Overview of the Draft Biological Evaluations (BEs) for the ESA Pilot Chemicals (Chlorpyrifos, Malathion, and Diazinon)

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Overview

- Brief background
- Overview of the Draft BE process
  - Problem Formulation
  - Effects Characterization
  - Exposure Characterization
  - Effects Determinations
- Navigating the documents
- Instructions for public comment
- Next steps

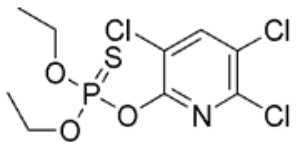
Brief Background

- Endangered Species Act (ESA)
  - Section 7 requires federal agencies to consult with the Services* on actions that may affect a federally listed species
- First national-level pesticide ESA consultations
- Following the recommendations of the 2013 National Academy of Sciences' (NAS) (National Resource Council) report on assessing risks to endangered and threatened species from pesticides

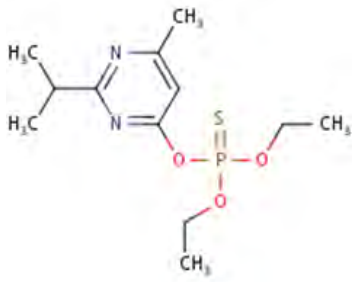
*Services = National Marine Fisheries Service and the United States Fish and Wildlife Service

Brief Background

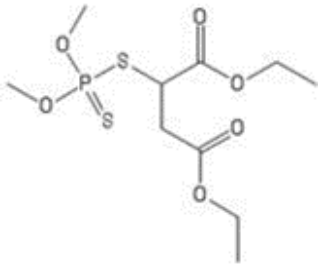
- First three pilot chemicals (all organophosphate insecticides):
  - Chlorpyrifos
  - Diazinon
  - Malathion
- Conducted as part of EPA's Registration Review Process
  - Registration Review – the EPA periodically reviews all pesticides to ensure they meet current standards for human health and environmental safety



Chlorpyrifos



Diazinon



Malathion

Brief Background

- Collaborative effort among the:
  - United States Environmental Protection Agency (EPA)
  - National Marine Fisheries Service (NMFS)
  - United States Fish and Wildlife Service (FWS)
  - United States Department of Agriculture (USDA)
- November 2013 – release of interim scientific methods for implementing NAS recommendations
  - https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and
- Current Interim scientific method developed in 2013 - 2015
  - Four interagency meetings
  - Four stakeholder workshops

Brief Background

- Updates on the interim process were provided at scientific meetings in 2014 and 2015
  - Society of Environmental Toxicology and Chemistry (SETAC)
  - American Chemical Society (ACS)
- A subset of the draft BE documents for chlorpyrifos, malathion, and diazinon were posted to an EPA website in Dec. 2015
  - https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and
- The entire draft BEs (including all associated documents) were posted to the EPA's ESPP website in April 2016
  - https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and
- Currently seeking public comments on the draft BEs
  - The public comment period on the draft BEs close on June 10, 2016

Brief Background

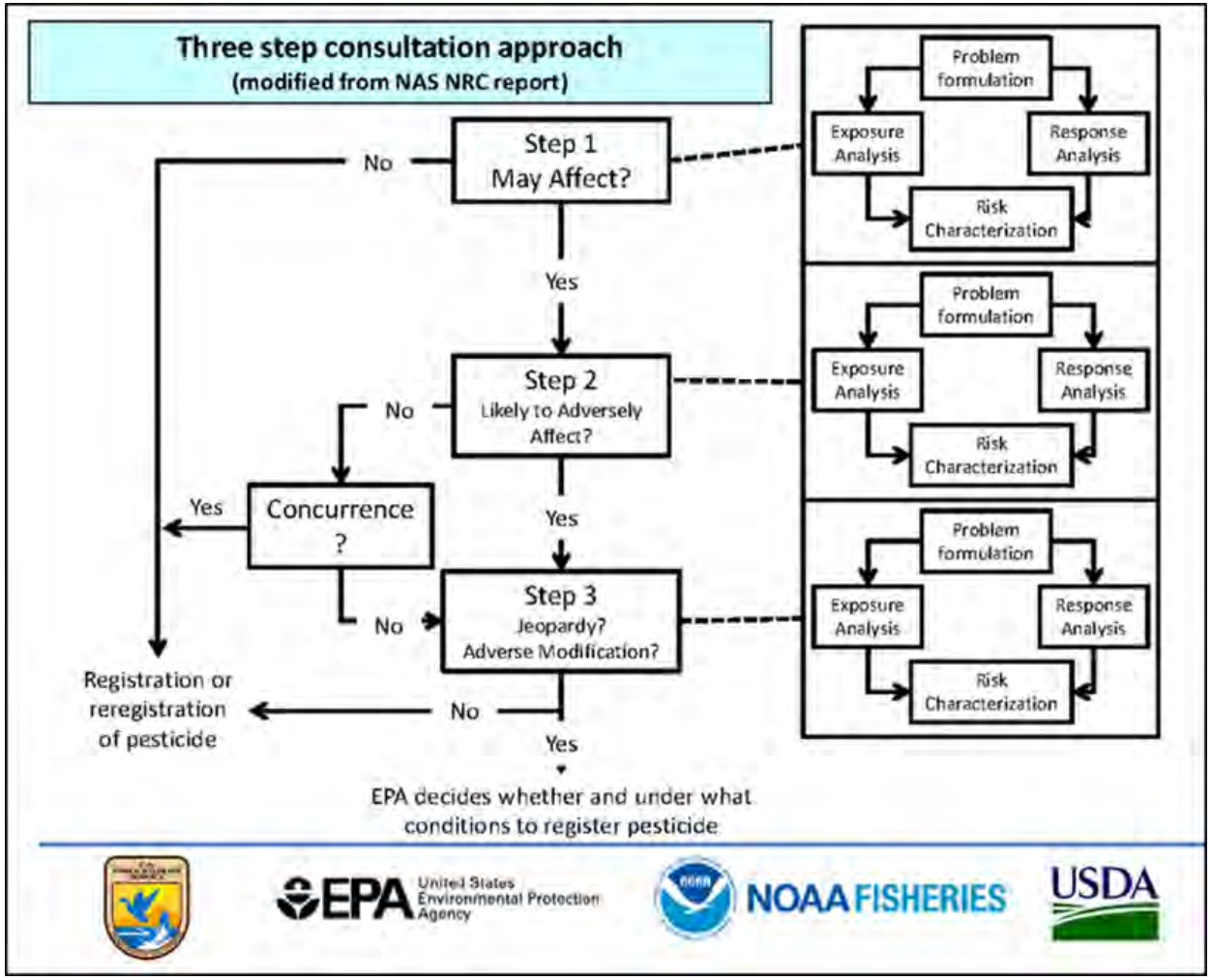
- The consultation process involves:
  - EPA's risk assessment (*i.e.*, the Biological Evaluation) that serves as the basis for the Services' Biological Opinion






Brief Background

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



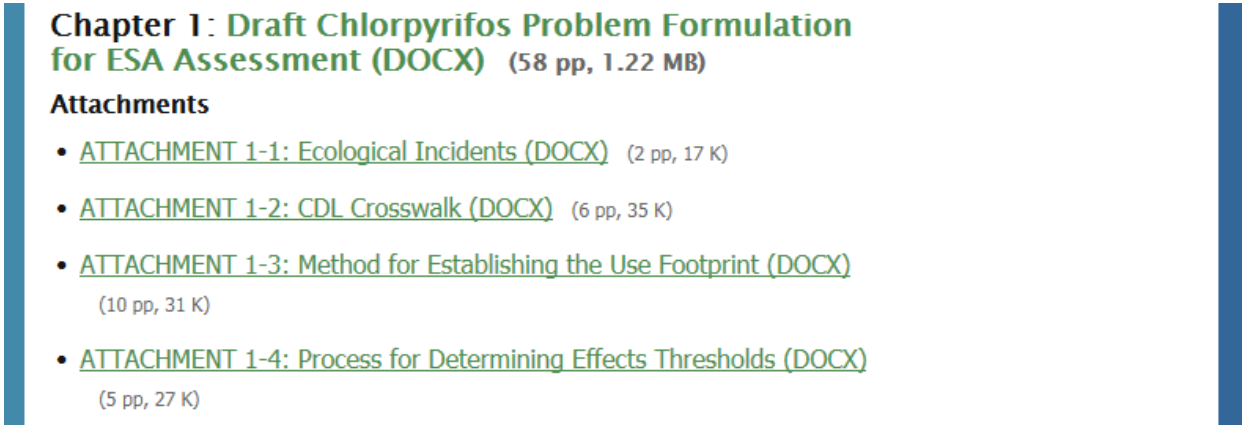
Brief Background

- The Biological Evaluation (BE) determines whether registered pesticides adversely affect one or more individuals of a listed species and 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 registered pesticides result in 'jeopardy' for a listed species or 'adverse modification' of designated critical habitat
  - **Step 3** ["Jeopardy/No Jeopardy" Determination and "Adverse Modification/No Adverse Modification" Determination]

Overview of the Draft BE Process – Problem Formulation

- Outlines the strategic framework and analysis plan for evaluating risk posed by the stressors of the action to one or more individuals of a listed species and their critical habitats
  - Describes the Federal Action
  - Provides information on the pesticide active ingredient
  - Discusses conceptual models
  - Describes the analysis plan



Chapter 1: Draft Chlorpyrifos Problem Formulation for ESA Assessment (DOCX) (58 pp, 1.22 MB)

Attachments

- ATTACHMENT 1-1: Ecological Incidents (DOCX) (2 pp, 17 K)
- ATTACHMENT 1-2: CDL Crosswalk (DOCX) (6 pp, 35 K)
- ATTACHMENT 1-3: Method for Establishing the Use Footprint (DOCX) (10 pp, 31 K)
- ATTACHMENT 1-4: Process for Determining Effects Thresholds (DOCX) (5 pp, 27 K)

Overview of the Draft BE Process – Problem Formulation

- Description of the federal action being assessed:
  - The Federal Action under the ESA – encompasses the EPA's registration of the uses, as described by product labels, of all pesticide products containing the pesticide being assessed
  - The Federal Action includes products registered under Section 3 (national labels), Section 24c (Special local need labels) and Section 18 (emergency exemptions)

Overview of the Draft BE Process – Problem Formulation

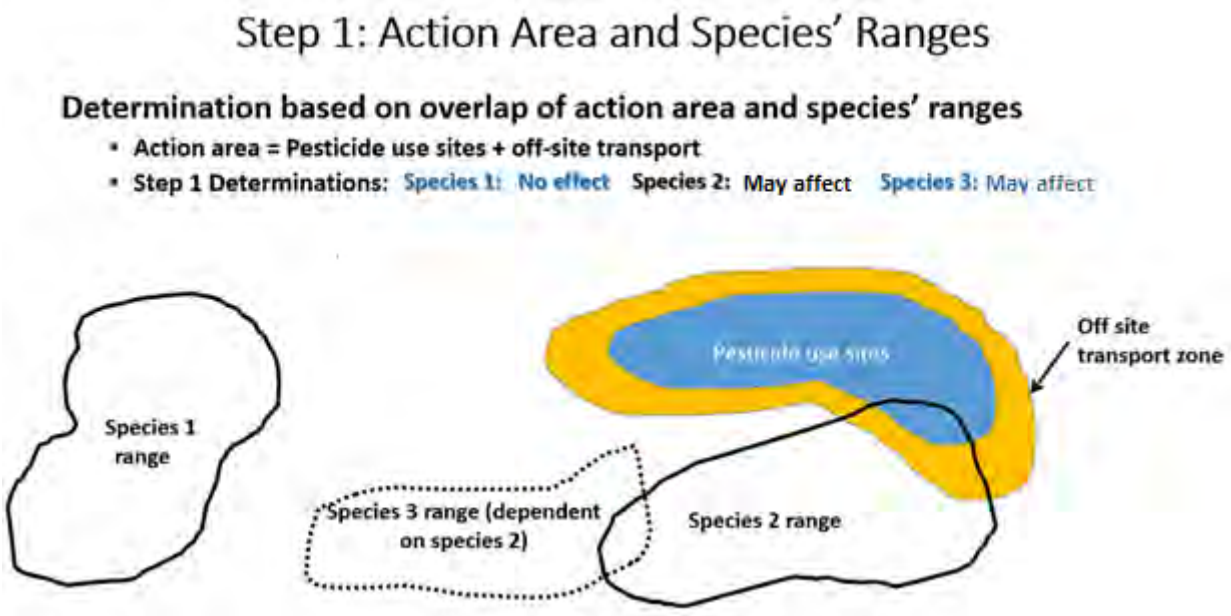
- Fate overview
  - Chlorpyrifos, malathion, and diazinon:
    - Vary in their persistence in the environment
    - Are moderately mobile
    - Show some evidence for volatilization
    - Have variable aquatic solubility limits (chlorpyrifos is the least soluble of the three chemicals)
    - Are not expected to bioaccumulate in the environment (see Chapter 3)
  - Potential sources of offsite transport are spray drift, volatilization, and runoff

Overview of the Draft BE Process – Problem Formulation

- Risk Hypotheses:
  - Use of the pesticide, according to registered labels, results in exposure that reduces the fitness of an individual of a listed species based on:
    - direct effects
    - indirect effects
  - Use of the pesticide, according to registered labels, results in effects to designated critical habitat by adversely impacting primary constituent elements (PCEs) or other essential physical and biological features (PBFs)
- Considers all of the known stressors of the action [*e.g.*, parent active ingredient and its degradate of concern (oxon), formulations, and mixtures] and abiotic or biotic factors likely present in the environment that may alter the toxicity of the pesticide

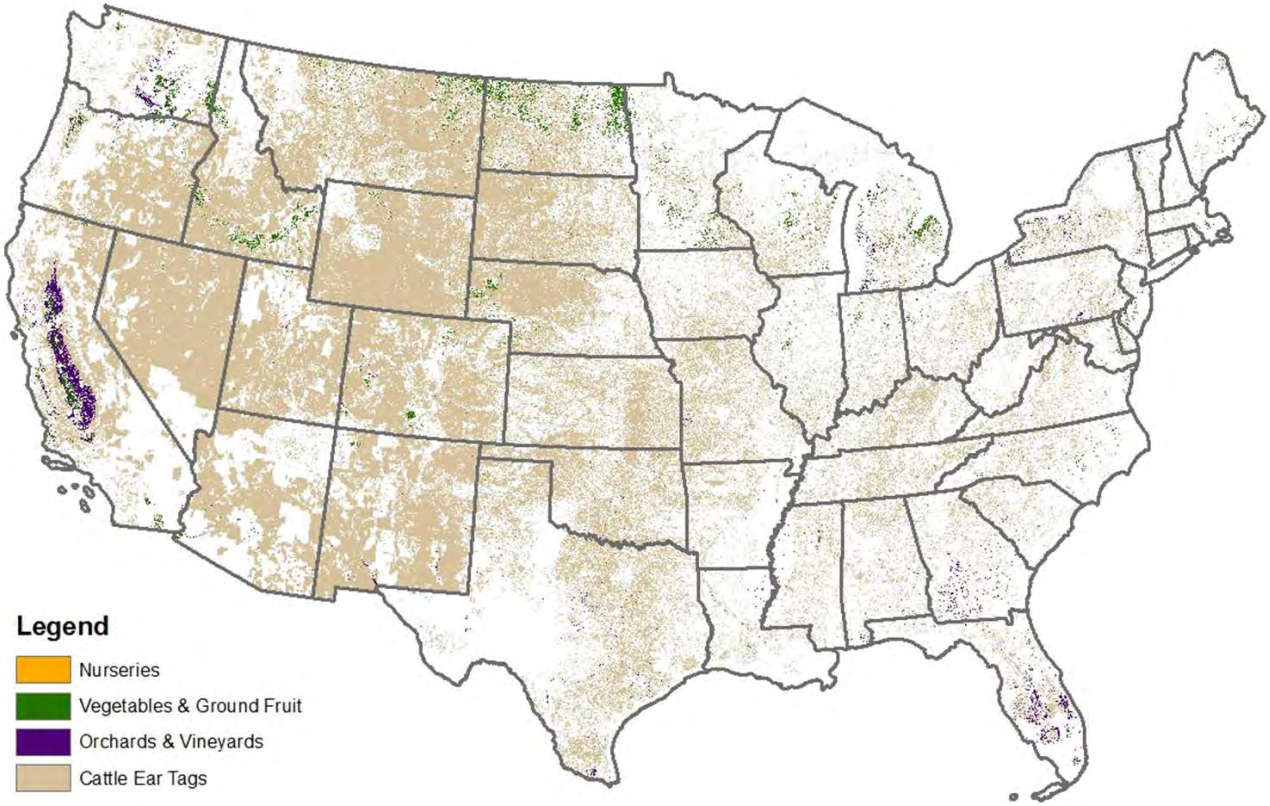
Overview of the Draft BE Process – Analysis Plan (Step 1)

- Step 1
  - "May Affect" determination will be made for any listed species and/or designated critical habitat that overlaps with the action area
  - Action area – "…all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action" (50 CFR §402.2)



Overview of the Draft BE Process – Analysis Plan (Step 1)

- Step 1
  - The footprint layer represents the application site for agricultural and non-agricultural label uses.



Overview of the Draft BE Process – Analysis Plan (Step 1)

- Step 1
  - Agricultural Use Sites:
    - The Cropland Data Layer (CDL), produced by the USDA, is used to spatially represent potential agricultural use sites.
      - The CDL is a land cover dataset that has over 100 cultivated classes that the Agency groups into 11 general classes.
      - 5 years of the most recent CDLs, from 2010-2014, are aggregated to account for crop rotations.
    - The agricultural classes are further refined by comparing county level National Agricultural Statistics Service (NASS) Census of Agriculture (CoA) acreage reports to county level CDL acreages.
    - If a county's CDL acreage for a given class is lower than the NASS acreage, the CDL class's extent is expanded within cultivated areas until the CDL acreage matches the NASS Census acreage.

