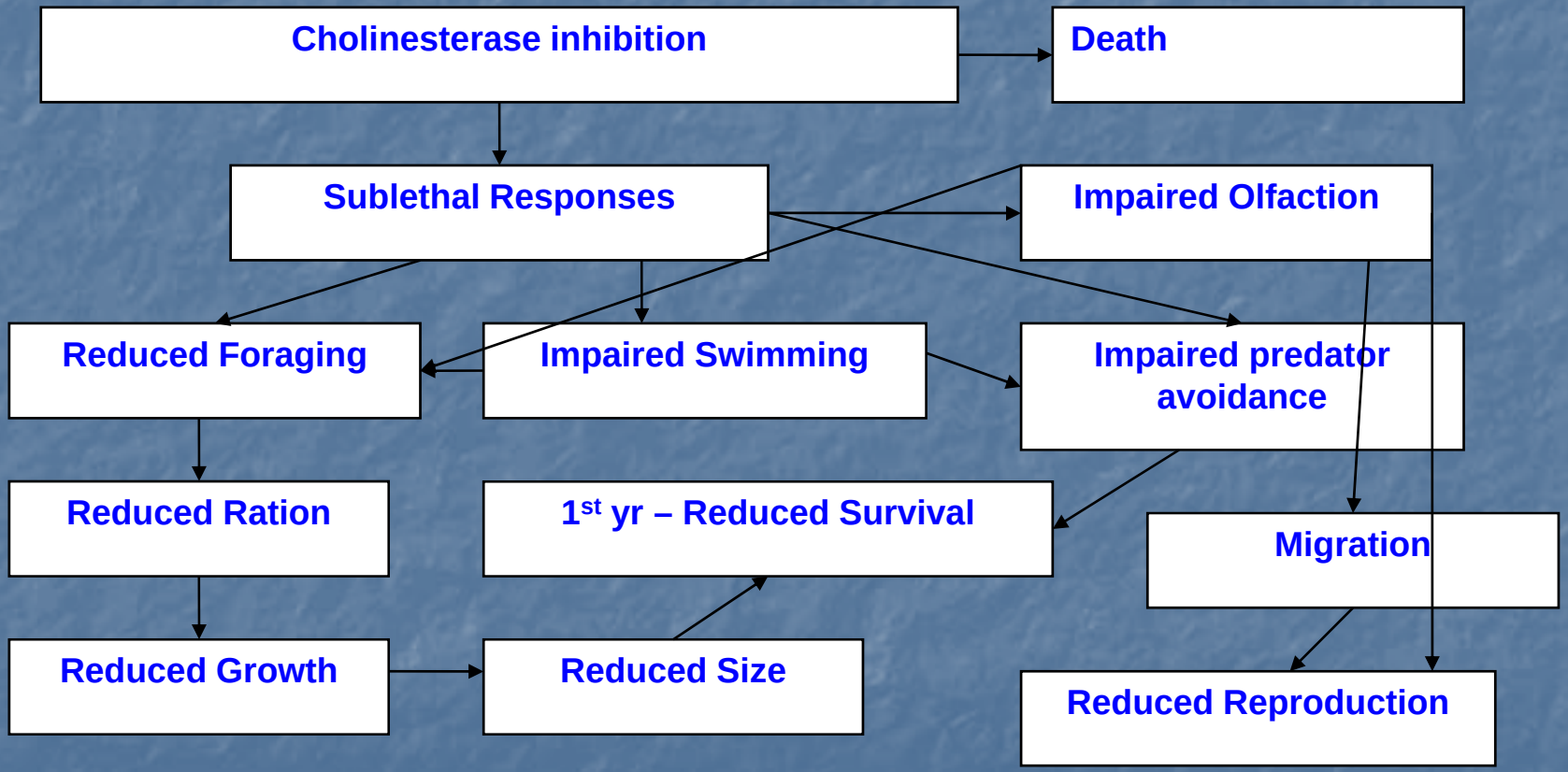


*Mixture concentrations from peak CDPR monitoring

Dose Addition: Percent AChE inhibition and percent mortality expected from mixtures of chlorpyrifos, diazinon, and malathion

