Update on ESA Pesticide Consultations

June 19, 2017

Background: Endangered Species Act (ESA) Obligations for Pesticide Decisions

- Why are pesticide decisions impacted by the ESA?
  - Under Section 7(a)(2) of the ESA, Federal agencies must ensure that the "actions" they authorize will not result in jeopardy or adversely modify designated critical habitat for species listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service (NMFS) (jointly the Services)
  - For EPA's Office of Pesticide Programs (OPP), the actions we authorize are the sale, distribution, and use of pesticides according to the product labeling
- Conventional pesticide decisions impacted by ESA:
  - Registration review actions (~50-60/yr)
  - New chemical registrations (~10-12/yr)
  - New use registrations (~50-60/yr)
  - Section 18 Emergency Exemptions (~100/yr)
  - Section 24(c) Special Local Need (SLN) registrations (~200/yr)

Background

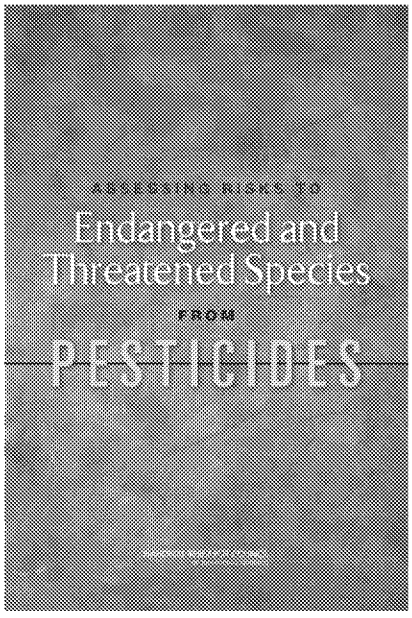
- ESA Authority
  - Section 7(a)(2) of ESA: EPA makes "effects determination" for individual listed species in a biological evaluation (BE):
    - No effect (NE) – no consultation required
      - Overview Document-compliant method (2004): Risk Quotient (RQ) < listed species Level of Concern (LOC)
      - NAS-recommended method (2013): No geospatial co-occurrence of pesticide use footprint with listed species range
    - Not likely to adversely affect (NLAA) – informal consultation; concurrence from Services
    - Likely to adversely affect (LAA) – formal consultation including Biological Opinion (BiOp) from Services (jeopardy/no jeopardy determination)

- Nationwide consultations must consider direct/indirect effects to 1850 listed species and 600+ designated critical habitats

Background - OPP History with the Services

- Disagreement on:
  - Scientific methods to assess the risk of pesticides to listed species
  - Specific actions needed to protect listed species
- EPA has completed over 200 chemical-specific BEs as the result of court-imposed ESA obligations. The Services have issued 9 BiOps based on court-mandated schedules. None of these BEs or BiOps were nationwide evaluations.
  - Time required to complete BiOp is lengthy (typically 2-3 yrs)
  - EPA has often been unable to follow the science logic behind the BiOps
- Of 7 BiOps for listed Pacific Northwest salmon species submitted by NMFS (covering 32 chemicals), EPA has implemented only one (thiobencarb); NMFS 1st BiOp was overturned.
  - Reasonable and Prudent Alternatives (RPAs)/Reasonable and Prudent Measures (RPMs) not feasible/practical to implement:
    - Arbitrary spray drift buffers
    - Lack of a target concentration where effects to listed salmon do not cause jeopardy
- EPA has implemented 2 BiOps submitted by FWS for Rozol and Kaput rodenticides
  - Geographically-specific Bulletins which restrict product use or timing of application

