Bijlage 2.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE-2016-12020-REV 0
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) …/…

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"). It is also the view of the Scientific Committee on consumer Safety[5]. It is therefore appropriate to

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).

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 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) 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 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.

(6) 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 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.

(7) 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.

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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.

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~~this 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

EUROPEAN
COMMISSION

Brussels, XXX
SANTE-2016-12011-REV 0
C(2016) 3751 projet

ANNEX 1

DRAFT

ANNEX

to the

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

amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge

ANNEX

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

(1) The first paragraph of point 3.6.5. is replaced by the following:

"An active substance, safener or synergist shall only be approved if, on the basis of the assessment of the available evidence carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, it is not considered, in accordance with the criteria specified in the fifth paragraph, to have endocrine disrupting properties that may cause adverse effect in humans, unless the risk to humans from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible, in particular where the product is used in closed systems or in other conditions which aim at excluding contact with humans, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed can, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener, be set in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection."

(2) The first paragraph of point 3.8.2. is replaced by the following:

"An active substance, safener or synergist shall only be approved if it is not considered, in accordance with the criteria specified in the second paragraph, to have endocrine disrupting properties that may cause adverse effects on non-target organisms, unless the risk to the non-target organisms from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible."

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amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge

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amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge

(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[8], and in particular Article 78(1)(a) thereof,

Whereas:

(1) Commission Regulation XX[9] is setting scientific criteria for the determination of endocrine disrupting properties of active substances, safeners and synergists, 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) The first paragraph of point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 currently provide that an active substance, safener or synergist meeting the criteria to be considered as having endocrine disrupting properties that may cause adverse effects on humans or non-target organisms respectively, are not to be approved unless the exposure of humans or non-target organisms, respectively, to the substances, safeners or synergist is negligible under realistic proposed conditions of use.

(3) The opinion of the European Food Safety Authority ('the Authority') adopted on 28 February 2013[10] (hereinafter "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 may also be subject to risk assessment, instead of hazard assessment. The Authority specifies that the approach concerning

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8 OJ L 309, 24.11.2009, p. 1.

9 OJ L XXXXX

10 "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.

substances with endocrine disrupting properties is to be based on a level of concern and that 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 its Memorandum[11] issued in 2014.

(4) Union provisions concerning chemical substances with endocrine disrupting properties which entered into force later than Regulation (EC) No 1107/2009 should be also taken into consideration, in particular as regards similar criteria set out in Regulation (EU) No 528/2012[12] of the European Parliament and of the Council.

(5) The new scientific and technical knowledge described in recital 3 above should be taken into account in accordance with Article 78(1)(a) of Regulation (EC) No 1107/2009. Doing so, it is appropriate not to deviate from the approach concerning the approval of active substances having endocrine disrupting properties currently laid down in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009. Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 should therefore be amended so that an active substance, safener or synergist should only be approved if it is not considered to have endocrine disrupting properties that may cause adverse effect in humans or on non-target organisms, respectively, unless the risk to humans or to non-target organisms, respectively, from exposure to that active substance, safener or synergist in a plant protection product under realistic proposed conditions of use is negligible.

(6) [*This recital is currently under review in order to further improve clarity of the rationale. An updated version will be circulated as soon as possible]* Given the changes mentioned in recital 5, it is necessary to ensure that the level of residues of active substances, to be approved or renewed, having endocrine disrupting properties do not, taking account of the most recent relevant opinion of the Authority, present an unacceptable risk to humans or to animals respectively, 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[13] of the European Parliament and of the Council. Point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 should therefore be amended accordingly.

(7) The amendments to the first paragraph of point 3.6.5 and to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 provided for by this Regulation should start to apply at the same time as the new criteria for the determination of endocrine disrupting properties provided for by Regulation XX. Therefore those amendments should not apply 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 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.

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11 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.

12 OJ L 155, 11.6.2011, p. 127.

13 OJ L 70, 16.3.2005, p. 1

(8) 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 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