Source	Concentration chlor, diaz, mal (ug/L)	%AChE Inhibition	% Mortality
PRZM-EXAMS Simulations 60-day average concentration Application rates 1 – 1.29 lbs/A	0.84, 6.4, 3.9	58.12	68.3
GENEEC Simulations for onion 90-day average concentrations 1 – 4 lbs/A	6.77, 39.37, 4.11	77.84	99.14
NAWQA monitoring maximum values in 4 states	0.40, 3.8, 1.35	20.42	7.74
CDPR monitoring maximum values in California	2.42, 29.37, 0.42	58.12	68.30
Lower Salinas monitoring Maximum values	5.79 (chlor) 67.24 (diaz)	76.05	97.27
Lower Salinas monitoring Mean values	0.36 (chlor) 21.61 (diaz)	24.82	2.36

Individual Consequences of Exposure to AChE inhibitors

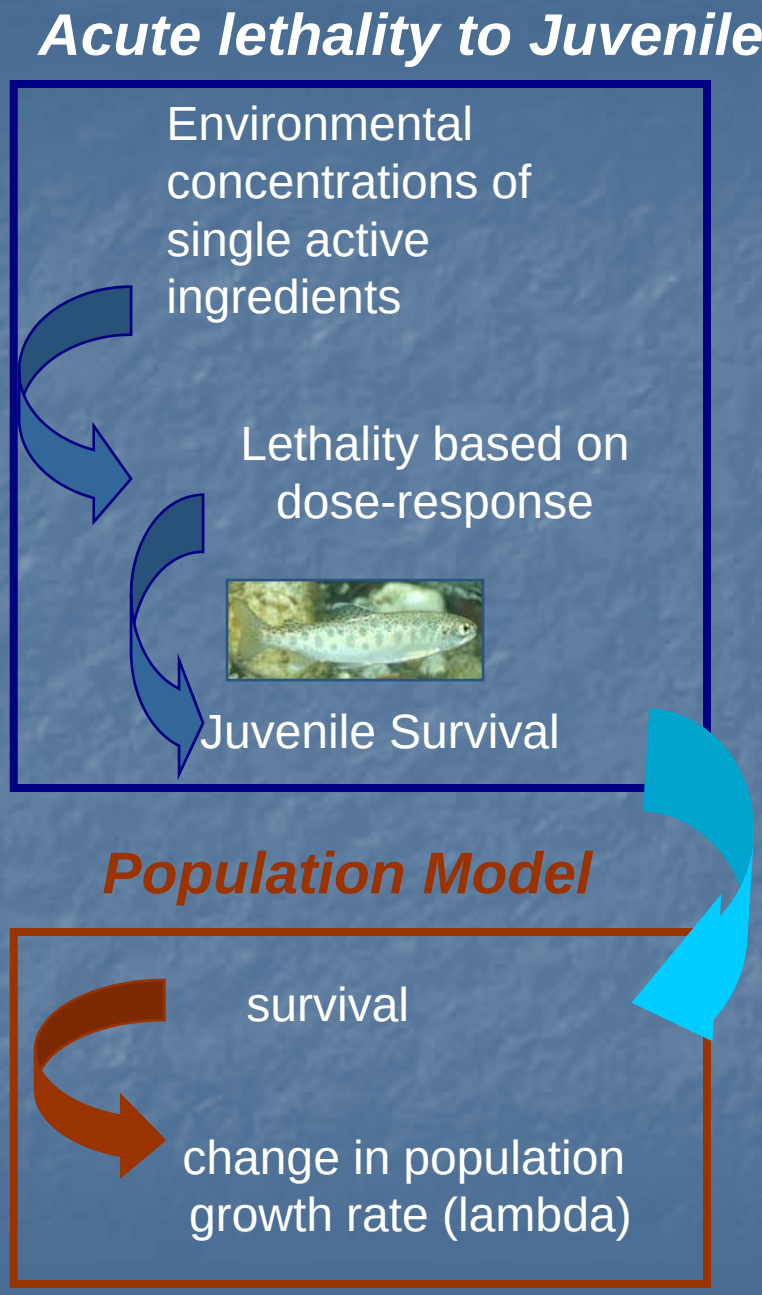


Linking the available Information:

