Approach to Weight of Evidence for Listed Animals and Plants
Breakout Groups 5 and 6 – Report Out

June 30, 2016

Exposure: Charge Question

- **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 1: Animals

SHORT TERM TASKS

- Probability distribution
  - What aspects of distribution will be used for decision making
- Duration of exposure – how to correlate with the effect endpoint
- Timing of exposure with species life history
  - *E.g.,* Species underground when foliar application made
- Use a range of exposure estimates
- More characterization around the habitat used for the species –
  - *E.g.,* Bins that species are located in at what time of year
  - For species with extremely specific habitats, narrow down range and refine overlap area

Charge Question 1: Animals

LONG TERM TASKS

- Spatial and temporal distributions to characterize risk, an automated process to characterize multiple factors yet still protect the species
- Matching duration of exposure with toxic effect (way of characterizing likelihood of impact); how long exposure needs to occur to reach an endpoint
- Options for refinements using life history data (narrow scope of time of concern)
  - Migratory and other temporal considerations
- Geospatial refinement of labeled application rates/use restrictions
- Use of percent cropped treated and species data to refine likelihood and magnitude of exposures
- Chemical specific residues on terrestrial food items
- Incorporation of nozzle requirements into drift modeling (if labeled)
- Use of monitoring data in weight of evidence lines

Charge Question 1: Plants

SHORT TERM TASKS

- Use more than maximum labeled rate to better express the range of potential exposures (Short Term) or use and rates relevant to the specific species (Long Term)
  - Highest use rates are typically the least frequently used
  - Would help focus potential mitigation options
- Use the available toxicity data to focus the exposure assessment (*e.g.,* if seedling emergence is the major concern, then focus on runoff exposure)
- Spray drift- consider species habitat (forest vs. open field)? Crosswalk between species habitat categories and typical use patterns that overlap. (Where is off-field exposure likely to go?)
  - Types of habitats and types of uses and how they relate to each other. Develop a matrix (Short Term) or a GIS proximity analysis (Long Term)?
    - CDPR may have done something similar
- Incorporate general wind tunnel data and monitoring data into the weighting criteria for the exposure data.
- Use the residue data and decline studies
- Link exposure time of the study to the EECs- aquatics only.

Charge Question 1: Plants

LONG TERM TASKS

- Incorporate temporal aspect into exposure analysis at the coarse scale. (Does application occur when species is present?)
- Probability distribution (contingent on implementation of Audrey III).
  - Need to consider how to incorporate a distribution for drift.
    - Use the label information and weather information.
  - Joint probability is most transparent weight of evidence approach. Develop criteria related to how much overlap exists. Quantitatively talk about the confidence. Build an SSD where appropriate or use dose response for a single species.
- Check data for information on recovery time for plants. This information may be included in the WOE for use in Step 3.
  - Include incident data in weighting criteria. A lack of reported incidents should be used as a piece of “negative evidence;” may be a qualitative piece of information.
  - Meta-analysis of incident database for classes of chemicals (number of incidents versus acres of use)

Effects: Charge Questions

- **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 3: Animals

SHORT TERM TASKS

- All studies need at least a minimum study review
  - ECOTOX performs a basic study review for inclusion of studies in the database
  - Some more influential studies go through more rigorous review
- Incorporating other studies with other life stages, need to screen to determine if formulations are current
  - Field studies – use to “ground truth” results when available

LONG TERM TASKS

- Consideration for other sources of data than ECOTOX
  - If additional studies are identified, they are considered; however the studies need to go through the same data review process
- Level of review and quality of studies are included in the final weighting of line of evidence

Charge Question 3: Plants

SHORT TERM TASKS

- Clarify Attachment 1-8 Figure 1-8.1, which currently focuses on SSDs
- Focus review on studies driving threshold/endpoint
  - Or use some other approach to prioritizing studies

LONG TERM TASKS

- After “broad net”, need to score the reliability and relevance of each study
  - “Impact grid” to display results
  - Check literature for approaches

Effects: Charge Questions

- **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 4a: Animals

SHORT TERM TASKS

- Consideration of pulling mollusks and amphibians out of SSDs and see how that affects endpoints
- Some AOPs may be well conserved across all vertebrates
  - However, difficult to assess significance of the cholinesterase inhibition from one species to another
  - Would need to capture uncertainty in the extrapolation

LONG TERM TASKS

- Lumping data versus splitting; dichotomy of insufficient data for SSD compared to data for which you have confidence
- Using mode of action to rule out effects to certain taxa
- Literature review to investigate adequacy of surrogacy for taxa for which there are limited data (e.g. birds and reptiles); consider within an AOP
- Determining what additional data might be useful to generate to fill data gaps
- Better surrogates for coral; explanation of surrogacy

Charge Question 4b: Plants

DISCUSSION

- Need more groupings:
  - Geographic, taxonomic, habitat, chemical properties, crop properties
  - May group differently for direct or indirect, aquatic or terrestrial
  - Hawaii may be its own group/subgroups
- Grouping may be refined over time
- The ten test species represent the range of sensitivities and vv/se tests represent the most sensitive growth stages
  - See SETAC information
  - Some exceptions (*e.g.*, lichens)

SHORT TERM TASKS

- Incorporate “broad” habitat types into grouping
  - Obvious groups with “high” or “low” exposure for certain uses
- Habitat types assigned to the species can be used to represent the indirect effects
  - Could use the FESTF attribute database to group species into habitat categories
- Group species by pollinator/seed dispersal mechanism

LONG TERM TASKS

- Develop approach to incorporate taxonomic groupings (*e.g.,* are there some species that can be represented at the family level? genus level?)
- Score the surrogacy based on available data

