

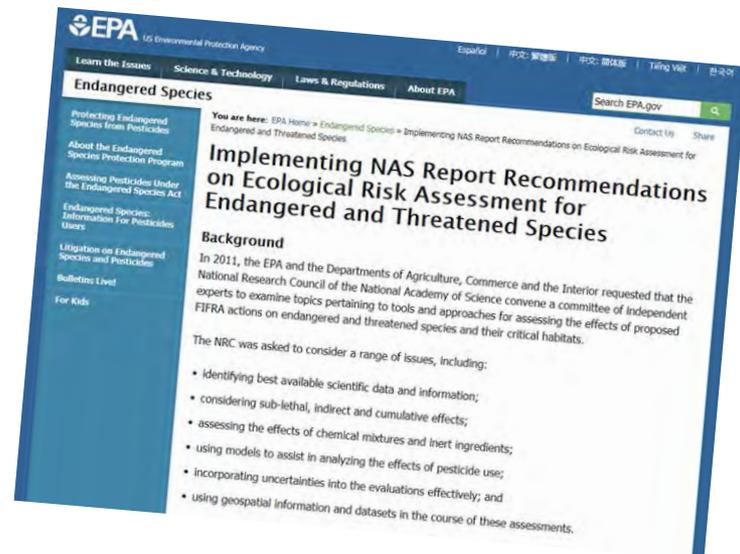
ESA Stakeholder Workshop: Refinements Breakout Groups

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June 29 and 30, 2016

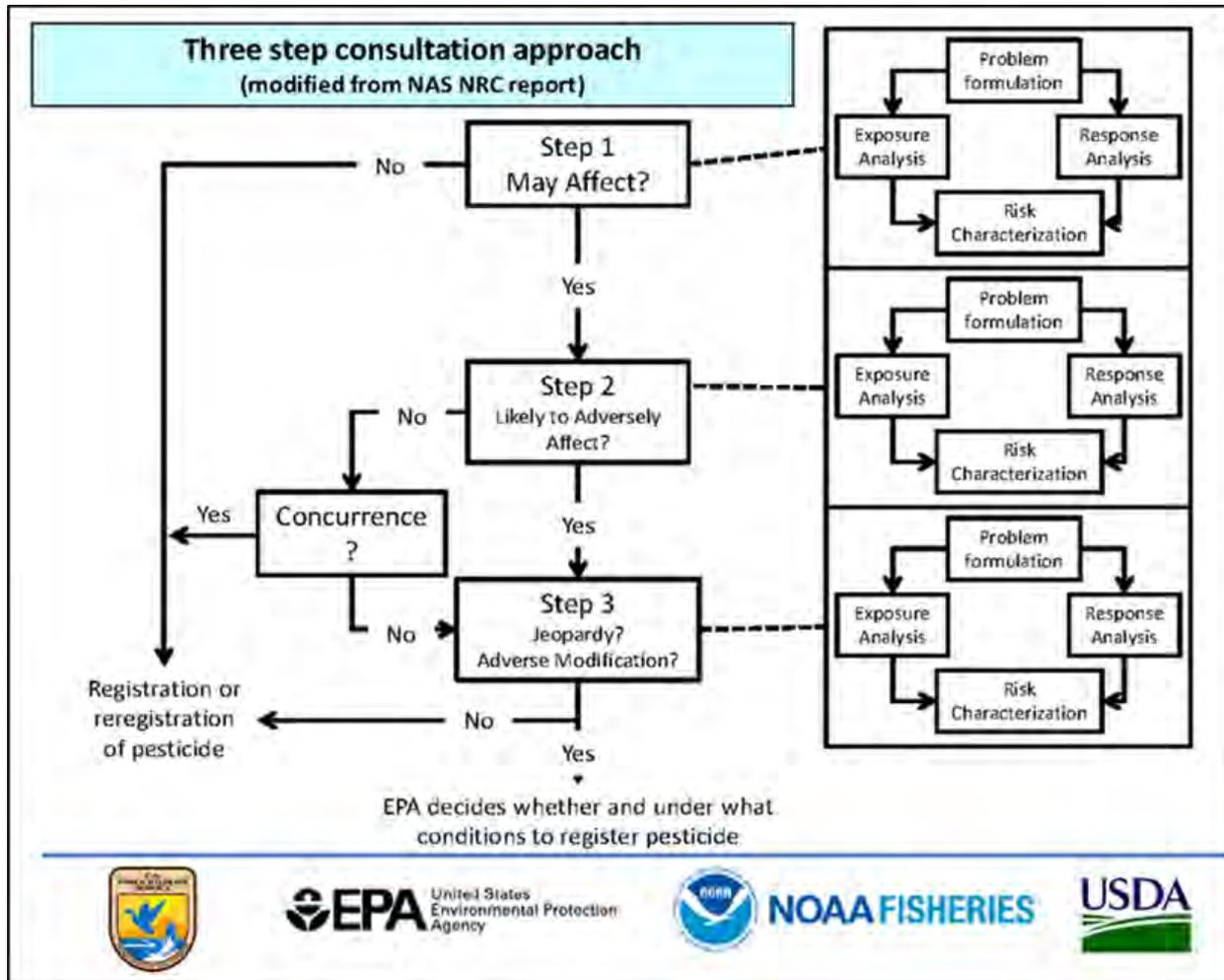
Overview

- Overview
- Breakout Group 1 (Spatial analyses)
 - Current BE process
 - Charge Questions
- Breakout Group 2 (Non-spatial analyses)
 - Current BE process
 - Charge Questions
- Questions