- Acute lethality (LC50)
- Slope
- Juvenile survival
- Population growth rate

Not Incorporated:

- Sublethal responses
- Indirect effects
- Mixture toxicity
- Other ingredients
- Baseline stressors



Characteristics of model evaluating lethality response

- 4 generalized life history strategies modeled based on life-history parameters
  - Ocean-type Chinook
  - Stream-type Chinook
  - Coho
  - Sockeye
- S1 age-class is the only one directly affected

Population projections from juvenile death

	Decrease in Lambda from 4 day exposure					
Life History	Chlorpyrifos		Diazinon		Malathion	
	ug/L	% change	ug/L	% change	ug/L	% change
Ocean type Chinook	1.8 – 3	4 - 18*	50-75	3 - 12*	2-3	1 - 8*
Stream type Chinook	1 - 1.8	1 - 4*	10-50	0 - 3*	2-3	2 - 7*
Coho	1 - 1.8	1 - 5*	50-75	4 - 13*	2-3	2 - 9*
Sockeye	1.8 – 3	3 - 15*	50-75	3 - 9*	2-3	2 - 6*

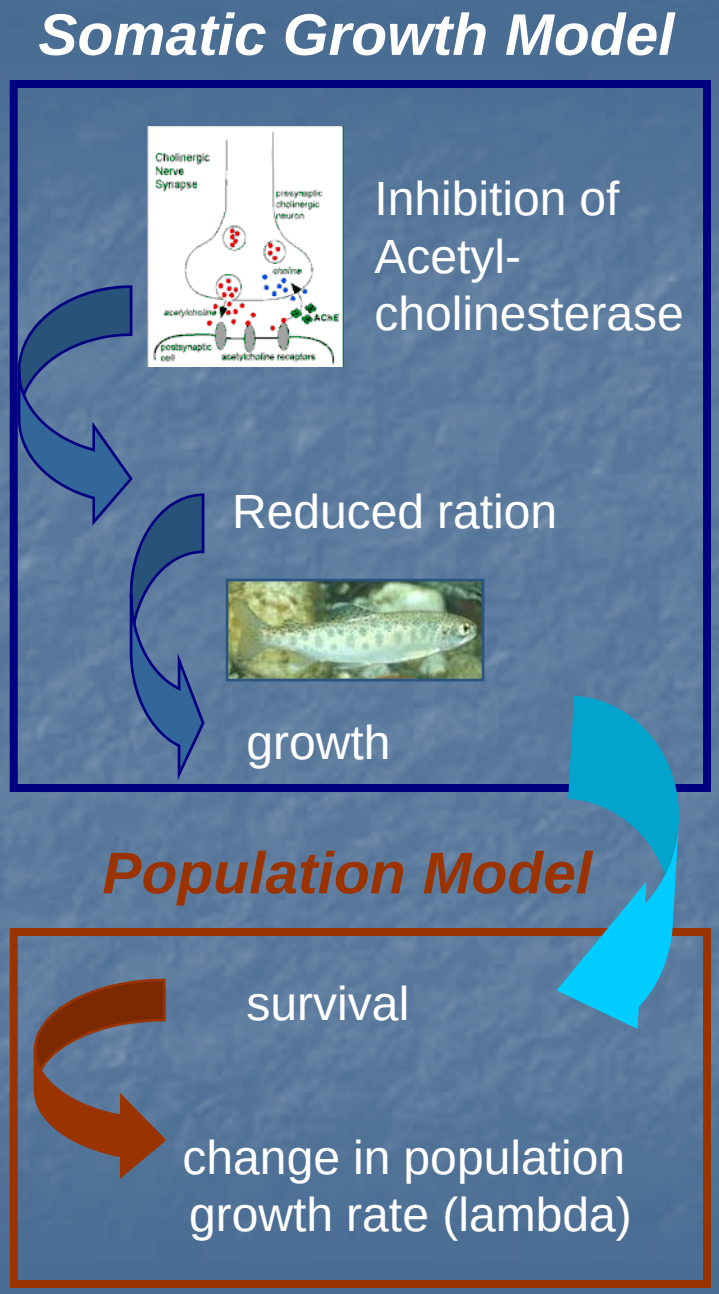
*Percent change in lambda > 1 standard deviation from unexposed population

