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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: General Secretariat of the Council

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Subject: COMMISSION REGULATION (EU) .../... of XXX amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 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

Delegations will find attached document [...] (2022) XXX draft - D 081969/2.

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

of **XXX**

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(Text with EEA relevance)

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

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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 (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 13(2) and (3) thereof,

Whereas:

- (1) Article 13(3) of Regulation (EC) No 1907/2006 provides that, where tests on substances are required to generate information on intrinsic properties of substances, they are to be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised as being appropriate by the Commission or the European Chemicals Agency.
- (2) Commission Regulation (EC) No 440/2008² contains, in its Annex, test methods recognised as being appropriate for generating information on the physicochemical, toxicological and eco-toxicological properties of chemicals for the purpose of Regulation (EC) No 1907/2006.
- (3) Most of the test methods contained in the Annex to Regulation (EC) No 440/2008 are equivalent to internationally agreed and accepted methods (such as test guidelines of the Organisation for Economic Co-operation and Development). These methods are frequently reviewed and modified to reflect the state of science.
- (4) Repeating the full description of those internationally agreed and accepted methods in the Annex to Regulation (EC) No 440/2008 for the purpose of their incorporation into the Union legislation has led to delays in adapting that Regulation to scientific progress. As a consequence, the test methods laid down in the Annex to Regulation (EC) No 440/2008 are frequently not aligned with the most up-to-date version of the

¹ OJ L 396, 30.12.2006, p. 1

² 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).

corresponding international methods. Relatedly, new international test methods are added to Regulation (EC) No 440/2008 only after a prolonged period of time.

- (5) This situation has created uncertainty for registrants under Regulation (EC) No 1907/2006, as well as for duty holders under other Union legislation, as to which methods should be used for the generation of data for the purposes of that Regulation and other legislation. Article 13(2) of Regulation (EC) No 1907/2006 provides that methods are to be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved, and that the Commission is to, if appropriate, make a proposal as soon as possible to amend Regulation (EC) No 440/2008, so as to replace, reduce or refine animal testing. Furthermore, Article 13 of Directive 2010/63/EU of the European Parliament and of the Council³ on the protection of animals used for scientific purposes, makes it a legal obligation in the Union to use an alternative method that does not entail the use of a live animal, instead of an animal method, once such method is recognised under the legislation of the Union. Any delays to the process of introducing new alternative methods into Regulation (EC) No 440/2008 therefore could hinder a timely uptake of such methods once they are adopted at international level.
- (6) In the Decision in case 23/2018/SRS, the European Ombudsman suggested to the Commission to intensify its efforts to simplify and speed up the process for introducing new alternative test methods under Regulation (EC) No 440/2008. Also, the European Parliament, in its resolution 2021/2784(RSP) of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education, recalled that Article 13 of Regulation (EC) No 1907/2006 requires that the test method requirements be updated as soon as non-animal methods become available.
- (7) Therefore, in order to ensure that Regulation (EC) No 440/2008 provides correct, up-to-date and relevant test methods that are appropriate to generate information under Regulation (EC) No 1907/2006, a table should be included in the Annex to that Regulation, giving a comprehensive list of such methods with a reference to the respective international test method. The inclusion of a reference to an international test method in the table should be considered as a recognition by the Commission of such method for the purposes of Article 13(3) of Regulation (EC) No 1907/2006.
- (8) Full descriptions of test methods in Parts A, B and C of the Annex to Regulation (EC) No 440/2008 that no longer correspond to the most recent version of an international test method should be deleted from that Annex to prevent tests being performed following protocols that do not provide state-of-the-art scientific information.
- (9) Certain test methods set out in the Annex to Regulation (EC) No 440/2008, as well as their corresponding international test methods, are no longer considered appropriate to generate new information under Regulation (EC) No 1907/2006. The test methods B.22. Rodent dominant lethal test; B.25. Mouse heritable translocation; B.34. One-generation reproductive toxicity study; B.35. Two-generation reproductive toxicity study; B.39. Unscheduled DNA synthesis (UDS) test with mammalian liver cells *in vivo*; and C.15. Fish, Short term toxicity test on Embryo and Sac Fry Stages; should therefore be deleted from that Annex and there should be no entry referring to them in the table set out in that Annex.

³ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

- (10) Regulation (EC) No 440/2008 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 440/2008 is amended in accordance with the Annex to this Regulation.

Article 2

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
Ursula VON DER LEYEN