Overview

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



Overview

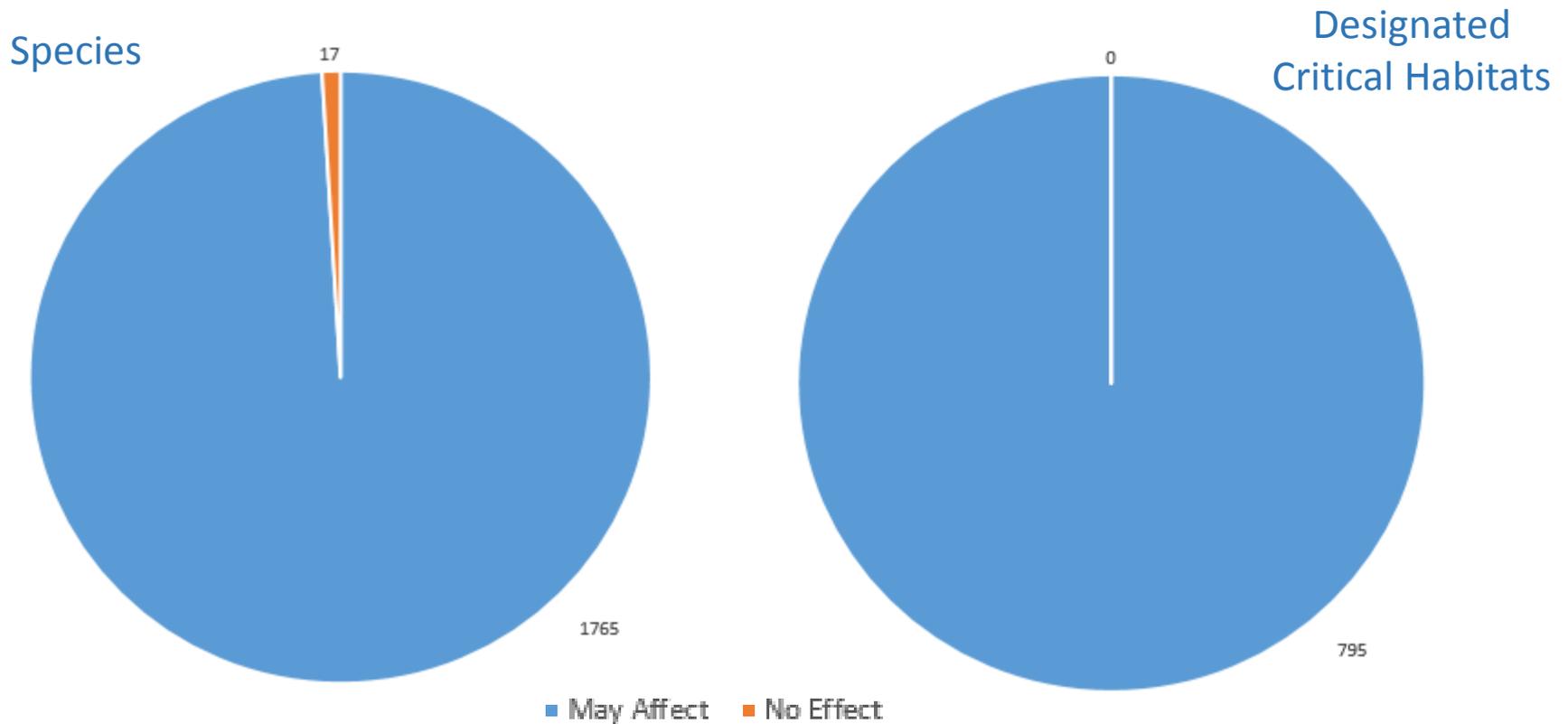
- The Biological Evaluation (BE) determines whether registered pesticides adversely affect **one or more individuals** of a listed species and their designated critical habitats
 - **Step 1** [“No Effect/May Affect” Determination]
 - **Step 2** [“Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA) Determination]

Overview

- **Step 1** is intended to identify those species/critical habitats that require species-specific analyses (*i.e.*, those that need to proceed to Step 2)
- **Step 2** is intended to identify the potential for adverse impacts to a single individual or critical habitat feature.
- Key to these processes is the ability to identify:
 - Areas of overlap among potential use sites,
 - Areas of potential effects, and
 - Species range/critical habitat areas over the duration of the proposed action (in some cases this may be 15 years or more).

