06-23-14

(Editor’s note: These are the notes as taken by a small subset of the participants during the CMF meeting. Every effort was made to be as thorough as possible but it can be challenging to participate in a meeting and document it at the same time. Consequently, these notes may not necessarily be inclusive of all viewpoints expressed or contain every point of discussion. These notes should also not be assumed to be the official conclusions of the CMF and are expressly provided to promote further discussion and consideration of the issues. Please direct all amendments and corrections to: [Brian.Dougherty@dep.state.fl.us](mailto:Brian.Dougherty@dep.state.fl.us))

CMF PRA Subgroup Meeting - Consolidated Notes

* + Testing the reliability of back-calculated outputs (run forward calculations to see if results match)
    - Get a different answer when calculated forward and background
    - How different is different?
      * Order of magnitude?
    - Error introduced is unknown
    - Will DEP always accept forward risk calculation?
      * Provisionally yes
      * Will ask for forward if only do backward
    - Discussion of what to do when the 2 calculated numbers are different. DEP would likely say use the lower number (i.e., more stringent).
    - The rule implies the forward-calculated number is the number by referencing a 90th percentile risk
      * The rule also has a parenthetical reference to a 10th percentile CTL, which would typically be generated using the back calculation method.
      * This is a statistical issue, so the question is what is the standard generally accepted among the industry of statisticians?
      * This is a statistical issue, so the question is what is the standard generally accepted among the industry of statisticians?
      * The two PRAs that the DEP has done used Iterative Forward Calculation (no backward calculations). (One was associated with rulemaking for the Surface Water rule.)
      * The language in the Rule is sufficiently ambiguous that it can be interpreted either way.
      * The fundamental notion of PRAs is that you plug in your distributions, you run the program, you get a range of answers, and then you pick the one that equals the 1x10-6.
      * Would only do a back-calculated analysis to get the number you want
    - Group to provide addl background for next meeting
    - Conclusion: Further discussion at next meeting following review of additional information. Generally acknowledged that forward and backward calculation will yield different numerical answers. Questions remain as to how large a difference between those answers may be meaningful and how to administratively apply two different numerical results to risk management decisions

* + PRAs based upon both variability and uncertainty distributions and 2D-PRA approaches
    - Should variability and uncertainty be treated the same or different?
    - Exs variability in body weight, uncertainties in measurement
    - Bioavailability - Not as much data, still variability but more uncertainty.
    - Use point estimate if too much uncertainty?
      * Unless do 2D -
      * Need confidence bounds for uncertainty
    - "Poor Man's 2D" - run 1D with variability parameters, use point estimates or distribution secondarily to see effect of adding uncertainty
    - Could also simply leave out uncertainty and address qualitatively
    - Conclusion: Variability and uncertainty need to be treated independently and not combined in the PRA. Full analysis of uncertainty requires a 2 dimensional PRA. Reduced versions can be run by substituting point estimates for the uncertain values and running multiple 1 dimensional PRAs.

* + Distributions (uniform, triangular, etc.) based on professional judgment due to lack of available data
    - How much data do you need
      * Depends on the data
      * Ex. Exposure Frequency - know it varies but no data
    - What do you do when you don't have data?
      * Can use point value
      * Point value will bring in tails on distribution vs using distribution based on professional judgment
    - Reasonable lack of data
    - Use 'best professional judgment' for those distributions for which you know something
    - Need to provide justification for distribution
    - Conclusion: A proposed distribution based on professional judgment can be considered providing that the rationale for the distribution is also provided.

* + Distributions for toxicity values and toxic equivalency factors
    - EPA recommends against using distributions for toxicity factors
      * EPA R IV recently re-affirmed
      * 62-302 - not using
    - Distributions provided by EPA for TEFs and toxicity values
      * But represent uncertainty rather than variability
    - TEFs better suited to 2D approach
    - May not be suitable for toxicity values
    - Benchmark dose approach
      * More to mathematical modeling on dose/response relationship
      * Not a probabilistic approach - modeling approach
    - Conclusion: A distribution for TEFs as a second dimension in a PRA may be appropriate given the current state of knowledge. A similar approach for toxicity values may be theoretically possible but is not a recommended practice at this time. It may be possible to use the benchmark dose approach to model the uncertainty but methods for doing so are still being explored.

* + Exposure start age, and focus on protection of children for other exposure factors
    - Identify population for exposure
      * Deterministic number exposure begins at age 1
    - If use random start age then children end up in upper tail
    - Management decision - need to include children
      * Question with regard of how to model start age
        + Everyone starts at one
        + Or use child migration data (1-6)
    - Conclusion: There needs to be some constraint on start age to ensure that children are protected when using a PRA. There will be further discussion at the next meeting with regard to how that constraint is applied. Options discussed included: start age always begins at 1, start age begins between 1 and 6 based upon child migration data, start age begins between 1 and 6 with a uniform distribution.

* + Adjusting the soil ingestion distribution
    - Need to discuss appropriate resampling frequency & correlation
      * Increased resampling drives soil ingestion rate to the central tendency and may exclude substantial portions of the tails.
        + Several variations on resampling frequency discussed:

Six times a year

Once per year

Once per age bin

One for child and one for adult

And others

* + - * General agreement that subsequent draws from soil ingestion distribution should be correlated but questions remain with regard to degree of correlation and how to apply that correlation
        + Rates used in examples varied from r2 of .75 to .95
        + Correlation can be applied against first draw (i.e., always correlate with first value drawn for individual) or can be applied draw by draw (i.e., correlate with most recent value drawn for an individual).
    - Conclusion: For further discussion.

* + Relative Bioavailability (literature-based variability distributions versus site-specific bioavailability studies)
    - Don't want department to say always has to be site-specific study
    - Consider other information if it's out there
    - Defer further discussion to next meeting