Commission Regulation (EU) 2018/1513 of 10 October 2018 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) 2018/1513

of 10 October 2018

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,

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other textiles or footwear through contact with the skin or through inhalation. These products are widely available for use by consumers, including in a private capacity or when using a product within the context of a service provided to the general public (for example bedlinen 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, inter alia, 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, bedlinen, 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) Wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners should for the time being be exempted from the new restriction due to potential regulatory overlap and because other substances may be relevant for them. The Commission should review the exemption as well as the appropriateness of a separate restriction.

(9) 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.

(10) 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

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the process for developing the restriction and its recommendations have been taken into account.

(11) 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.

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

(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

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, 10 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

72	The substances listed in column 1 of the Table in Appendix 12	1. Shall not be placed on the market after 1 November 2020 in any of the following: (a) clothing or related accessories; (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing; (c) footwear; if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12. 2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter. 3. Paragraph 1 shall not apply to: (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. 4. Paragraph 1 shall not apply to clothing, related accessories, textiles

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other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**).

5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.

6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.

7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.

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

(**) 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).

(2) the following Appendix 12 is added:

Appendix 12 Entry 72 — restricted substances and maximum concentration limits by weight in homogeneous materials:

Substances	**Index- No**	**CAS No**	**EC No**	**Concentration limit by weight**
Cadmium and its compounds (listed in Annex XVII,	—	—	—	1 mg/kg after extraction (expressed as Cd metal