Overview

- 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

- Step 2 (Chlorpyrifos and Malathion)

TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSELY 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	1782
Percent of Total Number of Species	1%	99%	2%	97%	

Results for listed species

DESIGNATED CRITICAL HABITAT TAXON	STEP 1 EFFECTS DETERMINATION		STEP 2 EFFECTS DETERMINATIONS		Totals
	NO EFFECT	MAY AFFECT	NOT LIKELY TO ADVERSELY 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	795
Percent of Total Number of Species	0%	100%	1%	99%	

Results for critical habitats

Overview

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)

Interim BE process resulted in very long and complex documents (thousands of pages long).

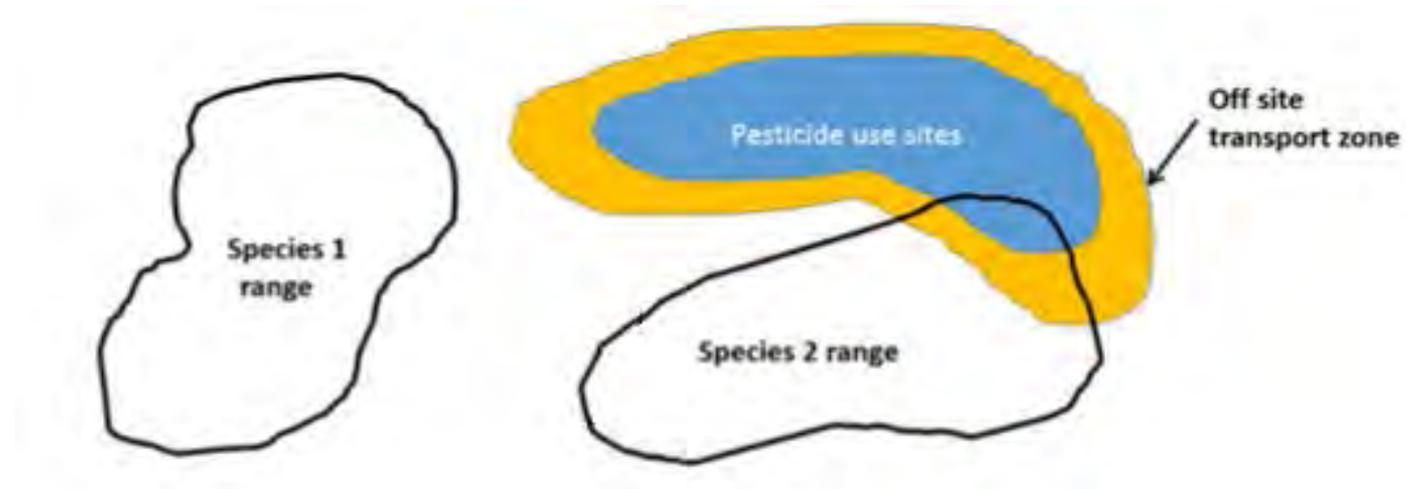
Overview

- Interim BE process resulted in:
 - Most species and critical habitats progressing to Steps 2 and 3
 - Very long documents
- **Not Sustainable!**
- Are there ways to 'streamline' the BE process and/or improve the analyses used to make effects determinations in future BEs (while still being protective)?



Overview

- Key = the ability to better identify:
 - Areas of overlap among potential use sites,
 - Areas of potential effects, and
 - Species range/critical habitat areas over the duration of the proposed action (in some cases this may be 15 years or more).



Overview

- Breakout Groups:
 - REFINEMENTS 1: Spatial Analyses (GIS focus)
 - REFINEMENTS 2: Non-Spatial Analyses



REFINEMENTS 1: Spatial Analyses

- Current BEs
 - 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.

