

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

EFSA consultation on draft guidance document on the use of the benchmark dose in risk assessment

Introduction

1. The European Food Safety Authority (EFSA) has issued a public consultation on a draft guidance document on the use of the benchmark dose (BMD) in risk assessment. The draft guidance is provided to the Committee for information, and to consider any implications for its working practices.

The draft EFSA guidance

2. A benchmark dose (BMD) is defined as the dose of a substance associated with a specified low incidence of risk, generally in the range of 1-10%, of a health effect; or the doses associated with a specified measure or change of a biological effect (IPCS, 2009). In 2009, EFSA produced guidance on the use of the use of the BMD approach in risk assessment. This document recommended using the BMD approach instead of the traditionally used no observed adverse effect level (NOAEL) approach, when setting health-based guidance values or calculating margins of exposure since it makes a more extended use of dose-response data and allows for a quantification of the uncertainties in the dose-response data.

3. This draft EFSA guidance confirms the 2009 recommendation and updates the guidance, taking into account experience in use in EFSA and more recent developments in the modelling methodology. The major changes relate to the preferred approaches to calculating BMD confidence intervals, assessment of 'goodness of fit' of different statistical models, and a template to support consistency in reporting the results of the modelling.

4. Members are asked to note that EFSA offers training in dose-response modelling to its experts and staff.

Questions on which the views of the Committee are sought

5. Members are asked to consider the following questions:

- i). Do Members have comments on the document that should be transmitted to EFSA?

- ii). Do Members have general comments on the use of the BMD approach and any implications of the draft guidance for the work of the Committee?

Secretariat
August 2016

References

EFSA (European Food Safety Authority) (2009). Guidance of the Scientific Committee on a request from EFSA on the use of the benchmark dose approach in risk assessment. EFSA Journal 2009, 1150, 1-72.

IPCS (International Programme on Chemical Safety) (2009). Principles and methods for the risk assessment of chemicals in food. Environmental Health Criteria vol. 240. Food and Agriculture Organization of the United Nations and World Health Organization, Geneva, Switzerland.

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**Public Consultation on the draft update of the guidance of the Scientific
Committee on the use of the benchmark dose approach in risk
assessment**

Available at: <https://www.efsa.europa.eu/en/consultations/call/160714>

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**Secretariat
August 2016**