Overview of the Draft BE Process – Analysis Plan (Step 1)

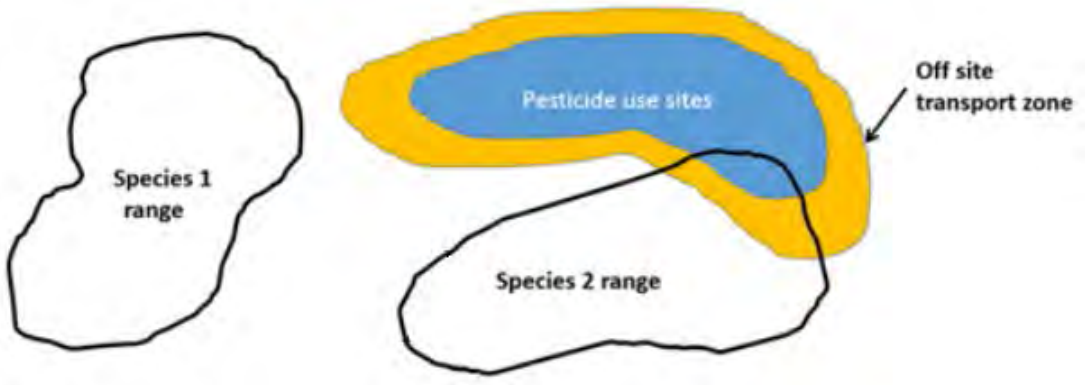
- Step 1
  - Non-Agricultural Use Sites:
    - Non-agricultural label uses include a wide range of land cover and land use categories.
    - Each label use is considered and represented by the best available land cover data.
    - Generally, the National Land Cover Dataset (NLCD) is used to represent non-agricultural label uses. When the NLCD is inadequate, other data sources are used as appropriate.

Overview of the Draft BE Process – Analysis Plan (Step 1)

- The action area is based on the lowest toxicity value for the most sensitive species in the environment that results in the farthest distance from the use site(s):
  - **Animals**:
    - Mortality - concentration that results in a 1-in-a-million chance of mortality [based on HC_{05} of SSD or most sensitive LC_{50}/LD_{50} (if an SSD cannot be derived)]
    - Sublethal Effects – concentration equal to the lowest NOAEC/NOAEL/EC_x value for an effect relatable to survival, growth, or reproduction and environmentally relevant exposure routes
  - **Plants**:
    - Concentration equal to the lowest NOAEC or EC_{05} value

Overview of the Draft BE Process – Analysis Plan (Step 1)

- Evaluation conducted primarily with GIS tools looking at Crop Data Layers as surrogate for pesticide use sites and species range and critical habitat data provided by the Services
  - Answering the question "Is there potential for direct and/or indirect effects from the action?"
- No Effect /May Affect determination
  - 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 Draft BE Process – Analysis Plan (Step 2)

- Process is intended:
  - To be conservative
    - Use “high end” estimates of exposure
    - Use toxicity thresholds based on sensitive endpoints
  - Support weight of evidence approach
    - Use range of exposure estimates
    - Use other toxicity data considered
  - To assess risks of a pesticide to approximately 1800 species
    - Efficiently
    - Transparently
    - Consistently

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Step 2 - Describe how 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

Overview of the Draft BE Process – Analysis Plan (Step 2)

- The Analysis Plan also includes a description of:
  - Weight-of-evidence approach
  - Lines of evidence
  - Estimating exposures (in aquatic and terrestrial habitats)
  - Effects thresholds (direct and indirect effects)
  - Effects arrays
  - Incident data
  - Mixture analysis
  - Consideration of biotic and/or abiotic effects on toxicity

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Weight-of-Evidence approach (WoE) - Uses various lines of evidence to evaluate the totality of the direct and indirect impacts of the action on the species and/or critical habitat. Lines of evidence include:
  - Mortality
  - Growth
  - Reproduction
  - Behavior
  - Sensory effects
  - Mixtures
  - Abiotic/Biotic factors
- Evaluate both the exposure and effects data to determine the weight of the 'risk' and 'confidence' associated with the data available for each line of evidence

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Exposure
  - Relevance of environmental models for generating EECs for receiving habitats (terrestrial and aquatic)
  - Robustness of EECs derived from environmental models
- Effects
  - Biological relevance of effects data
    - Is there a relationship between the effects data and line of evidence?
  - Surrogate relevance of effects data
    - Is the effects data measured with the listed species or an appropriate surrogate?
  - Robustness of information
    - Do we have multiple, independent studies that show the same effect?

Overview of the Draft BE Process – Analysis Plan (Step 2)

- WoE template (animals) – filled out for each listed species included in Step 2:

Lines of Evidence	Weight of evidence (confidence in exposure and effects data)					Risk Estimate (Overlap of exposure and effect)	Overall confidence high, medium, low
	Factors to consider for confidence in data						
	EXPOSURE		EFFECTS				
	Relevance	Robustness	Biological Relevance	Species Surrogacy	Robustness		
Mortality							
Growth							
Reproduction							
Behavioral							
Sensory effects							
Indirect effects							
Mixtures							
Abiotic/Biotic factors (bacterial/viral. pH, temperature)							

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Effects determinations based on pairings of risk and confidence for the lines of evidence:

Risk Estimate (for any line of evidence)	Confidence	Effect Determination
High	High	LAA
High	Med	LAA
High	Low	LAA
Medium	High	LAA
Medium	Medium	LAA
Medium	Low	NLAA or LAA*
Low	High	NLAA
Low	Medium	NLAA or LAA*
Low	Low	NLAA or LAA*

* The selection of the appropriate effects determination associated with this 'risk' and 'confidence' pairing may require additional discussion with FWS and NMFS.

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Exposure Conceptual Approach:
  - Scale of assessment is at field or water body
    - Terrestrial species:
      - Assume that individual can be exposed on the field
      - Assume that individual can be exposed in area adjacent to field (via spray drift and/or runoff)
    - Aquatic species:
      - Assume that individual can be exposed in water body adjacent to field
      - Off site transport via drift and downstream movement considered for species not adjacent to field

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating aquatic exposures
  - Use current aquatic models available in EFED
  - Regional (HUC 2) scale modeling of pesticide applications to variety of waterbodies
    - 3 flowing, 3 static, and 3 estuarine/marine
  - Regional use scenarios developed by modifying existing use scenarios to reflect weather in region

HUC 2 map of the continental US

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating aquatic exposures
  - Step 1 (overlap of action area w/ species range)
    - Use most protective scenario, smallest waterbodies, and lowest toxicity threshold
    - Incorporate impacts of spray drift and downstream dilution
  - Step 2 (LAA/NLAA evaluation)
    - Conduct regional analyses using all relevant use scenarios and waterbodies (bins as assigned to specific species)

Overview of the Draft BE Process – Analysis Plan (Step 2)

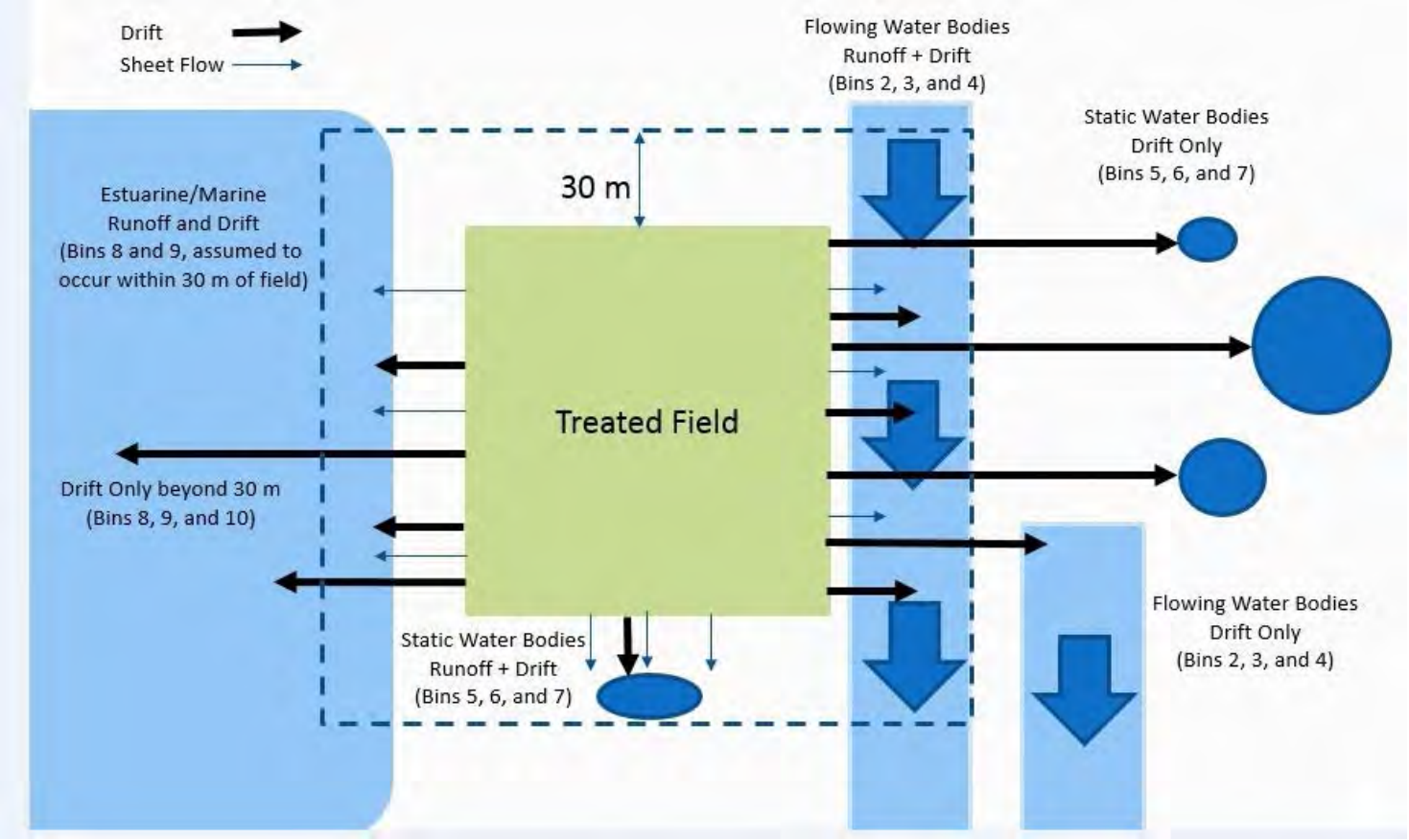
- Estimating aquatic exposures
  - Aquatic Bins:

Generic Habitat	Depth (meters)	Width (meters)	Length (meters)	Flow (m^3/s)
1 – Aquatic-associated terrestrial habitats	NA	NA	NA	NA
2- low-flow	0.1	2	Length of field[1]	0.001
3- Moderate-flow	1	8	Length of field[1]	1
4- High-flow	2	40	Length of field[1]	100
5 – Low-volume	0.1	1	1	0
6- Moderate-volume	1	10	10	0
7- High-volume	2	100	100	0
8- Intertidal nearshore	0.5	50	Length of field	NA
9- Subtidal nearshore	5	200	Length of field	NA
10- Offshore marine	200	300	Length of field	NA

[1] length of field – The habitat being evaluated is the reach or segment that abuts or is immediately adjacent to the treated field. The habitat is assumed to run the entire length of the treated area.

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating aquatic exposures
  - Conceptual model

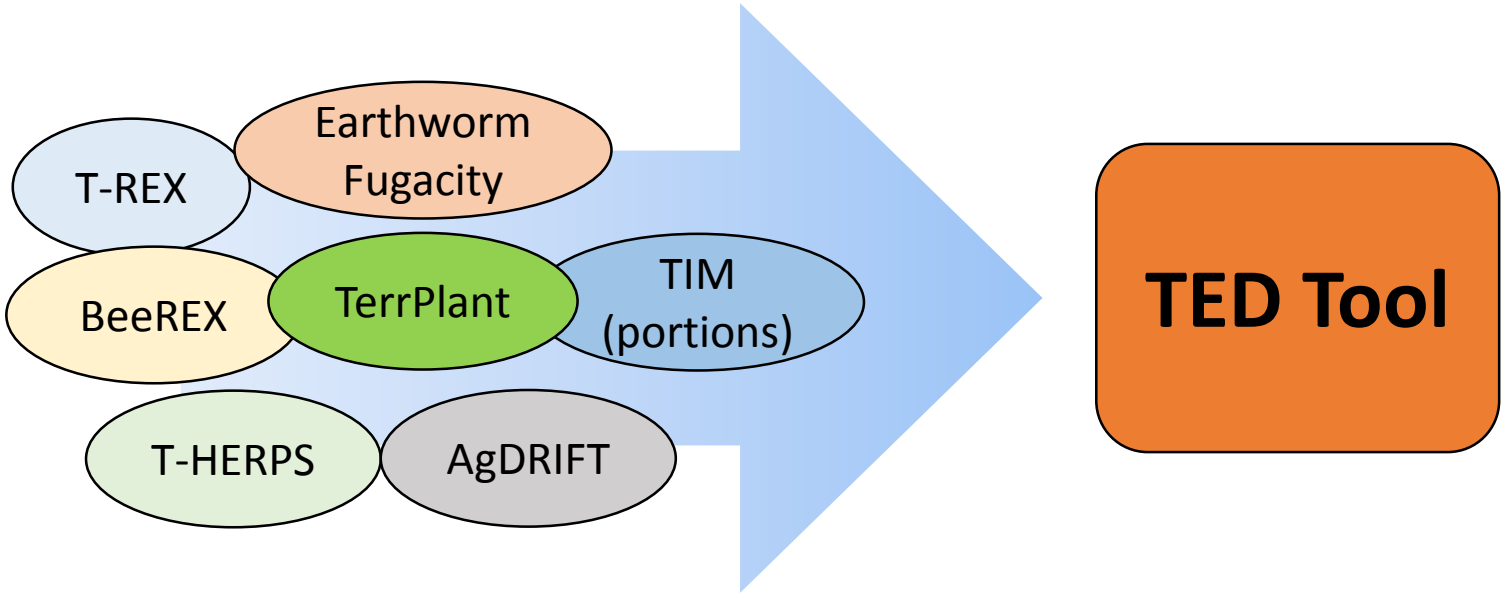


Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating aquatic exposures
  - Updates to tools
    - Pesticide in Water Calculator (PWC)
    - New use scenarios
    - Ability to batch run hundreds to thousands of files
  - PWC Postprocessor
    - Spreadsheet tool designed to post process PWC runs and generate graphs and tables to assist in making an effects determination
    - Generates:
      - Probability distribution
      - Spread of EECs by Julian date
      - Number of exceedances per month
      - Exceedance determination for each species in HUC 2 and aquatic bin

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating terrestrial exposures
  - Terrestrial Effects Determination (TED) Tool
    - Assesses exposures to mammals, birds, reptiles, amphibians, invertebrates (terrestrial) and plants
    - Relies upon species-specific information (diet, body weight)
    - Integrates existing Tier I models
      - T-REX, T-Herps, Earthworm fugacity model, BeeREX, Terrplant, AgDRIFT, portions of TIM



Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating terrestrial exposures
  - TED Tool:
    - Assesses dietary and dose based exposures
      - Dose based exposures include diet, dermal, inhalation and drinking water routes
        - Adapted from Terrestrial Investigation Model (TIM)
    - Food items included for dietary exposures
      - Plants (grass, broadleaves, flowers, nectar, seeds, fruit)
      - Invertebrates (terrestrial above and below ground, aquatic)
      - Vertebrates (mammals, birds, reptiles, amphibians, carrion, fish)
    - Dermal = direct spray, contact with contaminated foliage
    - Drinking water = dew, puddles
    - Inhalation = direct spray, vapor phase
  - The TED tool considers different exposure routes, but does NOT combine the exposures across these routes

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Estimating terrestrial exposures
  - Refined assessment for a subset of listed bird species (13)
    - TIM – Terrestrial Investigation Model
    - MCnest – Markov Chain Nest Productivity Model
  - Determine probability and magnitude of mortality to exposed individuals (TIM)
  - Determine declines in fecundity (MCnest)
  - For diazinon (for one species):
    - Explore refined methods for estimating proportion of population exposed
    - Identify preferred habitats of species within county-level ranges provided by the Services

Least Bells vireo

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Effects thresholds (animals)

Mortality:
- *Direct effects* – 1 in a million chance
- *Indirect effects* – 10% chance of mortality

Sublethal:
- *Direct effects* – Most sensitive NOAEC
- *Indirect effects* – most sensitive LOAEC

Taxon (Direct Effects) (Indirect Effects) or Taxa on which a listed species depends	Mortality	Sublethal Effects
Birds[1]	Direct Effects: Concentration (or dose) that would result in a chance of 1 in a million of causing mortality to an individual. This is calculated by using HC05 of SSD2 of LC50, LD50, or EC50 values for taxa and representative slope. If SSD cannot be derived, most sensitive LC50, LD50, or EC50 for taxa will be used and most representative slope Indirect Effects: Concentration (or dose) that would result in a decrease of 10% of individuals (i.e. the EC_{10}). This is calculated by using HC_{05} of SSD of LC_{50}/LD_{50} or EC_{50} values and representative slope. If SSD cannot be derived, most sensitive LC_{50}/LD_{50} or EC_{50} will be used.	Direct effects: Lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (EC_x) that can be linked to survival or reproduction of a listed individual will be used. Indirect Effects: LOAEC/LOAEL for growth or reproduction will be used (see text for details).
Mammals[1]		
Reptiles		
Terrestrial-phase amphibians		
Aquatic-phase amphibians		
Fish		
Aquatic invertebrates		
Terrestrial invertebrates		

[1]Lowest LD50 or NOAEL/LOAEL for birds and mammals determined by normalizing results to 100 g body weight for birds and 15 g body weight for mammals prior to establishing threshold values.
[2] SSD = Species Sensitivity Distribution

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Effects thresholds (plants)

Mortality:
- None

Sublethal:
- *Direct effects* – most sensitive NOAEC
- *Indirect effects* – most sensitive LOAEC/EC_{50} (aquatic plants)/EC_{25} (terrestrial plants)

