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COMMISSION REGULATION (EU) .../...

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1A or 1B in childcare products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) .../...

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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/EC¹, and in particular Article 68(2) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council² 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 categories of the 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 substances on their own, in mixtures and in 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 to Regulation (EU) No 1907/2006 using the simplified procedure referred to in Article 68(2) of that Regulation.
- (3) Children are particularly vulnerable to the negative effects of exposure to hazardous chemicals. Due to developmental age-specific behaviour patterns of children, their exposure to hazardous substances from articles is different compared to adults. For instance, their hand-to-mouth behaviour or their habit of playing on the floor increases the exposure to chemicals. In the particular case of chemicals contained in childcare products, children can be exposed through various routes, including direct contact with the skin, oral exposure by placing such products in the mouth or licking them, or

¹ OJ L 396, 30.12.2006, p 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>.

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, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

inhalation of volatile substances emitted from such products or those inhaled with dust. Therefore, it is necessary for this restriction to cover any product designed for the care of children other than substances or mixtures on their own ('childcare products').

- (4) Regulation (EC) No 1907/2006 includes some restrictions for substances in 'childcare articles' restricting certain substances in articles on their own or in complex products intended for the care of children. To facilitate the reading and avoid confusion with the definition of 'article' in Article 3 the term 'childcare product' should be used for the purpose of the entry introduced in Annex XVII by this Regulation.
- (5) Childcare products were identified as a priority by the Member States during the discussions that followed the introduction of the restriction on CMR substances in clothing and related accessories, textiles other than clothing and footwear by means of Commission Regulation (EU) 2018/1513³. Subsequently, the Commission commissioned a study to gather evidence about the presence of CMR substances in childcare products. The aim of this study published in 2019⁴ was to collect information that could be used in the context of defining the scope of a proposal to restrict CMR substances present in childcare products in accordance with Article 68(2) of Regulation (EC) No 1907/2006 or other possible risk management measures under that Regulation as appropriate, in order to limit the exposure of consumers, and in particular children, to those substances.
- (6) Moreover, the Chemicals Strategy for Sustainability of 14 October 2020⁵ identified the need to better protect vulnerable population groups such as children, pregnant women and elderly people who are particularly sensitive to chemicals with certain hazardous properties. To this end, the strategy included *inter alia* a commitment to ensure the safety of children from hazardous chemicals in childcare articles and other products for children (other than toys) by providing the same level of protection as in toys, through the legal requirements of Directive 2001/95/EC of the European Parliament and of the Council⁶ and the restrictions in accordance with Regulation (EC) No 1907/2006.
- (7) In order to gather further information, on 29 November 2022, the Commission sent a request to the European Chemicals Agency ('the Agency') seeking its support for the preparation of a restriction proposal for the use and presence of CMR substances in childcare products, in particular by preparing an investigation report and collecting available information on products⁷.
- (8) In this context, the Agency carried out a call for evidence between 15 February and 31 March 2023 to collect information on the presence of CMR substances in childcare products including, among others, on the categorisation of childcare products, on existing certification schemes, standards, on company or sector specific lists of

³ 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 (OJ L 256, 12.10.2018, p. 1, ELI: <http://data.europa.eu/eli/reg/2018/1513/oj>).

⁴ Assessment of presence of CMR substances in certain categories of consumer articles that could be subject of Article 68(2) of REACH Final Report Contract 07.0203/2018/789896/ENV.B.

⁵ COM(2020)667 final.

⁶ OJ L 11, 15.1.2002, p. 4, ELI <http://data.europa.eu/eli/dir/2001/95/oj>.

⁷ https://echa.europa.eu/documents/10162/17233/rest_mandate_cmrs_childcare_articles_investigation_en.pdf/de98f68e-bec5-5023-a15c-66818f5c2d4c?t=1699424178765

substances restricted in childcare products, on available analytical methods and on a list of CMR substances for which evidence of their presence in childcare products was already collected by the Agency, including on their technical function and measured concentration. The Agency organised a second call for evidence between 10 May and 7 June 2023 focusing on the collection of information on suitable analytical methods to measure CMR substances in childcare products.

