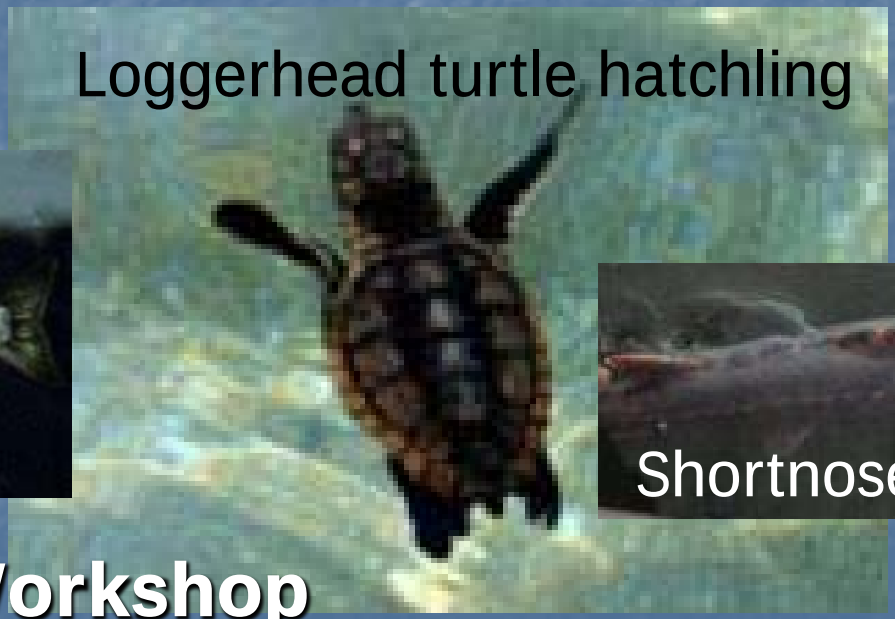
Threatened and Endangered Species:
An Overview of NMFS' Process for Assessing EPA Pesticide Registration Actions Pursuant to the ESA


Coho salmon


Loggerhead turtle hatchling


Shortnose sturgeon

MCFA ESA Workshop
May 24-25, 2011

Consultation Activity

- **Informal:**
  - Sept 2006 - April 2007: EPA effect determinations for shortnose sturgeon, loggerhead turtle, green turtle, Kemp's ridley turtle, leatherback turtle associated with atrazine use in Chesapeake Bay region.
- **Formal:**
  - 2002 – 2012: EPA registration of 37 active ingredients – threatened and endangered Pacific salmonids
    - Batch 1: chlorpyrifos, malathion, diazinon (Nov 2008)
    - Batch 2: carbofuran, carbaryl, methomyl (April 2009)
    - Batch 3: azinphos methyl, dimethoate, phorate, methidathion, naled methyl parathion, disulfoton, fenamiphos, methamidophos, phosmet, ethoprop, bensulide (August 2010)
    - Batch 4: 2,4-D, triclopyr BEE, diuron, linuron, captan, chlorothalonil (June 2011)
    - Batch 5: oryzalin, trifluralin, molinate, thiobencarb, propargite, fenbutatin-oxide, diflubenzuron, 1,3-D , lindane, racemic metolachlor, bromoxynil, prometryn, pendimethalin (April 2012)

Purpose of ESA Section 7 Consultation

Each federal agency shall insure that any action authorized, funded, or carried out is not likely to:

- Jeopardize T/E species
- Result in destruction or adverse modification of designated critical habitat

Entities Involved in FIFRA Consultations

Action Agency:	U.S. EPA/ Office of Pesticide Programs
Consulting Agency:	NOAA/ NMFS/Office of Protected Resources/ Endangered Species Division
Applicants:	Designated by EPA- Pesticide companies

Scope of Effects

Informal consultations

Purpose: Insure no jeopardy /adverse modification

Product: NLAA concurrence / non-concurrence

Scale: individual organisms, critical habitat, duration of project

Screening assessment: If NLAA then no jeopardy

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"

Scope of Effects (continued)

Informal consultations

Purpose: Insure no jeopardy /adverse modification

Product: NLAA concurrence / non-concurrence

Scale: individual organisms, critical habitat, duration of project

Screening evaluation: If NLAA then no jeopardy

Formal consultations

Purpose: Insure no jeopardy /adverse modification

Product: Biological Opinion

Scale: individual organisms, critical habitat, population, species

Comprehensive evaluation: includes quantification of amount and extent of take

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.

How Does NMFS Reach Conclusions in a Biological Opinion?

- Our process is outlined in the USFWS/NMFS Consultation Handbook (1998)
- Major sections of a Biological Opinion:
  - Status of the Species
  - Environmental Baseline
  - Effects of the Action
  - Cumulative Effects
  - Integration and Synthesis

Use of Best Scientific and Commercial Data

1. Evaluate all scientific and other information to assure reliability and credibility.
2. Use primary and original sources as basis for recommendations and document in administrative record.
3. Consider quality and relevance of information.

Information Sources Used

- EPA Biological Evaluations (BEs), REDs, science chapters, etc.
- Registrant labels, submitted information
- Peer reviewed literature, gray literature, books
- Monitoring data and other regional and state information

What is the Federal “Action” ?

- “any action authorized, carried out, or funded”
- EPA authorized actions subject to consultation
  - New product registrations (FIFRA section 3)
  - Re-registrations, special review (FIFRA section 4)
  - Special local needs (FIFRA section 24C)
  - Emergency use (FIFRA section 18)
- 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."

Definition reached at NMFS-USFWS-USEPA meeting 12/12/2007


TOUCHDOWN PRO

Herbicide

Nonselective Foliar Systemic Herbicide for Weed Control

Active Ingredient:
*Glyphosate:
N-(phosphonomethyl) glycine 28.3%
Inert Ingredients: 71.7%
Total: 100.0%
*Contains 3 pounds of glyphosate acid in each gallon, in the diammonium salt form.

See directions for use in attached booklet.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-1121
EPA Est. 100-LA-001^SSG
EPA Est. 100-NE-001^MHA
Superscript identifies manufacturing site

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Syngenta Crop Protection, Inc.
Greensboro, North Carolina 27409
www.syngenta-us.com
SCP 1121A-L1 0601

KEEP OUT OF REACH OF CHILDREN.

CAUTION

FIRST AID

If in eyes	• Flush eyes with plenty of water. Call a physician if irritation persists.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER
For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call
1-800-888-8372

Precautionary Statements

Hazards to Humans and Domestic Animals

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water.

Storage and Disposal

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!

2.5 gallons
U.S. Standard Measure

syngenta

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

EPA Registered Atrazine Labels (examples from 2006 Greenbook)

Product (% atrazine)	% other Ingredients	Label Recommended Tank Mixes
ATREX 4L (42.6%)	Inerts 56%	s-metolachlor, glyphosate, alachlor, simazine
Banvel-K-Atrazine (22.23%)	Dicamba 13.42% Inerts 64.35%	cyanizine, simazine, paraquot, EPTC, acetochlor,2,4-D, pendimethalin
Bullet (14.5%)	Alachlor 25.4% Inerts 59.3%	pendimethalin, paraquat, linuron
Basis gold (82.44%)	Nicosulfuron 1.34% Rimsulfuron 1.34% Inerts 10.54%	dicamba, esfenvalerate, methomyl
Cinch (33%)	s-metolachlor 26.1% Inerts 40.2%	atrazine, paraquat, glyphosate, simazine,

Description of the Action

- Information reviewed
  - Labels
    - Where it can be applied (Ag commodities, residential, etc.,)
    - Methods of application, rates, existing restrictions that reduce risk
    - Ingredients
    - Tank mixtures
- Duration: 15 years- consistent with EPA registration review cycle

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.

