



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE-2016-12011-REV 2
C(2016) 3751 projet

DRAFT

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

of **XXX**

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)

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

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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/EEC¹, and in particular Article 78(1)(a) thereof,

Whereas:

- (1) **Commission Regulation XX²** introduces 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, safer 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 synergists is negligible under realistic proposed conditions of use.
- (3) The opinion of the European Food Safety Authority ('the Authority') adopted on 28 February 2013³ (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 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

¹ OJ L 309, 24.11.2009, p. 1.

² **OJ L XXXXX**

³ "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.

assessment. The Scientific Committee on Consumer Safety (SCCS) supports the use of risk assessment to assess endocrine disruptors in its Memorandum⁴ 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 similar criteria set out in Regulation (EU) No 528/2012⁵ of the European Parliament and of the Council.

(5) The new scientific and technical knowledge described in recital 3 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) Maximum residue levels set pursuant to Regulation (EC) No 396/2005 of the European Parliament and of the Council ensure that the residues of approved or renewed active substances do not have immediate or delayed harmful effects on human health including that of vulnerable groups such as children and the unborn. Given the amendments mentioned in recital 5 and the scientific criteria for the determination of endocrine disrupting properties of active substances introduced by Commission Regulation XX, it is appropriate to amend point 3.6.5. as regards the situations where maximum residue levels of the active substance concerned in or on food and feed can be set in accordance with Regulation (EC) No 396/2005, taking account of the latest opinion of the Authority with respect to that active substance.

(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 introduced 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.

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

⁴ Scientific Committee on Consumer Safety (SCCS) Memorandum on Endocrine Disruptors. Retrieved from: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/scos_s_009.pdf.

⁵ OJ L 155, 11.6.2011, p. 127.

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 XX]**, 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*



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ANNEX 1

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ANNEX

to the

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account current scientific and technical knowledge**

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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."