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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products[1] (hereinafter the BPR) aims to improve the functioning of the internal market for biocidal products, whilst ensuring a high level of protection of human and animal health and the environment. Annexes II and III to the BPR set out the information requirements for active substances and biocidal products.

According to Article 5(1)(d) of the BPR, active substances considered as having endocrine-disrupting properties on the basis of the scientific criteria specified in Commission Delegated Regulation (EU) 2017/2100[2] shall not be approved unless it is shown that at least one of the conditions in Article 5(2) of the BPR is met. Commission Delegated Regulation (EU) 2017/2100 applies since 7 June 2018. The European Chemical Agency (ECHA) and the European Food Safety Authority (EFSA) have developed, with the support of the Joint Research Centre (JRC), a common guidance document for implementing the criteria laid down in that Regulation, specifying an assessment strategy and information requirements supporting such an assessment[3].

Therefore, the information requirements in Annexes II and III to the BPR should be adapted to scientific and technical progress in relation to the determination of endocrine-disrupting properties. In addition, these Annexes should also be adapted to the current state of science, for example in relation to new test methods ensuring a better protection of human and animal health or reducing the number of tests conducted on vertebrate animals.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission has consulted an expert group (the 'Biocides CA meeting') attended by representatives of Member States' competent authorities for biocidal products, the European Chemicals Agency and observers in 6 meetings between September 2018 and September 2019 on possible amendments of the BPR Annexes II and III. A draft Commission Delegated act was discussed in February 2020 and May 2020.

In accordance with the Better Regulation agenda, the draft Commission Delegated act was open for feedback for a period of four weeks[4]. During this consultation concerns were raised pertaining to … Those concerns were taken into account in the final proposal as follows:

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1 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making 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 *(*OJ L 167, 27.6.2012, p. 1).

2 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 *(*OJ L 301, 17.11.2017, p. 1).

3 The Guidance has been published in the EFSA Journal: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311.

4 Add ref to the have your say portal

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for the delegated act is Article 85 of the BPR. The delegated act amends Annexes II and III to Regulation (EU) No 528/2012, and adapts them to scientific and technical progress.

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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 products[5] and in particular Article 85 thereof,

Whereas:

(1) Annexes II and III to Regulation (EU) No 528/2012 set out the information requirements for respectively active substances and biocidal products which an application for approval of an active substance and an application for authorisation of a biocidal product need to fulfil.

(2) It is necessary to modify the information requirements concerning biocidal active substances and biocidal products in order to take into account new methods for generating better information on toxicological properties (such as irritation, neurotoxicity, genotoxicity, etc.), new testing strategies favouring *in vitro* tests against *in vivo* tests in order to reduce testing on vertebrate animals and a testing strategy and methods for the determination of endocrine disrupting properties of substances in accordance with the criteria laid down in Commission Delegated Regulation (EU) No 2017/2100[6].

(3) A dossier should be considered as complete if it complies with the requirements of Article 6(1) and Article 20(1), and in particular with the information requirements of Annexes II and III to Regulation (EU) No 528/2012. Pre-submission consultations between the applicant for the approval of an active substance or for the authorisation of a biocidal product and the evaluating competent authority contribute to the quality of the dossier and the progress of the evaluation process. The text of paragraphs 5 and 7, respectively, of points 2 of the introductory parts of Annexes II and III should be modified to ensure that the applicants include the conclusions of such consultation in the application to ensure the smooth operation of the procedure.

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5 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making 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 (OJ L 167, 27.6.2012, p. 1).

6 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 (OJ L 301, 17.11.2017, p. 1).

(4) In accordance with Annexes II and III to Regulation (EU) No 528/2012, tests submitted for the purpose of the approval of an active substance or the authorisation of a biocidal product, respectively, are to be conducted in accordance with the methods described in Commission Regulation (EC) No 440/2008[7]. As there may be a period between the validation of an internationally recognised test method and its inclusion in Regulation (EC) No 440/2008, point 5 of the introductory parts of Annexes II and III to Regulation (EU) No 528/2012 should be amended to allow applicants to apply the most updated version of test methods.

(5) Specific rules for the adaptation of the information requirements listed in the first column of the tables in Titles I and II of Annexes II and III to Regulation (EU) No 528/2012 are limited to concerns related to the recourse to testing of vertebrates. As some requirements listed in that first column do not include testing of vertebrates, the scope of adaptations listed in the third column of the tables listed in Titles I and II of Annexes II and III should be extended to cover cases where no testing of vertebrates is involved.

(6) Section 2 of Title 1 of Annex II sets out the information requirements for the identification of the active substance. Those requirements need to be adapted in order to allow identification of active substances generated *in situ*.

(7) Section 6 of Title 1 of Annexes II and III set out the requirements for the assessment of the effectiveness of an active substance or a biocidal product, respectively, against target organisms. Such effectiveness should be demonstrated for the activity of an active substance in the absence of other substances that may affect the effectiveness. For treated articles, the effectiveness of the biocidal properties conferred to the article should be demonstrated. Moreover, the current provisions on unintended side-effects in Section 6 do not specify on which type of organisms or objects, information should be provided. Therefore, it should be clarified that any observation on undesirable or unintended side effects is to be limited to non-target organisms or objects and material to be protected by the active substance or biocidal product.