Linking the available Information:

- Reduced prey
- Enzymatic inhibition
- Reduced foraging
- Reduced size
- Juvenile survival
- Population growth rate

Not incorporated:

- Lethality to fish
- Mixture toxicity
- Other ingredients
- Baseline stressors



Slide: D. Baldwin

Characteristics of model evaluating growth response

- 4 generalized life history strategies modeled based on life-history parameters.
- Prey reductions based on field and laboratory lethality to salmonid prey.
- Assumed prey reduction would not go below 20%.
- Prey abundance recovery $t_{1/2}$ = 30 day.

Characteristics of model evaluating growth response

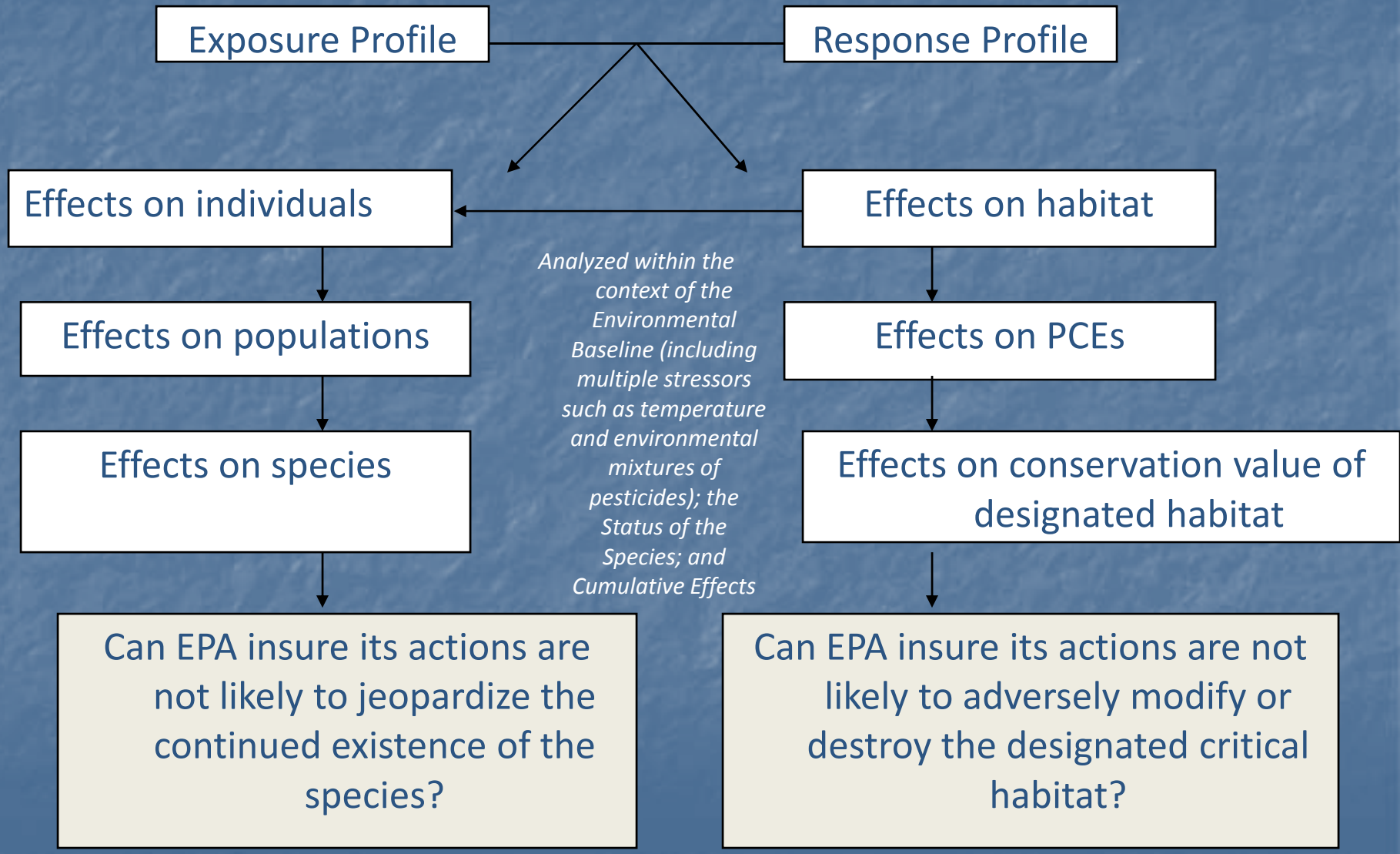
- Behavior reductions that lead to reduced growth based on the following
  - AChE – feeding activity
  - Feeding activity – ration size
  - Ration – growth
  - Growth – survival
- First year survival plugged into population matrix to determine changes in Lambda.

