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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 78(1)(a) and the second paragraph of point 3.6.5 of Annex II thereto,

Whereas:

(1) Scientific criteria for the determination of endocrine disrupting properties of active substances, safeners and synergists, should be developed taking into account the objectives of Regulation (EC) No 1107/2009, which are to ensure a high level of protection of both human and animal health and the environment, in particular ensuring that substances or products placed on the market have no harmful effect on human or animal health or unacceptable effects on the environment, and to improve the functioning of the internal market while improving agricultural production.

(2) In 2002, the World Health Organisation (WHO) through its International Programme for Chemical Safety proposed a definition for endocrine disruptors[(2)] and in 2009 a definition of adverse effects[(3)]. Those definitions have by now reached the widest consensus among scientists. The European Food Safety Authority ('the Authority') endorsed those definitions in its Scientific Opinion on endocrine disruptors adopted on 28 February 2013[(4)] (hereinafter 'the Scientific Opinion of the Authority'). Such is also the view of the Scientific Committee on Consumer Safety[(5)]. It is therefore appropriate to base the criteria for the determination of endocrine disrupting properties on those WHO definitions.

(3) In order to implement those criteria, weight of evidence should be applied considering in particular the approach provided for in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(6)] on the weight of evidence. Previous experience with the Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption of OECD[(7)] should also be considered. In addition, the implementation of the criteria should be based on all relevant scientific evidence, including studies submitted in accordance with the current regulatory data requirements

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/605. (See end of Document for details)*

of Regulation (EC) No 1107/2009. These studies are mostly based on internationally agreed study protocols.

(4) The determination of endocrine disrupting properties with respect to human health should be based on human and/or animal evidence, therefore allowing for the identification of both known and presumed endocrine disrupting substances.

(5) As the specific scientific criteria laid down by this Regulation reflect the current scientific and technical knowledge and are to be applied instead of the criteria currently set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, they should be provided for in that Annex.

(6) In order to take into account the current scientific and technical knowledge, specific scientific criteria should also be specified in order to identify active substances, safeners or synergists having endocrine disrupting properties that may cause adverse effects on non-target organisms. Therefore point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 should be amended to introduce these specific criteria.

(7) The Commission should assess, in light of the objectives of Regulation (EC) No 1107/2009, the experience gained from the application of the scientific criteria for the determination of endocrine disrupting properties introduced by the present Regulation.

(8) The criteria for the determination of endocrine disrupting properties reflect the current state of scientific and technical knowledge and allow identifying active substances having endocrine disrupting properties more accurately. The new criteria should therefore apply as soon as possible, while taking into account the time necessary for Member States and the Authority to prepare for applying those criteria. Therefore, from 20 October 2018, those criteria should apply except where the relevant Committee has voted on a draft Regulation by 20 October 2018. The Commission will consider the implications for each procedure pending under Regulation (EC) No 1107/2009 and, where necessary, take appropriate measures with due respect for the rights of the applicants. This may include a request for additional information from the applicant and/or for additional scientific input from the rapporteur Member State and the Authority.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1107/2009 is amended in accordance with the Annex to this Regulation.

Article 2

Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by this Regulation, shall apply as of **[**[X1]10 November 2018, except for procedures where the Committee has voted on a draft Regulation by 10 November 2018**]**.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 101 of 20 April 2018).

Article 3

By **[**[X1]10 November 2025**]**, the Commission shall present to the Committee referred to in Article 79 of Regulation (EC) No 1107/2009 an assessment of the experience gained from the application of the scientific criteria for the determination of endocrine disrupting properties introduced by this Regulation.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 101 of 20 April 2018).

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from **[**[X1]10 November 2018**]**.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 101 of 20 April 2018).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/605. (See end of Document for details)*

ANNEX

Annex II to Regulation (EC) No 1107/2009 is amended as follows:

(1) in point 3.6.5 the following paragraphs are added after the fourth paragraph:

From **[**[X1]10 November 2018**]**, an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effect in humans if, based on points (1) to (4) of the sixth paragraph, it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant to humans:

(1) it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(2) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(3) the adverse effect is a consequence of the endocrine mode of action.

The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effect in humans in accordance with the fifth paragraph shall be based on all of the following points:

(1) all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies informing about endocrine modes of action):

(a) scientific data generated in accordance with internationally agreed study protocols, in particular those listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;

(b) other scientific data selected applying a systematic review methodology, in particular following guidance on literature data which is listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;

(2) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in the fifth paragraph are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall, in particular, consider all of the following factors:

(a) both positive and negative results;

(b) the relevance of the study designs, for the assessment of adverse effects and of the endocrine mode of action;