NAS Report Implementation



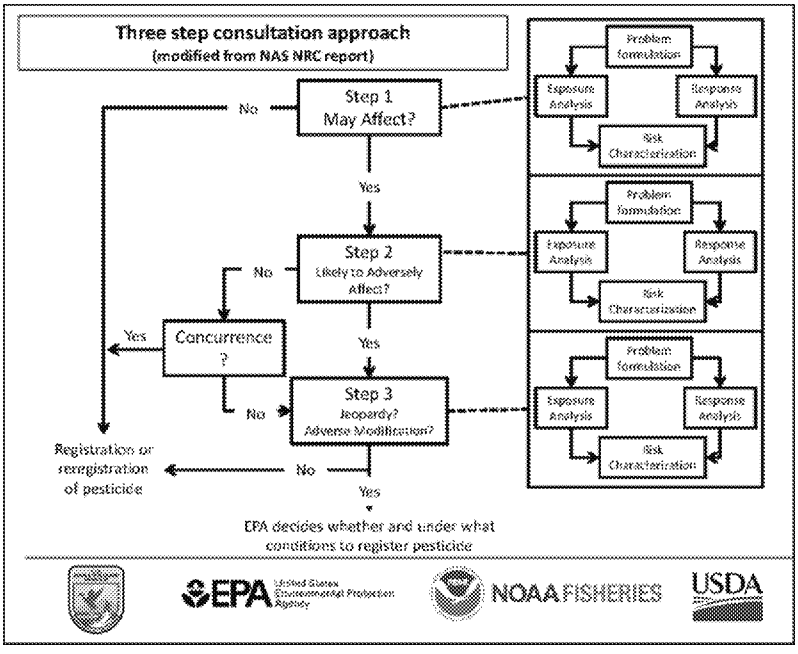
- Released on April 30, 2013
- Developed in response to a joint request by EPA, NMFS, FWS, and USDA in 2011 to address scientific areas of disagreement
- Recommended 3-step process that integrates ecological risk assessment methods with ESA Section 7 consultations
- Goal: unified interagency approach with agreement on process across all steps
- Multiple interagency workshops where interim methods for EPA's BEs (Steps 1 and 2) have been developed
- Several stakeholder meetings held to engage public on potential refinements
- Interim methods need streamlining to meet available resources
- Final BEs for chlorpyrifos, diazinon, and malathion released in January 2017

NAS Report Implementation

- The **Biological Evaluation** (BE) determines whether registered pesticides adversely affect one or more individuals of a listed species and/or their designated critical habitats
  - Step 1 ["No Effect/May Affect" Determination]
  - Step 2 ["Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA) Determination]
- The **Biological Opinion** (BiOp) determines whether the registration of a pesticide is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of its designated critical habitat
  - Step 3 ["Jeopardy/No Jeopardy" Determination and "Adverse Modification/No Adverse Modification" Determination]

Methodology for Pesticide Consultations

The draft process follows the 2013 NAS recommendations for a 3-step approach:



The draft BE process was developed in close coordination with the Services – EPA has worked very hard to provide information in Steps 1 and 2 that the Services said they would need to conduct Step 3.

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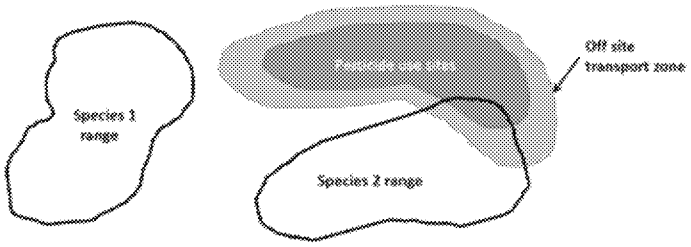
Overview of the BE Method – Step 1

- Two sets of spatial data are compared
  - Pesticide exposure area
    - Based on national-level GIS data to identify potential use sites
    - Buffered to account for transport to levels that potentially represent effects (based on most sensitive toxicity data)
  - Species range – provided by Services
- No Effect /May Affect determination
  - Based on whether or not there is overlap of the potential exposure area and the species range
    - No Effect (*i.e.*, no overlap) – no need to seek consultation with Services
    - May Affect (*i.e.*, overlap) – move to step 2



Overview of the BE Method –Step 2

- Step 2
  - Weight-of-Evidence Approach
    - Risk and confidence evaluated for multiple lines of evidence (mortality, growth, reproduction and other sublethal effects) based on estimated exposure and effects thresholds
    - Incident data
    - Qualitative discussion of mixtures and abiotic influence (e.g., temperature, pH) on toxicity
- Intended to answer the questions:
  - Is there a potential for an individual's fitness to be reduced?
  - Is there a potential for important physical and biological features of a species habitat to be adversely affected?
- Describes the process for making Likely to Adversely Affect(LAA)/Not Likely to Adversely Affect (NLAA) Determinations
  - LAA – species/critical habitat moves to Step 3 (jeopardy/adverse modification determination)
  - NLAA – concurrence from the Services

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

From Anita

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Stakeholder Concerns

- April 13, 2017 letter from registrants of 3 pilot OPs to political leadership of EPA and the Services requesting:
  - EPA to withdraw the BEs
  - Services to stop work on the BiOps
  - Services to modify settlement agreements to allow more time to complete consultation
- Registrants/Growers:
  - Too large and complex; inadequate comment period
  - Current methods are not sustainable
  - Do not account for taxon-specific toxicity data early enough in the process
  - Overly conservative
  - GIS layers used are too broad (for use site and species range layers)
  - Use of invalid and un-reviewed studies
  - Need to consider public health, usage data and benefits
- NGOs
  - Too large and complex
  - Generally agreed with the overall process

Deliberative Process / Ex. 5

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