ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Session: Refinements to Steps 1 and 2 (Ideas for 'streamlining' and/or improving the analyses used to make effects determinations in future BEs)

In accordance with the Endangered Species Act (ESA), the Biological Evaluation (BE) determines whether there is a potential for a single individual of a listed species, or its designated critical habitat, to be adversely affected (directly or indirectly) by a federal agency's proposed action (in this case registering pesticide labels). This is accomplished by first identifying which species ranges/critical habitats overlap with the 'action area' (from the BE Step 1: 'May Affect'/'No Effect' determinations). Once a determination is made for each listed species and critical habitat, species- and critical habitat-specific analyses for all listed resources that have 'May Affect' determinations are conducted to evaluate whether there is a potential for a single individual (or essential critical habitat feature) to be adversely affected² by the use of a pesticide (BE Step 2: 'Likely to Adversely Affect'/Not Likely to Adversely Affect' determinations). Therefore, 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) and Step 2 is intended to identify the potential for adversely affecting 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).

- Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):

O For agricultural uses, the interim process identifies potential use sites by collapsing >100 Cropland Data Layer (CDL) classes into 11 agricultural use categories, some of which are unambiguous major crops (corn, cotton, etc.), and some of which are aggregated "minor" crops, e.g., orchards and vineyards, or ground fruit and vegetables. (These minor crops were aggregated to address uncertainties in crop identification in the CDL, and to anticipate future use areas for pesticides, based on current uses.) Therefore, 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.

¹ The action area is defined by statue as all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the Action (50 CFR 402.02). The action area is, thus, related to the proposed action and is independent of the geographic area in which listed resources occur.

² Adverse effects to an individual are not limited to mortality, and include short-term and temporary effects (from direct and/or indirect effects) to individuals. Step 2 analyses do not evaluate the potential for "jeopardy" or "adverse destruction/modification" for species and critical habitat, respectively. Such an analysis would be conducted in Step 3 in a Biological Opinion.

- 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,
 - O How should we deal with "undisclosed" census values?
 - O Do these data (or other suitable data) reflect "no usage" or "low" levels of usage over the duration of the proposed action?
- O Non-agricultural label uses include a wide range of land cover and land use categories. In the BEs, 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.
 - <u>CHARGE QUESTION 2a</u>: 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?
- O 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.
 - <u>CHARGE QUESTION 3a</u>: 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?
 - o 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?

- For uses such as mosquito adulticide use, what other information could be pulled in to the analyses 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 wont' be) applied that would provide spatial refinement (i.e., it will not be applied to open water, or urban areas, etc.).
- O 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.
 - <u>CHARGE QUESTION 4a</u>: 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)?
 - 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)?
- O In the pilot BEs, any overlap of the action area with a species range or critical habitat is considered a 'May Affect'.

- 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)?
 - Would using a weighting approach for the likelihood of an overlap be useful 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)?
- Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):
 - O 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.
 - 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)?

- O 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).
 - 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)?
 - 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)?
- O 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)].
 - <u>CHARGE QUESTION 3b</u>: 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)?
 - O 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.*).
- 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?