Appendix A

A-A. 2016 June Stakeholder Workshop Break Out Group Charge Questions

JUNE 2016 STAKEHOLDER WORKSHOP BREAK OUT GROUP CHARGE QUESTIONS

Aquatic Group 1

Improving Aquatic Modeling: Changes to conceptual and mathematical approaches incorporated into Bins 3 and 4 (flowing waters)

a. Modifications to Bins 3 and 4 for use in PWC
b. Discuss alternative models that may be more suitable

Charge Questions:

1. The EPA explored several factors in using the PWC, including incorporation of a baseflow and use of the daily average instead of the instantaneous peak EEC. What are the strengths and weaknesses of these modifications? Are there other modifications that can be made and what are their strengths and weaknesses?
2. How appropriate are the methods used in the draft BEs to develop field/watershed sizes and waterbody lengths for these Bins? What reasonable alternatives could be used to model watershed processes that allow for accurate estimation of possible exposure concentrations (including the maximum) in these flowing bins based on product labeling?
3. For the Bins (3 and 4) that represent larger flowing systems, what ways of incorporating the effects of dispersive mixing and/or peak desynchronization into concentration estimates are reasonable?
4. What are the strengths and weaknesses of alternative mechanistic or regression-based watershed models such as the Soil and Watershed Assessment Tool (SWAT), the Hydrological Simulation Program-Fortran (HSPF) and the Watershed Regressions for Pesticides (WARP) for simulating aquatic pesticide concentrations at the temporal resolution and national scales required for ESA assessment? Are there other watershed models that should be considered?
5. What is the desired and appropriate spatial scale for EECs for Bins 3 and 4? Specific PWC EECs were developed for HUC2 regions. Can or should the EECs for Bins 3 and 4 be at a finer spatial scale given a nationwide consultation?

Aquatic Group 2

Improving Aquatic Modeling: Evaluating watershed sizes of different water bodies

a. Determining appropriate watershed sizes
b. Parameterization of dimensions of flowing waterbody relative to watershed Evaluation of EECs using monitoring data

Charge Questions:

1. In what ways are a "multiple lines of evidence" approach appropriate for evaluating the results from a watershed model? What would be the "lines of evidence" and sources of information?
2. How can different types of monitoring data be distinguished? What metadata requirements (e.g., use info, sample frequency, etc.) can be used to distinguish types of monitoring data?
3. What roles can the various types of monitoring data play in the evaluation of results from a watershed model (e.g., general monitoring doesn't predict maximum but has other roles)?
4. What other approaches are available for evaluating results from watershed models?
5. To what extent can we rely on historical monitoring data when product labeling has changed and application-specific information is lacking?
6. Are there new or different types of monitoring that could be employed to further our understanding of aquatic modeling estimates?

Refinements 1

Refinements to Steps 1 and 2: Spatial analysis

a. Potential ways to better identify pesticide use sites (ag and non-ag)
b. Potential ways to better understand the distribution of individuals within a listed species range
c. Potential ways to improve the overlap analyses between species range and potential pesticide use

Charge Questions:

1. 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?
    a. Are there some CDL classes that we have more confidence in than others?
    b. 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,
        i. How should we deal with "undisclosed" census values?
        ii. Do these data (or other suitable data) reflect "no usage" or "low" levels of usage over the duration of the proposed action?

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.

2. 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.
    a. Are there additional data not considered in the BEs that may be useful for geographically identifying non-agricultural use sites?
    b. Are there surrogate data (those that could be used to help inform potential use sites) that could be used for non-agricultural categories that we have not considered?

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 United States and its territories.

3. 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?
    a. 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?
        i. 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?
    b. 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?
    c. 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.).

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.

4. Are there methods available that would allow for a refined understanding of the distribution of individuals within the range polygons?
    a. 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)?

b. 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)?
c. 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)?
d. 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?
e. Can we incorporate this information to apply a weighting to the overlap analysis (see charge question 5a below)?

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

5. Does the overlap approach used in the pilot draft BEs to determine a 'May Affect/No Effect' determination provide an adequate screening process (one that is protective but not unrealistically conservative)?
    a. 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)?
    b. 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)?
    c. 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 (Refinements to Steps 1 and 2: Non-spatial analysis)

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.

Charge Questions:

1. 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)?
    a. 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)]?
    b. Of these fate properties, how could they be considered - keeping in mind use site parameters?
    c. Of these use site parameters, how could they be considered (e.g., personal ready-to-use spray can for mosquitos)?

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).

2. 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)?
    a. 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.)?
    b. Of these fate properties, how could they be considered (e.g., a full assessment might not be needed for pesticides that have a log Kow <4)?
    c. What types of biological/ecological attributes of the species would need to be considered (e.g., its habitat)?
    d. 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)?

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 HC_{05} of a SSD or the lowest LC_{50}/LD_{50} 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)].

3. 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 toward a more probabilistic approach for assessing risks as recommended by NAS)?
    a. How could joint probability distributions of effects (the thresholds) and exposures (the EECs) be used to help inform the potential for risk?
    b. Are there other probabilistic approaches that can help better inform risk at the individual and field levels?
    c. 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)?
        i. 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.).
4. Is there an efficient way to incorporate exposure durations into the analysis of potential effects?
    a. The pilot draft 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)?
    b. Are there factors, other than duration, that should be considered when comparing the effects data to the EECs?

Weight of Evidence 1

Weight of Evidence for Listed Animals

a. Potential ways to improve evaluation of information and criteria used to draw risk conclusions
b. Potential ways to incorporate additional information into the weight of evidence approach

Charge Questions:
Exposure Information: 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 relevance of predicted EECs for species' habitats and the robustness 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.

Effects Information: 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) biological relevance- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) relevance of surrogate- 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) robustness- 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.

Risk Estimation: 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.

Weight of Evidence 2

Weight of Evidence for Listed Plants

a. Potential ways to improve evaluation of information and criteria used to draw risk conclusions
b. Potential ways to incorporate additional information into the weight of evidence approach

Exposure Information: 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 relevance of predicted EECs for species' habitats and the robustness 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.

Effects Information: 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) biological relevance- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) relevance of surrogate- 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) robustness- 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.

Risk Estimation: 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.