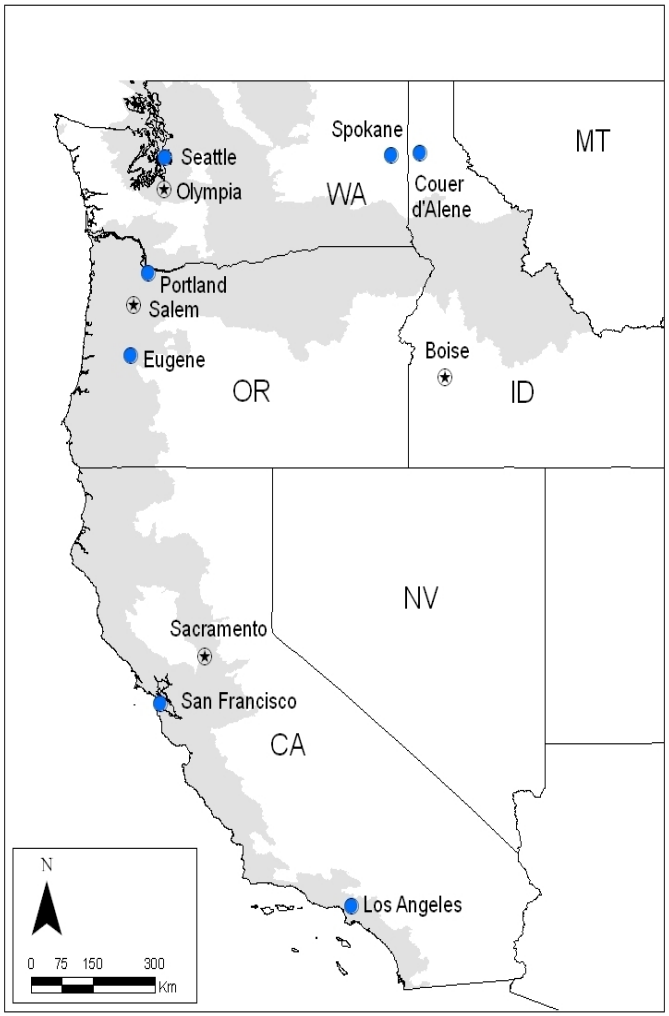
- **Chinook (9)**

- **Steelhead (11)**

- **Coho (4)**

- **Sockeye (2)**

- **Chum (2)**

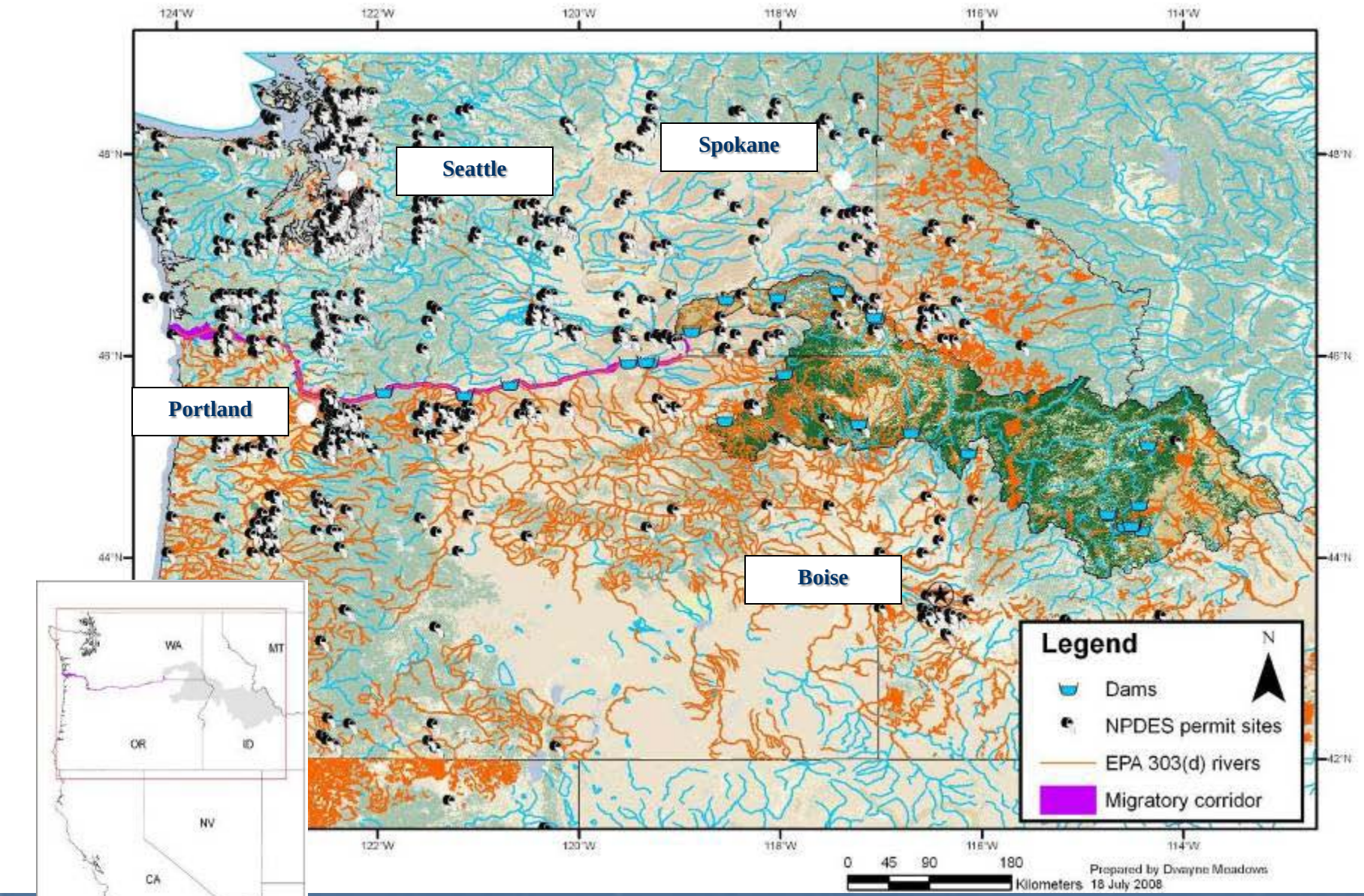


Status of the Species

- Species life history description
- Status and distribution
  - Reasons for listing
  - Trends
  - Threats
- Population Viability Elements
  - Genetic diversity
  - Abundance
  - Productivity
  - Distribution

Environmental Baseline

By regulation, environmental baselines for biological opinions include the past and present impact 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).



