

COMMISSION NOTICE**Availability and applicability of a guidance document to implement Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards endocrine disrupting properties****(Text with EEA relevance)**

(2018/C 340/03)

The 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009'⁽¹⁾ was developed by the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) with the support of the European Commission's Joint Research Centre (JRC). It provides guidance to applicants and assessors of competent regulatory authorities on how to apply the scientific criteria for the determination of endocrine-disrupting properties introduced by Commission Regulation (EU) 2018/605⁽²⁾. These scientific criteria are applicable from 10 November 2018 to on-going and future applications for approval or renewal of active substances, safeners or synergists under Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁽³⁾.

During the development of this guidance document, EFSA and ECHA consulted on several occasions Member States, stakeholders, and the general public. In addition, Member States discussed case-studies in a workshop organised by the European Commission, EFSA and ECHA for this purpose on 1-2 February 2018. Furthermore, the final draft of the guidance document was discussed at the Standing Committee on Plants, Animals, Food and Feed (Section Phytopharmaceuticals — Legislation) on 25 May 2018. The development of the guidance and the comments received by the agencies are documented and published by EFSA and ECHA.

On 5 June 2018, EFSA and ECHA adopted the guidance document and published it on 7 June 2018. Consequently, the guidance document is available before the scientific criteria laid down in Regulation (EU) 2018/605 become applicable.

In consultation with the Standing Committee on Plants, Animals, Food and Feed and aiming at a harmonised and efficient application of the scientific criteria introduced by Regulation (EU) 2018/605, the Commission notifies that the published guidance document is to be used for the purposes of application of points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009 as of the date of application of Regulation (EU) 2018/605 (10 November 2018).

⁽¹⁾ European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA) with support from the Joint Research Centre (JRC). Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, <http://www.efsa.europa.eu/en/efsajournal/pub/5311>.

⁽²⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

⁽³⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).