Population projections from reduced juvenile growth

	Decrease in Lambda from 4-d exposure					
Life History	Chlorpyrifos		Diazinon		Malathion	
	ug/L	% change	ug/L	% change	ug/L	% change
Ocean type Chinook	1 - 3	5 – 13*	1 - 3	5 – 9	3 - 6	6 – 9*
Stream type Chinook	0.5 - 1	2 – 4*	0.5 - 1	2 – 4	1 – 3	1 – 5*
Coho	0.5 - 1	2 – 6*	1 - 3	4 – 10	1 – 3	2 – 6*
Sockeye	0.5 - 1	2 – 5*	1 - 3	4 - 8	1 – 3	1 – 5*

*Percent change in lambda > 1 standard deviation from unexposed population

Integration and Synthesis



Conclusions of the Opinion

- The action jeopardizes all but one species assessed
- The action adversely modifies 25 species' designated critical habitats

Reasonable and Prudent Alternative:

- Elements address drift and runoff

- One element addresses data gap of pesticide concentrations in off-channel habitats

RPA elements:

1. No-application buffers: 500 ft (ground)

   1000 ft (aerial)
2. 20 ft vegetative filter strips
3. Wind speed restriction

RPA elements continued:

4. Do not apply when soil moisture is at field capacity or when weather patterns are predicted to produce runoff within 48 hrs post application

5. Report all incidences of fish mortality within 4 days following application

6. Effectiveness monitoring program for off-channel habitats

What's Next?

As per a court settlement agreement:

-2nd Opinion – 3 carbamtes , 2009

-3rd Opinion – 12 organophosphate, 2010

-4th Opinion – 4 herbicides & 2 fungicides, 2011

-Remaining - 13 pesticides (herbicides and insecticeds), 2012

Questions?


Questions?

Endangered Species Act definitions

ESA Consultation Handbook

- Not likely to adversely affect (NLAA) – effects on listed species are expected to be *discountable*, or *insignificant*, or *completely beneficial*.

- Discountable – Extremely unlikely to occur… can't measure or detect

- Insignificant – should never reach the scale where *take* occurs.

