Council of the
European Union

Brussels, 29 November 2021
(OR. en)

14475/21

COMPET 874
ENT 186
MI 901
SAN 713
CONSOM 277
ENV 937
CHIMIE 122

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	19 November 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	[…](2021) XXX draft - D (2021) 76145
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annexes VI to X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Delegations will find attached document […](2021) XXX draft - D (2021) 76145.

Encl.: […](2021) XXX draft - D (2021) 76145

EUROPEAN
COMMISSION

Brussels, XXX
D076145/01
[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes VI to X 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)

Commission Regulation (EU) …/…

of XXX amending Annexes VI to X 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 lays down specific registration duties and obligations on manufacturers, importers and downstream users 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) Annex VI to Regulation (EC) No 1907/2006 sets out information requirements referred to in Article 10, point (a)(i) to (v) and (x), of that Regulation. Annexes VII to X to that Regulation 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.

(3) In June 2019, the Commission and the European Chemicals Agency ('the Agency') concluded in the REACH Evaluation Joint Action Plan[2] that certain information requirements in the Annexes to Regulation (EC) No 1907/2006 should be amended to provide more clarity on the obligations of registrants regarding the submission of information.

(4) To increase clarity of the registrants' obligations, a number of information requirements in Annexes VII to X to Regulation (EC) No 1907/2006 and the general rules for adaptation of the standard testing regime in Annex XI to that Regulation have been amended by Commission Regulation (EU) 2021/979 of 17 June 2021, but in line with the objectives of the REACH Evaluation Joint Action Plan a number of information requirements remain to be clarified.

(5) Requirements concerning the general registrant information and substance identification information which a registrant is to submit for general registration

[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.pdf/0003c9fc-652e-5f0b-90f9-dff9d5371d17).

purposes, laid down in Annex VI, sections 1 and 2, to Regulation (EC) No 1907/2006 should therefore be amended.

(6) Certain specific rules for adaptation from the standard information requirements set out in Annexes VII to X to Regulation (EC) No 1907/2006 should be amended to align the terminology of the classification of hazardous substances to that used in Annex I, parts 2 to 5, to Regulation (EC) No 1272/2008 of the European Parliament and the Council[3].

(7) Specific rules for adaptation from the standard information laid down in Annex VII to Regulation (EC) No 1907/2006 on mutagenicity and aquatic toxicity should be amended for reasons of clarity and to ensure that useful information is provided. In particular, subsection 8.4 should be amended to clarify the consequences of a positive result in the *in vitro* gene mutation study, as well as the situations when the study required under point 8.4.1does not need to be conducted. In addition, parts not referring to standard information required should be removed from column 1 of point 9.1.1, while column 2 of that point should describe more accurately the situations where the study does not need to be conducted and where long-term aquatic toxicity testing is required. Point 9.1.2 should also be modified to clarify when the study does not need to be conducted.

(8) The information requirements on testing for mutagenicity and for reproductive toxicity, and on ecotoxicological information in Annex VIII to Regulation (EC) No 1907/2006 should be amended in order to clarify the obligations of registrants. In particular, the rules on testing for mutagenicity in subsection 8.4 should specify the situations that do not require testing referred to in that Annex and the situations that require further testing referred to in Annex IX. Furthermore, the nomenclature of the studies in point 8.4.2 should be aligned with that of the corresponding technical guidance documents of the Organisation for Economic Co-operation and Development (OECD)[4]. In addition, to ensure that useful information on reproductive and developmental toxicity is generated, the preferred animal species and the preferred administration routes for testing should be added to point 8.7.1, while certain specific rules for adaptation from the standard information requirements should be clarified. Finally, a subsection heading 9.1 for aquatic toxicity that was missing should be added and the information requirement on short-term toxicity testing on fish in point 9.1.3 should be amended in order to remove the parts that do not list standard information from column 1 and to clarify the situations when the test is not required in column 2. Subsections 9.2 on degradation and 9.3 on fate and behaviour in the environment should also be modified in order to better describe the situations requiring further information on degradation and bioaccumulation as well as further degradation and bioaccumulation studies.

(9) Information requirements on testing for mutagenicity in Annex IX to Regulation (EC) No 1907/2006 should be amended to specify in points 8.4.4 and 8.4.5 the studies to be conducted in mammalian somatic cells and, when relevant, in mammalian germ cells, as well as the cases where such studies need to be conducted. In addition, the information requirements in point 8.7.2 on testing for pre-natal developmental toxicity in a first and second species and in point 8.7.3 for Extended One-Generation Reproductive Toxicity studies should be clarified with regard to the preferred animal

---

[3] 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).

[4] OECD TG 473 and 487.

species and the preferred administration routes for testing, as well as with regard to the possible deviations from the general rules. Finally, as regards the section on ecotoxicological information, certain information requirements on long-term toxicity testing on fish should be removed due to animal welfare reasons. The subsection 9.2 on degradation should also be amended to align the wording of point 9.2.3 concerning identification of degradation products with that of the related provision in Annex XIII, and to reflect the amended requirement on further degradation testing accordingly. The subsection 9.4 on effects on terrestrial organisms should also be amended to clarify that a long-term toxicity study should be proposed by the registrant or may be required by the Agency for substances that have a high potential to adsorb to soil or that are very persistent.

(10) Annex X to Regulation (EC) No 1907/2006 should be amended to clarify certain information requirements on mutagenicity, developmental and reproductive toxicity and ecotoxicological information. In particular, the amendments should describe the situations meeting the requirement for a second *in-vivo* somatic cell study or a second *in-vivo* germ cell study and specify the need to conduct such studies in mammalian species. Those studies should be listed together with the mutagenicity concerns they are to address. In addition, the information requirements on pre-natal developmental toxicity and Extended One-Generation Reproductive Toxicity studies should be amended to clarify the need for a study in, and the choice of, a second species, as well as the preferred administration routes for testing and the deviations from the general rules. Furthermore, the reference to a specific requirement on biotic degradation in point 9.2.1 is no longer necessary and should therefore be deleted, while relevant specific rules for adaptation in subsection 9.2 should be amended accordingly. Finally, it should be clarified in subsection 9.4, as well as point 9.5.1 that in addition to degradation products, long-term toxicity testing of transformation products is required to investigate their effects on terrestrial and sediment organisms.

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

(12) The proposed amendments aim at providing clarifications of certain standard information requirements and specific rules for their adaptation, as well as at increasing the legal certainty of the evaluation practices already applied by the Agency. Nevertheless, it cannot be discarded that as a result of the amendments, certain registration dossiers will need to be updated. The application of this Regulation should therefore be deferred.

(13) 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 VI to X 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 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