- (9) Childcare products cover a range of very diverse products, including sleeping and transportation products, relaxation tools and feeding and hygiene products. Therefore, the investigation report covered the childcare products falling under the definition laid down in entries 51 and 52 of Annex XVII to Regulation (EC) No 1907/2006, combined with the definition applied by the relevant technical subcommittee of CEN (CEN/TC 252): any product intended to facilitate seating, sleep, relaxation, hygiene such as bathing, changing and general body care, feeding, sucking, transportation and protection of children.
- (10) The Agency's investigation report was published on 23 August 2023⁸. It reflects that CMR substances may be present in childcare products, either as impurities from the production process or because they were added intentionally to give childcare products specific properties. In addition, the Agency also noted that children may be exposed to the substances in childcare products during normal and reasonably foreseeable conditions of use as well as in a non-intended or non-foreseeable way and that children are particularly vulnerable to chemicals.
- (11) Taking into account the findings of the investigation report, the Commission concludes that it is necessary to restrict CMR substances in childcare products to protect children against those substances.
- (12) The investigation report provided supporting information on definitions, concentration limits, testing strategy and other possible elements to help with the implementation of a potential restriction. The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1), point (f), of Regulation (EC) No 1907/2006, was consulted during the preparation of the investigation report and its advice on the enforceability of potential elements of a restriction was reflected in the report.
- (13) The investigation report indicated that a non-intended presence of small amounts of CMR substances, stemming from impurities of natural or synthetic ingredients, the production process, storage or migration from packaging, is technically unavoidable even under good manufacturing practices. Taking into account that this could impact enforcement, the Commission considers that concentration limits for the substances in the homogeneous material should be established. As indicated in the investigation report, the current development of analytical methods allows for the quantification of almost any substance with a Limit of Quantification (LOQ) of at least 10 mg/kg. Therefore, it is appropriate to set a default concentration limit of 10 mg/kg in homogenous materials (0.001 % w/w).
- (14) For certain substances, specific, individual or cumulative concentration limits should be established in an Appendix where deemed appropriate, taking into account factors regarding LOQs of standard analytical methods, thresholds for toxicity, and where

⁸ Investigation report on the Assessment of the presence of CMR substances in childcare articles in view of a restriction proposal on the basis of REACH Article 68(2). <https://echa.europa.eu/documents/10162/304346ad-3280-1680-18e0-7531260c44ee>

appropriate, alignment with limit values in other relevant Union legislation. In setting those specific limits, the Commission has taken into account the investigation report.

- (15) The specific concentration limits established for Dibutyltin (DBT) and Dioctyltin (DOT) should be more stringent than the concentration limits set out for these substances in paragraphs 5 and 6 of column 2 of entry 20 of Annex XVII to Regulation (EU) No 1907/2006.
- (16) A harmonised classification of substances under Regulation (EC) No 1272/2008 is based on a careful assessment of the hazard properties of those substances. Since children are particularly vulnerable to chemical substances and childcare products may also contain newly identified CMR substances, the Commission in this case, contrary to certain other restrictions of CMR substances in consumer products set out in Annex XVII to Regulation (EC) No 1907/2006, considers that a dynamic link between the scope of the restriction with Regulation (EC) No 1272/2008 is appropriate and will thus take into account all future new or amended classifications of substances as CMR substances listed in Part 3 of Annex VI of that Regulation. Therefore, the restriction in this Regulation should not only cover substances currently classified as CMR substances in Part 3 of Annex VI to Regulation (EC) No 1272/2008 but also substances classified in those hazard classes and categories at any point in the future, following an amendment to Part 3 of Annex VI to that Regulation adding or changing a harmonised classification of a substance. However, the restriction in this Regulation should only apply to such substances 36 months after entry into force of the act amending Part 3 of Annex VI to Regulation (EC) No 1272/2008 to classify or re-classify those substances. That 36-month period enables the Commission to assess whether specific concentration limits for newly classified CMR substances should be included in the Appendix, taking into account the latest scientific developments, and to make any necessary adjustments to ensure a high level of protection for children's health while avoiding unnecessary burdens on operators.
- (17) Taking into account the findings of the investigation report, the Commission also considers that the restriction should not apply when substances which would otherwise be covered by the restriction, are contained in certain childcare products. To ensure the restriction is effective and proportionate, it is considered necessary to exclude substances in second-hand childcare products from its scope. The restriction should not apply to second-hand childcare products as this would, in effect, extend its reach to products that were lawfully placed on the market by manufacturers, and could inadvertently capture private individuals and second-hand sales operators who may not have access to the necessary information from the original producer, thereby creating undue burdens on those individuals or operators. Furthermore, substances in childcare products, that are also devices with an intended medical purpose or their accessories within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council⁹, should be excluded as these devices are already regulated by a dedicated legislative framework that ensures their safety and performance. Finally, substances in childcare products that are intended or can reasonably be expected to come into contact with food, as covered by the scope of Regulation (EC) No 1935/2004 of the

⁹ 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, pp. 1-175, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

European Parliament and of the Council¹⁰, should also be excluded, since that Regulation already sets out specific rules ensuring that only substances that have been assessed and authorised can be used in those products and restricting substances, including CMRs, in food contact materials and articles. Furthermore, Regulation (EC) No 1935/2004 provides a legal basis for introducing specific rules for materials other than plastic, to protect consumers, including children, from substances including CMRs.

- (18) Taking into account the findings of the investigation report, the Commission also considers that the restriction should not apply to substances present in homogeneous materials in childcare products that are, and during foreseeable conditions of use remain, inaccessible to children in any form.
- (19) The Commission considers that operators should be allowed sufficient time to take appropriate measures such as developing analytical methods, finding alternatives and depleting existing stocks, to comply with this restriction, including for substances already having a harmonised classification at the time of entry into force of this restriction. The restriction should therefore only apply 36 months after this Regulation enters into force.
- (20) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (21) 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
Ursula Von der Leyen

¹⁰ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, pp. 4–17, ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>.