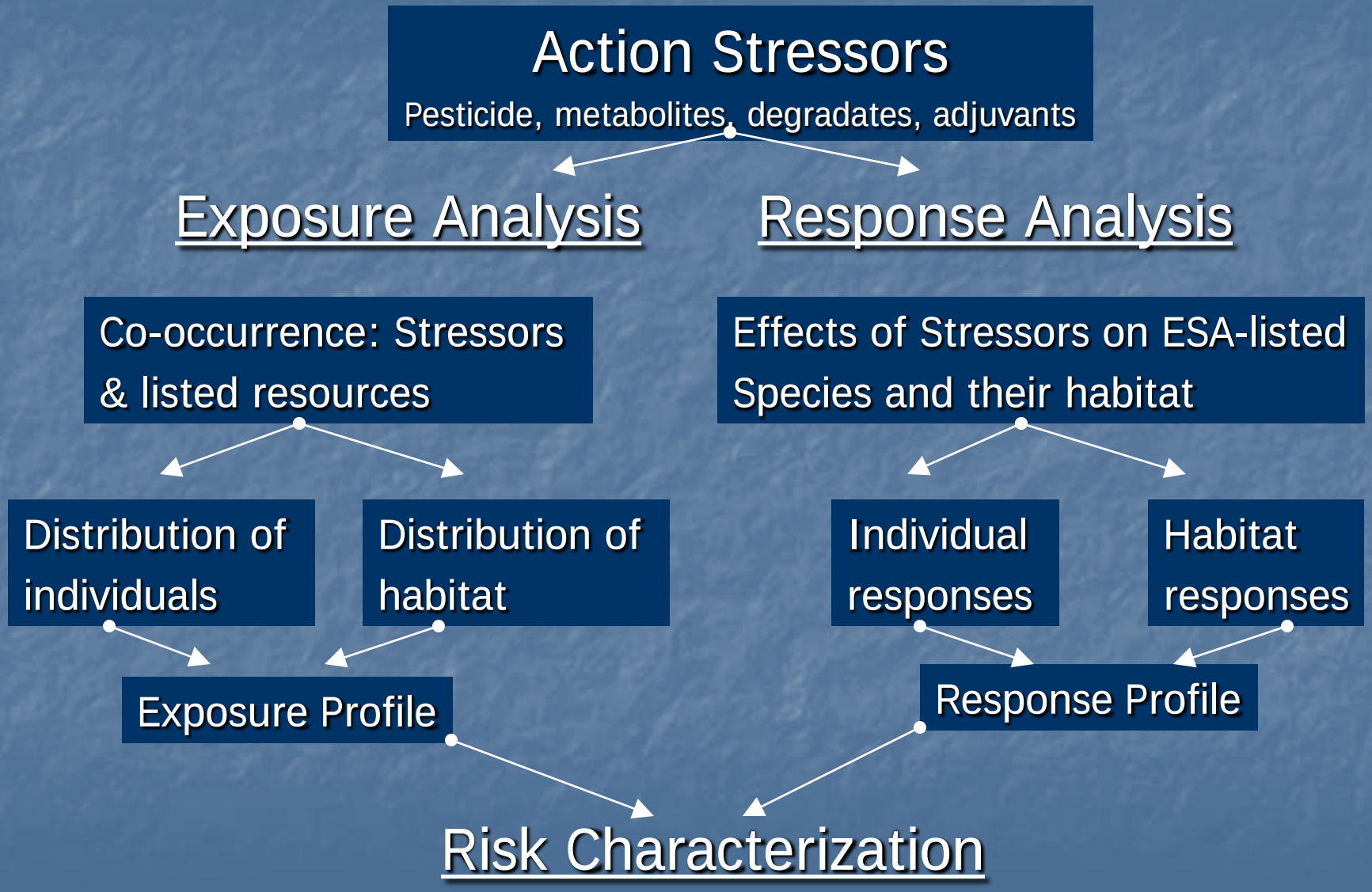
Snake River Spring/Summer-run Chinook

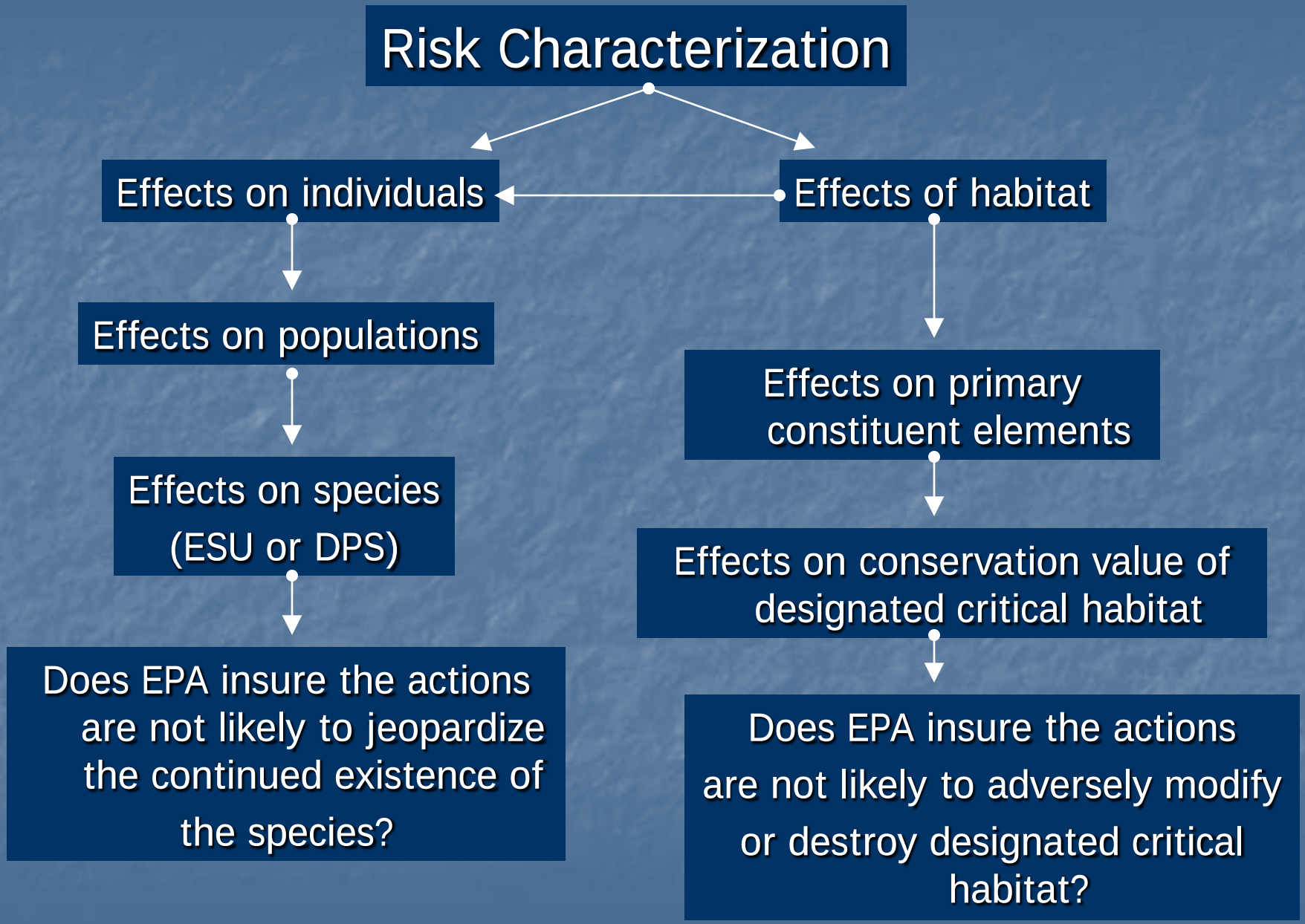
Approach to the Assessment

A roadmap for how the analysis is conducted

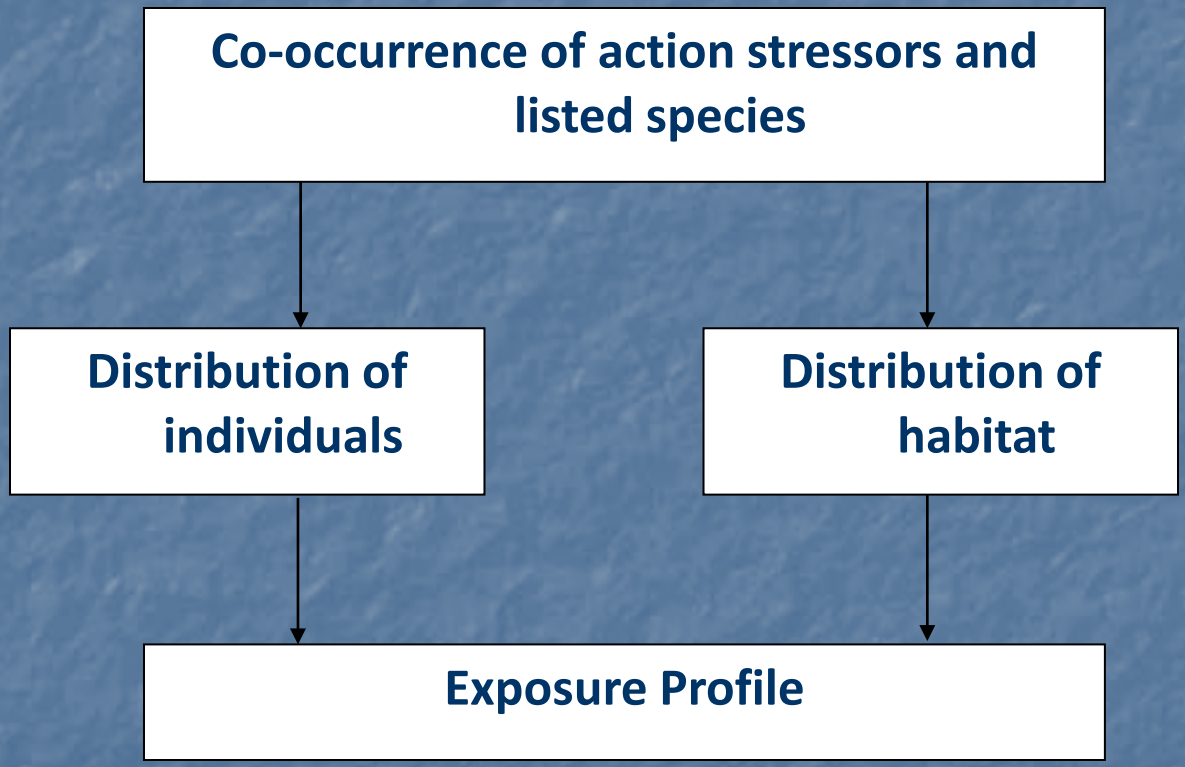
- Identify stressors that may have direct and indirect effects on environment;
- Characterize exposure to individuals and designated critical habitat;
- Identify risk at the individual level;
- Evaluate risk to species (considering effects of action, condition of environmental baseline, status of the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

