

PAFF-PPL-July22-Doc.A.07.03 14 July 2022

Guidance on the assessment of the biological relevance of data in scientific assessments

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This guidance has been developed in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

Introduction

European Food Safety Authority (EFSA), following its standard procedures for development of guidance documents, including consultation of stakeholders and general public, has published the following guidance document:

Guidance on the assessment of the biological relevance of data in scientific assessments.

EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Bresson J-L, Griffin J, Hougaard Benekou S, van Loveren H, Luttik R, Messean A, Penninks A, Ru G, Stegeman JA, van der Werf W, Westendorf J, Woutersen RA, Barizzone F, Bottex B, Lanzoni A, Georgiadis N and Alexander J, 2017. EFSA Journal 2017;15(8):4970, 73 pp. https://doi.org/10.2903/j.efsa.2017.4970

Implementation schedule

The Standing Committee on Plants, Animals, Food and Feed agreed that the EFSA GD should apply to dossiers submitted from <u>1 January 2023</u> onwards, in the context of (renewal of) approval of active substances under Regulation (EC) No. 1107/2009, in those cases where it is relevant for the risk assessment, in particular for ad-hoc situations or when specifically developed and established Guidance Documents are not considered fit for purpose.