Taxon (Direct Effects) (Indirect Effects) or Taxa on which a listed species depends	Sublethal Effects (Direct)	Sublethal Effects (Indirect)
Aquatic plants Terrestrial plants Wetland plants	*Aquatic plants*: Non-vascular - Concentration equal to the lowest value among the available NOAEC and EC05 values for non-vascular aquatic plants Vascular - Concentration equal to the lowest value among the available NOAEC and EC05 values for vascular aquatic plants *Terrestrial and wetland plants*: Monocots - Concentration equal to the lowest value among the monocot NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies Dicots - Concentration equal to the lowest of the dicot NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies Non-angiosperm - Concentration equal to the lowest of the NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies	*Aquatic plants*: Concentration equal to the lowest available LOAEC and EC_{50} value for aquatic plants *Terrestrial and wetland plants*: Concentration equal to the lowest LOAEC and EC_{25} value from the available seedling emergence and vegetative vigor studies

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Effects thresholds: New tools developed to facilitate analysis of large amounts of toxicity data
    - Array Builder
        - Spreadsheet designed to process effects data from ECOTOX as well as registrant submitted studies
        - Allows graphical presentation of data together and to evaluate all data holistically
        - Integrates Adverse Outcome Pathway
        - Filters data by species (family, genus), endpoint type (dietary, dose), and effect

Overview of the Draft BE Process – Analysis Plan (Step 2)

Array Builder – example output

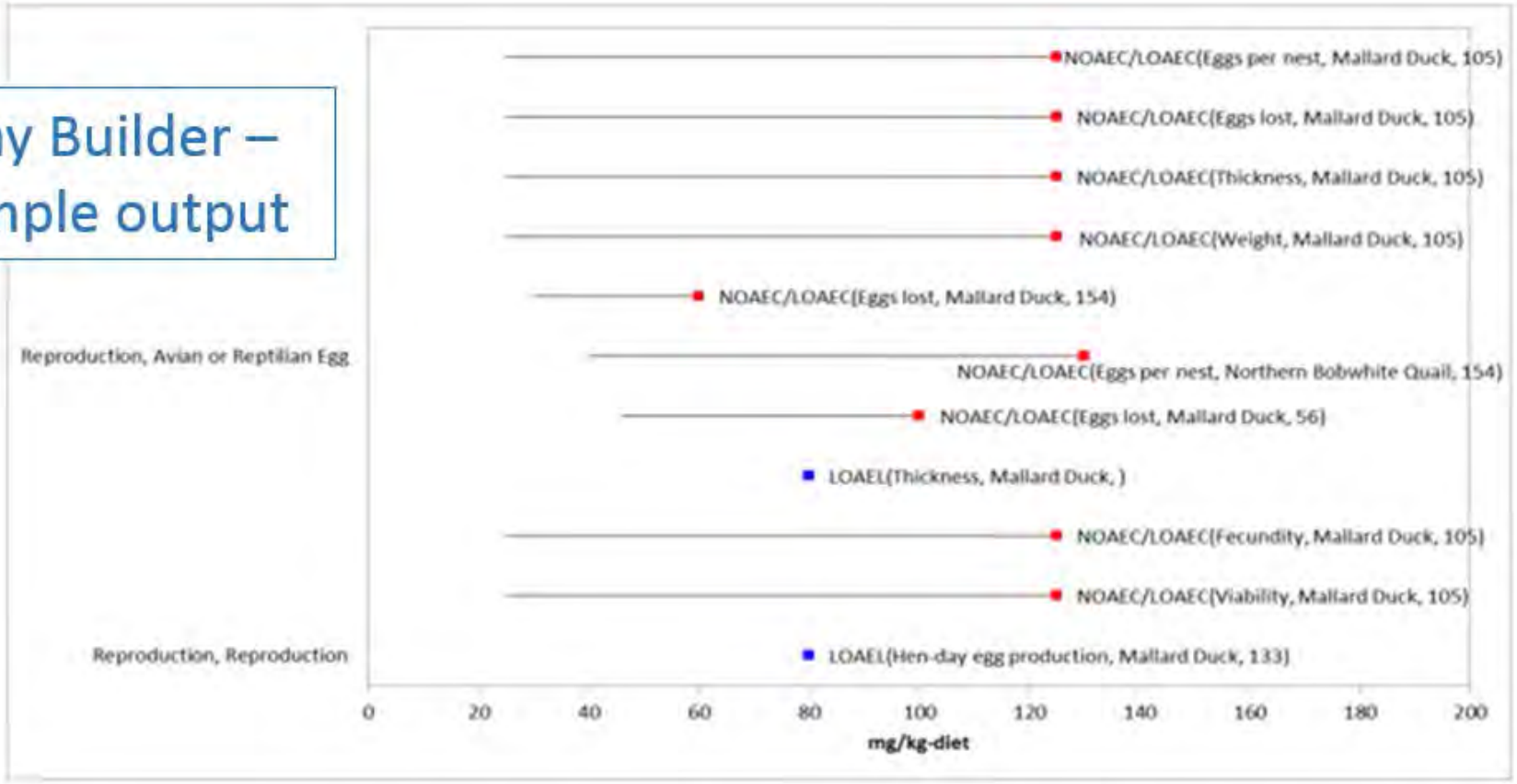


Figure 5-10. Dietary-based Reproduction Endpoints (mg a.i./kg-diet) for Birds Exposed to Chlorpyrifos. Data from registrant submitted (red) and open literature (blue). Bars represent NOAEC/LOAEC range with the LOAEC value represented by the colored data point (studies where only a LOAEC was identified are represented with single data point). (LC*x*=x% mortality, NR-LETH=100% mortality). Data label key: Endpoint (measured effect, species, duration in days).

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Effects thresholds: New tools developed to facilitate analysis of large amounts of toxicity data
  - SSD toolbox
    - Allows assessor to select best distribution from 5 different distributions
    - Improves consistency
    - Methods presented to SAP in 2012

Table 2-4. Summary Statistics for SSDs Fit to Malathion Test Results (toxicity values reported in unit of µg/L)

Statistic	All Vertebr.	FW Vertebr.	All Fish	FW Fish	SW Fish	Aquat. Amphib
Best Distribution (by AIC_c)	Triangular	Triangular	triangular	Triangular	Triangular	Triangu
Goodness of fit P-value	1	1	1	1	1	1
CV of the HC_{05}	0.3639	0.43	0.4132	0.5032	0.7305	1.74
HC_{05}	43.26	50.54	38.56	45.19	42.82	178.4
HC_{10}	77.24	90.9	68.09	80.74	57.85	261.1
HC_{50}	892.1	1082	750.1	934.37	228.12	1484
HC_{90}	10302	12882	8263	10813	1964	22686
HC_{95}	18395	23168	14590	19317	4471	64306
Mortality Thresh.[1] (slope = 4.5)	3.80	4.44	3.39	3.97	3.76	15.7
Indirect Effects Threshold[1] (slope = 4.5)	22.5	26.2	20.0	23.5	22.2	92.6

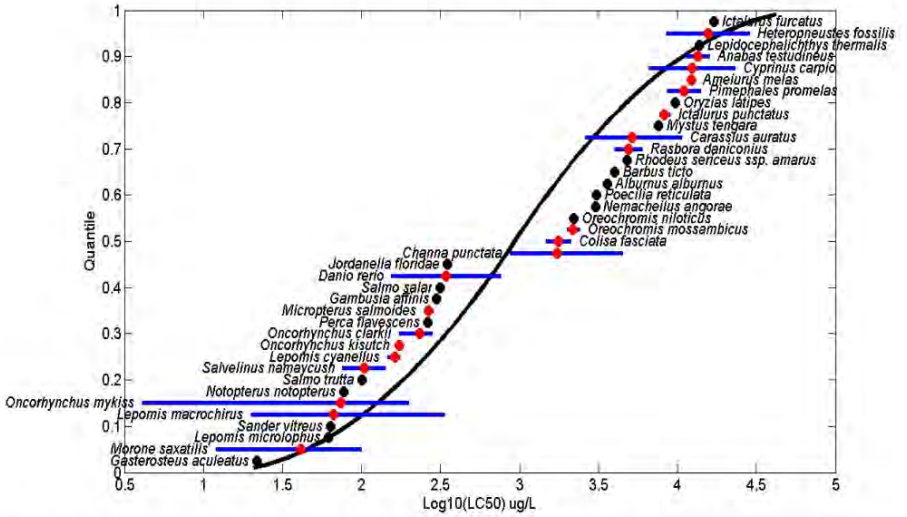


Figure 2-6. SSD for Malathion LC50s for Freshwater Fish. Black points indicate single toxicity values. Red points indicate multiple toxicity values. Blue line indicates full range of toxicity values for a given taxon.

Overview of the Draft BE Process – Analysis Plan (Step 2)

- Mixtures
    - Mixtures considered qualitatively
        - Additive toxicity of the pesticide being assessed with other chemicals is the default assumption based on inter-agency discussions and the NAS NRC report recommendations.
        - The NRC report states that “mixture components will contribute to the response only when present in the environment at concentrations that elicit relevant response... [and] such components do not need to be considered when present at concentrations below their toxic thresholds.” (NRC, 2013)

Overview of the Draft BE Process – Effects Characterization

- Summarizes effects of active ingredient on animals and plants
  - Also incorporates available formulation data
  - Uses data from both submitted studies and open literature (ECOTOX)
- Organized by taxon
  - Aquatic: fish, invertebrates, plants
  - Terrestrial: birds, amphibians and reptiles, mammals, invertebrates, plants
- Each taxon section:
  - Provides a table with the effects thresholds
  - Summary effects arrays
  - Specific effects information organized by lines of evidence
    - Mortality, growth, reproduction, behavior, and sensory

Overview of the Draft BE Process – Effects Characterization

- Chlorpyrifos, malathion, and diazinon are insecticides that act by inhibiting cholinesterase activity, thereby preventing the natural breakdown of various cholines and ultimately causing the neuromuscular system to seize.
- The effects of these chemicals have been studied extensively in many taxa, particularly in fish and aquatic and terrestrial invertebrates.
- Studies include acute and chronic laboratory studies with either technical or formulated products.

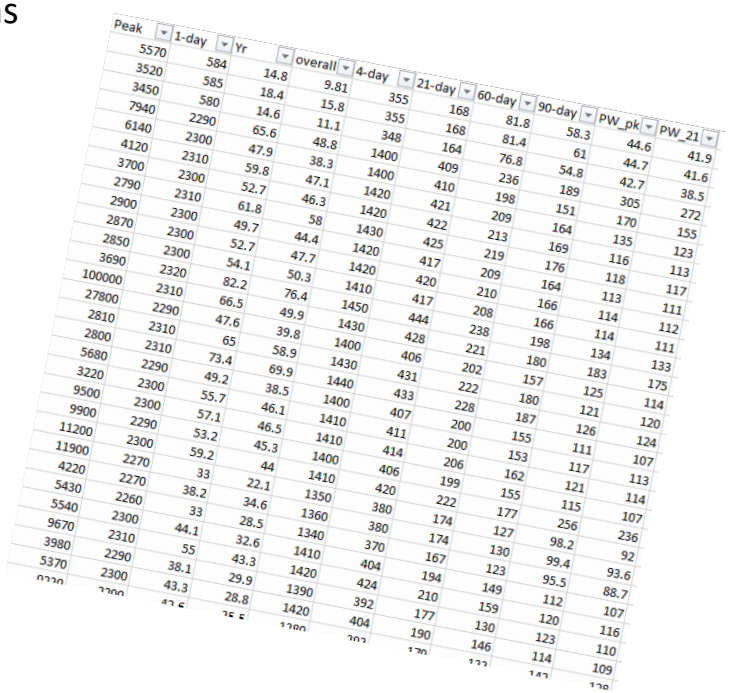
Overview of the Draft BE Process – Effects Characterization

- Chlorpyrifos:
  - The BE considered more than **1,400** ecotoxicity studies (including ~180 fish studies, 26 amphibian studies, ~ 330 aquatic invertebrate studies, 32 aquatic plant studies, 58 bird studies, 1 reptile study, ~160 mammalian studies, ~500 terrestrial invertebrate studies, and ~125 terrestrial plant studies).
- Malathion:
  - The BE considered more than **900** ecotoxicity studies for malathion (including (approximates) 225 fish and aquatic-phase amphibian studies, 260 aquatic invertebrate studies, 25 aquatic plant studies, 47 bird studies, 7 reptile and terrestrial-phase amphibian studies, 150 mammalian studies, 140 terrestrial invertebrate studies, and 49 terrestrial plant studies).
- Diazinon:
  - The BE considered more than **500** ecotoxicity studies for diazinon (including approximately 130 fish studies, 10 amphibian studies, 130 aquatic invertebrate studies, 10 aquatic plant studies, 80 bird studies, 1 reptile study, 70 mammalian studies, 170 terrestrial invertebrate studies, and 60 terrestrial plant studies).

Overview of the Draft BE Process – Exposure Characterization

- Provides information on:
  - The fate and transport properties for each chemical
  - Detailed information on specifically how the aquatic and terrestrial exposure estimates were determined for each chemical
  - Aquatic EECs (based on thousands of modeling runs):
    - Chlorpyrifos: >12,000 PWC runs
    - Malathion: ~6,000 PWC runs
    - Diazinon: >45,000 PWC runs

Sample PWC output



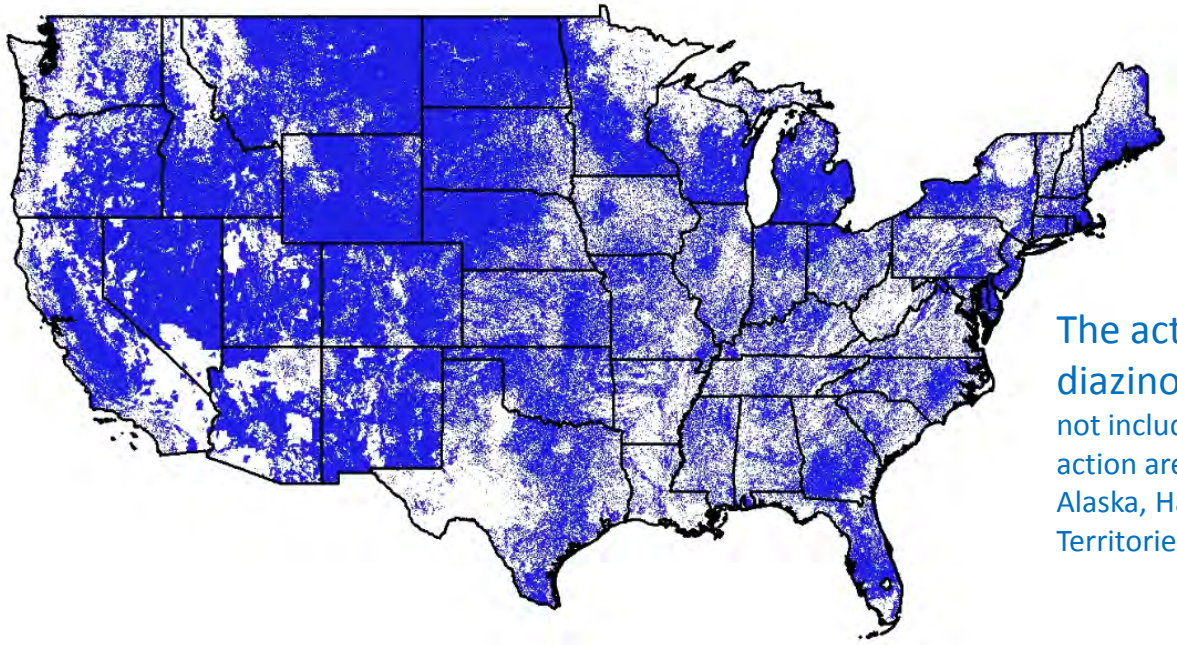
Peak	1-day	Yr	overall	4-day	21-day	60-day	90-day	PW_pk	PW_21
5570	584	14.8	9.81	355	168	81.8	58.3	44.6	41.9
3520	585	18.4	15.8	355	168	81.4	61	44.7	41.6
3450	580	14.6	11.1	348	164	76.8	54.8	42.7	38.5
7940	2290	65.6	48.8	1400	409	236	189	305	272
6140	2300	47.9	38.3	1400	410	198	151	170	155
4120	2310	59.8	47.1	1420	421	209	164	135	123
3700	2300	52.7	46.3	1420	422	213	169	116	113
2790	2310	61.8	58	1430	425	219	176	118	117
2900	2300	49.7	44.4	1420	417	209	164	113	111
2870	2300	52.7	47.7	1420	420	210	166	114	112
2850	2300	54.1	50.3	1410	417	208	166	114	111
3690	2320	82.2	76.4	1450	444	238	198	134	133
100000	2310	66.5	49.9	1430	428	221	180	183	175
27800	2290	47.6	39.8	1400	406	202	157	125	114
2810	2310	65	58.9	1430	431	222	180	121	120
2800	2290	73.4	69.9	1440	433	228	187	126	124
5680	2310	49.2	38.5	1400	407	200	155	111	107
3220	2290	55.7	46.1	1410	411	200	153	117	113
9500	2300	57.1	46.5	1410	414	206	162	121	114
9900	2290	53.2	45.3	1400	406	199	155	115	107
11200	2300	59.2	44	1410	420	222	177	256	236
11900	2270	33	22.1	1350	380	174	127	98.2	92
4220	2270	38.2	34.6	1360	380	174	130	99.4	93.6
5430	2260	33	28.5	1340	370	167	123	95.5	88.7
5540	2300	44.1	32.6	1410	404	194	149	112	107
9670	2310	55	43.3	1420	424	210	159	120	116
3980	2290	38.1	29.9	1390	392	177	130	123	110
5370	2300	43.3	28.8	1420	404	190	146	114	109

Overview of the Draft BE Process – Effects Determinations

- Step 1
  - "No Effect" determination –
    - When no co-occurrence is identified between the listed species range (including designated critical habitat) and the action area (area of effect including the site of application and off-site transport).
    - "No Effect" determinations were also made for species with no designated critical habitat that met at least one of the following criteria: a) the species is presumed by the U.S. Fish and Wildlife Service (USFWS) to be extinct; b) the species no longer occurs in the US; or c) the species exists only in captivity.
  - "May Affect" determination = When co-occurrence is identified between the listed species range (and/or designated critical habitat) and the action area (area of effect including the site of application and off-site transport).
    - Species and/or its designated critical habitat with 'May Affect' determinations move to Step 2 for further analysis.