Risk Framework




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

Exposure Analysis



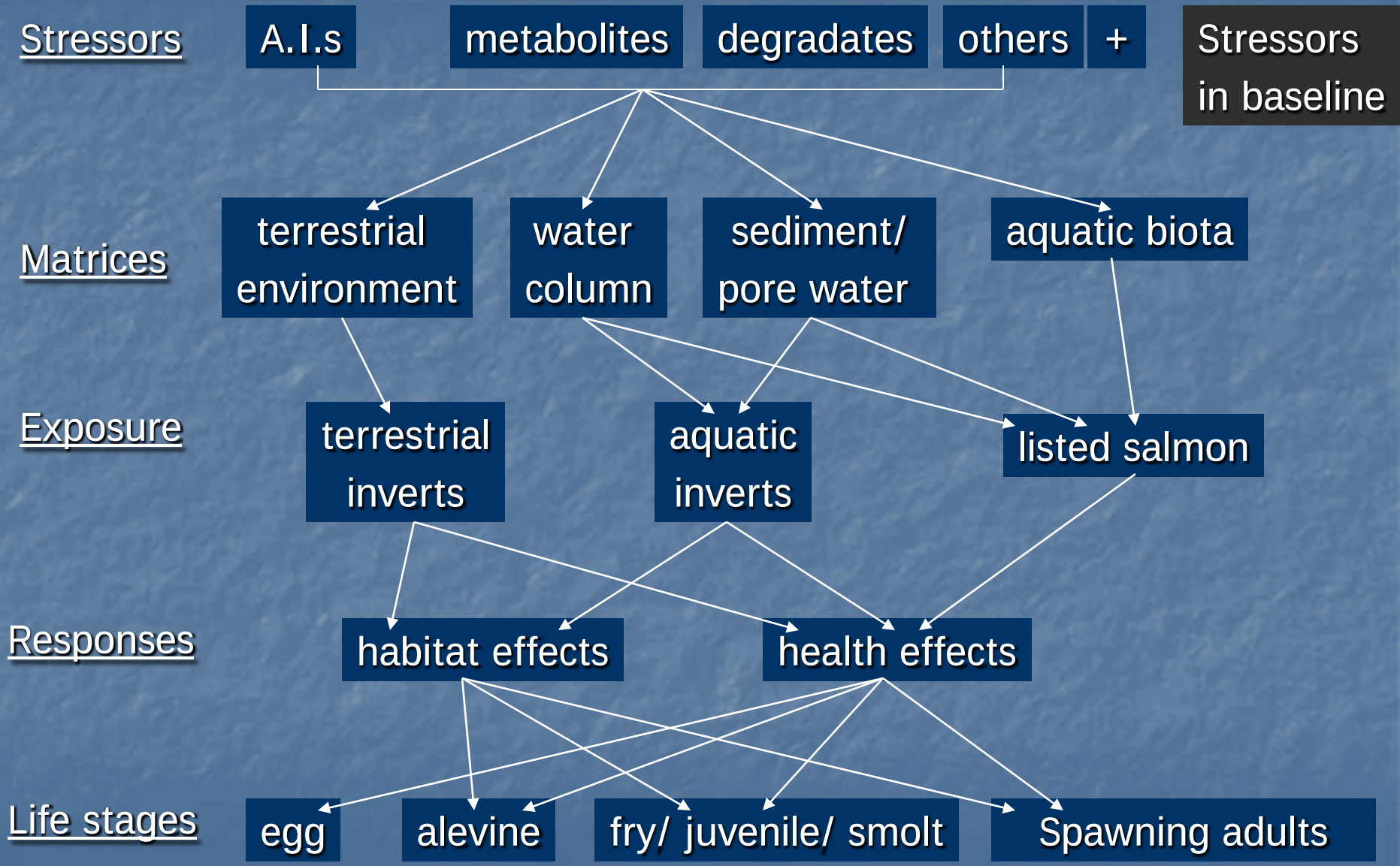
Product Uses

- Agricultural crops (crops, noncrop)
- Residential (turf, golf course)
- Industrial
- Rights-of-way
- Aquatic weed management
- Forestry

Listed Species Information: Life history considerations

Species (ESUs)	Spawning	Fresh Water 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

Distribution of Stressors

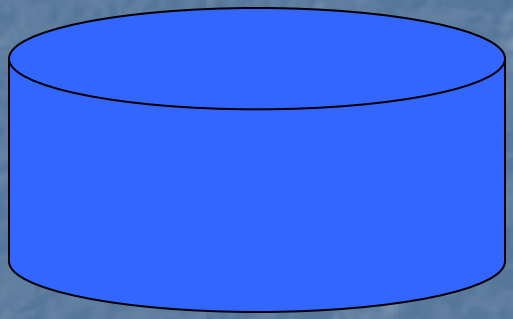


Exposure Information Evaluated

- Modeling
  - EPA aquatic species screening estimates
  - NMFS floodplain habitat estimates
- Monitoring data
  - Ambient water quality data
  - Targeted monitoring

EPA Model Estimates

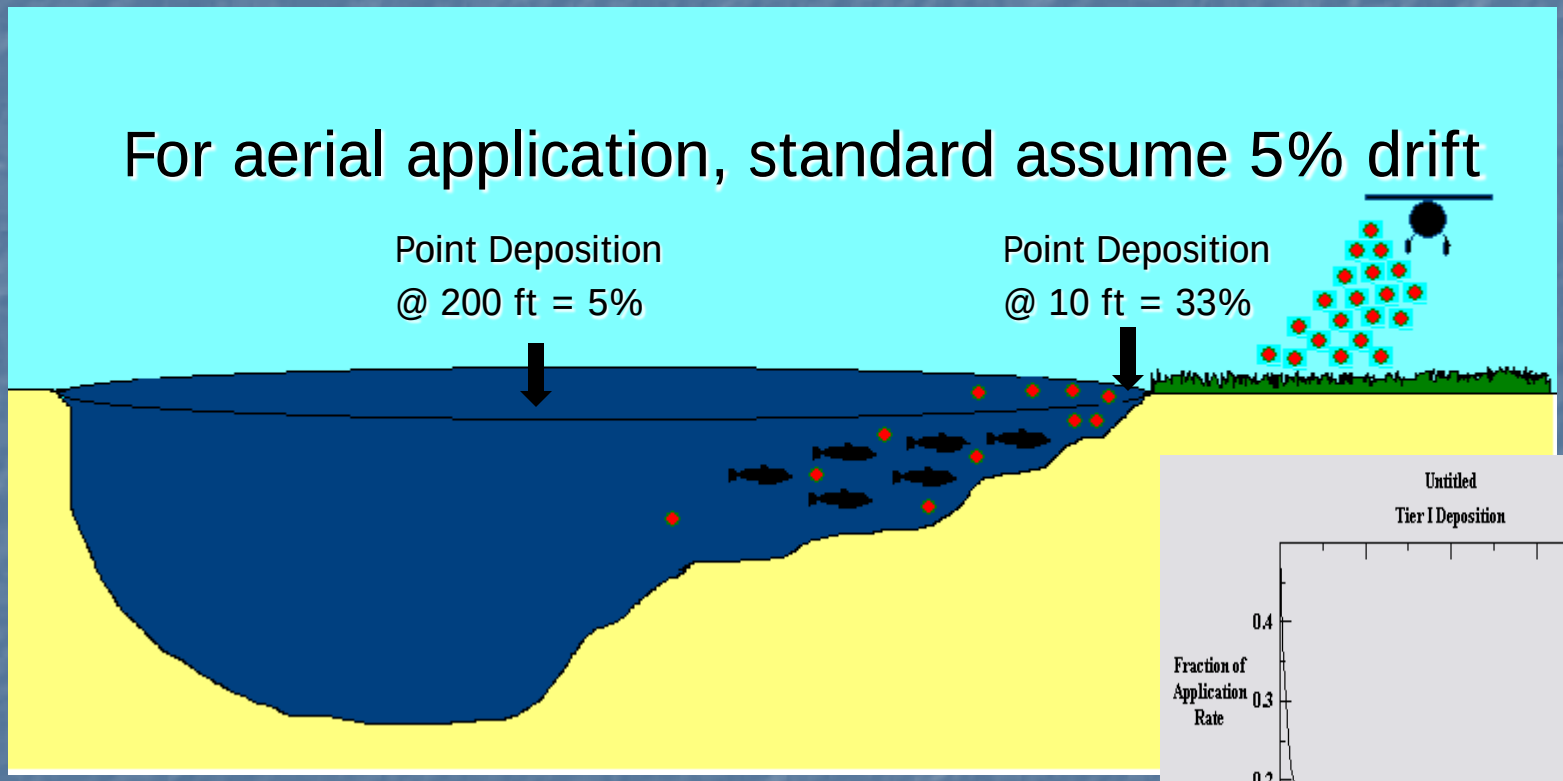
- PRZM-EXAMS, GENEEC
- Characterized as high-end screening tools
- Typically model estimates greater than monitoring values
- Predictive capability depends on site-specific conditions

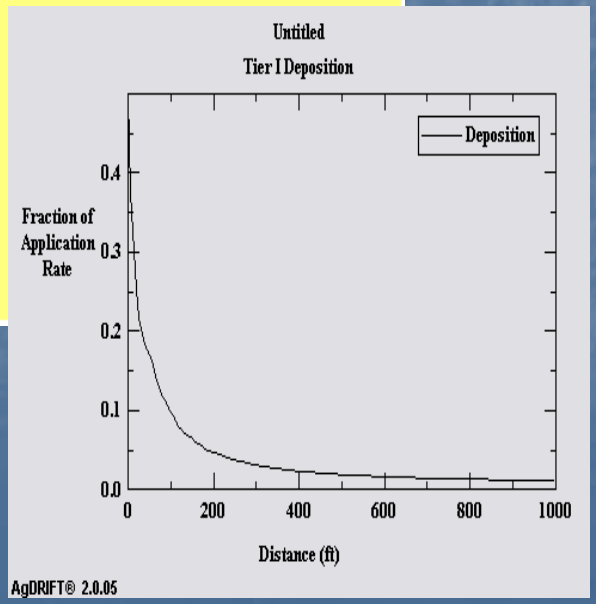


- 10 hectare watershed
- 1 hectare pond, 2 meters deep
- Static system

EPA “Farm Pond”

Distribution of Chemicals and Fish





Floodplains and Small Streams

- Habitat for rearing, spawning
- Essential habitat for small fry/juveniles to rear and seek protection from high velocity flows
- Spatially and temporally variable in occurrence, flow, and size
- Restoration focus

AgDrift Estimates for Floodplain Habitats

- AgDrift model develop by pesticide industry task force
- Field-validated model with relatively high predictive capability (Bird et al. 2002)
- Predicts downwind deposition in aquatic habitats from ground and aerial applications
- Assumed small floodplain habitat representative of those used by rearing salmon (2 m wide, 0.1 m deep)
- Does not factor in contributions from other transportation pathways (*e.g.* runoff)
- Does not factor in accumulation from multiple applications or chemical degradation after deposition

Monitoring Data Used

- USGS NAWQA monitoring
- California Department of Pesticide Regulation's surface water monitoring database
- Washington State Department of Ecology's EIM monitoring database (Environmental Information Management)
- Oregon Department of Environmental Quality (LASAR database)
- Targeted Monitoring Studies

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.

