EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex VII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin sensitisation

(Text with EEA relevance)

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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/EC ([1]), and in particular Articles 13(2) and 131 thereof,

Whereas:

(1) Article 13(2) of Regulation (EC) No 1907/2006 provides that test methods used to generate information on intrinsic properties of substances required by that Regulation are to be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. When appropriate validated test methods become available, the Commission Regulation (EC) No 440/2008[2] and the Annexes to Regulation (EC) No 1907/2006 should be amended, if relevant, so as to replace, reduce or refine animal testing. The principles of replacement, reduction and refinement, enshrined in Directive 2010/63/EU of the European Parliament and of the Council[3] should be taken into account.

(2) Regulation (EC) No 1907/2006 establishes requirements for the registration of substances manufactured or imported in the Union on their own, in mixtures or articles. The registrants have to provide the information required by Regulation (EC) No 1907/2006, as appropriate, in order to fulfil the registration requirements.

(3) Pursuant to Regulation (EC) No 1907/2006, in vivo studies are required for the generation of information on skin sensitisation in point 8.3 of Annex VII to Regulation (EC) No 1907/2006.

(4) In recent years, significant scientific progress has been made in the development of alternative test methods for skin sensitisation. Several in chemico/in vitro test methods

[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).

[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).

have been validated by the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) and/or internationally agreed by the OECD. These test methods may allow the generation of adequate information to assess whether a substance causes skin sensitisation without the need to resort to *in vivo* testing, when applied in an appropriate combination in the framework of an integrated approach to testing and assessment (IATA). To reduce animal testing and in view of the known limitations to of the Murine Local Lymph Node Assay (LLNA), specified as the first-choice method for in vivo testing for skin sensitisation, point 8.3 of Annex VII to Regulation (EC) No 1907/2006 should explicitly allow waiving of the *in vivo* test for skin sensitisation, if adequate information can be obtained through a non-animal approach.

(5) To be considered adequate, information from a non-animal approach should allow classification and, where required, risk assessment. The available in chemico/in vitro OECD test guidelines and IATAs allow identifying and classifying skin sensitisers, but currently do not provide information sufficient for sub-categorisation of skin sensitisers into categories 1A and 1B according to the criteria in Annex I, point 3.4.2.2 of Regulation 1272/2008[4], as these are based on human and animal data. However, indications for sensitising potency of a substance may be obtained i.a. from *in vitro* test methods, structural characteristics and knowledge on related substances. In the absence of a formalised approach to sub-categorise skin sensitisers based on *in vitro* test results, registrants should make an effort to undertake a potency assessment based on such indications. If such a potency assessment gives rise to the presumption that a substance has the potential to produce significant sensitisation in humans, a weight-of-evidence based decision to classify them as skin sensitiser category 1A and to apply appropriate risk management measures may be warranted.

(6) In addition, the standard information requirements and adaptation rules in 8.3 of Annex VII should be revised in order to remove redundancies with rules set by Annex VI and Annex XI and in the introductory parts of Annex VII as regards the review of available data, the waiving of studies for a toxicological endpoint if the available information indicates that the substance meets the criteria for classification for that toxicological endpoint, or to clarify the intended meaning as regards the waiving of studies for substances that are flammable under certain conditions. Where reference is made to the classification of substances, adaptation rules should be updated to reflect the terminology used in Regulation (EC) No 1272/2008.

(7) ECHA, in cooperation with Member States and stakeholders, should further develop guidance documents for the application of the test methods and waiving possibilities for the standard information requirements provided by this Regulation for the purposes of Regulation (EC) No 1907/2006. In doing so, ECHA should take full account of the work carried out in OECD, as well as in other relevant scientific and expert groups.

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

(9) 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,

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[4] 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)

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VII and VIII 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 […] 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
[…]