Overview of the Draft BE Process – Effects Determinations

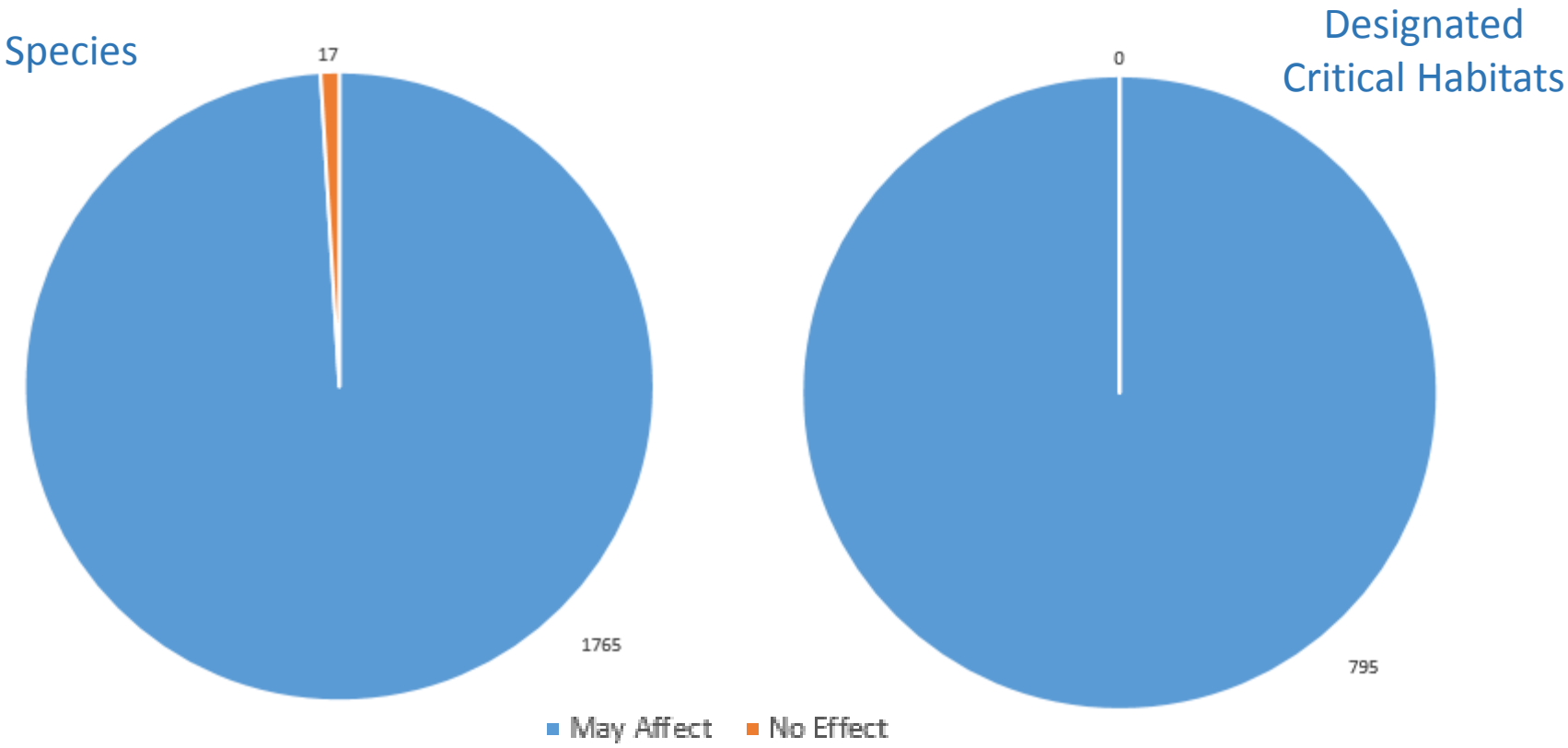
- Step 1 (Action Area)
  - Chlorpyrifos and Malathion = the entire US and its territories
    - Due to uses that could not be geographically limited based on label information (e.g., mosquito adulticides)
  - Diazinon =
    - Includes all label uses (vegetable and ground fruit, orchard and vineyards, nurseries, and cattle eartag) and offsite transport



The action area for diazinon (this figure does not include the parts of the action area associated with Alaska, Hawaii, or the US Territories)

Overview of the Draft BE Process – Effects Determinations

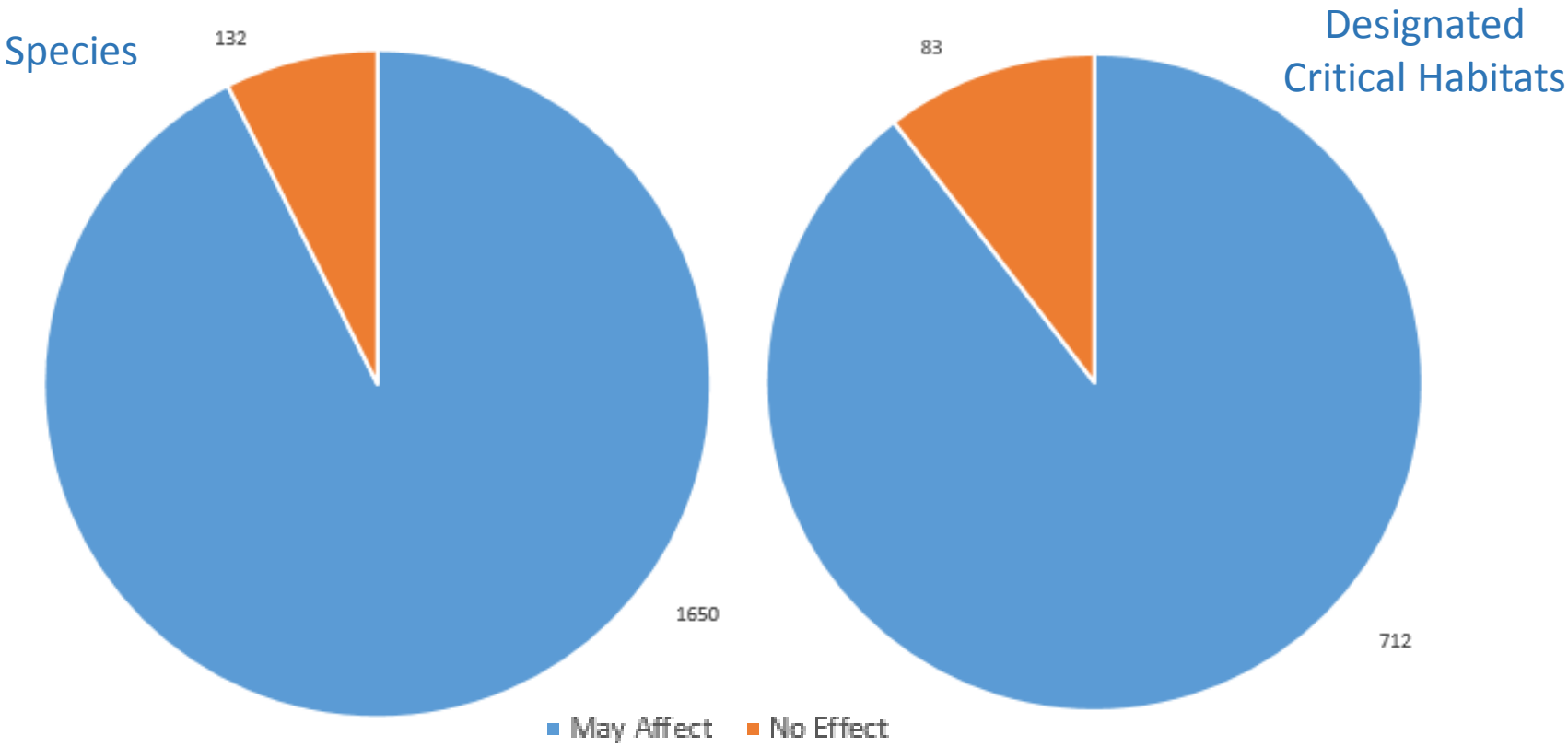
- Step 1 – Chlorpyrifos and Malathion



Additional 20 species not considered further in Step 2 (14 extinct; 6 found on uninhabited Islands of Nihoa and Laysan).

Overview of the Draft BE Process – Effects Determinations

- Step 1 – Diazinon



Additional 20 species not considered further in Step 2 (14 extinct; 6 found on uninhabited Islands of Nihoa and Laysan).

Overview of the Draft BE Process – Effects Determinations

- Step 2
  - Most of the effects determinations in Step 2 were made using a Weight of Evidence Matrix Generator
    - Automates completion of matrix to include species characteristics, exposure values and toxicity endpoints
      - Relies upon listed species life history database
    - Incorporates direct effects, indirect effects (based on diet and habitat) and obligate relationships
    - Includes overlap data for range and potential use sites (based on the labels)
    - Tool for overlap analysis

Overview of the Draft BE Process – Effects Determinations

	Species scientific name	*Palmeria dolei*	Species order:	Passeriformes			
	Species common name	Crested honeycreeper		MIGRATORY SPECIES?	No	ALTERNATE RATE OUTPUT DISPLAYED FOR THIS SPECIES?	Yes
	Species number	74		CRITICAL HABITAT?	Yes		
	TAXA	Birds		OBLIGATE RELATIONSHIP?	No		
Risk hypothesis:	Use of malathion according to registered labels results in exposure that reduces the fitness of an individual based on direct effects [Crested honeycreeper]						

Line of evidence	Summary of considerations impacting risk and confidence					Risk (extent of overlap of exposure and effects data)	Confidence (associated with risk conclusion)
	Exposure		Effects				
	Relevance	Robustness	Relevance (biological)	Surrogacy	Robustness		
Mortality	Occurs in Maui, Hawaii; Inhabits: Forest, monane wet and mesic forest; Elevation restriction: 1500 to 2100 meters	T-REX EECs based on empirical residues.	Mortality is relevant to species fitness.	Seven avian species represented in LD50 results which included two Passeriforme species.	18 LC50 and LD50 avian values are available.	HIGH	HIGH
	HABITAT: Top species range overlap(s): 100.00, 16.96, 1.76, 1.73 and 1.05%. Corresponding CDL layer(s): Mosquito Control, Pasture, Vegetables and Ground Fruit, Developed and Open Space Developed.This species has overlap with nonspecified agricultural uses in Hawaii corresponding with 1.50% overlap, respectively. This species also occurs on federal land. The range overlap is 6.49% with the corresponding federal lands of Federally Managed Lands.	Chemical specific foliar dissipation half-life based on 90th percentile of observed foliar dissipation half-life values (n = 37; 0.3 and 10.9 days).	Endpoints beyond 1/million threshold were considered.	SSD derived for dose-based endpoints.	Data available for dose and dietary rate units.	Upper bound EECs based on dietary exposure through food exceeds the 1-in-a-million threshold, does not exceed the LD50 and does not exceed the HC50 for a single application at the minimum application rate of 0.5 lb a.i./A as compared to dose-based endpoints. At the upper bound single application rate of 2 lb a.i./A the maximum EEC based on the highest food item concentration exceeds the 1-in-a-million threshold, exceeds the LD50 and does not exceed the HC50. For the minimum application rate and mean EECs based on the minimum dietary food item concentration, the EEC exceeds the 1-in-a-million threshold, does not exceed the LD50 and does not exceed the HC50.	

Overview of the Draft BE Process – Effects Determinations

- Step 2
  - Potential risks to some listed species/critical habitats were assessed qualitatively because EPA does not currently have methods available to adequately quantify potential exposures for these species.
    - In many cases, these species live exclusively (*i.e.*, whales, deep fish) or primarily (*i.e.*, sea turtles, marine mammals) in marine environments, or are cave dwellers (invertebrate species).
  - Other qualitative analyses focus on certain uses for which reliable exposure methods are not available as current terrestrial methods are focused on non-ULV flowable applications.
    - Cattle ear tag use (for chlorpyrifos and diazinon)
    - Granular and seed treatment uses (for chlorpyrifos)
    - Mosquito adulticides (chlorpyrifos and malathion)

Overview of the Draft BE Process – Effects Determinations

- Step 2 (Chlorpyrifos and Malathion)

TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSLY AFFECT	LIKELY TO ADVERSELY AFFECT	
Birds	5	105	12	93	110
Mammals	3	107	20	87	110
Amphibians	0	43	1	39	40
Reptiles	0	40	0	43	43
Terrestrial Invertebrates	9	115	0	115	124
Fish	0	185	4	182	186
Aquatic Invertebrates	0	221	1	220	221
Plants	0	946	2	946	948
Total	**17**	**1765**	**40**	**1725**	
Percent of Total Number of Species	**1%**	**99%**	**2%**	**97%**	**1782**

Results for listed species

DESIGNATED CRITICAL HABITAT TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSLY AFFECT	LIKELY TO ADVERSELY AFFECT	
Birds	0	30	0	30	30
Mammals	0	34	5	29	34
Amphibians	0	18	0	24	24
Reptiles	0	24	0	18	18
Terrestrial Invertebrates	0	43	0	43	43
Fish	0	107	0	107	107
Aquatic Invertebrates	0	77	0	77	77
Plants	0	462	3	459	462
Total	**0**	**795**	**8**	**787**	
Percent of Total Number of Species	**0%**	**100%**	**1%**	**99%**	**795**

Results for critical habitats

Overview of the Draft BE Process – Effects Determinations

- Step 2 (Diazinon)

TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSLY AFFECT	LIKELY TO ADVERSELY AFFECT	
Birds	7	103	19	84	110
Mammals	3	107	24	83	110
Amphibians	0	40	2	38	40
Reptiles	1	42	0	42	43
Terrestrial Invertebrates	23	101	10	91	124
Fish	1	185	25	160	186
Aquatic Invertebrates	5	216	8	208	221
Plants	92	856	146	710	948
Total	**132**	**1650**	**234**	**1416**	**1782**
Percentage of total #	**7%**	**93%**	**13%**	**79%**	

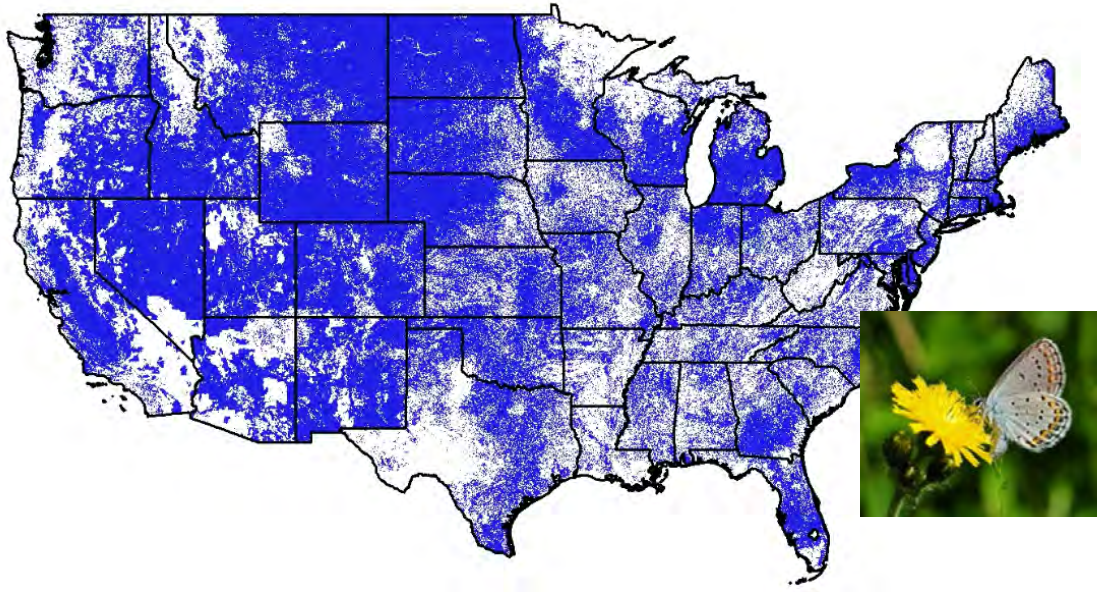
Results for listed species

DESIGNATED CRITICAL HABITAT TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSLY AFFECT	LIKELY TO ADVERSELY AFFECT	
Birds	4	26	5	21	30
Mammals	2	32	8	24	34
Amphibians	2	22	1	21	24
Reptiles	2	16	1	15	18
Terrestrial Invertebrates	11	32	8	24	43
Fish	0	107	13	94	107
Aquatic Invertebrates	3	74	2	72	77
Plants	59	403	203	200	462
Total	**83**	**712**	**241**	**471**	
Percentages of Total number	**10%**	**90%**	**30%**	**59%**	**795**