Uncertainty of Exposure to other Action Stressors

- Exposure to “other ingredients”
  - 1000’s of potential “inerts”, some toxic
- Exposure to other pesticides: formulation mixtures, tank mixtures, sequential applications
- Current and future actual use of pesticides (rates, locations) versus labeled use of pesticides
- Uncertainty regarding exposure is factored into the final conclusion

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

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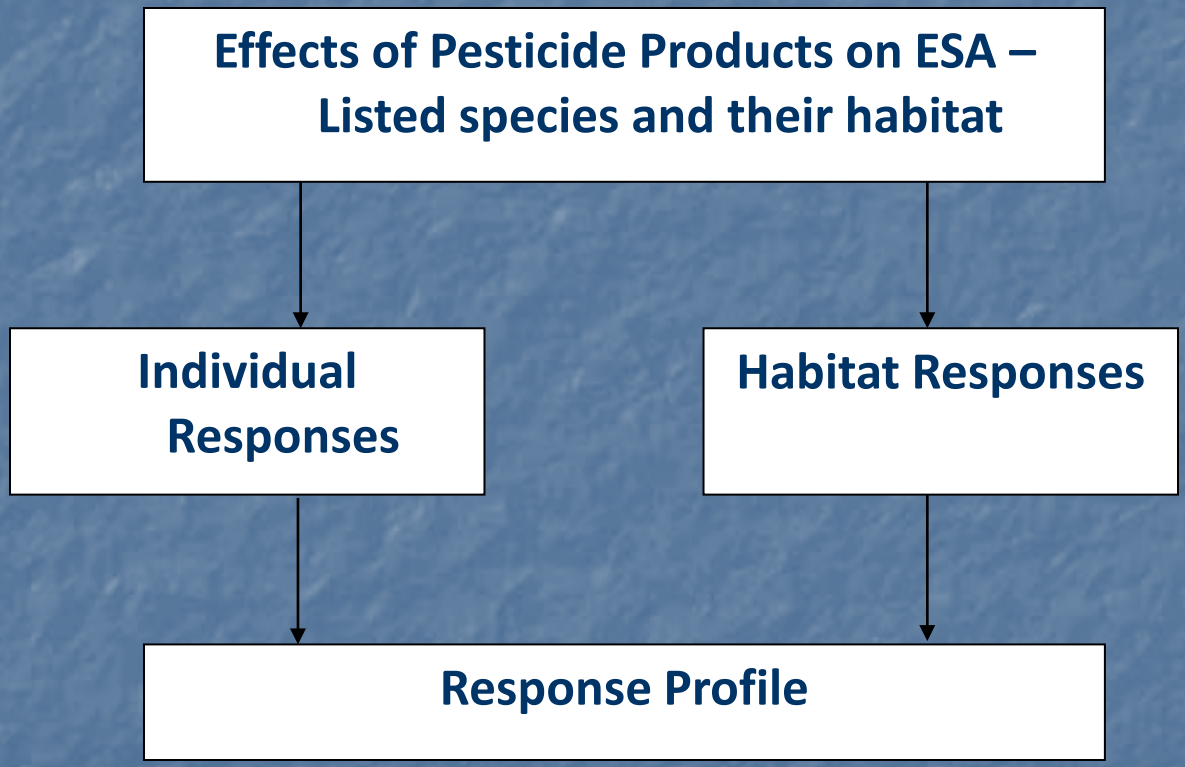
Response Analysis



Examples of Salmonid Health Assessment Endpoints

Assessment Endpoints	Assessment Measures
Juvenile growth	Foraging behavior Growth rate Condition index
Reproduction	Courtship behavior Number of eggs produced Fertilization success
Early development	Gastrulation Organogenesis Hatching success
Smoltification	ion exchange (*i.e.* gill Na^+/K^+ ATPase activity) Blood hormone (*i.e.* thyroxin) Salinity tolerance
Disease-induced mortality	Immunocompetence Pathogen prevalence in tissues Histopathology
Migration or distribution	Use of juvenile rearing habitats Adult homing behavior Selection of spawning sites

Examples of Habitat Assessment Endpoints

Assessment Endpoints	Assessment Measures
Prey availability	Acute and chronic toxicity (LC_{50}) Species abundance (aquatic and terrestrial) Indices of biological integrity (IBIs)
Primary productivity	Macro-algal cover Chlorophyll concentration Dissolved oxygen production
Habitat structure	Sediment grain size (embeddedness) Shelter availability Large woody debris
Riparian function	Plant community composition Allochthonous inputs of organic matter Riparian buffer width
Water quality	Temperature Dissolved oxygen concentration Sediment load

Summarize Effects Data

- Summarize effects data from EPA's biological evaluations and open literature.
- Discuss the relevancy of the effect to our assessment endpoints (growth, survival, etc.)
- Score the degree of confidence we have 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

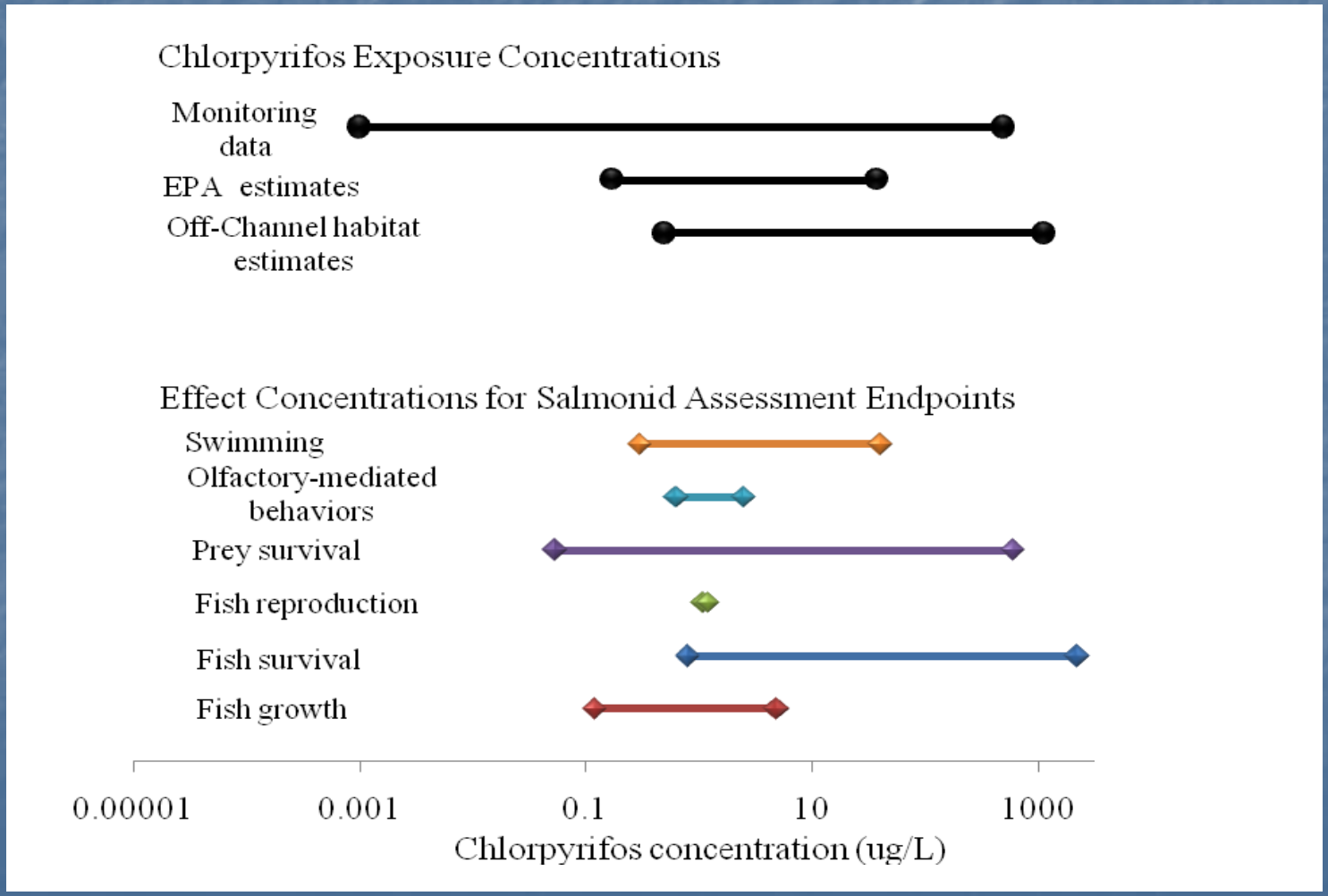
Develop Risk Hypotheses Based on Toxicity Information

