EUROPEAN
COMMISSION

Brussels, XXX
[…](2020) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes VII to XI to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes VII to XI to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(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/EC ([1]), and in particular Article 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 imposes specific registration duties and obligations on manufacturers, importers and downstream users with a view to generate data on substances they manufacture, import or use, to assess the risks related to those substances and to develop and recommend appropriate risk management measures.

(2) Annexes VII to X to Regulation (EC) No 1907/2006 set out standard information requirements for substances manufactured or imported in quantities of one tonne or more, 10 tonnes or more, 100 tonnes or more and 1 000 tonnes or more, respectively. Annex XI to that Regulation sets out the general rules for adaptation of the standard testing regime set out in Annexes VII to X thereto.

(3) In June 2019 the Commission and the European Chemicals Agency ('the Agency') concluded in REACH Evaluation Joint Action Plan[2] that certain provisions in the Annexes to Regulation (EC) No 1907/2006 should be amended to provide more clarity on the obligations of registrants and on the role and responsibilities of the Agency under Titles II and VI of that Regulation, respectively.

(4) Experience has shown that the introductory texts of Annexes VII to X to Regulation (EC) No 1907/2006 are insufficient and that additional requirements should be introduced for human health and environmental purposes as regards the chosen study design where a test method offers flexibility. This should, among others, ensure that animal testing is performed at appropriately high dose levels.

(5) In order to ensure the provision of useful information, certain provisions on information on the physicochemical properties of the substance in Annex VII to

1 OJ L 396, 30.12.2006, p. 1.

2 European Commission and European Chemicals Agency REACH Evaluation Joint Action Plan of June 2019 (https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en).

Regulation (EC) No 1907/2006 should be clarified as regards the information requirements for surface tension and water solubility of metals and sparingly soluble metal compounds.

(6) Certain provisions on toxicological information in Annex VII to Regulation (EC) No 1907/2006 should be modified with a view to clarifying the obligations for registrants and the responsibilities of the Agency as regards the performance of in vitro studies for eye irritation.

(7) Various provisions on toxicological information in Annex VIII to Regulation (EC) No 1907/2006 have been found to be unclear and should be rephrased. Those provisions concern, in particular, the performance of in vivo studies for skin or eye irritation and of the 28-day repeated dose toxicity study.

(8) Certain provisions on information on the physicochemical properties of the substance in Annex IX to Regulation (EC) No 1907/2006 should be clarified in order to add new specific rules for adaptation for dissociation constant and viscosity.

(9) The provisions on toxicological information in Annex IX to Regulation (EC) No 1907/2006 require certain clarifications on when the sub-chronic toxicity study does not need to be conducted. In addition, it is necessary to amend the specific rules laid down in Annexes IX and X to Regulation (EC) No 1907/2006 about adaptation for the reproductive toxicity studies in order to better specify the cases where testing does not need to be conducted. It should also be clarified how to demonstrate low toxicological activity of a substance in order to adapt testing. Finally, the provision setting out the conditions under which no further testing is necessary for sexual function and fertility or developmental toxicity should be simplified.

(10) Annex IX to Regulation (EC) No 1907/2006 should also be amended in order to exclude the waiving of conducting relevant studies on fate and behaviour in the environment on the sole basis of a low octanol water partition coefficient.

(11) The general rules for adaptation of the standard testing regime in Annex XI to Regulation (EC) No 1907/2006 should be modified in order to update them and to avoid ambiguity of certain provisions. Those changes concern, in particular, the provisions on use of existing data, weight of evidence and grouping of substances.

(12) Given uncertainty with regard to what can be considered as existing data, that term as used in Annex XI, subsection 1.1., to Regulation (EC) No 1907/2006 should be clarified by aligning it to Article 13(3) and (4) of that Regulation. The reference to good laboratory practice should be deleted to ensure consistency with the enacting terms of that Regulation.

(13) In Annex XI to Regulation (EC) No 1907/2006, it should be clarified how a weight of evidence adaptation can be applied to specific information requirements and how it should be documented.

(14) It is necessary to clarify the rules laid down in Annex XI to Regulation (EC) No 1907/2006 concerning the establishment of structural similarity. It should further be clarified what documentation is required for read-across, including specifically for substances of unknown or variable composition, complex reaction products and biological materials. In addition, the reference to the Agency issuing guidance on this topic should be removed as the guidance has already been published.

(15) The footnote in the section “Substance-tailored exposure-driven testing” of Annex XI to Regulation (EC) No 1907/2006 should be moved to the main text to enhance its

visibility. Finally, the provisions of that section should be amended to clarify the legal text and align it to the changes on toxicological information.

(16) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(17) The proposed amendments aim at providing clarifications of certain information requirements and at increasing the legal certainty of the evaluation practices already applied by the Agency. Nevertheless, it cannot be discarded that the amended provisions might trigger an update of registration dossiers. Therefore, the application of this Regulation should be deferred.

(18) 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

Annexes VII to XI to Regulation (EC) No 1907/2006 are 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*.

It shall apply from … [OP, please insert the date: 6 months after the entry into force of this 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