Advantages of BMD modelling

In this guide

23. Annex A - References

One of the primary strengths of BMD modelling is its use of the entire dose-response dataset. Unlike the NOAEL approach, which relies on identifying a single dose with no statistically significant effect, BMD modelling fits a mathematical curve to all available data points. This allows for a more comprehensive and data-efficient analysis, reducing the influence of arbitrary dose selection and, in theory, increasing the reliability of the derived RP. The BMD approach also enables the estimation of a lower confidence bound (BMDL), which provides a quantitative measure of uncertainty in the experimental data.

Another advantage is the flexibility of BMD modelling in accommodating different types of data. It can be applied to both continuous and quantal (binary) endpoints and is suitable for traditional toxicological studies as well as emerging data types such as gene expression and high-throughput screening data, as demonstrated in the Case study (Annex A). This adaptability makes BMD modelling particularly valuable in the context of New Approach Methodologies (NAMs), where complex and multi-dimensional datasets are increasingly common.

BMD modelling also facilitates the derivation of RPs that are consistent and comparable across substances. By defining a BMR, a predetermined level of change considered biologically relevant, BMD modelling ensures that the RP corresponds to a known effect size. This also supports more nuanced comparisons across substances and studies. Due to BMDs being linked to defined effect sizes, they can be used to calculate relative potency factors (RPFs) or toxic equivalency factors (TEFs), which are essential for assessing chemical mixtures or structurally related compounds. This capability is particularly useful in cumulative risk assessments and prioritisation exercises.