



Brussels, **XXX**
C(2016) 3752 projet

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

of **XXX**

**setting out scientific criteria for the determination of endocrine-disrupting properties
pursuant to Regulation (EU) No 528/2012**

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. **CONTEXT OF THE DELEGATED ACT**

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products sets out regulatory consequences for active substances having endocrine-disrupting properties and biocidal products containing these substances. Article 5(3) of the Regulation provides that, by 13 December 2013 at the latest, the Commission had to adopt delegated acts specifying scientific criteria for the determination of endocrine-disrupting properties. In its judgement of 16 December 2015 on the Case T-521/14 Sweden versus the Commission, the EU General Court ruled that the European Commission breached EU law by failing to set criteria to identify endocrine disruptors within the deadline indicated in Regulation (EU) No 528/2012.

The delegated act provides scientific criteria to identify endocrine disruptors. These criteria are based on the definitions for endocrine disruptors and adverse effects developed by World Health Organisation through its International Programme for Chemical Safety. These criteria reflect the current state of scientific and technical knowledge and allow a more accurate identification of active substances having endocrine disrupting properties.

On 15 June 2016, the Commission adopted a Communication of the Commission to the European Parliament and the Council on endocrine disruptors and presented the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products (COM(2016) 350 final). This communication puts the established scientific criteria for biocidal products in a broader context, in particular the link with the setting of scientific criteria for the determination of endocrine-disrupting properties in the domain of plant protection products, the implication for other regulatory areas and other on-going activities of the Commission on endocrine disruptors.

2. **CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

A public consultation was carried out from September 2014 till January 2015 in the context of an impact assessment. The report was published on 24 July 2015.

The Commission published a draft of the delegated act the 15 of June 2016. This draft delegated act was consulted with the general public between the 30 of June and the 28 of July 2016 via the Better Regulation Portal. A total of 120 responses were received which are publicly available¹. This draft delegated act was also notified on the 23 June 2016 under the Agreement on Technical Barriers to Trade and comments were received of five members.

The Commission has consulted an expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products, in meetings which took place the 22 of June 2016, the 21 of September 2016, the 18 of November and the 21 of December 2016.

¹ https://ec.europa.eu/info/law/better-regulation/share-your-views_en

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3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act specifies scientific criteria for the determination of endocrine-disrupting properties in accordance with Article 5(3) of Regulation (EU) No 528/2012.

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

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**setting out scientific criteria for the determination of endocrine-disrupting properties
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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products², and in particular the first subparagraph of Article 5(3) thereof,

Whereas:

- (1) Scientific criteria for the determination of endocrine disrupting properties pursuant to Regulation (EU) No 528/2012 should be developed taking into account the purpose of that Regulation to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment.
- (2) In 2002, the World Health Organisation (WHO) through its International Programme for Chemical Safety, proposed a definition for endocrine disruptors³ and in 2009 a definition of adverse effects⁴. Those definitions have by now reached the widest consensus among scientists. The European Food Safety Authority endorsed those definitions in its Scientific Opinion on endocrine disruptors adopted on 28 February 2013⁵. It is also the view of the Scientific Committee on Consumer Safety⁶. 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 (EU) No 528/2012 and in

² OJ L 167, 27.6.2012, p. 1.

³ 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/.

⁴ 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>.

⁵ "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.

⁶ Scientific Committee on Consumer Safety, Memorandum on Endocrine disruptors, 16.12.2014 (SCCS/1544/14)

Regulation (EC) No 1272/2008 of the European Parliament and Council⁷ on the weight of evidence. Previous experience with the application of the Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption of OECD⁸ should be also 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 (EU) No 528/2012, which are mostly based on international agreed study protocols.

(4) In order to take into account the current scientific and technical knowledge, specific scientific criteria should also be specified in order to identify substances having endocrine disrupting properties that may cause adverse effects on non-target organisms. For active substances whose intended biocidal mode of action, as defined under- point 6.5 of Annex II of Regulation (EU) No 528/2012 Commission Regulation (EU) No 283/2013, is to control target harmful organisms via their endocrine system, this mode of action should not be considered for the identification of the endocrine disrupting properties.

(3) The Commission should assess the experience gained from the application of the scientific criteria for the determination of endocrine disrupting properties introduced by the present Regulation in light of the objectives of Regulation (EU) No 528/2012.

(5) _____

(4)(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. Without prejudice to Article 90(2) of Regulation (EU) No 528/2012, 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 of this Regulation] those criteria should apply except where the Committee referred to in Article 82 of Regulation (EU) No 528/2012 has voted on the draft Regulation presented to it without that Regulation having been adopted by the Commission by [date of ~~IEF~~ application of this Regulation]. The Commission will consider the implications for each pending procedure 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 a revised opinion from the Agency.

HAS ADOPTED THIS REGULATION:

Article 1

The scientific criteria for the determination of endocrine-disrupting properties referred to in the first subparagraph of Article 5(3) of pursuant to Regulation (EU) No 528/2012 shall be as are set out in the Annex to this Regulation.

⁷ 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).

⁸ OECD Series on Testing and Assessment No. 150

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Article 2

The criteria laid down in the Annex to this Regulation shall apply as of [~~date of EIF~~application], except for procedures where the Committee referred to in Article 82 of Regulation (EU) No 528/2012 has voted on the draft Regulation ~~presented to it without that draft Regulation having been adopted~~ by [date of application-EIF].

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Article 3

Within seven years from [date of application], the Commission shall assess the experience gained from the application of the scientific criteria for the determination of endocrine disrupting properties introduced by the present Regulation, in light of the objectives of Regulation (EU) No 528/2012.

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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 [6 months after date of EIF].

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

Done at Brussels,

*For the Commission
The President*