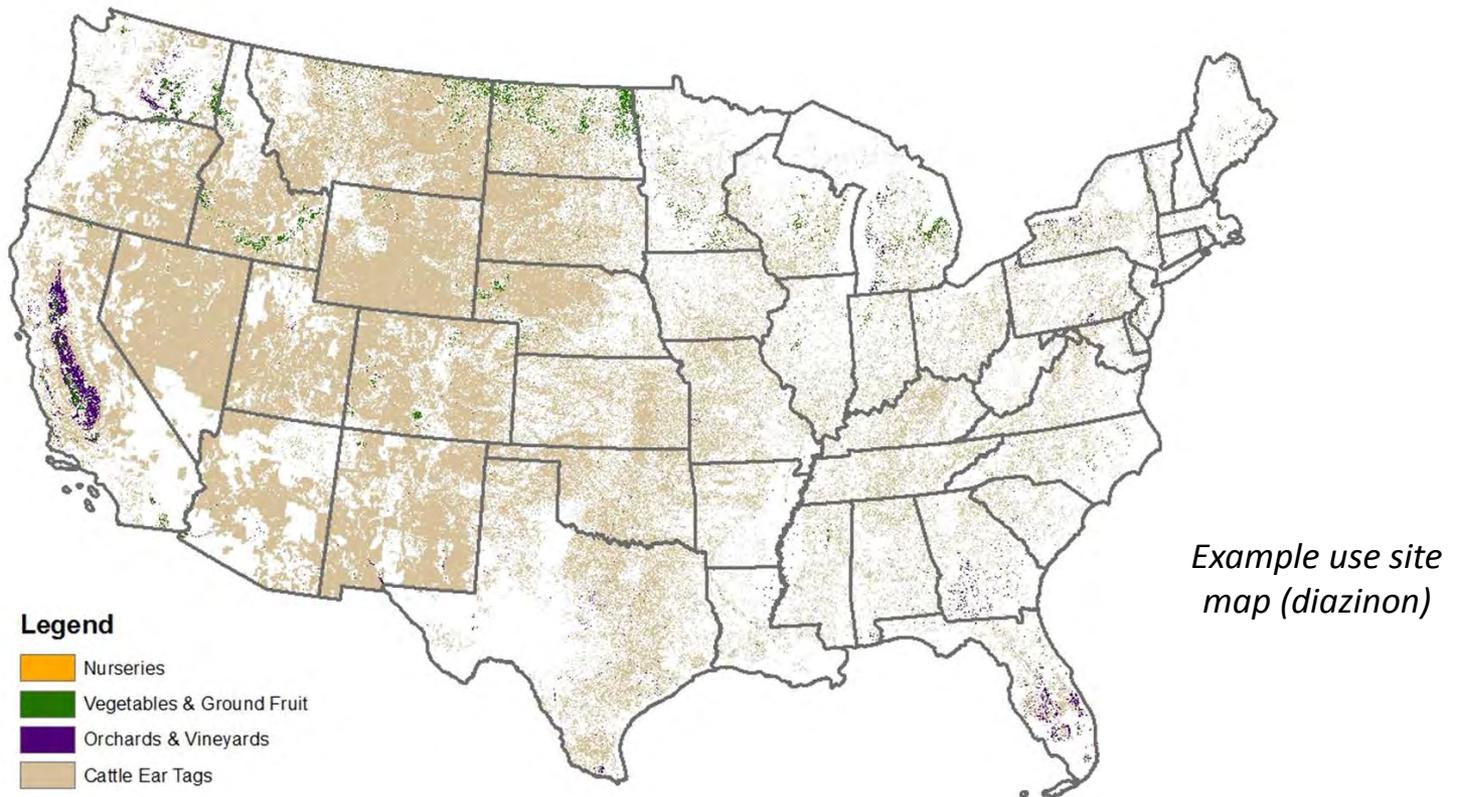
REFINEMENTS 1: Spatial Analyses

- Current BEs
 - Agricultural uses, the 11 agricultural use categories used (collapsed from over 100 CDL classes):
 - Some are unambiguous major crops (corn, cotton, *etc.*)
 - Some are aggregated “minor” crops, *e.g.*, orchards and vineyards, or ground fruit and vegetables.
 - These were aggregated to address uncertainties in crop identification in the CDL, and to anticipate future use areas for pesticides, based on current uses.



