EUROPEAN
COMMISSION

Brussels, XXX
SANTE-2016-12020-REV 4
C(2016) 3751 projet

DRAFT

COMMISSION REGULATION (EU) …/…

of XXX

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

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) 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 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[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.

---

1 OJ L 309, 24.11.2009, p. 1.

2 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/.

3 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.

4 "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.

5 Scientific Committee on Consumer Safety, Memorandum on Endocrine disruptors, 16.12.2014 (SCCS/1544/14).

(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 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) One of the characteristics of endocrine disrupting substances is their endocrine mode of action. Several endocrine modes of action exist. Organisms belonging to different taxonomic phyla differ biologically on essential traits, involving different endocrine modes of action. Therefore, a certain endocrine mode of action relevant for a specific phylum may not be biologically plausible for organisms of a different phylum. Substances whose intended plant protection mode of action, within the meaning of point 3.6. of Part A of the Annex to Commission Regulation (EU) No 283/2013, is to control target organisms other than vertebrates via their endocrine system, therefore present a mode of action which is not expected to be relevant for vertebrates. These substances consequently do not generally pose a risk via this intended mode of action to humans and vertebrates in the environment and are therefore particularly effective and useful in integrated pest management. When setting the criteria for the determination of endocrine disrupting properties that may cause adverse effects on non-target organisms, it is appropriate, in view of the objectives of Regulation (EC) No 1107/2009 and of Directive 2009/128/EC, and the principle of proportionality, to take account of the above scientific considerations. Therefore, where the intended mode of action consists of controlling target organisms other than vertebrates via their endocrine systems, the effects caused by that intended mode of action on organisms of the same taxonomic phylum as the targeted one should not be considered for the purposes of point 3.8.2. of Annex II of Regulation (EC) No 1107/2009. The active substances with such an intended mode of action may however be approved only if, following a risk assessment, and taking into consideration specific data requirements

[6] 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).

[7] OECD Series on Testing and Assessment No. 150.

set by Commission Regulation (EU) No 283/2013, their use does not lead to unacceptable effects on non-target organisms, including on organisms of the same phylum as the target organism .

(8) 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.

(9) 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 [*Date of application*], those criteria should apply except where the relevant Committee has voted on a draft Regulation by [*Date of application*]. 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.

(10) 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 this Regulation, shall apply as of [*date of application*], except for procedures where the Committee has voted on a draft Regulation by *[Office of Publication please insert date of application]*.

Article 3

By *[Office of Publication please insert date of seven years from the date of application*], 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.

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 [*Office of Publication please insert date of 6 months after date of EIF*].

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