(8) Article 62 of Regulation (EU) No 528/2012 requires that testing on vertebrate animals be undertaken as, a last resort. In setting data requirements for the approval of active substances and the authorisation of biocidal products, priority should be given to reliable *in vitro* methods as a substitute to *in vivo* methods requiring the use of vertebrate animals. The testing strategies included in Annexes II and III to Regulation (EU) No 528/2012 therefore need to be adapted to recent validated Organisation for Economic Co-operation and Development (OECD) *in vitro* test guidelines and other international standards.

(9) The first mandatory requirement for following up on a positive *in vitro* gene mutation test is currently the *in vivo* unscheduled DNA synthesis (UDS) test, which has inherent limitations and low sensitivity. The European Food Safety Authority Scientific Committee[8] concluded in an opinion published in November 2017 that negative UDS results are not a proof that a substance does not induce gene mutation. The reference to the UDS test should be removed and replaced by a reference to an appropriate *in vivo* somatic cell genotoxicity study.

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[7] Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

[8] Scientific Opinion on the clarification of some aspects related to genotoxicity assessment. EFSA Journal 2017;15(12):5113, 25 pp. https://doi. org/10.2903/j.efsa.2017.5113

(10) The current data requirements in Annex II to Regulation (EU) No 528/2012 require a two-generation reproductive toxicity study (TGRTS) to be used to investigate the reproductive toxicity of a substance. That Annex furthermore stipulates that the extended one-generation reproductive toxicity study (EOGRTS) can be considered as an alternative approach to the TGRTS. The EOGRTS offers a number of advantages in comparison to the TGRTS as it assesses in addition to effects on the male and female reproductive system more toxicological effects linked to endocrine-disrupting mode of actions. Therefore, if there is no TGRTS available, an EOGRTS should be performed instead.

(11) Exposure to developmental neurotoxicants in utero or during childhood can contribute to a variety of neurodevelopmental and neurological disorders that manifest themselves only as the person ages, and may contribute to neurodegenerative diseases such as Parkinson's or Alzheimer's diseases. To address this concern, test guidelines to adequately screen and characterise active substances potentially toxic for the developing brain should be included in Annex II to Regulation (EU) No 528/2012.

(12) The current structure of the information requirements relating to health data and medical treatment in points 8.12.1 to 8.12.8 of Title 1 of Annex II to Regulation (EU) No 528/2012 may lead to submission of overlapping information under a number of those points. The data requirements should therefore be streamlined to reduce compliance costs and unnecessary delays in the evaluation of applications.

(13) An evaluation of the potential for unintended effects of substances on the immune system should be conducted. However, as no specific developmental immunotoxicity study is available in a OECD test guideline, relevant data should be required to be provided as additional data set.

(14) Point 8.18 of Title 1 of Annex II to Regulation (EU) No 528/2012 duplicates the content of Section 13 of that Title and should therefore be deleted.

(15) Point 9.1.1 of Title 1 of Annex II to Regulation (EU) No 528/2012 should be amended in order to clarify when long-term toxicity testing on fish is to be carried out. The list of OECD test methods in point 9.1.6.1 is to be replaced in order to take into account on-going developments as regards the information requirements on long-term toxicity studies on fish.

(16) Several information requirements for microorganisms included in Title 2 of Annexes II and III to Regulation (EU) No 528/2012 are either overlapping with other provisions in the Annexes or are irrelevant for microorganisms. Title 2 of Annexes II and III to Regulation (EU) No 528/2012 should therefore be amended in order to eliminate such overlaps and irrelevant information requirements.

(17) The fourth paragraph of point 2 of the introductory part of Annex III to Regulation (EU) No 528/2012 provides that for non-active substances, the applicants are to use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006. That paragraph should be amended in order to clarify that applicants may need to provide additional information on substances of concern included in biocidal products in particular in order to prepare a data set that enables the identification of their endocrine disrupting properties]

(18) In order to avoid imposing a disproportionate burden on economic operators, certain tests required by Annex II or Annex III to Regulation (EU) No 528/2012 that were already initiated or carried out before the date of application of this Regulation should be considered appropriate to address the information requirements.

(19) A reasonable period should be allowed to elapse before the data requirements, as modified by this Delegated Regulation become applicable so that the applicants can make the necessary arrangements to meet those requirements. However, in the interests of the protection of human and animal health and of the environment, the applicants should be allowed to apply the changes introduced by this Regulation before its date of application on a voluntary basis.

(20) Regulation (EU) No 528/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) No 528/2012 is amended in accordance with Annex I to this Regulation.

Annex III to Regulation (EU) No 528/2012 is amended in accordance with Annex II to this Regulation.

Article 2

Notwithstanding the date of application of this Regulation laid down in Article 3, applications for approval of an active substance and applications for authorisation of a biocidal product submitted before … [*OJ: please insert a date - 12 months after entry into force of this amending Regulation*] shall be evaluated based on information requirements applicable on the day of submission of such applications.

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*.

It shall apply from … [*OJ: please insert a date - 12 months after entry into force of this amending Regulatio*n].

By way of derogation, applicants may choose to apply the data requirements as set out in the Annexes I and II to this Regulation from … [*OJ: please insert the date of entry into force of this amending Regulation*].

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

Done at Brussels,

For the Commission
The President
Ursula Von der Leyen