Effects: Charge Questions

- **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 5: Animals

SHORT TERM TASKS

- Proportion of tested species endpoints that exceed EECs
  - Using more of the SSD/range of endpoints for indirect effects (considering all species in taxa)
  - This information is useful for risk characterization

LONG TERM TASKS

- Determining level of effect to indirect lines that are biologically relevant (research to support other thresholds than 10% (animals)/EC25/LOAEC (plants); relevance of duration of effect and recovery of prey/habitat base, in field vs. off field)
  - OECD beneficial arthropod studies
  - Plant type considerations for habitat/relevance of endpoints
- Apply surrogacy rules for species to obligate organisms
- Consider different weighting for each line of evidence to inform Step 3
- Consideration of mesocosm/field studies further in weight of evidence
  - European studies – need to consider quality of study design
- Differentiate toxicity endpoints by life stage

Charge Question 5: Plants

DISCUSSION

- Consider the range of data and plant life-stages at time of exposure
- Direct effects- consider magnitude of effects
  - Data arrays- include the magnitude of response from LOAECs, where available
  - (Short Term) show the un-reviewed endpoints with a different symbol in data arrays
  - (Long Term) show lower reliability endpoints with a different symbol in data arrays
- Indirect effects
  - (Long Term) Develop SSD approach and how to apply it
    - How to deal with unbounded data
  - (Long Term) Potentially include efficacy and crop tolerance studies to understand the range of sensitivities and sensitive growth stages (where information is available)

Effects: Charge Questions

- **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 6: Animals

SHORT TERM TASKS

- None identified

LONG TERM TASKS

- Determining how other stressors (abiotic or chemical factors) feed the model in a meaningful way is a challenge; data available is sparse for many taxa, have to work within the data that is available and consider uncertainties associated with extrapolation

Charge Question 6: Plants

DISCUSSION

- The question should be re-written as- Would abiotic factors affect the NLAA/LAA call?
- The stronger the data on the impact of other stressors the more likely it will be incorporated into the assessment.
  - Use available data, AOP and MOA, to determine whether it is appropriate to use data from one taxa to assess another taxa.
  - Potential source of information- timing of application (as described on the label) may be indicative of impact of temperature/sunlight on toxicity.
    - Open dialogue with registrants earlier in the process.
- Document what you know and what you don't know.
  - Absence of information does not indicate a problem.
- Consider as a qualitative approach.

Effects: Charge Questions

- **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 7: Animals

SHORT TERM TASKS

- None identified

LONG TERM TASKS

- Consider for each chemistry in problem formulation

Charge Question 7: Plants

DISCUSSION

- Sublethal effects must have an impact on an assessment endpoint to be considered.

Exposure: Charge Question

- **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.

- **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.

Charge Question 2/8: Animals

SHORT TERM TASKS

- Within the matrices, it would be helpful to show the rank for each column that leads to the confidence finding
  - Present a rubric for clarity and transparency, (many columns/factors, each with score, more quantitative)
  - Add sensitivity analysis context
  - Provide ancillary information that would be helpful for risk management and Step 3

LONG TERM TASKS

- Continue to provide ancillary info that would be helpful for risk management
- Numerical system?
- Consideration of specific species habitat preferences and uses
- Improved communication of likelihood of exposure on population level
- Model evaluation
  - Define how that influences confidence

Charge Question 2: Plants

SHORT TERM TASKS

- Rank confidence of model output as well as model input
- Include species attributes (*e.g.,* known to inhabit agricultural fields) in the weighting.

Charge Question 8: Plants

DISCUSSION

- Use consistent terminology with other described WOE methods when describing the criteria for confidence
  - General criteria of weight of evidence to help with transparency and understanding
  - When using the data arrays to weight confidence in effects data, ensure repeated values truly represent unique values
- Criteria for confidence weighting (4 monocots/6 dicots as an example) should consider relevance and reliability of the individual effects data in the weighting.
  - Rather than number, more emphasis on the quality of data (relevance and reliability link)

Risk Estimation: Charge Questions

- **CHARGE QUESTION 9**:
  - Comment on the criteria used to weight Risk as described in Supplemental Information to Attachment 1-9.

Charge Question 9: Animals

SHORT TERM TASKS

- Qualify overlap for certain species (*e.g.*, species underground during application)
- Define "discountable"
  - Biological considerations to alter the risk call for species
  - Quantitative definition associated with a probability
  - Other species where general pesticide use is discountable

LONG TERM TASKS

- Determine proportion of exposed population, critical to step 3; Need more confidence for individual location

Charge Question 9: Plants

DISCUSSION

- Develop a Risk Table:
  - Factor in surrogacy, habitat etc.
  - Essentially rolls up short term and long term items into risk estimate
- Individual confidences for effect and exposure together in the risk determination

Other topics (Animals): WOE Framework Recommendations

- Weight of evidence methodology used
  - Consider reorganizing lines of evidence
    - Current lines of evidence are not independent of one another
    - Toxicity is one line of evidence; field studies, incident reports, etc. are additional lines of evidence
  - Revisit terminology to be consistent with the literature

Other topics (Plants): WOE Framework Recommendations

- Confidentiality of datasets should factor into the weighting criteria
- Reformatting the WOE
  - (Short Term) adding columns for assessment endpoints, break out confidence calls for exposure and effects, presenting individual weights for each line of evidence.
    - Evaluate within lines of evidence for quality and across lines of evidence for consistency.
  - (Short Term) More transparency
    - Very low, low, medium, high, very high categories
    - Use consistent terminology with other described WOE methods
  - (Long Term) assign numerical weights to each line of evidence

Other topics (Animal): Information needed for transition to step 3

- 5-year recovery plans/baseline consideration for step 3
  - Consider historical use of pesticide
  - Try to consider as a reality check sooner than Step 3
- Proportion of population exposed
- Uses and formulations relevant to the species

Questions?