Endangered Species Act definitions

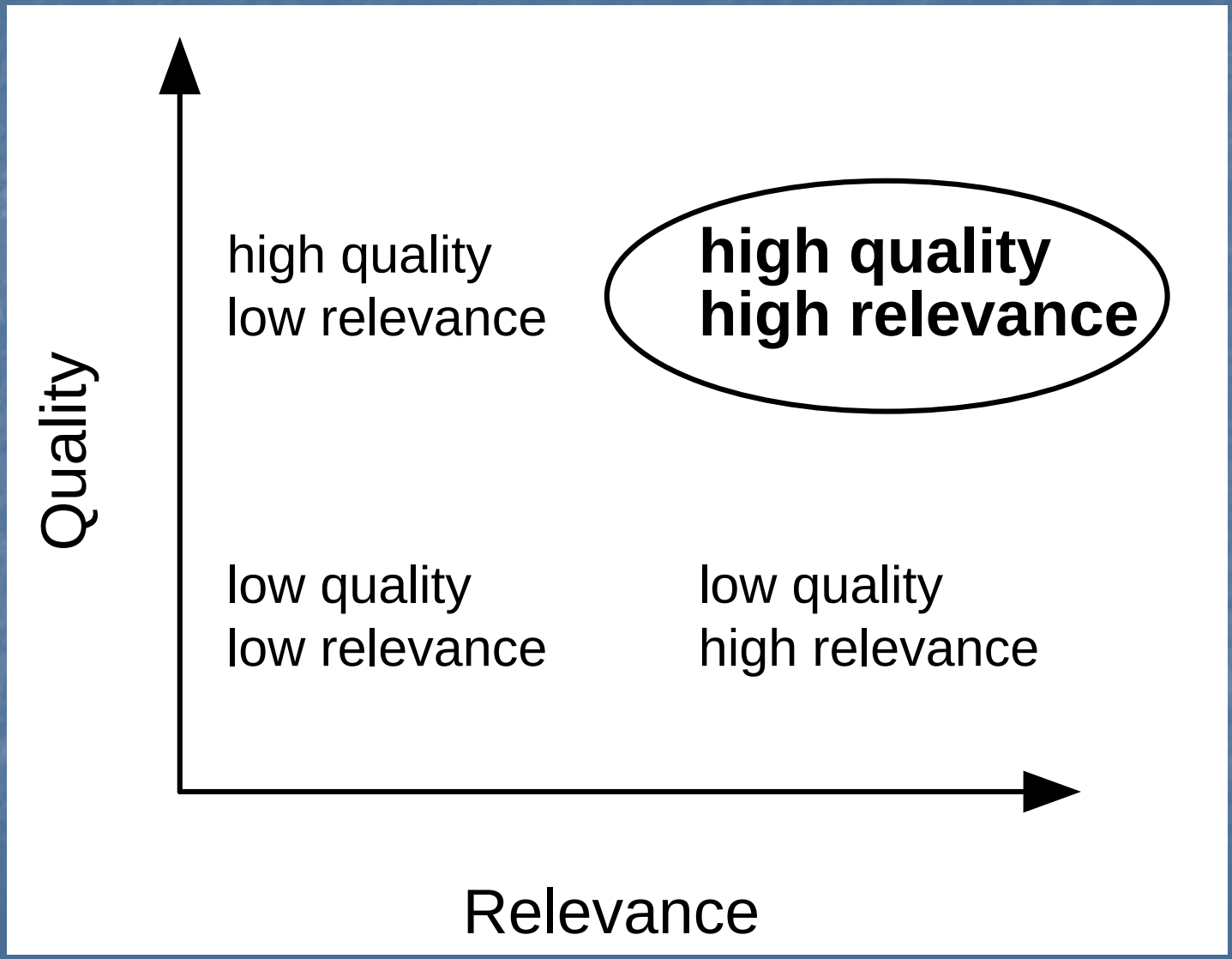
ESA Consultation Handbook

- Take- "to *harass*, *harm*, pursue…"
- Harm – "any significant habitat modification or degradation that results in death or injury… significantly impairing behavioral patterns such as breeding, feeding, or sheltering"
- Harass – "…to significantly disrupt normal behavior patterns which include but are not limited to, breeding, feeding or sheltering"

Data Standards

- The data standard for consultation is “Best Scientific and Commercial Data Available”
- We have guidelines for what constitutes “Best Available” [59 FR 34271 (July 1, 1994)]
- We do not exclude any data from consideration including:
  - Toxicity tests that are not conducted according to standard protocols
  - Studies not conducted according to GLP

Use of Best Scientific and Commercial Data



Handling Uncertainty

Type 1 Error	Type 2 Error
Reject true null hypothesis - Claim an effect when none exists	Accept false null hypothesis- Claim no effect when one exists
Protect Species more than necessary	Protect species less than necessary, even lose species
Lose scientific credibility	Lose practical and scientific credibility
Increase socioeconomic costs more than necessary	Permit activities that should not have been approved

Table adapted from: Science and the Endangered Species Act. Committee on Scientific Issues in the Endangered Species Act. National Research Council. 1995.