- 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)

Evaluate Support for Each Risk Hypothesis

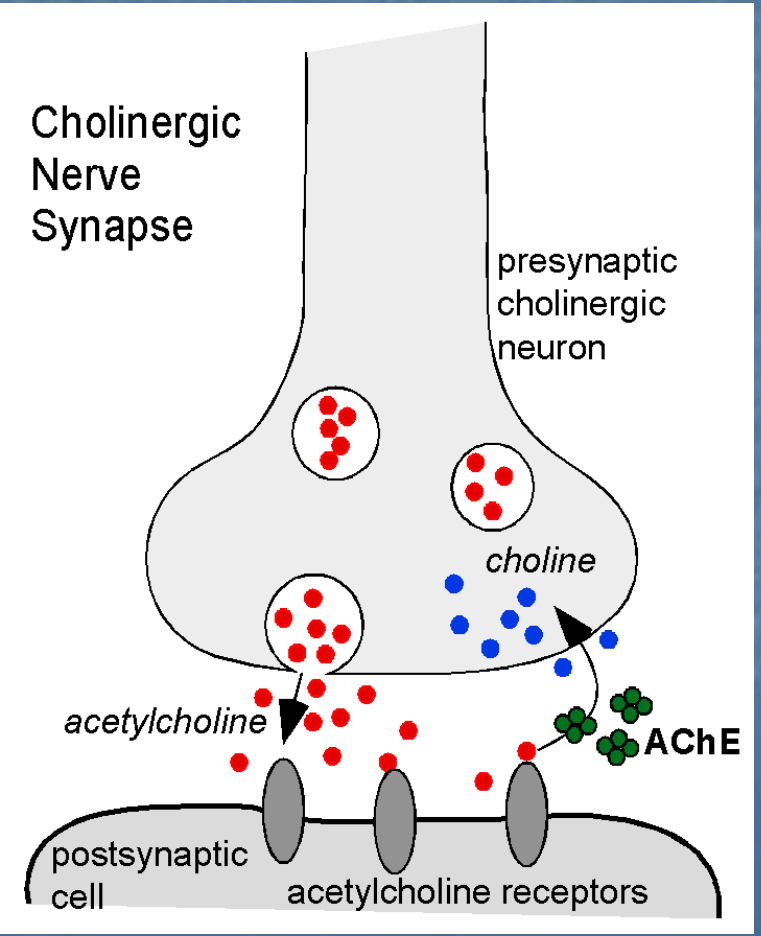
- If exposure and response information support a risk hypothesis then we evaluate if population level effects likely.
- If exposure and response information do not support a risk hypothesis then we do not evaluate population level effects.
- Data uncertainties discussed for each risk hypothesis.

General Overlap of Exposure and Response Concentrations

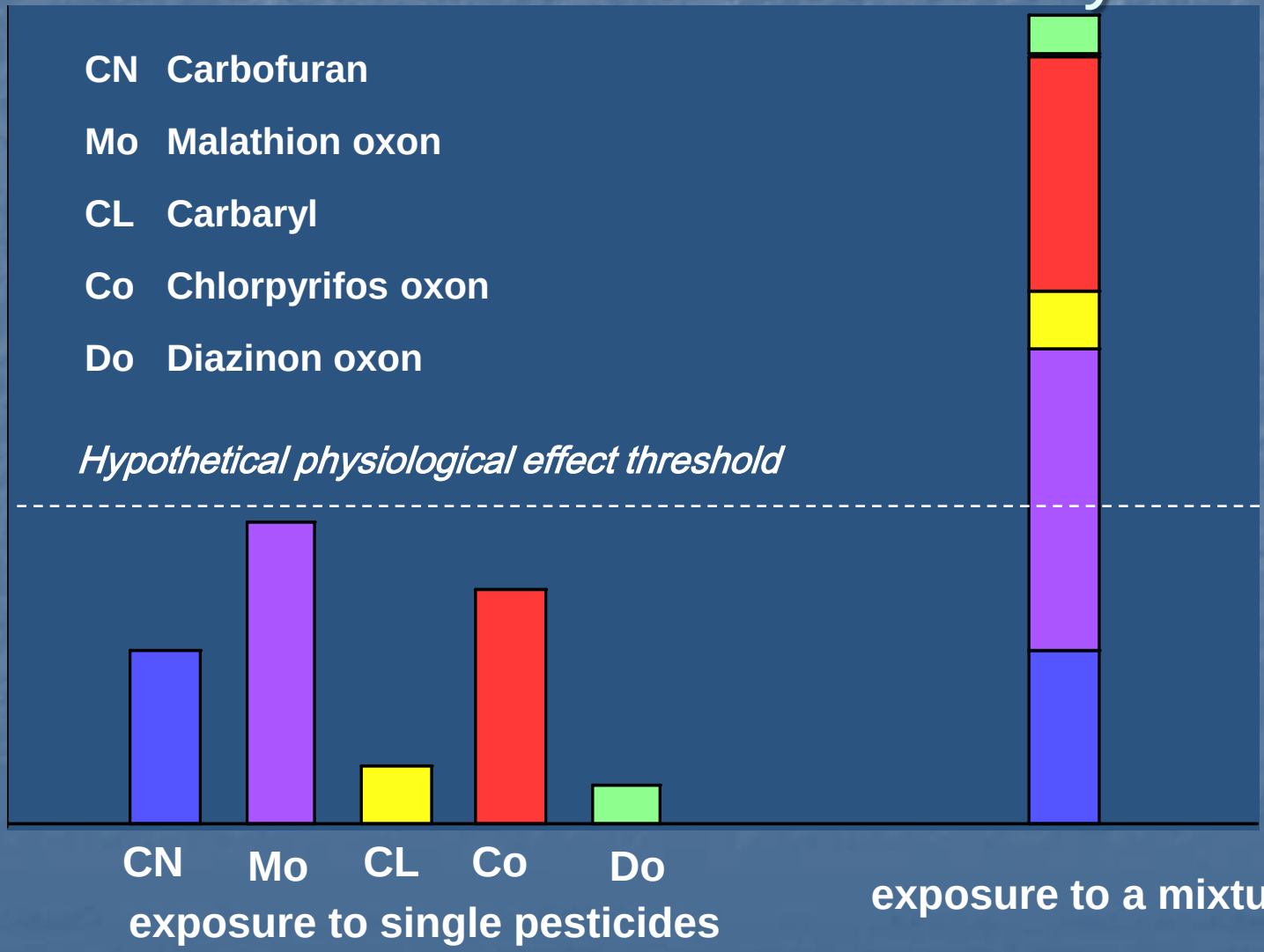


First Three Opinions: Nervous System Toxicants

- Mode of toxic action:
  - disrupt neurotransmission
  - inhibits an enzyme, acetyl-cholinesterase, by binding to it
  - Nerve cells continue to fire



Risk Hypothesis: Pesticides with a similar mode of action can act in combination to increase toxicity



Population modeling

- Risk hypotheses indicated effects to juvenile growth and survival, and prey availability.

- Population models were used to evaluate the impacts on the first year survival of juvenile salmonids from direct lethality and from reductions in growth.