Results for critical habitats

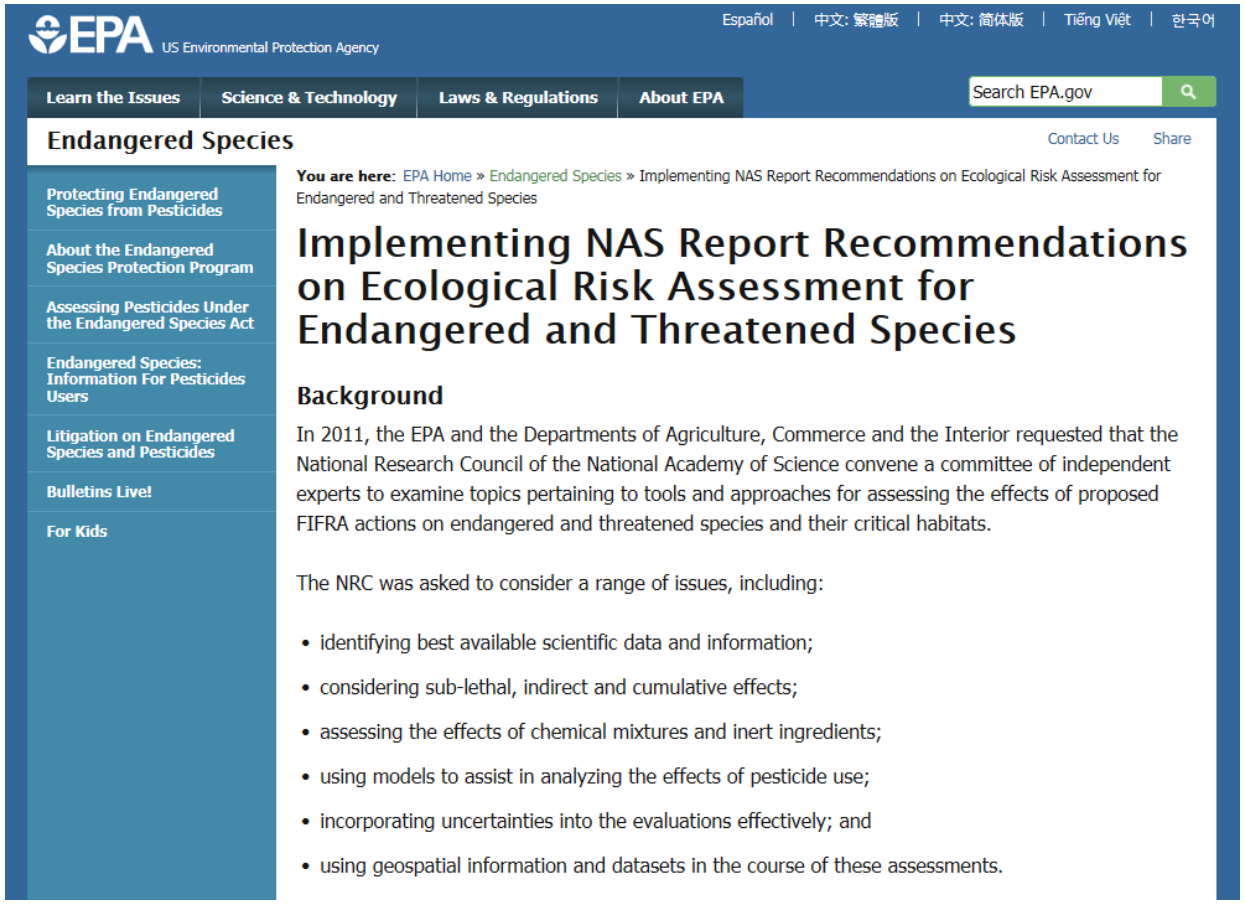
Overview of the Draft BE Process – Effects Determinations

- LAA for most listed species/designated critical habitats:
  - Due to overlap of range/critical habitat and potential uses sites
  - High toxicity (low thresholds), maximum use rates, other assumptions of exposure
  - LAA determination is based on the potential to impact a single individual of a listed species



Overview of the Draft BE Process – Navigating the Documents

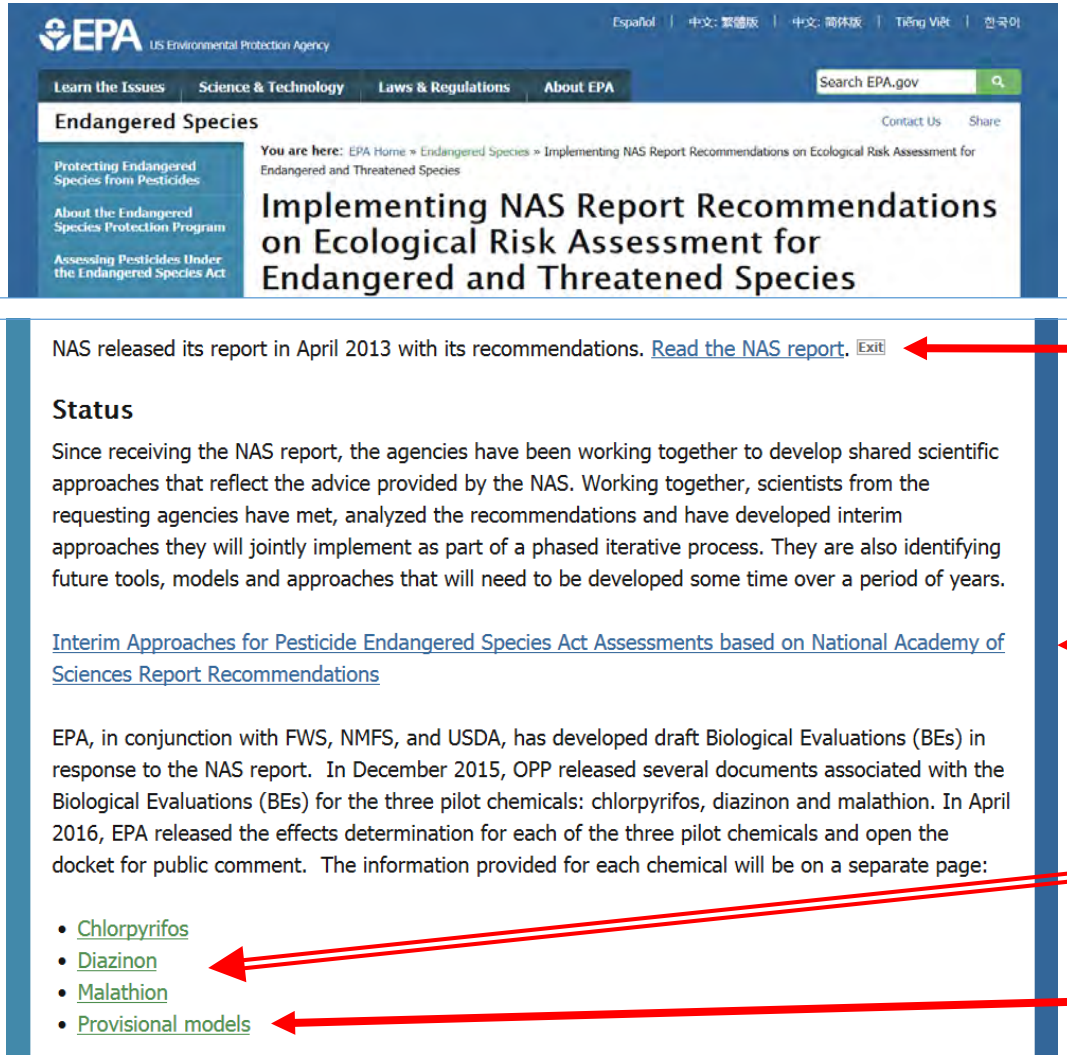
The draft BEs (and supporting documents) can be found at:
https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and



Overview of the Draft BE Process – Navigating the Documents

Scroll down to find the following links:

Scroll down



2013 NAS Report

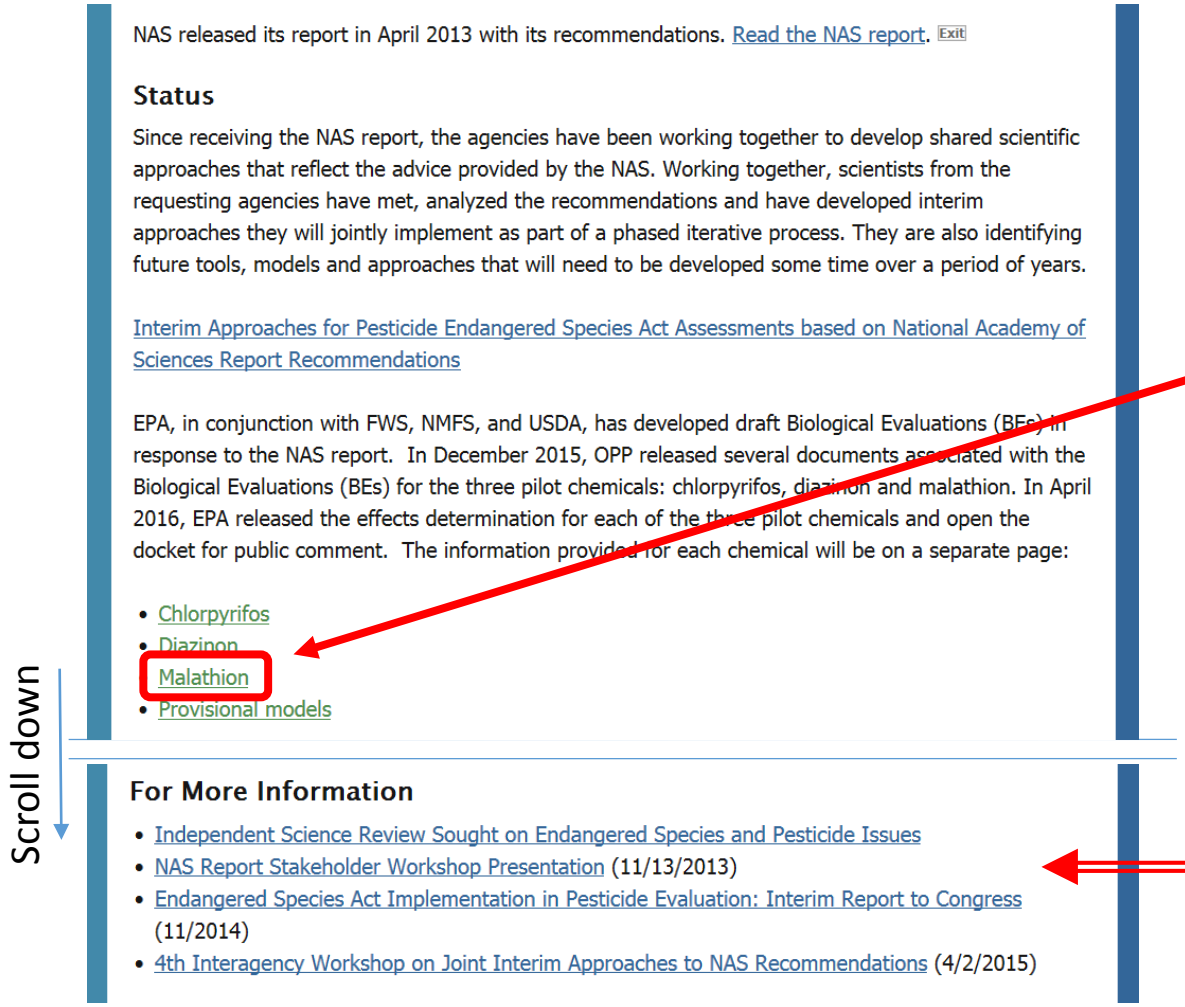
Interim Approaches

Chemical-specific BEs

Provisional Models and Tools

Overview of the Draft BE Process – Navigating the Documents

Scroll down to find the following links:



NAS released its report in April 2013 with its recommendations. Read the NAS report. Exit

Status

Since receiving the NAS report, the agencies have been working together to develop shared scientific approaches that reflect the advice provided by the NAS. Working together, scientists from the requesting agencies have met, analyzed the recommendations and have developed interim approaches they will jointly implement as part of a phased iterative process. They are also identifying future tools, models and approaches that will need to be developed some time over a period of years.

Interim Approaches for Pesticide Endangered Species Act Assessments based on National Academy of Sciences Report Recommendations

EPA, in conjunction with FWS, NMFS, and USDA, has developed draft Biological Evaluations (BEs) in response to the NAS report. In December 2015, OPP released several documents associated with the Biological Evaluations (BEs) for the three pilot chemicals: chlorpyrifos, diazinon and malathion. In April 2016, EPA released the effects determination for each of the three pilot chemicals and open the docket for public comment. The information provided for each chemical will be on a separate page:

- Chlorpyrifos
- Diazinon
- Malathion
- Provisional models

For More Information

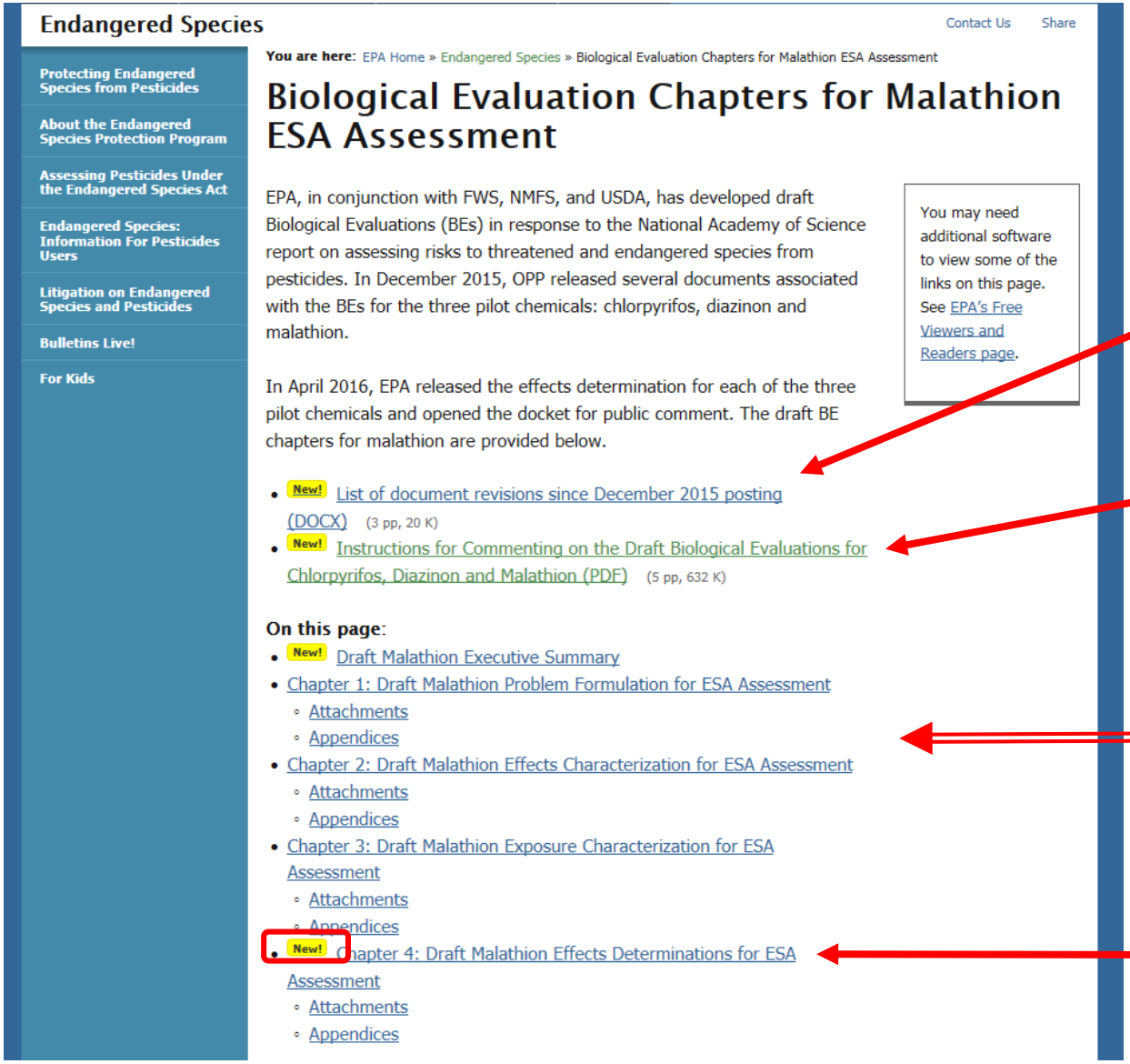
- Independent Science Review Sought on Endangered Species and Pesticide Issues
- NAS Report Stakeholder Workshop Presentation (11/13/2013)
- Endangered Species Act Implementation in Pesticide Evaluation: Interim Report to Congress (11/2014)
- 4th Interagency Workshop on Joint Interim Approaches to NAS Recommendations (4/2/2015)

Scroll down

Once a document has been opened on your computer, the text turns from blue to green

Additional Information

Overview of the Draft BE Process – Navigating the Documents



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You are here: EPA Home » Endangered Species » Biological Evaluation Chapters for Malathion ESA Assessment

Biological Evaluation Chapters for Malathion ESA Assessment

EPA, in conjunction with FWS, NMFS, and USDA, has developed draft Biological Evaluations (BEs) in response to the National Academy of Science report on assessing risks to threatened and endangered species from pesticides. In December 2015, OPP released several documents associated with the BEs for the three pilot chemicals: chlorpyrifos, diazinon and malathion.

You may need additional software to view some of the links on this page. See EPA's Free Viewers and Readers page.

In April 2016, EPA released the effects determination for each of the three pilot chemicals and opened the docket for public comment. The draft BE chapters for malathion are provided below.

