

Report 66: Science-based Risk Assessment

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Brief History: Our knowledge base of toxicology and environmental health has increased dramatically in the last 25 years, but risk assessment frequently reverts to using “default” approaches rather than a strong science-based approach. The NIEHS is positioned to champion the use of detailed science-based approaches to improve the risk assessment process. This is seen as a critical element for the Strategic Plan of the NIEHS.

Discussion Highlights:

- The Framework Mode of Action (MOA) approach outlined by Sonich-Mullin (2001) provides an excellent approach to evaluate and incorporate scientific research on MOA into the risk assessment process so that decisions are transparent.
- A major factor that drives the use of “default” approaches is insecurity associated with uncertainties. Research on MOA, dose-response and PBPK modeling can reduce uncertainties. As such, it represents an important area deserving high priority in the Strategic Plan.
- Likewise, Systems Biology of the underlying pathways and dose-response leading to disease are both supported by NIEHS and highly relevant to risk assessment.
- The NIEHS should support the development of tools and data to facilitate the use of in vitro assays to predict in vivo effects in a quantitative manner.
- The Report on Carcinogens should evolve from a “Strength of evidence” to a “Weight of evidence” approach to incorporate our improved scientific understanding of exposure and dose-response in chemically-induced diseases in order to move from Hazard Identification to Hazard Characterization.

Recommendations:

- The NIEHS should strongly support research that provides better and high quality information to fill knowledge gaps relevant to risk assessment, such as better data on MOA, improved PBPK models and vastly improved information on human exposures.
- NIEHS should support scientific meetings to examine the risk assessment process and identify where scientific data were or were not well used, where data disagree, and how the risk assessment process could be improved by better incorporating scientific data.
- NIEHS should return to offering RO3 grants to enhance interactions between researchers and the NTP to improve our understanding of the MOA.
- The NTP needs to increase the number of studies on mixtures to enhance knowledge our understanding of MOA and cumulative risk.

- The NTP is encouraged to contrast the cost of their toxicology and research studies with the costs of remediation and human health.
- Training of graduate students and postdoctoral fellows in science-based risk assessment should be an important feature of NIEHS training grants.
- The ROC should enhance the incorporation of MOA and dose response information to support a weight of evidence approach leading to Hazard Characterization.

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