REFINEMENTS 1: Spatial Analyses

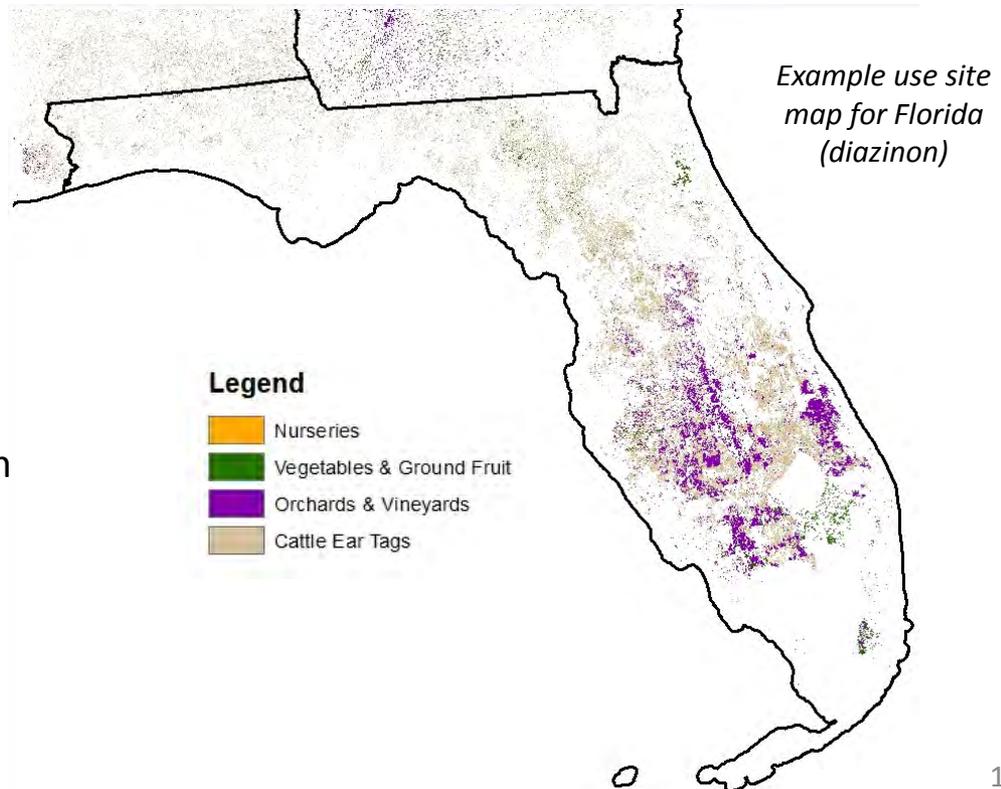
- Current BEs



REFINEMENTS 1: Spatial Analyses

- Current BEs
 - In some cases, specific crop uses are being identified in areas where the specific crop likely does not occur.

For example, the orchard-vineyard layer is used for **all orchard crops**, including citrus. Diazinon is registered for some orchard crops, but **not citrus** – the spatial analysis is showing orchard use sites for diazinon in Florida – but most of those use sites are likely citrus.



REFINEMENTS 1: Spatial Analyses

- CHARGE QUESTION (1a):
 - **Is there a better way to accurately identify potential agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?**
 - Are there some CDL classes that we have more confidence in than others?
 - Is using the Census of Agriculture to eliminate counties where labeled uses do not occur a viable option for both current uses and future uses (within the duration of the proposed action)? If so, ...
 - How should we deal with “undisclosed” census values?
 - Do these data (or other suitable data) reflect “no usage” or “low” levels of usage over the duration of the proposed action?

REFINEMENTS 1: Spatial Analyses

- Current BEs
 - 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.



REFINEMENTS 1: Spatial Analyses

- CHARGE QUESTION (2a):
 - **Is there a better way to accurately identify potential non-agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?**
 - Are there additional data not considered in the BEs that may be useful for geographically identifying non-agricultural use sites?
 - Are there surrogate data (those that could be used to help inform potential use sites) that could be used for non-ag categories that we have not considered?

REFINEMENTS 1: Spatial Analyses

- Current BEs
 - Some uses do not have clear geographic boundaries (*i.e.*, they are difficult to limit geographically via label language). For some chemicals, this can result in an action area that encompasses the entire US and its territories.



*Example use site
map (chlorpyrifos
– mosquito
adulticide)*

REFINEMENTS 1: Spatial Analyses

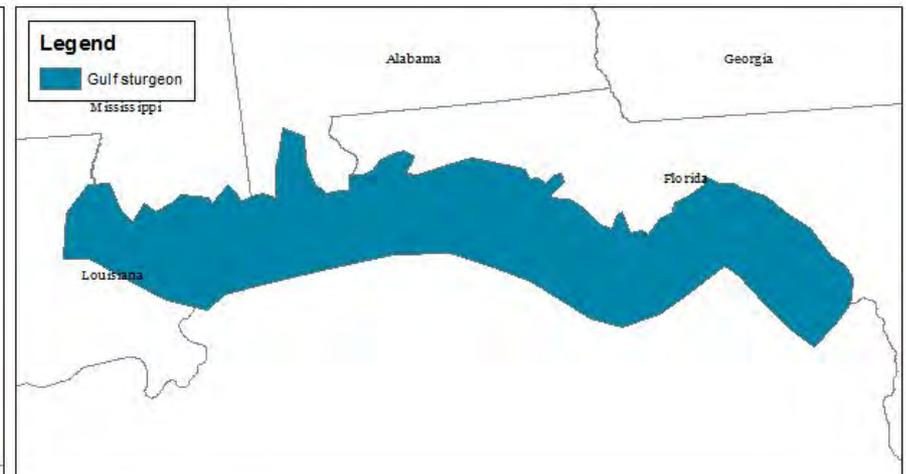
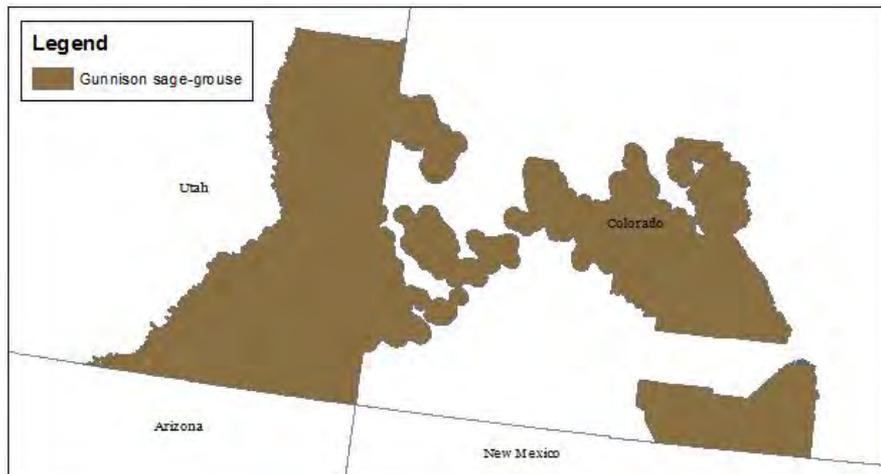
- CHARGE QUESTION (3a):
 - **How can we better identify potential use sites for pesticide uses that do not have clear geographic boundaries? How could these potential use sites be better identified spatially?**
 - Could a process to modify labels (to clarify potential use sites) be developed during the BE process? If so, what would that process look like?
 - For example, when in the BE process would label clarifications be most useful? Could label modifications be in the form of a registrant commitment to modify a label as part of the final decision? How could Bulletins Live Two be best used in the process?

