Refinements to Steps 1 and 2: Non-Spatial Analyses
Breakout Group 2 - Report Out

June 30, 2016

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)?**

REFINEMENTS 2: Non-Spatial Analyses

- Report Out (1b):
  - In Steps 1 and 2, it's important to determine the likelihood of a potential exposure (*i.e.*, how likely an exposure may occur)
    - It's fairly easy to draw hypothetical pathways of exposure, but it's important to try to understand how likely that potential exposure may occur
    - This can be especially important for uses not expected to result in significant exposures (for example, ready-to-use spray cans, spot treatments, greenhouses, and cattle ear tags)

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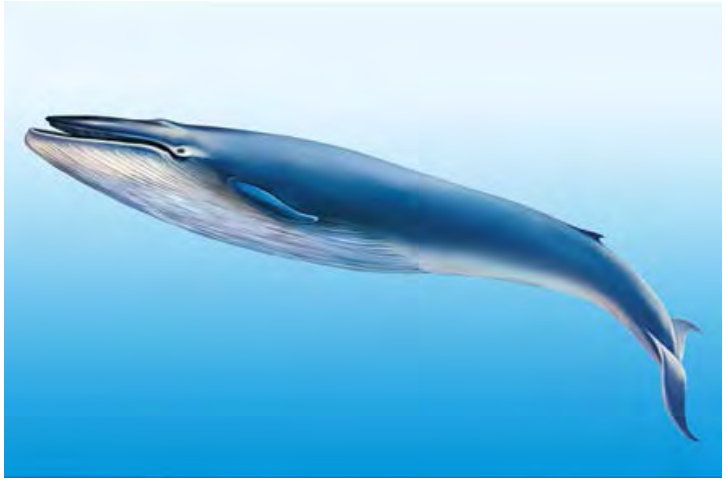
- Report Out (1b):
  - Include species-specific toxicity data earlier in the process (*e.g.*, assign species-specific surrogacy data in Step 1)
  - Learn from past assessments
    - Develop criteria for factors to consider in future assessments for pesticides with similar use patterns
    - Develop a process: We could reach agreement among the agencies to make future effects determinations for chemicals that meet certain criteria without going through the entire risk assessment process (*i.e.*, we could refer back to previous assessments)

REFINEMENTS 2: Non-Spatial Analyses

- Report Out (1b):
  - Label clarifications and mitigations (*e.g.*, rate changes based on risk assessment) can be important and can be very useful at different stages in the consultation process (*e.g.*, in Steps 1 and 2)
    - For species with small ranges (~100 species/CH with ranges < 2 mile^2), the agencies and stakeholders can explore mitigations using Bulletins Live Two
    - Registrants and agencies will need to have discussions with folks on the ground (*e.g.*, landowners, users) before making any mitigations on labels
    - It would be useful to try to develop mitigations (those for species with small ranges) by chemical class, if possible.

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)?**



REFINEMENTS 2: Non-Spatial Analyses

- Report Out (2b):
  - General agreement on the NLAAs for whales, sharks, and Arctic species
  - Discussion on listed endemic Hawaiian plants
    - Can mitigations be incorporated on the label that place limits on who can apply a pesticide in a certain area?
    - Can Special Local Needs [SLNs; 24(c)] labels be used in HI?
    - Should elevation restrictions on the label be considered (driven by known species distributions)?
    - Again, before mitigations can be made, the agencies and registrants will need to discuss with landowners, the user community, and other stakeholders
    - Some of these ideas could be applied to non-Hawaiian species

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- Report Out (2b):
  - Considerations for listed species found only on Federal lands
    - A significant number of species are only found on Federal lands
    - Explore leveraging past BiOps (Section 7 consultations) for use of pesticides on the Federal lands
    - Need to be aware that BiOps may not be available for all specific chemicals, uses, or species
    - Explore developing generic Bulletins Live language for use on Federal lands
    - Consider making Federal landowners co-applicants
    - Explore leveraging information in the boll weevil eradication consultation for malathion

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- Report Out (2b):
  - Need to consider habitat/biological features early in the process
    - Example – plants only found on sand dunes
    - Important to identify species that could be found on potential use sites (*e.g.*, those that could be found in agricultural fields; urban areas)
  - For species ranges, it's important to get information on the density of the species within the range (to get an understanding of the potential for an individual to be exposed)
    - Example – species with very large home range sizes (*e.g.*, wolves, grizzly bears) are not in any part of their range for long
    - Understanding the biology of the species is key

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- Report Out (2b):
  - How are species that are clearly recovering handled in the consultation process?
    - These species still need to be considered
    - They may be handled differently in the BiOps (*e.g.*, may still have take but not jeopardy)
  - If making Step 2 determinations for species based on past assessments, there was general agreement that the following fate parameters are important to consider: potential for bioaccumulation, persistence, and mobility
    - Understanding hazard is also important

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- Report Out (2b):
  - Consider having separate analyses for direct and indirect effects
    - Important to use data from the most taxonomically close species as possible to the species being assessed

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)?**

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- Report Out (3b):
  - Standard modeling makes worse case assumptions at each step
    - May happen, but could be very rare
    - Joint probabilities assessments could be very informative in the process
  - Goal: Trying to determine likelihood of exposure and effects (*e.g.*, frequency of exposures, intensity of effects, and probabilities of those)

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- Report Out (3b):
  - There are several variables that could be considered in a probabilistic approach
    - Exposure (distributions of exposure – aquatic and terrestrial; both through time and spatially)
    - Usage data (*e.g.*, number of applications, application rates, the pesticide used per site – also can consider information on resistance management practices)
    - Distributions of individuals in their range
    - Likelihood of effect (*e.g.*, mortality or sublethal)
      - Mortality tends to be easier than sublethal effects (but tools are available for sublethal effects – *e.g.*, benchmark-dose analyses)
      - Not always easy to link sublethal effects to specific effects on growth, mortality, or reproduction
      - One long-term item is obtaining data that allows us to quantify the relationship between sublethal effects and apical endpoints [*e.g.*, what they are trying to do in the Endocrine Disruptor Screening Program (EDSP)]
      - Two factors to consider: what is the probability of co-occurrence of exposure with responses; and what is the magnitude of effect?

