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

## Breakout Sessions WOE 1 and WOE 2: Weight of Evidence for Listed Animals and Plants

The draft biological evaluations for chlorpyrifos, diazinon and malathion rely upon a weight of evidence (WoE) approach to make species-specific effects determinations. Risk conclusions are based on the integration of exposure and effects information relevant to an individual of a listed species, as well as life history characteristics that may influence exposure or indirect effects (e.g., diet). Different types of effects are identified in this approach as separate lines of evidence; including: mortality, growth, reproduction, behavior, sensory effects and indirect effects. Additionally, other factors that could affect the magnitude of both direct and indirect effects (*e.g.*, chemical or abiotic stressors) are evaluated as lines of evidence. Weighting is applied to each line of evidence and the weighting criteria provide guidelines for supporting effects determinations based on the pairings of risk and confidence. The current weighting criteria are defined in Attachment 1-9.

An effort was made to incorporate and evaluate as much toxicity and exposure data as possible to determine whether adverse effects are anticipated from the effects of the action. Both the toxicity and exposure information are evaluated to determine the risk and confidence associated with each line of evidence. Currently, the process uses numeric thresholds to determine risk. EPA and the services have discussed integrating distributions of effects and exposures to move towards a more probabilistic approach (*e.g.*, such as the method used in the Terrestrial Investigation Model); however, this is seen as more of a long term goal for application to all species. EPA and the Services are interested in suggestions that improve the WoE method. When addressing the questions below, answers will be grouped into "short term" or "long term" solutions, considering the magnitude of work associated with developing and applying the methods to all listed species ( $n \approx 1800$ ).

The same set of questions will be considered by the WoE groups focused on plants and on animals; however, the discussions are expected to differ. For instance, issues related to exposure differ between animals and plants in that the routes and models are conceptually and mathematically different. For effects, data are available for multiple lines of evidence for assessing direct effects to animals (i.e., mortality, growth, reproduction, behavior and sensory); whereas mortality, growth and reproduction data are only available for plants. It is expected that discussions related to animals will likely surround the topics of assessing direct effects to listed individuals as well as indirect effects due to impacts on animals and plants. For plants, discussions should probably focus more on indirect effects due to impacts to animals upon which they depend (e.g., for pollination or seed dispersal).

- <u>Exposure Information</u>- Criteria used to assess exposure estimates ultimately answer the question, "how confident are we that exposure estimates represent environmental concentrations that could occur based on allowable labeled use?" The current approach for characterizing exposure considers the <u>relevance</u> of predicted EECs for species' habitats and the <u>robustness</u> of EECs derived from environmental fate models (see Attachment 1-9 for more details). Considering the current approach to characterizing exposure:
  - **CHARGE QUESTION 1**: Comment on/suggest alternative methods for presenting exposure information (e.g., probability distributions, consideration of a range of exposure estimates, consideration of duration of exposure) and how the information can be weighed for each line of evidence's risk conclusion.
  - **CHARGE QUESTION 2**: Comment on the criteria used to weight Confidence in the estimation of exposure as described in Supplemental Information to Attachment 1-9.

- <u>Effects Information</u>- Similar to the exposure characterization, the effects data are evaluated to answer the question, "how confident are we that available toxicity data will accurately predict an effect to the listed species?" The current approach considers 1) <u>biological relevance</u>- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) <u>relevance of surrogate</u>- how representative the tested organisms used in the toxicity studies are at informing the potential for adverse effects to listed species or critical habitat, and 3) <u>robustness</u>- whether there is consistency within the line of evidence for the taxonomic grouping of interest (see Attachment 1-9 for more details). Considering the current approach to characterizing effects:
  - **CHARGE QUESTION 3**: Comment on approaches for incorporating data quality into the weight assigned to a line of evidence. The current approach to data quality is described in Attachment 1-8.
  - **CHARGE QUESTION 4a**: For animals, to what extent can taxa with robust data sets be used as surrogates for other taxonomic groupings where lines of evidence have little or no data (*e.g.*, mammals for reptiles)?
  - **CHARGE QUESTION 4b**: For plants, comment on the approach to surrogacy. Is there a better or more representative way to group species?
  - **CHARGE QUESTION 5**: How can we more effectively incorporate the breadth of the available toxicity information (*i.e.*, not just the most sensitive endpoints), including magnitude of effect, into the characterization of effects and weight of evidence?
  - CHARGE QUESTION 6: How can we effectively weigh the impacts of other stressors (*e.g.*, temperature) on the LAA/NLAA call, especially in the event of little or no data? CHARGE QUESTION 7: Are there additional sublethal effects that have an established relationship with an assessment endpoint that should be considered as lines of evidence?
  - **CHARGE QUESTION 8**: Comment on the criteria used to weight Confidence in the estimation of effects as described in Supplemental Information to Attachment 1-9.
- <u>**Risk Estimation**</u>- Risk is established by comparing the overlap of exposure with effect levels from available toxicity studies for each line of evidence. Consideration is given to the degree of overlap between exposure and effects data. Considering the current approach to estimating risk:
  - **CHARGE QUESTION 9**: Comment on the criteria used to weight Risk as described in Supplemental Information to Attachment 1-9.