- New! List of document revisions since December 2015 posting (DOCX) (3 pp, 20 K)
- New! Instructions for Commenting on the Draft Biological Evaluations for Chlorpyrifos, Diazinon and Malathion (PDF) (5 pp, 632 K)

On this page:

- New! Draft Malathion Executive Summary
- Chapter 1: Draft Malathion Problem Formulation for ESA Assessment
  - Attachments
  - Appendices
- Chapter 2: Draft Malathion Effects Characterization for ESA Assessment
  - Attachments
  - Appendices
- Chapter 3: Draft Malathion Exposure Characterization for ESA Assessment
  - Attachments
  - Appendices
- New! Chapter 4: Draft Malathion Effects Determinations for ESA Assessment
  - Attachments
  - Appendices

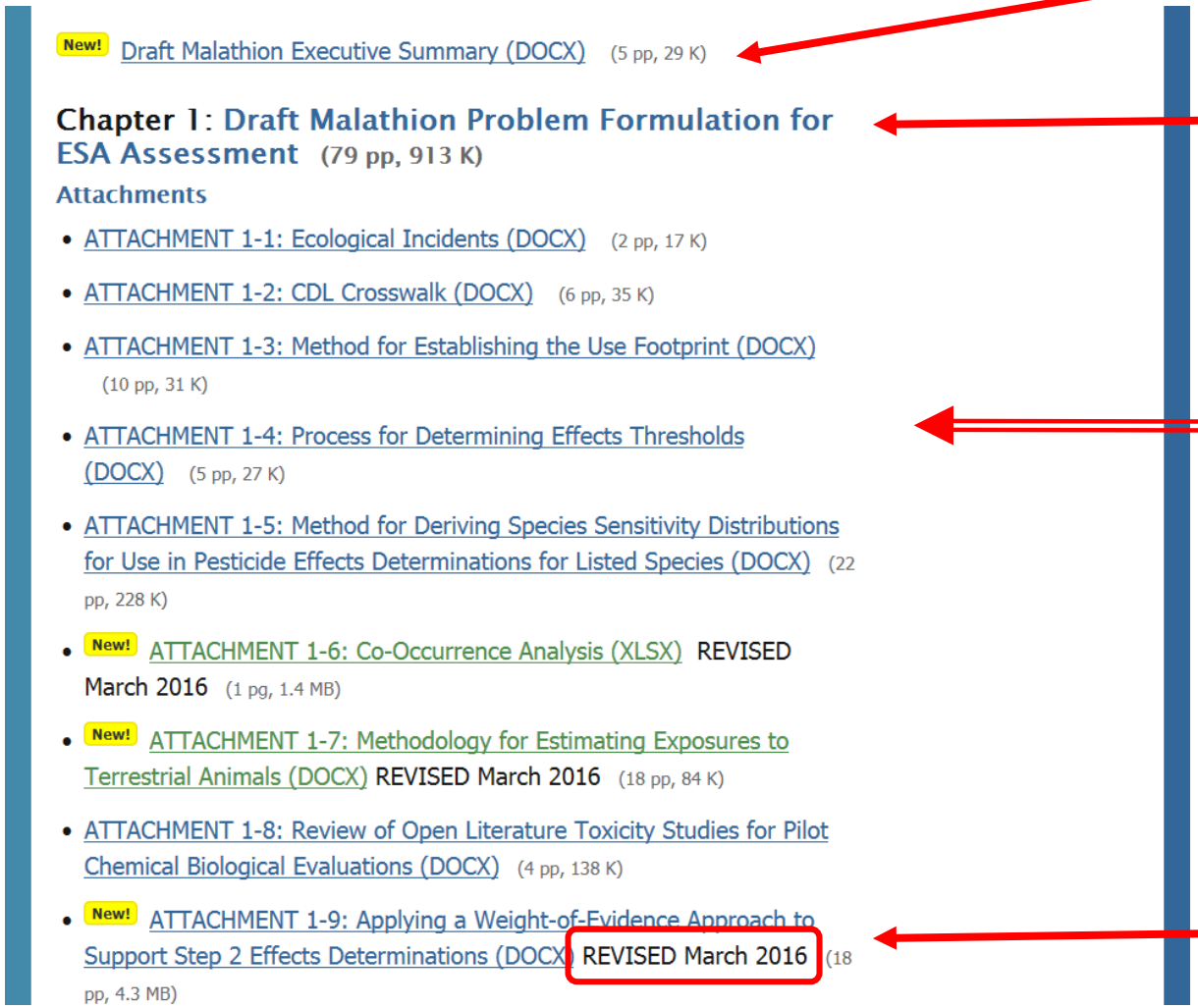
List of document revisions (since the Dec. 2015 posting)

Instructions for commenting on the draft BEs

Hyperlinks to location on page where you can find BE chapters and associated documents

New! = a 'new' or 'revised' document (since the Dec. 2015 posting)

Overview of the Draft BE Process – Navigating the Documents



New! Draft Malathion Executive Summary (DOCX) (5 pp, 29 K)

Chapter 1: Draft Malathion Problem Formulation for ESA Assessment (79 pp, 913 K)

Attachments

- ATTACHMENT 1-1: Ecological Incidents (DOCX) (2 pp, 17 K)
- ATTACHMENT 1-2: CDL Crosswalk (DOCX) (6 pp, 35 K)
- ATTACHMENT 1-3: Method for Establishing the Use Footprint (DOCX) (10 pp, 31 K)
- ATTACHMENT 1-4: Process for Determining Effects Thresholds (DOCX) (5 pp, 27 K)
- ATTACHMENT 1-5: Method for Deriving Species Sensitivity Distributions for Use in Pesticide Effects Determinations for Listed Species (DOCX) (22 pp, 228 K)
- New! ATTACHMENT 1-6: Co-Occurrence Analysis (XLSX) REVISED March 2016 (1 pg, 1.4 MB)
- New! ATTACHMENT 1-7: Methodology for Estimating Exposures to Terrestrial Animals (DOCX) REVISED March 2016 (18 pp, 84 K)
- ATTACHMENT 1-8: Review of Open Literature Toxicity Studies for Pilot Chemical Biological Evaluations (DOCX) (4 pp, 138 K)
- New! ATTACHMENT 1-9: Applying a Weight-of-Evidence Approach to Support Step 2 Effects Determinations (DOCX) REVISED March 2016 (18 pp, 4.3 MB)

Executive Summary

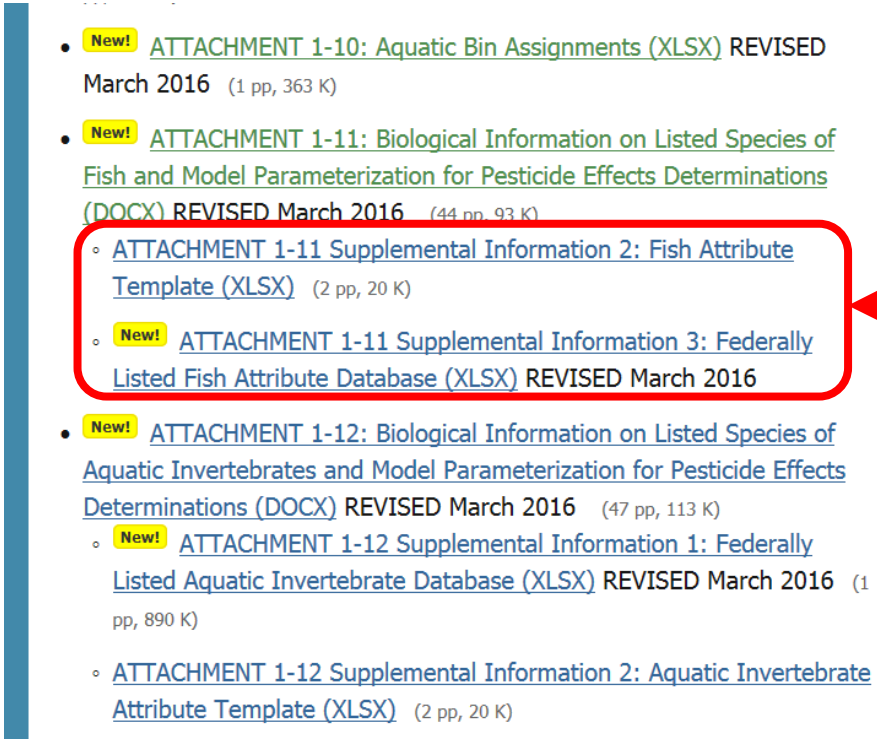
Chapter 1: Problem Formulation

Under each chapter are the links for the supporting documents:

- Attachments = documents shared across chemicals (they are not chemical specific)
- Appendices = documents with chemical-specific information

New! = a 'new' or 'revised' document (since the Dec. 2015 posting)

Overview of the Draft BE Process – Navigating the Documents



- New! ATTACHMENT 1-10: Aquatic Bin Assignments (XLSX) REVISED March 2016 (1 pp, 363 K)
- New! ATTACHMENT 1-11: Biological Information on Listed Species of Fish and Model Parameterization for Pesticide Effects Determinations (DOCX) REVISED March 2016 (44 pp, 93 K)
  - ATTACHMENT 1-11 Supplemental Information 2: Fish Attribute Template (XLSX) (2 pp, 20 K)
  - New! ATTACHMENT 1-11 Supplemental Information 3: Federally Listed Fish Attribute Database (XLSX) REVISED March 2016
- New! ATTACHMENT 1-12: Biological Information on Listed Species of Aquatic Invertebrates and Model Parameterization for Pesticide Effects Determinations (DOCX) REVISED March 2016 (47 pp, 113 K)
  - New! ATTACHMENT 1-12 Supplemental Information 1: Federally Listed Aquatic Invertebrate Database (XLSX) REVISED March 2016 (1 pp, 890 K)
  - ATTACHMENT 1-12 Supplemental Information 2: Aquatic Invertebrate Attribute Template (XLSX) (2 pp, 20 K)

Attachments may have additional information contained in separate documents called "Supplemental Information"

Overview of the Draft BE Process – Navigating the Documents

Chapter 1 (Problem Formulation) Appendices

Appendices

- APPENDIX 1-1: Regulatory History and Past Assessments for Malathion (DOCX) (3 pp, 20 K)
- APPENDIX 1-2: List of Current Malathion Registrations (Registration Numbers and Label Stamp Dates) (DOCX) (9 pp, 31 K)
- APPENDIX 1-3: Master Use Summary Table for Malathion (XLSX) (1 pp, 160 K)
- APPENDIX 1-4: Tank Mixes Specified on Malathion Product Labels (DOCX) (7 pp, 24 K)
- APPENDIX 1-5: Label Clarifications from Malathion Registrants (PDF) (54 pp, 1.65 MB, About PDF)
- New! APPENDIX 1-6: Use Site, General Land Cover Class, and HUC2 Matrix for Malathion (DOCX) REVISED March 2016 (16 pp, 33 K)
- APPENDIX 1-7: Malathion Scenario Development (DOCX) (3 pp, 23 K)
- APPENDIX 1-8: Usage Data for Malathion (PDF) (9 pp, 2.37 MB)
- APPENDIX 1-9: Degradate Line of Evidence (DOCX) (7 pp, 46 K)
- APPENDIX 1-10: Summary of Malathion Monitoring Data (DOCX) (9 pp, 42 K)
- APPENDIX 1-11: Multi-A.I. Formulation Analysis for Malathion (DOCX) (4 pp, 25 K)
- APPENDIX 1-12: ECOTOX Mixture Studies (Malathion) (DOCX) (3 pp, 17 K)

Overview of the Draft BE Process – Navigating the Documents

Chapter 2 (Effects Characterization) Appendices

Appendices

- APPENDIX 2-1: Data Used in the Data Array (XLSX) (1 pp, 604 K)
- APPENDIX 2-2: Accepted ECOTOX Database (XLSX) (1 pp, 2.4 MB)
- APPENDIX 2-3 Open Literature Review for Malathion (DOC) (172 pp, 5.5 MB)
- APPENDIX 2-4: OPPIN Bibliography for Malathion (PDF) (265 pp, 2.46 MB)
- APPENDIX 2-5: Malathion Rejected ECOTOX Bibliography (DOCX) (1,733 pp, 1.8 MB)
- APPENDIX 2-6: Malathion Species Sensitivity Distribution Analysis for Fish (DOCX) (15 pp, 656 K)
- APPENDIX 2-7: Additional Effects Arrays for Malathion (DOCX) (1 pp, 14 K)
- APPENDIX 2-8: Malathion Species Sensitivity Distribution Analysis for Aquatic Invertebrates (DOCX) (9 pp, 449 K)
- APPENDIX 2-9: Malathion Species Sensitivity Distribution Analysis for Birds (DOCX) (4 pp, 77 K)

Overview of the Draft BE Process – Navigating the Documents

Chapter 3 (Exposure Characterization) Appendices

Appendices

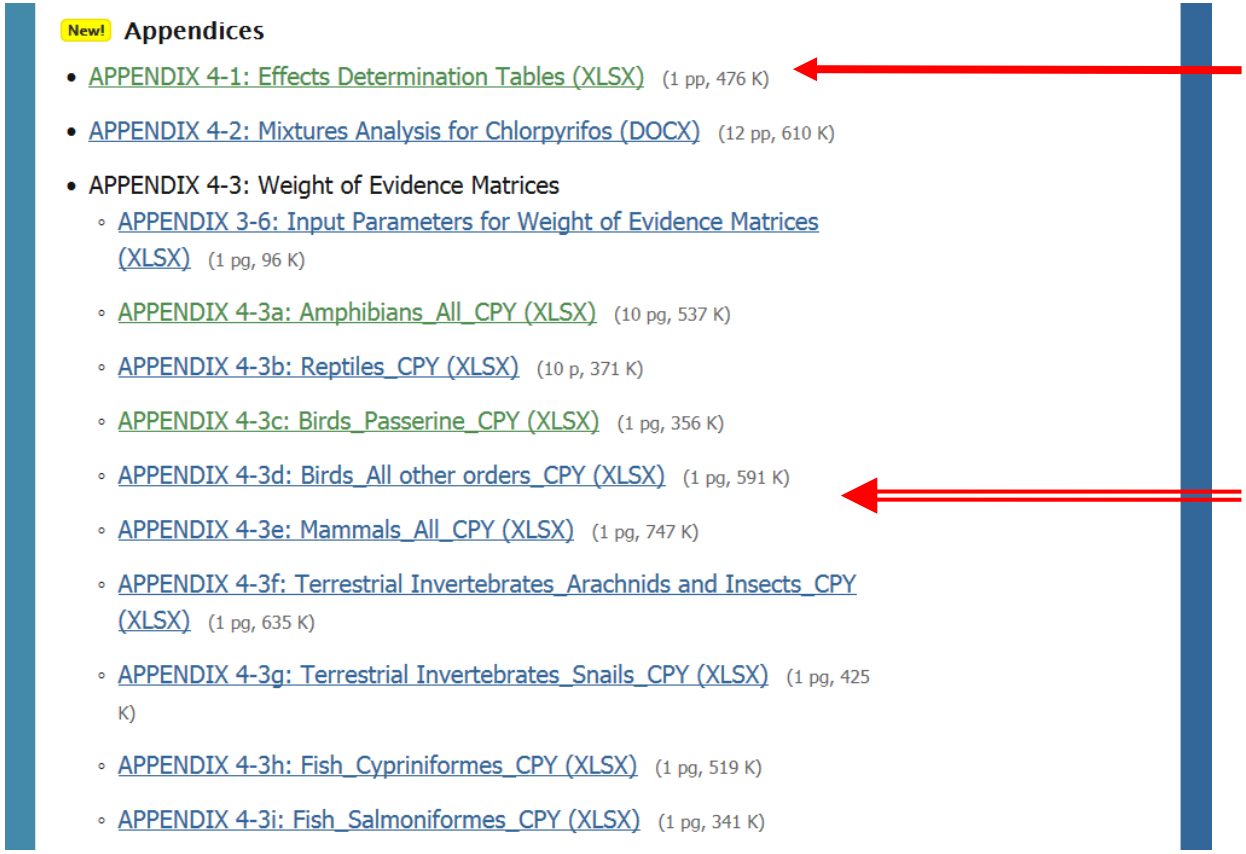
- APPENDIX 1-3: Master Use Summary Table for Malathion (XLSX) (1 pp, 160 K)
- New! APPENDIX 1-6: Use Site, General Land Cover Class, and HUC2 Matrix for Malathion (DOCX) REVISED March 2016 (16 pp, 33 K)
- APPENDIX 1-7: Malathion Scenario Development (DOCX) (3 pp, 23 K)
- New! APPENDIX 3-1: Environmental Transport and Fate Data Analysis for Malathion (DOCX) REVISED March 2016 (10 pp, 40 K)
- APPENDIX 3-2: Malathion Fate Open Literature Review (XLSX) (1 pg, 56 K)
- New! APPENDIX 3-3: Spray Drift Considerations for Malathion (DOCX) REVISED March 2016 (10 pp, 116 K)
- New! APPENDIX 3-4: Aquatic EECs (XLSX) REVISED March 2016 (1 pp, 3.18 MB)
  - New! APPENDIX 3-4f: PWC Postprocessor Output (ZIP) (1 file, 2.7 GB)
- New! APPENDIX 3-5: Malathion Downstream Dilution (DOCX) March 2016 (1 pp, 13 K)
- New! APPENDIX 3-6: Input Parameters for Weight of Evidence Matrices (XLSX)

NOTE: Due to the size of this file for Chlorpyrifos, it needs to be saved to your computer before opening, as indicated on the web page

- New! APPENDIX 3-4: Aquatic EECs (XLSX) REVISED March 2016 (1 pp, 3.70 MB)
  - New! APPENDIX 3-4f: PWC Postprocessor Output (ZIP) **(Please save this file prior to opening)** (1 file, 3.45 GB)

Overview of the Draft BE Process – Navigating the Documents

Chapter 4 (Effects Determination) Appendices



New! **Appendices**

- APPENDIX 4-1: Effects Determination Tables (XLSX) (1 pp, 476 K)
- APPENDIX 4-2: Mixtures Analysis for Chlorpyrifos (DOCX) (12 pp, 610 K)
- APPENDIX 4-3: Weight of Evidence Matrices
  - APPENDIX 3-6: Input Parameters for Weight of Evidence Matrices (XLSX) (1 pg, 96 K)
  - APPENDIX 4-3a: Amphibians_All_CPY (XLSX) (10 pg, 537 K)
  - APPENDIX 4-3b: Reptiles_CPY (XLSX) (10 p, 371 K)
  - APPENDIX 4-3c: Birds_Passerine_CPY (XLSX) (1 pg, 356 K)
  - APPENDIX 4-3d: Birds_All other orders_CPY (XLSX) (1 pg, 591 K)
  - APPENDIX 4-3e: Mammals_All_CPY (XLSX) (1 pg, 747 K)
  - APPENDIX 4-3f: Terrestrial Invertebrates_Arachnids and Insects_CPY (XLSX) (1 pg, 635 K)
  - APPENDIX 4-3g: Terrestrial Invertebrates_Snails_CPY (XLSX) (1 pg, 425 K)
  - APPENDIX 4-3h: Fish_Cypriniformes_CPY (XLSX) (1 pg, 519 K)
  - APPENDIX 4-3i: Fish_Salmoniformes_CPY (XLSX) (1 pg, 341 K)

Summary Effects Determination Tables

Weight of Evidence Matrices

Scroll Down

Overview of the Draft BE Process – Navigating the Documents

Chapter 4 (Effects Determination) Appendices

New! **Appendices**

- APPENDIX 4-1: Effects Determination Tables (XLSX) (1 pp, 476 K)
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  - APPENDIX 4-3a: Amphibians_All_CPY (XLSX) (10 pg, 537 K)

Effects Determination Tables

Taxa	Scientific Name	Common Name	EntityID[1]	Source of Species Effects Determination[2]	Species Call?	Source of Critical Habitat Effects Determination[2]	Critical Habitat Call?[3]
Birds	Accipiter striatus venator	Puerto Rican sharp-shinned hawk	128	Terr WoE	LAA	NA	NA
	Acrocephalus familiaris kingi	Nihoa millerbird (old world warbler)	75	Outside Use - NLAA	NLAA	NA	NA
	Acrocephalus luscinia	Nightingale reed warbler (old world warbler)	1222	Terr WoE	LAA	NA	NA
	Aerodramus vanikorensis bartschi	Mariana gray swiftlet	148	Terr WoE	LAA	NA	NA
	Agelaius xanthomus	Yellow-shouldered blackbird	117	Terr WoE	LAA	Terr WoE	LAA
	Amazona viridigenalis	Red-crowned parrot	10021	Terr WoE	LAA	NA	NA
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
	Ammodramus maritimus mirabilis	Cape Sable seaside sparrow	85	Terr WoE	LAA	Terr WoE	LAA
	Ammodramus savannarum floridanus	Florida grasshopper sparrow	133	Terr WoE	LAA	NA	NA
	Amphispiza belli clementeae	San Clemente sage sparrow	116	Terr WoE	LAA	NA	NA
	Anas laysanensis	Laysan duck	70	Outside Use - NLAA	NLAA	NA	NA
	Anas wyvilliana	Hawaiian (=koloa) Duck	69	Terr WoE	LAA	NA	NA
	Anthus spragueii	Sprague's pipit	9966	Terr WoE	LAA	NA	NA
	Aphelocoma coerulescens	Florida scrub-jay	140	Terr WoE	LAA	NA	NA
	Brachyramphus marmoratus	Marbled murrelet	143	Terr WoE	LAA	Terr WoE	LAA
	Branta (=Nesochen) sandvicensis	Hawaiian goose	73	Terr WoE	LAA	NA	NA

Summary Table All Calls | Call Counts | Animals WoE species summaries | Plant WoE species summaries | WoE species file ...

