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**DRAFT**

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**setting out scientific criteria for the determination of endocrine disrupting properties  
and amending Annex II to Regulation (EC) 1107/2009**

(Text with EEA relevance)

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**setting out scientific criteria for the determination of endocrine disrupting properties  
and amending Annex II to Regulation (EC) 1107/2009**

(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<sup>1</sup>, and in particular Article 78(1)(a) and second paragraph of point 3.6.5 of Annex II, thereof,

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<sup>2</sup> and in 2009 a definition of adverse effects<sup>3</sup>. 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<sup>4</sup> (hereinafter "the Scientific Opinion of the Authority"). It is also the view of the Scientific Committee on consumer Safety<sup>5</sup>. It is therefore appropriate to

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2002. Global Assessment of the State-of-the-science of Endocrine Disruptors. WHO/PCS/EDC/02.2, publicly available at [http://www.who.int/ipcs/publications/new\\_issues/endocrine\\_disruptors/en/](http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/).

<sup>3</sup> WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2009. Principles and Methods for the Risk Assessment of Chemicals in Food. Environmental Health Criteria 240, publicly available at <http://www.who.int/foodsafety/chem/principles/en/index1.html>.

<sup>4</sup> "Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment", EFSA Journal 2013;11(3):3132, doi: 10.2903/j.efsa.2013.3132.

<sup>5</sup> Scientific committee on Consumer Safety, Memorandum on Endocrine disruptors, 16.12.2014 (SCCS/1544/14).

base the criteria to identify substances with endocrine disrupting properties on those WHO definitions.

- (3) In order to implement those criteria, weight of evidence should be applied following in particular the methodology provided for in Regulation (EC) No 1272/2008 of the European Parliament and Council<sup>6</sup> on the weight of evidence. Previous experience with the Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption of OECD<sup>7</sup> should also be considered. In addition, the implementation of the criteria should be based on all relevant scientific evidence, in particular studies based on internationally agreed study protocols.
- (4) 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.
- (5) In addition, the first subparagraph of point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 currently provide that substances, safeners and synergists meeting the criteria to be identified as having endocrine disrupting properties may be approved in the case the exposure of humans or non-target organisms, respectively, to the substances, safeners or synergist is negligible under realistic proposed conditions of use.
- (6) However the Scientific Opinion of the Authority states that endocrine disruptors may be assessed like most other substances of concern for human health and the environment, that is to say be subject to risk assessment and not only to hazard assessment. The Authority specifies that the approach concerning substances with endocrine disrupting properties is to be based on a level of concern and whether or not this level of concern is reached, can only be determined by risk assessment. The Scientific Committee on Consumer Safety (SCCS) supports the use of risk assessment to assess endocrine disruptors in their Memorandum<sup>8</sup> issued in 2014.
- (7) Experience gained during the application of other Union provisions on endocrine disrupting properties of chemical substances which entered into force later than Regulation (EC) No 1107/2009 should be also taken into consideration, in particular as regards the application of similar criteria set out in Regulation (EU) No 528/2012 of the European Parliament and of the Council.
- (8) Considering recitals 6 and 7, it is necessary to ensure that the level of residues of active substances having endocrine disrupting properties to be approved or renewed do not, taking account of the most recent relevant opinion of the Authority, present an unacceptable risk to humans and, where relevant, to animals, and are kept as low as possible in accordance with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council.

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<sup>6</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>7</sup> OECD Series on Testing and Assessment No. 150.

<sup>8</sup> Scientific Committee on Consumer Safety (SCCS) Memorandum on Endocrine Disruptors. Retrieved from: [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_s\\_009.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_009.pdf).

- (9) In order to reflect current scientific and technical knowledge in accordance with Article 78(1)(a) of Regulation (EC) No 1107/2009, points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 should be amended.
- (10) 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, except where the relevant Committee has voted on the draft Regulation presented to it without that Regulation having been adopted by the Commission by [Date of EIF]. The Commission will consider on a case-by-case basis 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 scientific input from the Authority and comments from the applicants.
- (11) 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*

Point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by the present Regulation, shall apply as of [*date of EIF of the Regulation*], except for procedures where the Committee has voted on the draft Regulation presented to it without that draft Regulation having been adopted by [*date of EIF this Regulation*].

*Article 3*

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

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

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*