





5.03.P-Mo146. Realism, Conservatism, and Tiered Ecological Risk Assessment US Environmental Protection Agency, Office of Research and Development, Center for Computational Toxicology and Exposure Great Lakes Toxicology and Ecology Division, Duluth, MN

Innovative Research for a Sustainable Future

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Conceptual Model Analysis

A risk scenario is safe when the predicted effect is lower than the *a priori* maximum safe level (horizontal black line)

"True" (unknown and therefore not shown) risk is assumed to lie at the asymptote of the hyperbolic cone (green, yellow or red lines) of increasingly realistic and precise model predictions at higher tiers

Under the *efficiency principle*, a positively biased model prediction (e.g., the upper 95% confidence limit on model predictions) overestimates the true magnitude of effect

- The green scenario (left panel) can be determined safe with lower tier model (e.g., risk quotient)
- The yellow scenario (middle panel) can be determined safe with mid- or upper-tier model
- The red scenario (right panel) should never be determined safe

Under best practices, models give an unbiased estimate of effect magnitude (prediction lies somewhere within the hyperbolic cone, with higher uncertainty at lower tier)

Following best practices, at lower tiers there is a region (between the black and red lines on the right panel) where we could conclude that an unsafe scenario is safe

Conclusions

• In risk assessment, it can always be argued that more information & more realistic models are needed to identify true risk

The *efficiency principle* provides a mechanism for stopping when a risk scenario is identified to be safe, but requires monotonically declining conservative bias with tier escalation

However, the efficiency principle is in direct conflict with best practices for model development, which focus on unbiased prediction of outcomes

The *efficiency principle* may be impossible to implement in an increasingly realistic model escalation sequence

In contrast, best practices could lead to erroneous conclusions that risk is acceptable

Resolution of the conflict between best practices and the efficiency principle will be a formidable challenge as we deploy ever more complex models

Similar arguments, with similar challenges, could be made for quickly identifying risk scenarios that are *not* safe

Literature Cited



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