Overview of the Draft BE Process – Navigating the Documents

Effects Determination Tables

Species Effects Determination Totals

Species Group	LAA	NE	NLAA	Grand Total
Birds	93	5	12	110
Mammals	87	3	20	110
Amphibians	39		1	40
Reptiles	43			43
Terrestrial Invertebrates	115	9		124
Fish	182		4	186
Aquatic Invertebrates	220		1	221
Plants	946		2	948
Total	1725	17	40	1782

Critical Habitat Effects Determination Totals

Species Group	LAA	NLAA	Grand Total
Birds	30		30
Mammals	29	5	34
Amphibians	24		24
Reptiles	18		18
Terrestrial Invertebrates	43		43
Fish	107		107
Aquatic Invertebrates	77		77
Plants	459	3	462
Total	787	8	795

Summary Table All Calls | Call Counts | Animals WoE species summaries | Plant WoE species summaries | WoE species file location Key | NE_Extinct | NE_OutsideUseArea | NLAA_Extinct

Call Counts

WoE Summaries

WoE file locator

Additional information

SUMMARY OUTPUT

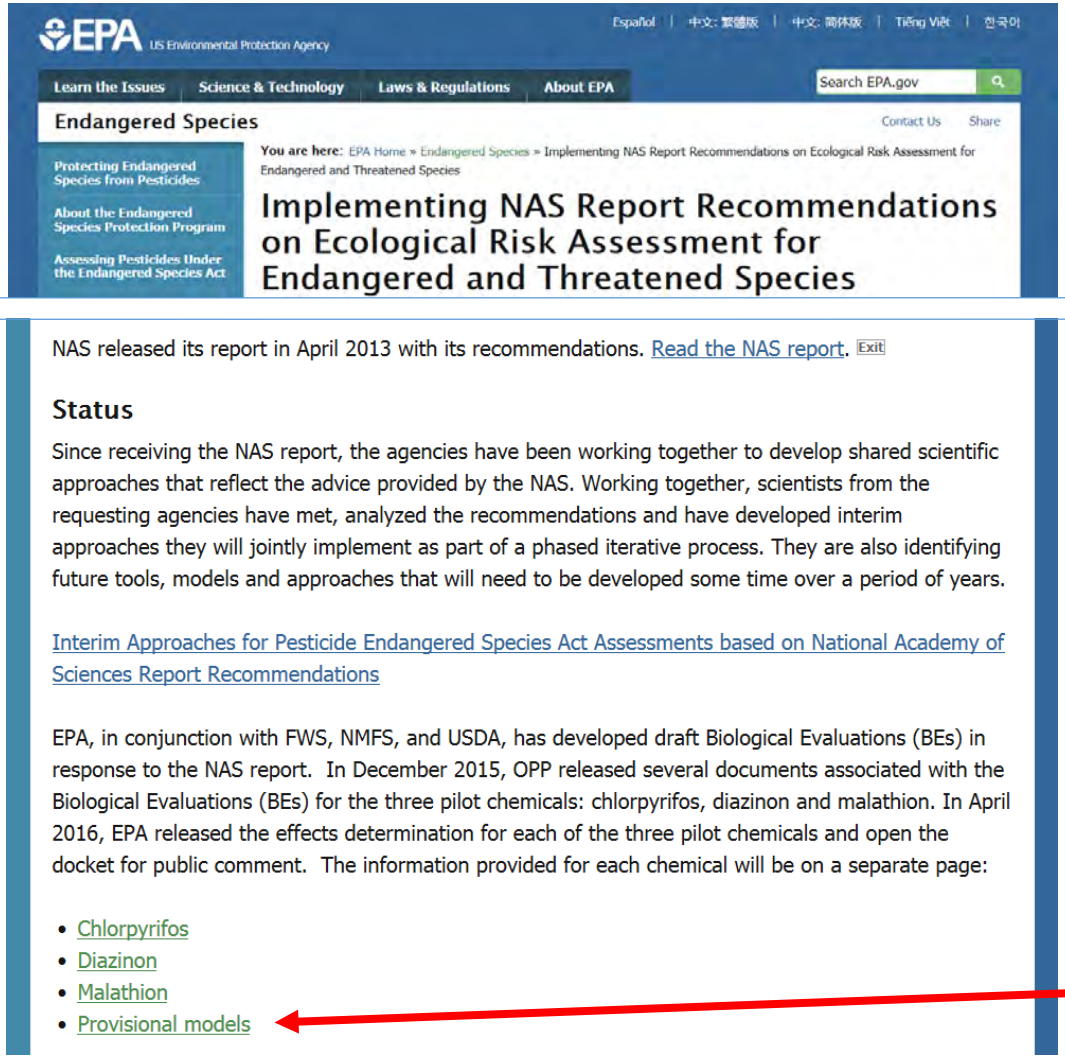
TAXA	Species name	ID number	Terr (T) or Aqua (A) WoE	Mortalty (Risk/Conf)		Growth (Risk/Conf)		Reproduction (Risk/Conf)		Behavioral (Risk/Conf)		Sensory (Risk/Conf)		Indirect - Prey (Risk/Conf)		Indirect-Habitat (Risk/Conf)		Indirect - Obligate (Risk/Conf)		Chemical Stressors (Risk/Conf)		Abiotic Stressors (Risk/Conf)		Species Call?	Critical Habitat Call?
AMPHIBIANS	Santa Cruz long-toed Salamander	188	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Texas blind salamander	189	A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Houston Toad	190	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Red Hills Salamander	192	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	MED	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Golden Coqui (frog)	193	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	MED	HIGH	MED	LAA	LAA
	San Marcos salamander	194	A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
	Puerto Rican Crested Toad	195	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Guajon (frog)	196	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Barton Springs salamander	197	A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Cheat Mountain Salamander	198	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	MED	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Frosted Flatwoods Salamander	199	T	HIGH	LOW	HIGH	LOW	MED	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Shenandoah Salamander	200	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	MED	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Sonora Tiger Salamander	201	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Wyoming Toad	202	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA

Summary Table All Calls | Call Counts | Animals WoE species summaries | Plant WoE species summaries | WoE species file ...

Overview of the Draft BE Process – Navigating the Documents

- Scroll down to find the following links:

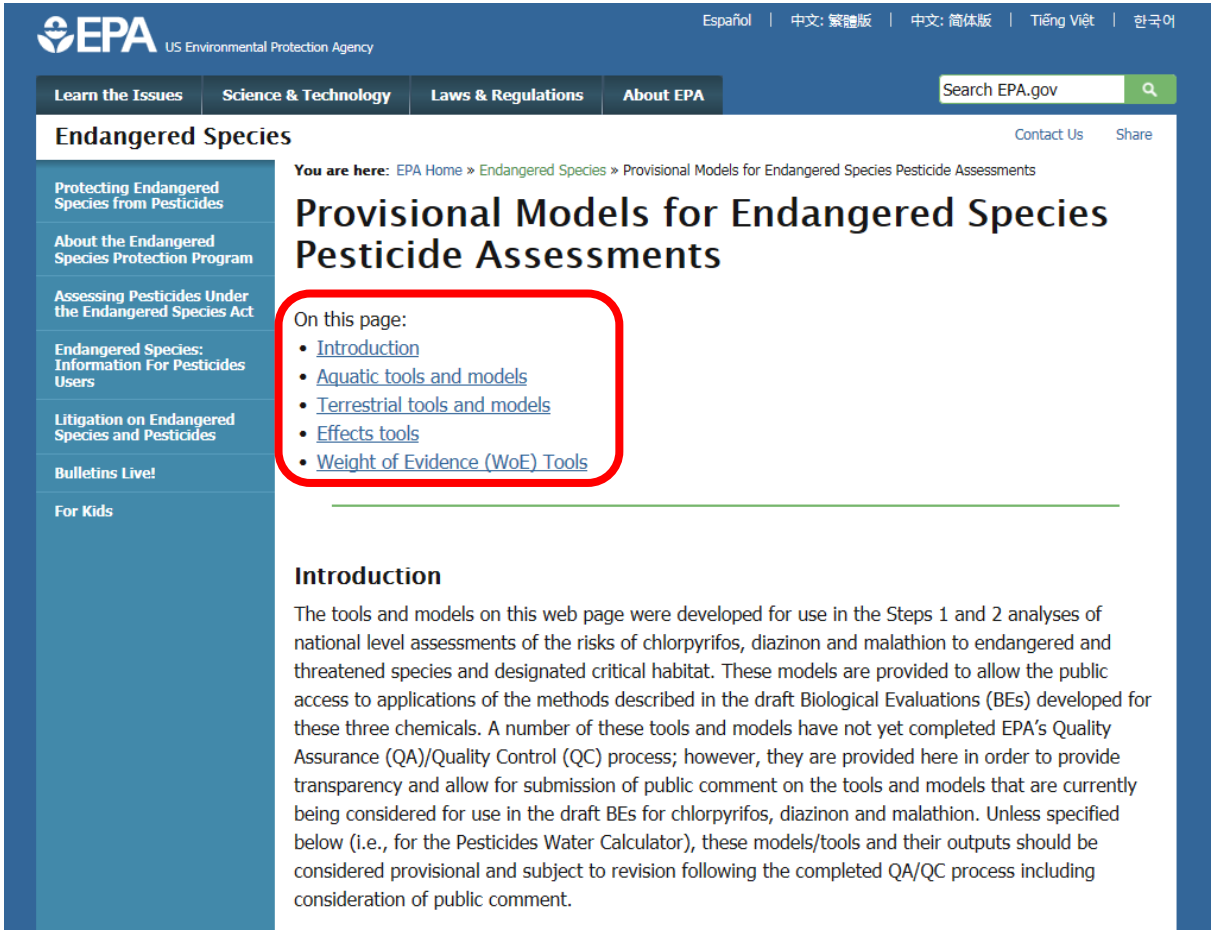
Scroll down



Provisional Models and Tools

Overview of the Draft BE Process – Navigating the Documents

Provisional models and tools can be found at: https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments



Overview of the Draft BE Process – Navigating the Documents

Aquatic tools and models:

New! **Pesticide Water Calculator (PWC) ESA Automation Tool, v. 1.01 beta (XLSX) Revised March 2016** (1 pg, 41 K) Free Viewers

The PWC ESA Automation Tool is a spreadsheet that has been built to assist in developing the inputs necessary to run the ESA Batch feature available in the new version of the PWC. Each row below row 2 represents a PWC run. The user enters the appropriate information in the columns that have headers in black (columns A-T and AB-PN). The red columns will fill in automatically once the user copies the functions contained in row 3 to the rows being created. Row 1 provides guidance on the information required for some of the column input values. For instance, Column D is the Koc flag, which should be entered as either True or False. Additional instructions and information regarding data processing can be found in the "ReadMe" worksheet within the workbook. The tool has been updated to include field and waterbody inputs for hydrologic unit code (HUC) Region 19 (Alaska).

New! **PWC ESA scenarios (zip file) Revised March 2016** (1 pg, 297 K) Free Viewers

For aquatic exposure assessments, input scenarios are used to represent a finite set of combinations of soil, weather, hydrology, and management/crop use conditions that are expected to maximize the potential for pesticides to move into surface water.

Overview of the Draft BE Process – Navigating the Documents

Aquatic tools and models:

New! **PWC Postprocessor, v. 1.0 beta (XLSX)** (1 pp, 2.95 MB) (1 pg, 39 K) Free Viewers

The PWC Postprocessor is a spreadsheet that has been built to assist in analyzing the results from the multitude of PWC runs conducted for the draft BEs. The tool allows the user to compare EECs to aquatic thresholds, summarize EECs by HUC2 and bin combination, and make effects determinations for all listed species associated with aquatic habitats. The tool also allows the user to evaluate individual PWC runs conducted in support of the draft BEs. Before running the tool, the user should store all of the PWC runs and the summary file in a single directory. Additionally, the user should check the ErrorSummary file and ensure that no errors occurred during the PWC batch run. Additional instructions and information regarding data processing can be found in the "ReadMe" worksheet within the workbook.

New! **PWC Non–ag Postprocessor, v. 1.0 beta (XLSX)** (1 pp, 10.8 MB) Free Viewers

The PWC Non-ag Postprocessor is a spreadsheet that postprocesses the residential, impervious, and rights-of-way time series generated in the PWC and allows for the generation of the 1-in-10 year and 1-in-15 year EECs. For some of the pilot chemicals, non-agricultural uses (e.g., applying to gardens, lawns, around commercial buildings, etc.) have been modeled using multiple PWC scenarios which represent the variety of surface types that could occur in a nonagricultural setting (e.g., turf, impervious, right-of-way). The time series for the individual runs are normally combined afterwards to generate a time series and 1-in-10 or 1-in-15 year statistics to represent the non-agricultural use. This spreadsheet automates this process. Additional instructions and information regarding data processing can be found in the "ReadMe" worksheet within the workbook. Note: This tool should be run prior to using the PWC Postprocessor so that the results can be incorporated into the analysis.

