EUROPEAN
COMMISSION

Brussels, XXX
C(2016) 3752 projet

DRAFT

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)

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 the delegated acts as regards the specification of the 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.

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 to identify active substances having endocrine disrupting properties more accurately.

On 15 June 2016 the Commission adopted a Communication of the Commission to the European Parliament and the Council on endocrine disruptors and 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 (XXX/2016). 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 has consulted an expert group (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products, of the European Chemicals Agency, [of the biocides industry and of the civil society] in meetings of XXX 2016 and of XXX 2016. An [updated] draft of the delegated act was made public in advance of each of those meetings.

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.

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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 ('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 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 following in particular the methodology provided for in Regulation (EU) No 528/2012 and in

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1 OJ L 167, 27.6.2012, 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)

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 on standardised test guidelines for evaluating chemicals for endocrine disruption of OECD[7] should be also considered. In addition, the implementation of the criteria should be based on all relevant scientific evidence, in particular studies based on international agreed study protocols.

(4) 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, 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 IEF of this Regulation*]. The Commission will consider on a case-by-case basis 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 a revised opinion from the Agency and comments from the applicants.

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 Regulation (EU) No 528/2012 shall be as set out in the Annex to this Regulation.

Article 2

The criteria laid down in the Annex to this Regulation shall apply as of [date of EIF], 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 EIF*].

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

[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

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ANNEX 1

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ANNEX

to the

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ANNEX

An active 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. An active substance shall be identified as having endocrine disrupting properties with respect to humans if it is a substance that meets all of the following criteria:

   (1) it is known to cause an adverse effect relevant for human health, 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;

   (2) it has an endocrine mode of action;

   (3) the adverse effect relevant for human health is a consequence of the endocrine mode of action.

2. The identification of an active substance as having endocrine disrupting properties in accordance with point 1 shall be based on all of the following:

   (1) all available relevant scientific evidence:

      (a) primarily performed according to internationally agreed study protocols (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro and mechanistic studies informing about endocrine modes of action) and on Guidance on the implementation of Regulation (EU) No 528/2012, issued by the European Chemicals Agency.

      (b) applying a systematic review methodology to analyse other relevant scientific information.

   (2) a comparison of the weight of the scientific evidence on endocrine mediated adverse effects with the criteria set out in point 1, considering whether or not the effects are adverse, the mode of action, together with the biological plausibility of the causal link between the adverse effect and the endocrine mode of action.

   (3) In applying the weight of evidence determination referred in point 2, using expert judgement and internationally agreed guidelines, all of the following elements shall be considered:

      (a) the assessment of quality, reliability, reproducibility and consistency of the scientific evidence shall, in particular, consider all of the following factors:

         (i) Both positive and negative results shall be considered together in a single weight of evidence determination.

         (ii) The weight of evidence should consider the relevance of the study designs for the assessment of adverse effects and for the evaluation of mechanistic information. For the assessment of adverse effects, generally adequate reliable and representative data on humans shall

have precedence over other data; but positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience.

(iii) The biological plausibility of the link between the adverse effects and the endocrine mode of action.

(iv) The quality and consistency of the data shall be given appropriate weight, considering the pattern and coherence of the results within and between studies of a similar design and across different species.

(v) The route of exposure, toxicokinetic and metabolism studies are assumed to be relevant to humans, unless convincing evidence exists to explain the differences between test animals and humans.

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

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

(c) where there is information demonstrating that the adverse effects are clearly not relevant for humans the substance should not be considered a human endocrine disruptor.

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

1. An active substance shall be identified as having endocrine disrupting properties with respect to non-target organisms if it is a substance that meets all of following criteria:

(1) it is known to cause an adverse effect for 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, considered relevant at the population level;

(2) it has an endocrine mode of action;

(3) the adverse effect relevant for the non-target organism at the population level is a consequence of the endocrine mode of action.

2. The identification of an active substance as having endocrine disrupting properties in accordance with point 1 shall be based on all of the following:

(1) all available relevant scientific evidence:

(a) primarily performed according to internationally agreed study protocols (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro and mechanistic studies informing about endocrine modes of action) and on Guidance on the implementation of Regulation (EU) No 528/2012, issued by the European Chemicals Agency;

(b) applying a systematic review methodology to analyse other relevant scientific information.

(2) a comparison of the weight of the scientific evidence on endocrine mediated adverse effects with the criteria set out in point 1, considering whether or not the effects are adverse, the mode of action, together with the biological plausibility of the causal link between the adverse effect and the endocrine mode of action.

(3) in applying the weight of evidence determination referred in point 2(2), using expert judgement and internationally agreed guidelines, all of the following elements shall be considered:

(a) the assessment of quality, reliability, reproducibility and consistency of the scientific evidence shall consider all of the following factors:

(i) both positive and negative results shall be considered together in a single weight of evidence determination, discriminating between taxonomic groups (e.g. mammals, birds, fish) where relevant.

(ii) the weight of evidence should consider the relevance of the study designs for the relevance of the adverse effects at the population level and for the evaluation of mechanistic information. Generally, evidence from field studies shall have precedence over other data. Nevertheless positive results from well-conducted laboratory studies shall be considered even in the case lack of positive results in field studies.

(iii) the adverse consequences on reproduction and growth/development, as these are the effects most likely to impact on populations. Adequate, reliable and representative higher tier experimental studies and/or results from reliable population models shall be considered where available for assessing the relevance of the adverse effect at the population level.

(iv) the biological plausibility of the link between the adverse effects and the endocrine mode of action, and its relevance for populations of non-target organisms.

(v) the quality and consistency of the data shall be given appropriate weight, considering the pattern and coherence of the results at different doses or exposure levels within and between studies of a similar design and across different taxonomic groups.

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

(b) adverse effects or endocrine modes of action 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.

(c) where there is information demonstrating that the adverse effects are clearly not relevant at the population level for non-target organisms, the substance should not be considered a endocrine disruptor with respect to non-target organisms.