

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

EFSA consultation on draft guidance on biological relevance

Introduction

1. The European Food Safety Authority (EFSA) has launched a public consultation on draft guidance prepared by its Scientific Committee on determining biological relevance, i.e. deciding whether an observed effect is adverse, or shows a beneficial health effect, or not.
2. The draft guidance is intended to cover all areas of EFSA's work and to provide guidance on the generic issues its Panels should consider when deciding on biological relevance. It aims to clarify a number of definitions and concepts, such as adverse, adaptive, harm, homeostasis and biological threshold in order to ensure that these concepts are used in a consistent way across EFSA areas of activity.
3. The draft guidance discusses such concepts as Mode of Action (MOA), Adverse Outcome Pathway (AOP) and thresholds, in addition to magnitudes of effect that should be considered relevant, relevance of species tested, and relevance of routes of exposure etc. in toxicity studies. It also provides guidance on how the assessments of relevance should be reported.
4. The draft guidance is attached at Annex A. The deadline for submitting comments is 1st May.

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 - i) Do Members have comments on the draft guidance that should be transmitted to EFSA? If so, the Secretariat will compile the comments and circulate to Members before submitting them on behalf of the COT.
 - ii) Do Members have general comments on the determining of biological relevance and on any implications of the draft guidance for the work of the COT?

**Secretariat
March 2017**

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The draft guidance released for consultation by EFSA.

Note: The document in the Annex is not included in the published version on the COT website, but can be downloaded from the EFSA website at <http://www.efsa.europa.eu/en/consultations/call/170306>

**Secretariat
March 2017**