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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2017/2100

of 4 September 2017

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

(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 products ([1]), 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 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 endorsed those definitions in its Scientific Opinion on endocrine disruptors adopted on 28 February 2013 ([4]). 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.

(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 Regulation (EC) No 1272/2008 of the European Parliament and Council ([6]) on the weight of evidence. Previous experience with the application of the Guidance document

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) WHO/IPCS (World Health Organisation/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 Organisation/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/publications/chemical-food/en/
([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).
([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).

on standardised test guidelines for evaluating chemicals for endocrine disruption of OECD [1] should also beconsidered. 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. These studies are mostly based on international 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) 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 biocidal mode of action, within the meaning of point 6.5, Title 1 of Annex II of Regulation (EU) No 528/2012, 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 (EU) No 528/2012, 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 the identification of endocrine-disrupting properties with respect to non-target organisms. 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 set by the Regulation (EU) No 528/2012, their use does not lead to unacceptable effects on non-target organisms, including on organisms of the same phylum as the target organism.

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

(7) The criteria for the determination of endocrine-disrupting properties reflect the current state of scientific and technical knowledge and allow identifying 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 European Chemicals Agency to prepare for applying those criteria. Therefore, from 7 June 2018 those criteria should apply except where the Committee referred to in Article 82 of Regulation (EU) No 528/2012 has voted on a draft Regulation by 7 June 2018. The Commission will consider the implications for each procedure pending under Regulation (EU) No 528/2012 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 input from the regulatory body and/or a revised opinion from the Agency,

HAS ADOPTED THIS REGULATION:

Article 1

The scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 are set out in the Annex to this Regulation.

Article 2

The criteria laid down in the Annex to this Regulation shall apply as of 7 June 2018, except for procedures where the Committee referred to in Article 82 of Regulation (EU) No 528/2012 has voted on a draft Regulation by 7 June 2018.

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

Article 3

By 7 June 2025, the Commission shall present to the expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products an assessment of the experience gained from the application of the scientific criteria for the determination of endocrine-disrupting properties introduced by the present 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 7 June 2018.

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

Done at Brussels, 4 September 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

A substance shall be considered as having endocrine-disrupting properties with respect to humans or non-target organisms, where it meets the criteria set out in section A or section B.

Section A — Endocrine-disrupting properties with respect to humans

(1) A substance shall be considered as having endocrine-disrupting properties that may cause adverse effect in humans if, based on points (a) to (d) of point (2), it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant to humans:

(a) it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(c) the adverse effect is a consequence of the endocrine mode of action.

(2) The identification of a substance as having endocrine-disrupting properties that may cause adverse effect in humans in accordance with point (1) shall be based on all of the following points:

(a) all available relevant scientific data (*in vivo* studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as *in vivo*, *in vitro*, or, if applicable, *in silico* studies informing about endocrine modes of action):

(i) scientific data generated in accordance with internationally agreed study protocols, in particular those referred to in Annexes II and III of Regulation (EU) No 528/2012;

(ii) other scientific data selected applying a systematic review methodology;

(b) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in point (1) are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall, in particular, consider all of the following factors:

(i) both positive and negative results;

(ii) the relevance of the study designs for the assessment of adverse effects and of the endocrine mode of action;

(iii) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different species;

(iv) the route of exposure, toxicokinetic and metabolism studies;

(v) the concept of the limit dose, and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;

(c) using a weight of evidence approach, the link between the adverse effect(s) and the endocrine mode of action shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge and under consideration of internationally agreed guidelines;

(d) adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor.

Section B — Endocrine-disrupting properties with respect to non-target organisms

(1) A substance shall be considered as having endocrine-disrupting properties that may cause adverse effects on non-target organisms if, based on points (a) to (d) of point (2), it is a substance that meets all of following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant at the (sub)population level for non-target organisms:

(a) it shows an adverse effect in non-target organisms, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

(c) the adverse effect is a consequence of the endocrine mode of action.

(2) The identification of a substance as having endocrine-disrupting properties that may cause adverse effects on non-target organisms in accordance with point (1) shall be based on all of the following points:

(a) all available relevant scientific data (*in vivo* studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as *in vivo*, *in vitro* or, if applicable, *in silico* studies informing about endocrine modes of action):

(i) scientific data generated in accordance with internationally agreed study protocols, in particular those referred to in Annexes II and III of Regulation (EU) No 528/2012;

(ii) other scientific data selected applying a systematic review methodology;

(b) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in point 1 are fulfilled; in applying the weight of evidence determination, the assessment of the scientific evidence shall consider all of the following factors:

(i) both positive and negative results, discriminating between taxonomic groups (e.g. mammals, birds, fish, amphibians) where relevant;

(ii) the relevance of the study design for the assessment of the adverse effects and its relevance at the (sub) population level, and for the assessment of the endocrine mode of action;

(iii) the adverse effects on reproduction, growth/development, and other relevant adverse effects which are likely to impact on (sub)populations. Adequate, reliable and representative field or monitoring data and/or results from population models shall as well be considered where available;

(iv) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different taxonomic groups;

(v) the concept of the limit dose and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;

(c) using a weight of evidence approach, the link between the adverse effect(s) and the endocrine mode of action shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge and under consideration of internationally agreed guidelines;

(d) adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms.

(3) If the intended biocidal mode of action of the active substance being assessed consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one shall not be considered for the identification of the substance as having endocrine-disrupting properties with respect to non-target organisms.

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