Recommendations

In this guide

1. BMD modelling should be a complementary rather than a replacement tool

The Committee recommended that at present BMD modelling should be viewed as a complementary approach to the traditional NOAEL method, rather than a replacement. While BMD modelling offers statistical sophistication and can be particularly useful when NOAELs are not identifiable, it is not universally applicable, particularly in view of current study designs. The NOAEL approach remains valid and may be the only viable option available in certain contexts, such as when adverse effects are observed only at the highest tested dose. Understanding BMD modelling as an additional tool rather than one that is necessary and appropriate in all instances provides a more pragmatic approach to risk assessment.

2. Improve Transparency and Understanding of BMD Tools

Members of the Committee raised concerns about the increasing complexity and opacity of some BMD software tools. They stressed the importance of users understanding the underlying algorithms and assumptions, rather than relying solely on the outputs. This is particularly important given the proliferation of software and modelling approaches, which can vary significantly in their results. To avoid the pitfalls of “black box” modelling, the Committee recommended that training and guidance be provided to ensure that practitioners of risk assessment can critically evaluate BMD modelling outputs and apply them appropriately in their evaluations.

3. Standardize and Validate BMD Methodologies Through Case Studies

To address concerns about subjectivity and variability in some of the choices in BMD modelling, the Committee recommended conducting a series of case studies and retrospective analyses. These would evaluate the reliability and comparability of different BMD models and software tools and examine past instances where BMD values were used to establish Acceptable Daily Intakes

(ADIs). Such efforts would help identify best practices, clarify the limitations of various approaches, and inform future updates to COT guidance documents. This evidence-based approach would support more consistent and scientifically robust applications of BMD modelling in regulatory contexts.

4. Align Study Design with Modelling Needs

The Committee highlighted that many traditional toxicology studies, particularly those that had been based on OECD guidelines now superseded, are not well-suited for BMD modelling. They recommended designing future studies to generate biologically relevant data with multiple dose levels and clear endpoints, rather than focusing solely on high dose statistical significance (i.e. large numbers in only a few dose groups).

5. Inter-Committee Harmonisation

The Committee recommended collaboration with other scientific advisory groups, such as the Committee on Carcinogenicity (COC), the Committee on Mutagenicity (COM), and the UK Expert Committee on Pesticides (ECP), to gather broader perspectives and experiences on the use of BMD modelling. This would also promote a more unified and coherent framework for chemical risk assessment in the UK.

6. Consider Resource Implications for the FSA and other government departments

It was recommended that the Food Standards Agency (FSA) evaluate its internal capacity to implement and utilize various BMD approaches. This involves a thorough assessment of current staff expertise, availability and maintenance of necessary tools and software, and overall readiness to integrate BMD modelling into routine risk assessment processes.