REFINEMENTS 1: Spatial Analyses

- CHARGE QUESTION (3a) – cont.:
 - For uses such as mosquito adulticide use, what other information could be pulled in to help accurately limit the spatial extent (for example census information, or protected/managed lands) for the duration of the proposed action? Is there a human population density threshold where the cost of applying a pesticide would be too high?
 - If it is not possible to geographically define a use site, can we geographically define where the pesticide isn't (or won't be) applied that would provide spatial refinement (*i.e.*, it will not be applied to open water, or urban areas, *etc.*).

REFINEMENTS 1: Spatial Analyses

- Current BEs
 - The range data currently available for listed species are geospatially represented using polygons and they are used in the BEs with the assumption that the species use all areas of their polygon equally throughout the year.



REFINEMENTS 1: Spatial Analyses

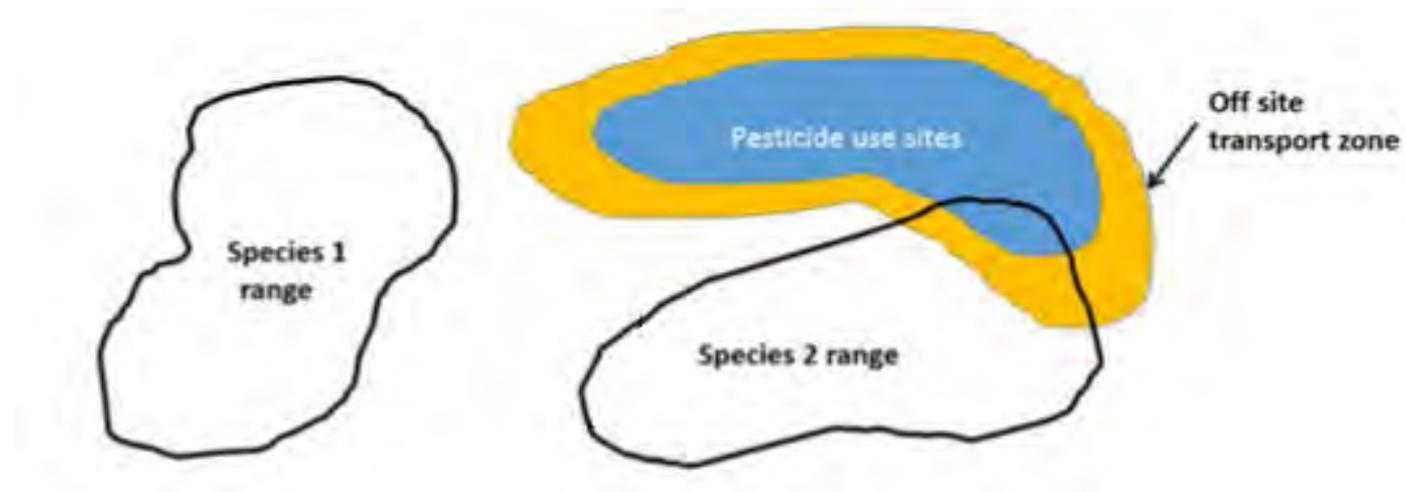
- CHARGE QUESTION (4a):
 - **Are there methods available that would allow for a refined understanding of the distribution of individuals within the range polygons?**
 - Are there methods that can be used to help identify areas of concern within a species' range to better estimate the likelihood of exposure – preferred habitat, distribution of individuals (do they cluster, are they territorial, min patches requirements for a home range, fragmentation indices)?
 - Is there biological information that could be used to help identify areas of the range where exposure is unlikely (*e.g.*, due to elevation restrictions) or very likely (*e.g.*, preferred habitat)?

