EUROPEAN
COMMISSION

Brussels, XXX
D055248/01
[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B

(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 68(2) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] lays down criteria for the classification of chemical substances in hazard classes, including the hazard classes carcinogenicity, germ cell mutagenicity and reproductive toxicity, category 1A or 1B. Substances classified in any of those three hazard classes are referred to collectively in this Regulation as 'CMR substances'.

(2) Annex XVII to Regulation (EC) No 1907/2006 lays down restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles. The Commission has developed criteria for the identification of articles that contain CMR substances and could be used by consumers, in relation to which it would be appropriate to add a new restriction to Annex XVII using the simplified procedure referred to in Article 68(2) of that Regulation. According to the criteria developed by the Commission, clothing, other textiles and footwear are considered a priority case[3].

(3) Certain CMR substances are present in clothing and related accessories, other textiles and footwear, either as impurities from the production process or because they have been added intentionally to give them specific properties.

(4) Information from public authorities and stakeholders' reports indicate the potential for consumers to be exposed to CMR substances present in clothing and related accessories, other textiles or footwear through contact with the skin or through

---

1 OJ L 396, 30.12.2006, p 1.

2 Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).

3 http://ec.europa.eu/DocsRoom/documents/10045/attachments/1/translations

inhalation. These products are widely available for use by consumers, including in a private capacity or when using a product within a public service (for example bed linen in a hospital or upholstery in a public library). Therefore, in order to minimise such consumer exposure, the placing on the market of CMR substances in clothing and related accessories (including sportswear and bags), or footwear for use by consumers should be prohibited where the CMR substances are present in concentrations above a certain level. For the same reason, this restriction should also cover the situation where CMR substances are present in those concentrations in other textiles that come into contact with human skin to an extent that is similar to clothing (for example, bed linen, blankets, upholstery or reusable nappies).

(5) The Commission has consulted stakeholders on the substances and articles that should fall within the scope of the new restriction under Article 68(2) of Regulation (EC) No 1907/2006[4] and discussed specific aspects of the restriction (including the concentration limits and availability of testing methods) with them in a technical workshop[5].

(6) The substances to be restricted each have different properties and are used in different processes in the clothing and related accessories, textile and footwear industries. Therefore, maximum concentration limits should be specified, either for individual substances or for groups of substances, taking into account the technical feasibility of achieving those limits and the availability of appropriate analytical methods. Formaldehyde is used in jackets and coats, and in upholstery, to confer structural and flame retardant properties respectively. Due to the lack of information on suitable alternatives, a less stringent concentration should apply, for a limited period, to formaldehyde in jackets, coats or upholstery in order to allow operators to adapt to the restriction.

(7) Clothing, related accessories and footwear, or parts of clothing, related accessories and footwear, that are made entirely out of natural leather, fur or hide should not be covered by the new restriction to be adopted by this Regulation because different chemical substances and processes are used in their production. For the same reason, non-textile fasteners and decorative attachments should not be covered by the new restriction.

(8) Personal protective equipment within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council[6] and medical devices within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council[7] should be exempted from the new restriction because of the need for such equipment and devices to fulfil specific requirements in terms of safety and functionality.

(9) The European Chemical Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the process for developing the restriction and its recommendations have been taken into account.

---

4 http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8299

5 http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9088

6 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51–98)

7 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1–175)

(10) Operators should be allowed sufficient time to take appropriate measures to comply with the restriction adopted by virtue of this Regulation. The new restriction should therefore only apply from a specified date that is later than the date on which this Regulation enters into force.

(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

Annex XVII to Regulation (EC) No 1907/2006 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
Jean-Claude Juncker