	A	B	C	D	E	F	G	H	I
1		Bin	Data						
2		2		5		6		7	
3	HUC2	Min of Overall F	Max of Overall	Min of Overall F	Max of Overall	Min of Overall F	Max of Overall	Min of Overall F	Max of Overall Peak
4	a.HUC_1	59.3	36300	0.618	234	0.207	40.8	0.0955	21.6
5	b.HUC_2	77.8	56100	0.585	267	0.235	73.6	0.117	38.6
6	c.HUC_3	69.2	61500	0.454	193	0.23	70.5	0.122	40.7
7	d.HUC_4	70.9	64800	0.871	473	0.331	125	0.165	65.8
8	e.HUC_5	52.2	38000	0.714	274	0.266	88	0.129	52.7
9	f.HUC_6	73.9	38400	0.255	193	0.153	21.8	0.0873	13.8
10	g.HUC_7	55.5	69900	1.86	1860	0.427	412	0.23	232
11	h.HUC_8	179	74200	0.208	192	0.17	33.8	0.0717	13.2
12	i.HUC_9	116	56100	3	1600	0.905	445	0.486	244
13	j.HUC_10a	125	59700	2.19	927	3.62	1350	2.06	743
14	k.HUC_10b	50.3	32700	1.2	507	1.84	717	0.992	406
15	l.HUC_11a	21.9	14400	1.25	583	2.28	1350	1.29	756
16	m.HUC_11b	21.5	17000	1.09	685	1.97	1250	1.13	654
17	n.HUC_12a	20.7	15900	1.1	628	1.1	668	0.629	351
18	o.HUC_12b	19	13000	1.11	512	1.48	540	0.83	322
19	p.HUC_13	125	96400	54.4	40200	9.6	6670	4.35	2680
20	q.HUC_14	129	146000	15.7	16900	5.66	4690	3	2450
21	r.HUC_15a	351	330000	25.1	22400	11.4	9050	2.83	2010
22	s.HUC_15b	168	227000	12.3	15400	5.75	6010	1.47	1300
23	t.HUC_16a	32.5	39200	14.2	16200	4.08	4550	2.21	2400
24	u.HUC_16b	16.8	12500	7.25	5200	1.9	1520	1	844
25	v.HUC_17a	163	67700	0.943	288	8.98	2240	5.83	1290
26	w.HUC_17b	32.5	43500	0.403	195	1.39	1430	0.752	774
27	x.HUC_18a	98.8	52500	6.34	3110	3.74	1470	2.07	818
28	y.HUC_18b	83.6	53000	5.19	3120	2.25	1240	1.3	652
29	z.HUC_19a	80.1	35500	2.55	912	1.14	531	0.613	269
30	za.HUC_19b	103	66300	2.93	1710	1.71	726	1.07	406
31	zb.HUC_20a	71.2	36000	7.57	3510	2.87	1440	1.68	846
32	zc.HUC_20b	76.5	29200	8.13	2820	1.88	650	0.945	335
33	zd.HUC_21	165	53100	1.93	581	0.296	67.8	0.22	35.8
34									
35									
36		Bin	Data						
37		2		5		6		7	
38	HUC2	Min of PW_pk	Max of PW_pk	Min of PW_pk	Max of PW_pk	Min of PW_pk	Max of PW_pk	Min of PW_pk	Max of PW_pk

Instructions | Thresholds | HUC Bin Summary Table | Individual Results | Species Summary

Instructions

Thresholds

HUC Bin Summary

Individual Results

Species Summary

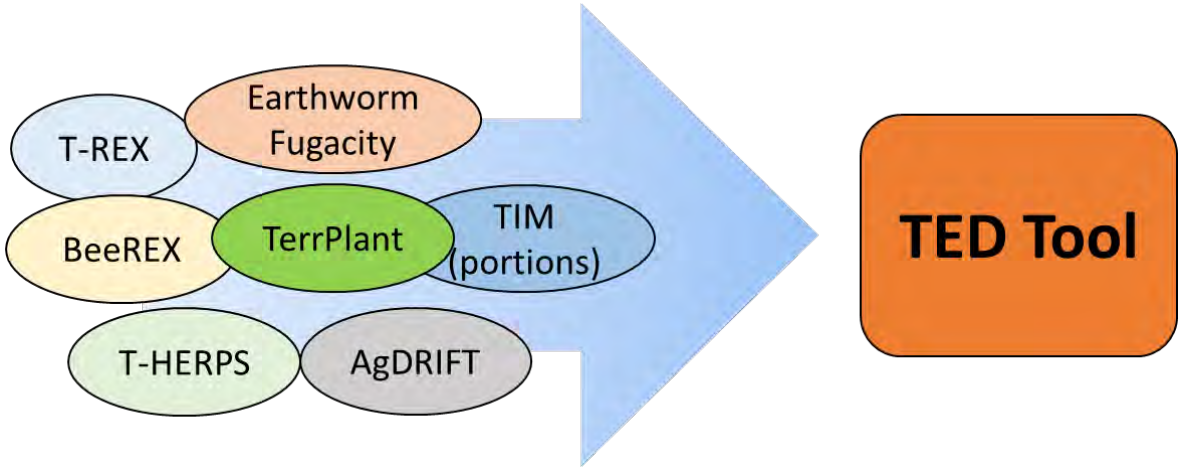
Overview of the Draft BE Process – Navigating the Documents

Terrestrial tools and models:

Terrestrial Tools and Models:

New! **Terrestrial Effects Determination (TED) tool, v. 1.0 beta (XLSX) Revised March 2016**
(1 pg, 1.21 MB) Free Viewers

In order to improve efficiency and expand EFED's modeling capabilities to other, non-dietary routes of exposure for terrestrial organisms, the TED tool was developed. This tool integrates T-REX, T-HERPS, the earthworm fugacity model, TerrPlant and AgDRIFT. In addition to dietary based exposures, the tool also estimates pesticide doses to animals exposed via drinking water, dermal and inhalation routes. The TED tool estimates concentration-based and dose-based pesticide exposures relevant to assessing risks of direct effects to listed species and indirect effects through declines in prey or impacts to habitat. Exposures are compared to relevant thresholds and endpoints and are used to estimate the distance from the edge of the field to which risk extends and the duration of time that residues are at levels representing a concern for effects to individual listed species.



Overview of the Draft BE Process – Navigating the Documents

Terrestrial tools and models:

New! **Integrated Terrestrial Investigation Model (TIM, v. 3.0 beta) and Markov Chain Nest Productivity Model (MCnest, v. 2.0 beta) (zip file) Revised March 2016** (1 pg, 704 K) Free Viewers

TIM has been integrated into the MCnest model to provide risk estimates associated with declines in survival and fecundity of birds exposed to pesticides. The models represent exposures on treated sites (e.g., agricultural fields and orchards) and adjacent areas receiving spray drift. A full description of TIM is available online. A full description of the basic MCnest model is also available online. The integrated version of TIM and MCnest replaces the T-REX portions of exposure used in the basic MCnest model.

The integrated TIM/MCnest model was designed in Matlab 2013b and requires the Matlab Compiler Runtime (MCR) to be installed on your computer. MCnest will not run without the MCR. Due to its size, we are not hosting the MCR on our website. It can be downloaded free of charge from the Mathworks Exit website. The required version is the Windows 64-bit MCR for Matlab release 2013b.

A new species library is available for use with the integrated TIM/MCnest model (XLSX) (1 pp, 14 K). This library includes life history parameters for 13 species of listed birds that are included in the refined avian risk assessment (Appendix 4-7). The metadata for these parameters are included in supplemental information 2 of Appendix 4-7.

Overview of the Draft BE Process – Navigating the Documents

Effects tools:

Data Array Builder (DAB), v. 1.0 beta (zip file) (1 pg, 258 K) Free Viewers

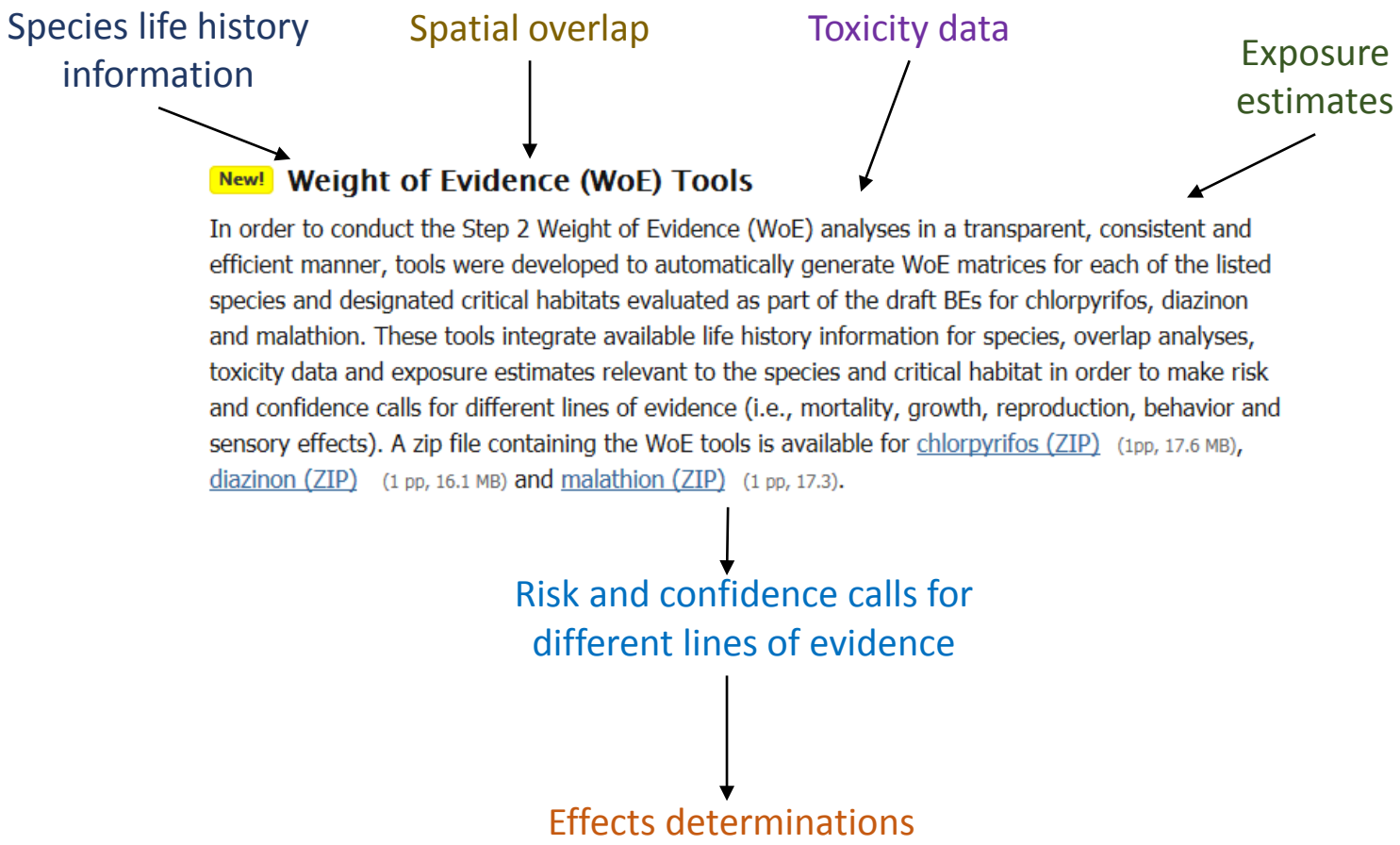
The DAB generates ecotoxicity data arrays, or graphic representations of effects data, based on formatted ECOTOX data reports and user-entered registrant-submitted studies. Once the data have been inserted into the workbook and formatted according to the tool's instructions, the DAB allows sorting of the data by user-defined taxonomic group, effect type, and endpoint and generates dot plots presenting the data. The user can also create summary plots by effect type that show the range of values and median concentration for each type of effect.

Species Sensitivity Distribution (SSD) toolbox, v. 1.0 beta (zip file) (1 pg, 258 K) Free Viewers

The SSD toolbox allows the user to fit distributions to acute toxicity data available for tested species that fall within the same group (*e.g.,* fish, birds, invertebrates). It combines a variety of algorithms to support fitting and visualization of simple SSDs.

Overview of the Draft BE Process – Navigating the Documents

Weight of Evidence (WoE) tools:



Overview of the Draft BE Process – Navigating the Documents

WoE tools:

	Species scientific name	*Hemignathus munroi*	Species order:	Passeriformes			
	Species common name	Akiapola`au (honeycreeper)		MIGRATORY SPECIES?	No	ALTERNATE RATE OUTPUT DISPLAYED FOR THIS SPECIES?	Yes
	Species number	65		CRITICAL HABITAT?	No		
	TAXA	Birds		OBLIGATE RELATIONSHIP?	No		

Risk hypothesis: Use of malathion according to registered labels results in exposure that reduces the fitness of an individual based on direct effects [Akiapola`au (honeycreeper)]

Line of evidence	Summary of considerations impacting risk and confidence					Risk (extent of overlap of exposure and effects data)	Confidence (associated with risk conclusion
	Exposure		Effects				
	Relevance	Robustness	Relevance (biological)	Surrogacy	Robustness		
Mortality	Lives mainly in forest rarely below 1300 feet (wet forest dominated by Koa and Ohi`a)	T-REX EECs based on empirical residues.	Mortality is relevant to species fitness.	Seven avian species represented in LD50 results which included two Passeriforme species.	18 LC50 and LD50 avian values are available.	HIGH	HIGH
	HABITAT: Top species range overlap(s): 100.00, 36.32, 5.54, 2.29 and 1.33%. Corresponding CDL layer(s): Mosquito Control, Pasture, Other Grains, Developed and Orchards and Vineyards.This species has overlap with nonspecified agricultural uses in Hawaii corresponding with 2.12% overlap, respectively. This species also occurs on federal land. The range overlap is 16.34 and 2.89% with the corresponding federal lands of Federally Managed Lands and FWS Refuge.	Chemical specific foliar dissipation half-life based on 90th percentile of observed foliar dissipation half-life values (n = 37; 0.3 and 10.9 days).	Endpoints beyond 1/million threshold were considered.	SSD derived for dose-based endpoints.	Data available for dose and dietary rate units.	Upper bound EECs based on dietary exposure through food exceeds the 1-in-a-million threshold, does not exceed the LD50 and does not exceed the HC50 for a single application at the minimum application rate of 0.5 lb a.i./A as compared to dose-based endpoints. At the upper bound single application rate of 2 lb a.i./A the maximum EEC based on the highest food item concentration exceeds the 1-in-a-million threshold, exceeds the LD50 and does not exceed the HC50. For the minimum application rate and mean EECs based on the minimum dietary food item concentration, the EEC exceeds the 1-in-a-million threshold, does not exceed the LD50 and does not exceed the	

The individual WoE matrix results (**APPENDIX 4-3**) are summarized in the Effects Determination tables (**APPENDIX 4-1**)

SUMMARY OUTPUT

TAXA	Species name	ID number	Terr (T) or Aqua (A) WoE	Mortalty (Risk/Conf)		Growth (Risk/Conf)		Reproduction (Risk/Conf)		Behavioral (Risk/Conf)		Sensory (Risk/Conf)		Indirect - Prey (Risk/Conf)		Indirect-Habitat (Risk/Conf)		Indirect - Obligate (Risk/Conf)		Chemical Stressors (Risk/Conf)		Abiotic Stressors (Risk/Conf)		Species Call?	Critical Habitat Call?
AMPHIBIANS	Santa Cruz long-toed Salamander	188	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Texas blind salamander	189	A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Houston Toad	190	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Red Hills Salamander	192	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	MED	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
	Golden Coqui (frog)	193	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	MED	HIGH	MED	LAA	LAA
	San Marcos salamander	194	A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
	Puerto Rican Crested Toad	195	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	NA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		
	Guajon (frog)	196	T	HIGH	LOW	HIGH	LOW	HIGH	LOW	HIGH	LOW	Unknown	LOW	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED	LAA	LAA
			A	HIGH	MED	HIGH	MED	HIGH	LOW	HIGH	HIGH	HIGH	MED	HIGH	HIGH	HIGH	HIGH	NA	NA	HIGH	MED	HIGH	MED		

... | Call Counts | Animals WoE species summaries | Plant WoE species summaries | WoE species file location Key | NE_Extinct | NE_OutsideUseArea | NLAA_Extinct | NLAA_OutsideUse

Overview of the Draft BE Process – Instructions for Public Comments

- Posting comments

The public comment period for the draft BEs will be open in April 2016. Because the file sizes of the draft BEs for chlorpyrifos, diazinon, and malathion exceed the docket system's file size limitation, the draft BEs will not be posted to the chlorpyrifos, diazinon, and malathion chemical dockets in www.regulations.gov. Instead, draft BEs for each of the three chemicals are posted on EPA's endangered species webpage. Commenters must post comments to each chemical's registration review docket at www.regulations.gov as detailed in Table 1.

Table 1. Links to the Draft BEs and Where to Post Comments

Chemical	Link to the Draft BEs	Where to Post Comments
Chlorpyrifos	https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos	EPA-HQ-OPP-2008-0850
Diazinon	https://www.epa.gov/endangered-species/biological-evaluation-chapters-diazinon	EPA-HQ-OPP-2008-0351
Malathion	https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion	EPA-HQ-OPP-2009-0317

Overview of the Draft BE Process – Instructions for Public Comments

- Looking for comments on improving the BE approach/methodology, particularly as it relates to:
  - Identification of "best available" spatial data to represent potential pesticide use sites and species locations (Attachments 1-2 and 1-3)
  - Methods used to identify potential overlaps (and extent) of species locations and potential use sites and their applications in effects determinations made in Steps 1 and 2 (Attachment 1-6)
  - Estimation of exposure in various aquatic environments (bins) that have been regionally delineated and the parameterization of the bins and their relevance across the landscape (Attachment 3-1)
  - Evaluation of exposures in flowing water bodies and in non-freshwater habitats (e.g. , tidal pools. estuaries) (Attachment 3-1)
  - Evaluation of exposure to terrestrial organisms, including dietary and non-dietary routes of exposure (Attachment 1-7)
  - Evaluation of mosquito adulticide applications including potential exposure and impact on the aquatic and terrestrial environments (Appendix 3-3 for chlorpyrifos and malathion)

Overview of the Draft BE Process – Instructions for Public Comments

- Cont. - Looking for comments on improving the BE approach/ methodology, particularly as it relates to:
  - Use of species sensitivity distributions to evaluate effects (Attachment 1-5)
  - Characterization of toxicity data from registrant submitted toxicity data and scientific literature and utility of sublethal effects data (Attachments 1-4, and 1-22)
  - Use of mortality effects thresholds based on a chance of effects (i.e., I -in-a-million chance for direct effects and 10% chance of effect for indirect effects) (Attachment 1-4)
  - Methodology for assessing risks to plants (Attachment 1-2 1)
  - Weight-of-evidence approach used, including the high, medium and low weighting assignments to the various lines of evidence to evaluate risk and make effects detem1inations (Attachment 1-9)
  - “Qualitative'' assessments for marine species and cave-dwelling terrestrial species (Chapter 4).

Overview of the Draft BE Process – Instructions for Public Comments

- Please direct questions related to this effort or concerning the registration reviews for chlorpyrifos, diazinon, and malathion, to the chemical review manager identified in the table below:

Pesticide Contacts for Chlorpyrifos, Diazinon, and Malathion

Registration Review Case Name and Number	Pesticide Docket ID Number	Chemical Review Manager, Telephone Number, Email Address
Chlorpyrifos, case 100	EPA-HQ-OPP-2008-0850	Dana Friedman, 703-347-8827, friedman.dana@epa.gov
Diazinon, case 238	EPA-HQ-OPP-2008-0351	Khue Nguyen, 703-347-0248, nguyen.khue@epa.gov
Malathion, case 248	EPA-HQ-OPP-2009-0317	Steven Snyderman, 703-347-0249, snyderman.steven@epa.gov

Overview of the Draft BE Process – Next Steps

- ESA Stakeholder Workshop
  - 2-day meeting in summer of 2016
  - Format will include plenary and break-out sessions
  - Prioritizing topics for break-outs
    - Refinements of the interim methods; earlier screening
    - Aquatic bin parameterization and estimation of flowing water EECs
    - Weight-of-Evidence Approach

Overview of the Draft BE Process – Next Steps

- Proposed schedule for chlorpyrifos, diazinon and malathion:
  - December 2016: Final BE
  - April 2017: Draft BiOp
  - December 2017: Final BiOp
- Proposed schedule for carbaryl and methomyl
  - December 2016: draft BEs
  - December 2018: Final BiOp