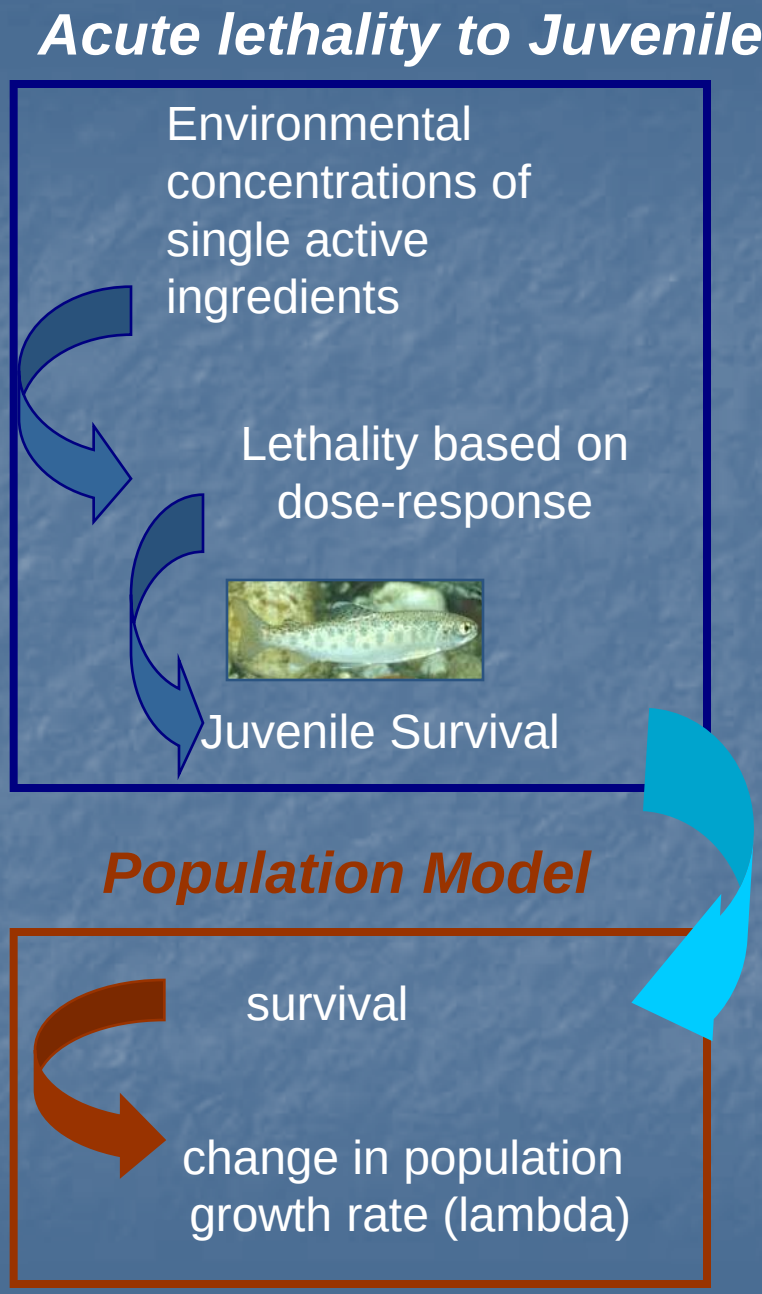
- Results of other non-modeled risk hypotheses also evaluated at the population level included:
  - survival of adults
  - swimming ability
  - olfaction-mediated behaviors
  - starvation

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



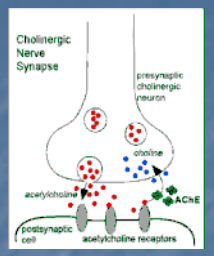
Linking the available Information:

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

Not incorporated:

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

Somatic Growth Model



Inhibition of Acetyl-cholinesterase

Reduced ration

growth

Population Model

survival

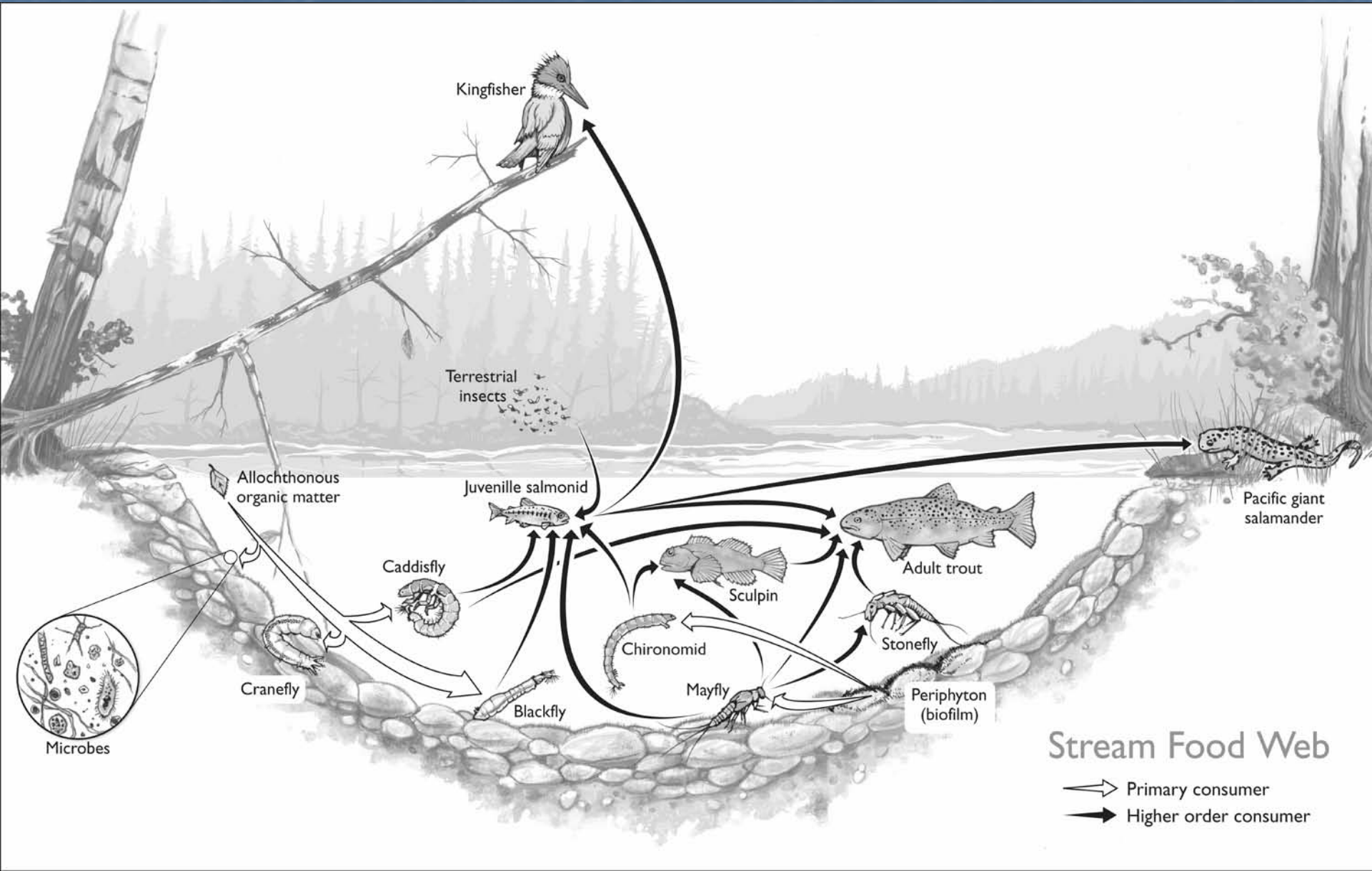
change in population growth rate (lambda)

Slide: D. Baldwin

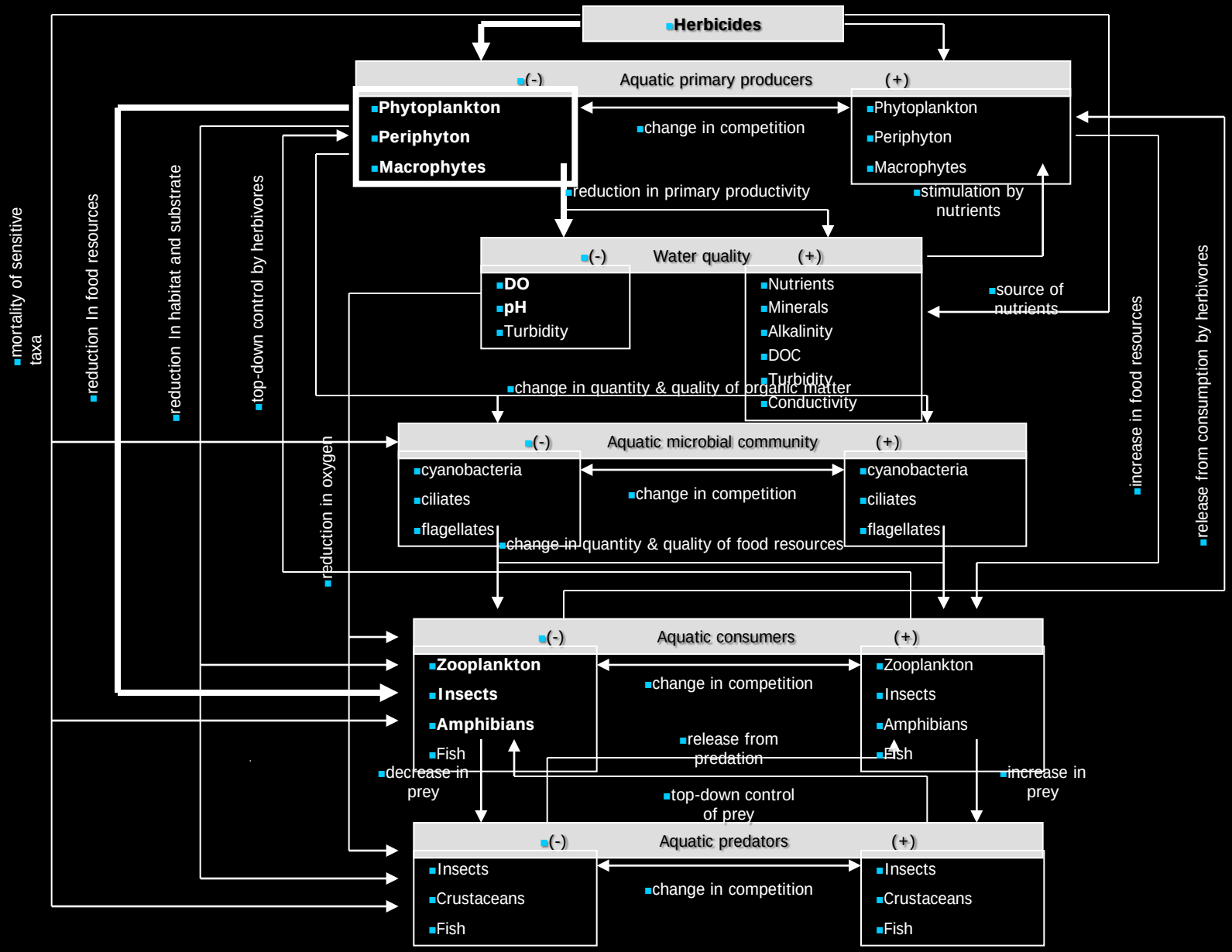
Developed Critical Habitat Risk Hypotheses to Evaluate Effects to Primary Constituent Elements (PCEs)

