Commission Regulation (EU) 2016/863 of 31 May 2016 amending Annexes VII and VIII 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 corrosion/irritation, serious eye damage/eye irritation and acute toxicity (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/863

of 31 May 2016

amending Annexes VII and VIII 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 corrosion/irritation, serious eye damage/eye irritation and acute toxicity

(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 irritation and eye irritation in points 8.1 and 8.2 of Annex VIII to Regulation (EC) No 1907/2006.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/863. (See end of Document for details)*

(4) In recent years, significant scientific progress has been made in the development of alternative test methods for skin corrosion/irritation and serious eye damage/ eye irritation. A number of test guidelines for alternative test methods have been internationally agreed by the Organisation for Economic Cooperation and Development (OECD), and have been included in Regulation (EC) No 440/2008.

(5) For skin corrosion/skin irritation, adequate information for the classification and risk assessment of a substance may be obtained in most cases solely on the basis of *in vitro* studies. A conclusion may be drawn on the basis of one *in vitro* test, if the result allows an immediate reliable decision on classification or non-classification, or from a combination of two *in vitro* tests, one for skin irritation and one for skin corrosion. *In vivo* studies may still be required in some exceptional cases for substances manufactured or imported in quantities of 10 tonnes or more, e.g. when the substance tested falls outside the applicability domain of the *in vitro* test methods or when no conclusive results can be obtained from a comprehensive set of *in vitro* tests.

(6) For serious eye damage/eye irritation, a set of *in vitro* test methods exists which would be sufficient in many cases to obtain information adequate for classification and risk assessment of substances. A conclusion about the potential of a substance to cause such eye effects may be drawn on the basis of one test, if the result allows an immediate reliable decision on classification or non-classification, or from a combination of two or more tests. *In vivo* studies may still be required in some cases for substances manufactured or imported in quantities of 10 tonnes or more, e.g. when the substance tested falls outside the applicability domain of the test methods or when no conclusive results can be obtained from a comprehensive set of *in vitro* tests.

(7) Points 8.1 and 8.2 of Annex VIII should thus be amended so that the standard information requirement should be for the *in vitro* studies while setting the conditions under which an *in vivo* study for skin irritation/corrosion and serious eye damage/eye irritation is still required. Nevertheless, adequate information from existing *in vivo* skin irritation or eye irritation studies can still be used to fulfil the information requirement at any tonnage level.

(8) In addition, the standard information requirements and adaptation rules in points 8.1, and 8.2 of Annex VII, and the adaptation rules in points 8.1 and 8.2 of Annex VIII should be revised in order to remove redundancies with rules set by Annex VI and Annex XI and in the introductory parts of Annexes VII and VIII 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 of the European Parliament and of the Council[(4)].

(9) For acute toxicity, in addition to a test via the oral route (Annex VII, point 8.5.1) point 8.5 of Annex VIII to Regulation (EC) No 1907/2006 provides a standard information requirement for substances other than gases by at least one additional route (inhalation

or dermal) depending on the likely route of human exposure. Recent scientific analysis of available data from *in vivo* acute toxicity studies have shown that substances that are not toxic via the oral route may be expected with high certainty to be also non-toxic via the dermal route. Therefore, testing those substances via the dermal route does not provide essential information for their safety assessment. Point 8.5 of Annex VIII to Regulation (EC) No 1907/2006 should thus be amended to provide for the possibility to waive the dermal test for such substances.

(10) 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.

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

(12) 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 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 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, 31 May 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/863. (See end of Document for details)*

ANNEX

Annexes VII and VIII to Regulation (EC) No 1907/2006 are amended as follows:

(1) points 8.1 and 8.2 of Annex VII shall be replaced by the following:

8.1. Skin corrosion/irritation	8.1. The study/ies do(es) not need to be conducted if: — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as skin corrosion (Category 1), or — the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or — the substance is classified as acute toxicity by the dermal route (Category 1), or — an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight). If results from one of the two studies under point 8.1.1 or 8.1.2 already allow a conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study need not be conducted.
8.1.1. Skin corrosion, *in vitro*	
8.1.2. Skin irritation, *in vitro*	
8.2. Serious eye damage/eye irritation	8.2. The study/ies do(es) not need to be conducted if: — the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1), or — the substance is classified as skin irritation and the available information indicates that it should be classified as eye irritation (Category 2), or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be