REFINEMENTS 1: Spatial Analyses

- CHARGE QUESTION (4a) – Cont.:
 - How can the effects on timing be better captured (considering both direct and indirect effects)? For example, for direct effects, at the time of year when a pesticide can be applied, is the species there at that time (*e.g.*, is it only there for part of the year because it is migratory?) or at a life-stage when exposure is or is not likely (*e.g.*, is it at an egg stage, subterranean, or in diapause at that time)? What about the resources it depends on (indirect effects)?
 - Should less refined species ranges (*e.g.*, county-level) be treated differently than those that are more refined [keeping in mind that in many cases a species range is not at a sub-county level for various reasons (*e.g.*, no survey data on private lands, wide-ranging species)]? Is the precision of the analysis equal?
 - Can we incorporate this information to apply a weighting to the overlap analysis (see charge question 5a below)?

REFINEMENTS 1: Spatial Analyses

- Current BEs
 - In the pilot BEs, any overlap of the action area with a species range or critical habitat is considered a 'May Affect'.



REFINEMENTS 1: Spatial Analyses

- CHARGE QUESTION (5a):
 - **Does the overlap approach used in the pilot BEs to determine a ‘May Affect/No Effect’ determination provide an adequate screening process (one that is protective but not unrealistically conservative)?**
 - When conducting a GIS overlap analysis using datasets with different levels of resolution, what are methods that could be used to ensure that decisions are made based on the datasets’ limits of precision (*e.g.*, how can we best avoid ‘false positives’ and ‘false negatives’ in the overlap analyses when considering the limits of precision of the datasets used)?

REFINEMENTS 1: Spatial Analyses

- CHARGE QUESTION (5a) – Cont.:
 - Would using a weighting approach for the likelihood of an overlap be useful (see charge question 4a) when making the Step 1 determinations (instead of using only an overlap of the species range/critical habitat and the action area)? For example, for agriculture uses could we incorporate the number of years a cell was classified as the crop in a weighting approach (while still accounting for the duration of the action)?
 - Are there approaches that could be used to screen out species from further analyses besides solely an overlap of the species range/critical habitat and the action area (*e.g.*, if no Step 1 thresholds for plants are exceeded, can plants that are not biologically pollinated be considered 'No Effect', if no other indirect effects are anticipated)?

REFINEMENTS 2: Non-Spatial Analyses

- Current BEs
 - There are a multitude of use patterns on currently registered labels, some which result in potentially higher exposures to non-target organisms than others. For example, although somewhat dependent on chemical fate properties, pesticides applied to large agricultural fields by air are expected to result in higher offsite exposure than pesticides applied to a small area via a ready-to-use spray can.

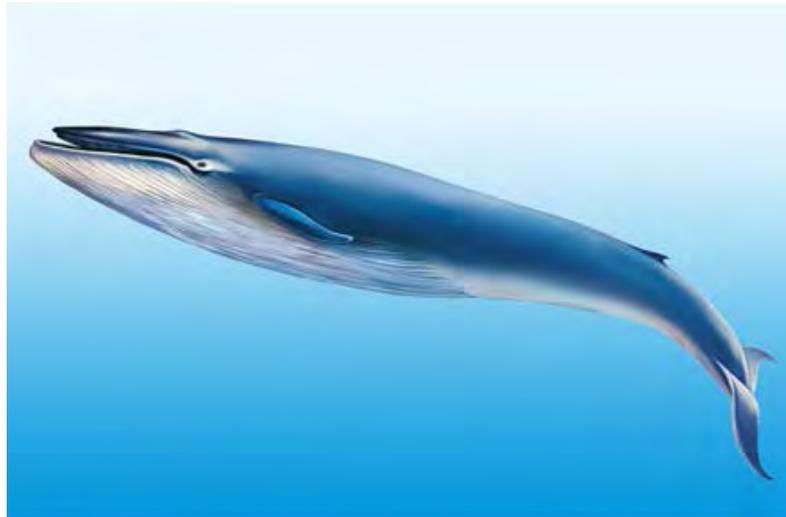


REFINEMENTS 2: Non-Spatial Analyses

- CHARGE QUESTION (1b):
 - **Is there a way to identify use patterns that would result in minimal exposures, such as spot treatments, that may not always need to be fully re-assessed for each pesticide going through the consultation process (*i.e.*, by applying what we have learned from an analysis with another pesticide with a similar use pattern)?**
 - What type of things regarding the pesticide and use site would need to be considered [*e.g.*, the fate properties of the pesticide, the amount of pesticide applied (*e.g.*, per the label and/or based on usage information), the application method used, potential application sites (*e.g.*, ready-to-use spray can)]?
 - Of these fate properties, how could they be considered-keeping in mind use site parameters?
 - Of these use site parameters, how could they be considered (*e.g.*, personal ready-to-use spray can for mosquitos)?

