Conclusions

In this guide

23. Annex A - References

BMD modelling offers a more sophisticated, data-driven and transparent alternative to traditional NOAEL-based approaches in chemical hazard characterisation. It allows for the use of full dose-response data, quantifies uncertainty in the experimental data, and supports more nuanced establishment of health-based guidance values. However, its broader adoption is challenged by methodological disagreements, technical complexities, and practical limitations. Key issues include differing views on statistical frameworks, benchmark response selection, and model averaging, all of which may lead to inconsistent outcomes. Technical hurdles such as model fitting difficulties, software variability, and the need for expert interpretation further complicate implementation. The growing complexity of BMD tools also raises concerns about transparency and the risk of “black box” modelling. Additionally, many existing toxicology studies are not well-suited for BMD analysis, and the integration of new data types like genomics and human epidemiology introduces further uncertainty. Despite these challenges, BMD modelling is seen as a valuable tool that bridges traditional toxicology and emerging mechanistic approaches. Its successful integration into regulatory practice will depend on harmonised guidance, improved training, and collaborative efforts to ensure consistency, transparency, and scientific integrity in its application. The COT considers the BMD approach to have considerable value in its work and hence would welcome clearer guidance to ensure transparency and harmonisation on its use.