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**18 May 2022**

## **Guidance on aneugenicity assessment**

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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:

*EFSA Scientific Committee, More SJ, Bampidis V, Bragard C, Halldorsson TI, Hernandez-Jerez AF, Hougaard Bennekou S, Koutsoumanis K, Lambre C, Machera K, Naegeli H, Nielsen SS, Schlatter J, Schrenk D, Turck D, Younes M, Aquilina G, Bignami M, Bolognesi C, Crebelli R, Guertler R, Marcon F, Nielsen E, Vleminckx C, Carfi M, Martino C, Maurici D, Parra Morte J, Rossi A and Benford D, 2021. Scientific Opinion on the guidance on a neogenicity assessment. EFSA Journal 2021;19(8):6770, 27 pp.*

<https://doi.org/10.2903/j.efsa.2021.6770>

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## Implementation schedule

The Standing Committee on Plants, Animals, Food and Feed agreed that the EFSA GD should apply to dossiers submitted from **1 January 2023** onwards, in the context of (renewal of) approval of active substances under Regulation (EC) No. 1107/2009.