REFINEMENTS 2: Non-Spatial Analyses

- Current BEs
 - There are a subset of listed species that are found in places or environments not expected to result in appreciable exposure to most pesticides (those that are not persistent and do not bioaccumulate) (*e.g.*, species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska).



REFINEMENTS 2: Non-Spatial Analyses

- CHARGE QUESTION (2b):
 - **Is there a way to identify species that may not always need to be fully re-assessed for each pesticide going through the consultation process (*i.e.*, by applying what we have learned from an analysis with another pesticides)?**
 - Once a species characteristics (*e.g.*, habitat) has been considered, what type of things regarding the fate properties of the pesticide would need to be considered (*e.g.*, aquatic half-life, mobility, bioaccumulation potential, *etc.*)?
 - Of these fate properties, how could they be considered (*e.g.*, a full assessment might not be needed for pesticides that have a $\log K_{ow} < 4$)?

REFINEMENTS 2: Non-Spatial Analyses

- CHARGE QUESTION (2b) – Cont.:
 - What types of biological/ecological attributes of the species would need to be considered (*e.g.*, its habitat)?
 - Of these species characteristics, how can they be considered (this may be different for species and designated critical habitats) (*e.g.*, a full assessment might not be needed for species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska, not present during windows of application; this may not apply to designated critical habitats)?

REFINEMENTS 2: Non-Spatial Analyses

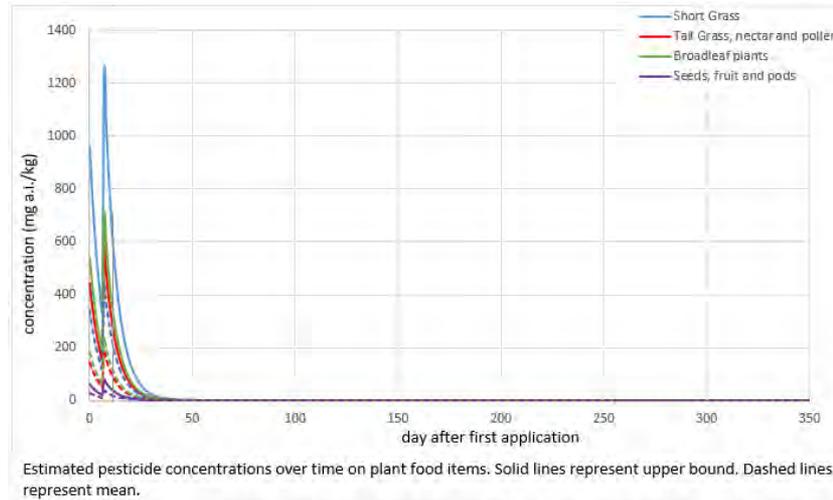
- Current BEs
 - The pilot BE process relies on thresholds for mortality that are based on probabilistic effects endpoints (*e.g.*, 1-in-a-million chance of mortality based on the HC05 of a SSD or the lowest LC50/LD50 values) compared to deterministic estimated environmental concentrations (EECs) (*e.g.*, 1-in-15 year peak EEC value).
 - Additionally, sublethal thresholds are assessed using deterministic sublethal thresholds (*e.g.*, NOAECs or LOAECs) and deterministic estimated environmental concentrations (EECs) (*e.g.*, 1-in-15 year peak EEC value).
 - The current approach in the BEs is comparing an exposure value to a threshold for possible exceedances [similar to a risk quotient approach (*i.e.*, exposure/effect)].

REFINEMENTS 2: Non-Spatial Analyses

- CHARGE QUESTION (3b):
 - **Is there a way to utilize the thresholds that is more informative (for example, in the weight of evidence) and goes beyond a deterministic approach (moving towards a more probabilistic approach for assessing risks as recommended by NAS)?**
 - How could joint probability distributions of effects (the thresholds) and exposures (the EECs) be used to help inform the potential for risk?
 - Are there other probabilistic approaches that can help better inform risk at the individual and field levels?
 - When making a “May Affect/No effect” determination, what are some practicable methods to better determine where both direct and indirect effects are either ‘no effect’ or ‘discountable’ (extremely unlikely to occur)?
 - For example, could an action be “discountable” for certain species (*e.g.*, when there is no direct exposure or effects expected and no or insignificant/discountable effects to prey, pollinators, *etc.*).

REFINEMENTS 2: Non-Spatial Analyses

- CHARGE QUESTION (4b):
 - **Is there an efficient way to incorporate exposure durations into the analysis of potential effects?**
 - The pilot BEs currently compare all effects thresholds to peak EEC values. How can other durations of potential exposure be utilized and related to available toxicity studies (which are conducted under a range of exposure durations)?
 - Are there factors, other than duration, that should be considered when comparing the effects data to the EECs?



Sample output from the TED tool (estimated residue concentrations on food items over time)

THANK YOU!

ANY QUESTIONS?