- PCEs
  - Freshwater spawning sites
  - Freshwater rearing sites
  - Freshwater migration corridors
  - Estuarine and nearshore marine
- Attributes of PCEs
  - Water quality
  - Substrate
  - Natural cover
  - Prey availability

Freshwater rearing of juvenile salmonids



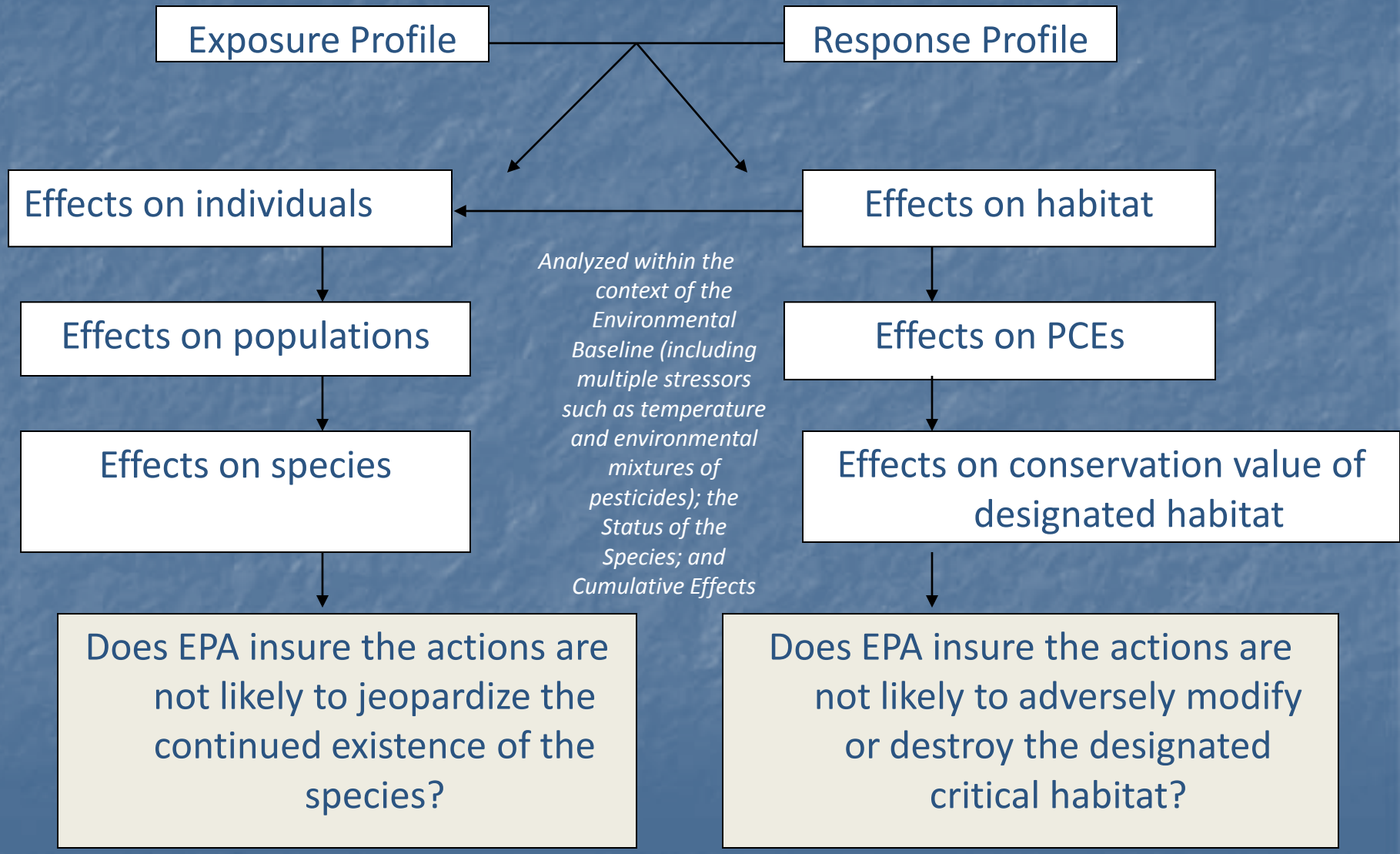
Restoration of riparian habitat on Lower Elwha River


Herbicides
(-) Aquatic primary producers (+)
Phytoplankton
Periphyton
Macrophytes
change in competition
Phytoplankton
Periphyton
Macrophytes
reduction in primary productivity
stimulation by nutrients
(-) Water quality (+)
DO
pH
Turbidity
Nutrients
Minerals
Alkalinity
DOC
Turbidity
Conductivity
source of nutrients
change in quantity & quality of organic matter
(-) Aquatic microbial community (+)
cyanobacteria
ciliates
flagellates
change in competition
cyanobacteria
ciliates
flagellates
change in quantity & quality of food resources
(-) Aquatic consumers (+)
Zooplankton
Insects
Amphibians
Fish
change in competition
Zooplankton
Insects
Amphibians
Fish
release from predation
decrease in prey
increase in prey
top-down control of prey
(-) Aquatic predators (+)
Insects
Crustaceans
Fish
change in competition
Insects
Crustaceans
Fish
mortality of sensitive taxa
reduction In food resources
reduction In habitat and substrate
top-down control by herbivores
reduction in oxygen
increase in food resources
release from consumption by herbivores

Integration and Synthesis

- Considers *Effect of the Action* in the context of *Status of the Species*, *Environmental Baseline*, and *Cumulative Effects*
- Each ESU/DPS and a.i. combination evaluated separately for species and critical habitat
- Factors considered
  - Intensity and distribution of use sites across ESU/DPS
  - Co-occurrence of use sites and salmon habitat
  - Salmon life history
  - Likelihood of individual and population level effects from use of pesticides
  - Exposure to additional stressors not related to action
  - Population trends and relative importance of populations within ESUs/DPSs

Integration and Synthesis



Reasonable and Prudent Alternatives

- Alternatives to the action that NMFS concludes are necessary to reduce the likelihood of jeopardy to species or adverse mod to designated critical habitat
- Developed in coordination with the action agency
  - within the scope of the action agency's legal authority and jurisdiction
  - economically and technologically feasible
- NMFS RPA elements rely on:
  - Conventional risk reduction measures for pesticides
  - Chemical-specific risk reduction measures

Reasonable and Prudent Alternatives: Examples from NMFS Opinions

Elements with required label amendments to reduce exposure from pesticide runoff and drift:

windspeed restrictions; soil moisture restrictions; chemical-specific buffers to salmonid habitat

Elements with provisions for EPA to develop risk reduction measures:

pesticide-specific maximum concentration limits; risk reduction plan to be approved by NMFS

Effectiveness monitoring elements:

mortality incident reporting; floodplain habitat monitoring

Terms and Conditions

To minimize the impact of take

1. Label instructions not to apply pesticide products:
    1. when wind speeds exceed 10 mph, or
    2. when storm events are likely to produce runoff
2. Label instructions for reporting fish kills
3. EPA annual reporting requirement- aquatic incidents classified as probable or highly probable

Completed consultations and related information:

www.nmfs.noaa.gov/pr/consultation/pesticides.htm