REFINEMENTS 2: Non-Spatial Analyses

- Report Out (3b):
  - Need to determine criteria for 'probability of exceedance' (protective threshold)
  - Tiered approach could be useful
    - Analyses become more complex as move through the process; stop if don't need to go any further
    - Probabilistic approaches probably most useful in Step 2 (but also might be useful in Step 1)
    - Definitely needed for Step 3

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- Report Out (3b):
  - Tools used may be different for direct and indirect analyses
  - If have good surrogate toxicity data, could use those data (*e.g.*, run Monte Carlo analyses)
  - Need to think about capturing uncertainties at each step (uncertainties could be bound)

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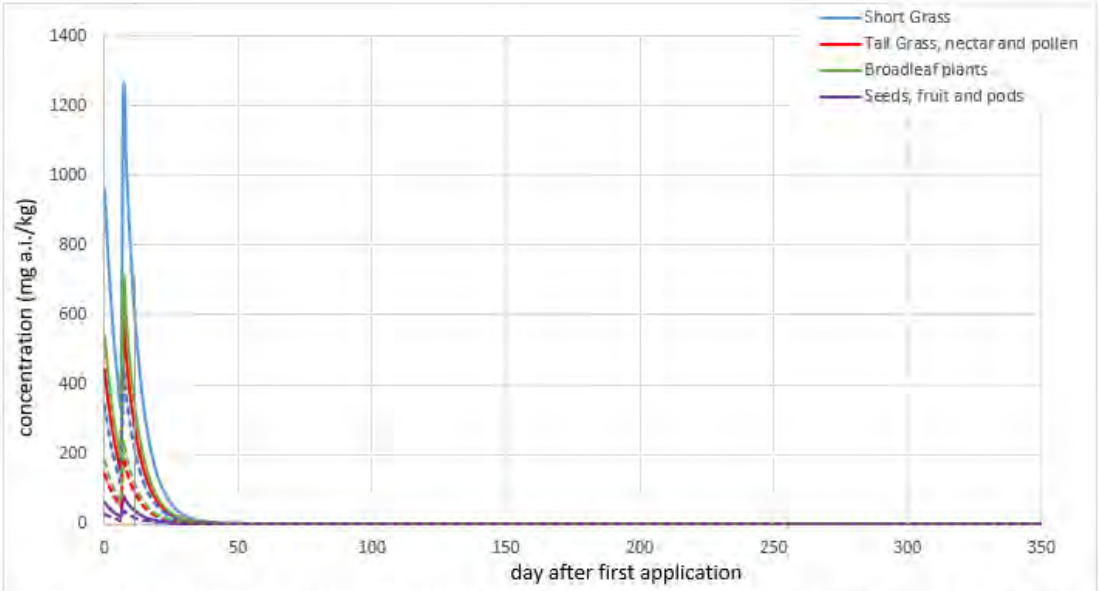
- Report Out (3b):
  - Messaging is **VERY IMPORTANT** – what does 'likely to adversely affect' mean
    - Making sure the user community has an understanding that LAAs will not necessarily result in changes to use patterns in the end. (It will depend on the results of the BiOp).
    - Having 'typical' scenarios in the assessments – may not be used necessarily in decision-making – but could be helpful in messaging

REFINEMENTS 2: Non-Spatial Analyses

- CHARGE QUESTION (4b):
  - **Is there an efficient way to incorporate exposure durations into the analysis of potential effects?**



Estimated pesticide concentrations over time on plant food items. Solid lines represent upper bound. Dashed lines represent mean.

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

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- Report Out (4b):
  - Lots of discussion on how to refine exposure estimates
    - Currently, for chronic endpoints, we use peak exposures. Can we do something better?
    - Consider uptake studies, studies that look at how chemicals are broken down in certain taxa, and PBK models (might be available for some taxa – *e.g.*, mammals, terrestrial invertebrates).
  - Should more fully utilize residue data from crop studies, if possible
    - Could be used to refine T-REX residue values
    - Could be more crop-specific
    - Could allow for more geographically specific exposure modelling (for terrestrial exposures)

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- Report Out (4b):
  - Link effects data with the durations of expected exposures
    - Give more weight to effects endpoints that match the expected exposure durations in the environment
  - Consider time to lethality in the mortality studies
    - Time to mortality curves for the first three chemicals have been provided by the registrants in their comments

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- Report Out (Others):
  - Should consider how temperature affects the degradation of chemicals over time (in both aquatic and terrestrial environments)
  - It would be useful to start tabulating specific data gaps (that could help inform future research)
    - For example, need for comprehensive life-history information
    - Information on plant pollinators (for listed plants)
    - Better surrogacy data (more taxon-specific information)
  - Need for centralization of and access to data used in the consultations