Executive Summary

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Benchmark Dose Modelling in a UK Chemical Risk Assessment Framework

Executive Summary

The benchmark dose (BMD) approach was introduced almost 40 years ago to provide a more quantitative and informative estimate of the reference point (RP) from dose-response experiments in laboratory animals. The BMD (or its lower limit) was proposed as an alternative to the traditionally used No Observed Adverse Effect Level (NOAEL) or Lowest Observed Adverse Effect Level (LOAEL) as the RP. Unlike the traditional NOAEL or LOAEL approaches, BMD modelling uses the full range of dose-response data in obtaining an estimate of the RP and provides a quantitative estimate of uncertainty. Regulatory bodies such as the European Food Safety Authority (EFSA) and the U.S. Environmental Protection Agency (EPA) have developed detailed guidance and software tools to support its implementation.

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has considered the potential role of BMD modelling within the UK's chemical risk assessment framework. The Discussion Paper outlines the theoretical basis, practical application, and regulatory context of BMD modelling. It reviews international guidance, compares modelling software, and presents a case study involving per- and polyfluoroalkyl substances (PFAS) to demonstrate the utility of BMD modelling in establishing health-based guidance values (HBGVs). The COT discussed the current state and future direction of BMD modelling in chemical risk assessment. The Committee recognised the advantages of BMD modelling for its scientific rigor and its particular value in specific circumstances, but highlighted a number of challenges around transparency, dataset suitability, and practical implementation.

This Science and Research Special Topics Report provides an overview of the discussion paper, which can be found in Annex A of this Report, and the COT's discussions thereon (COT, 2024).

Based on their review of the discussion paper, the COT have made the following recommendations for the ongoing assessment and implementation of BMD modelling in UK chemical risk assessment: