



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Ecosystem I: Chemicals, Food, Retail

Directorate-General for Environment
Directorate B - Circular Economy

The Directors

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**NOTE FOR THE ATTENTION OF
MR SHAY O'MALLEY, ACTING EXECUTIVE DIRECTOR ECHA**

Subject: Request to the European Chemicals Agency to support the Commission's preparation of a restriction proposal for the use and presence of hazardous chemicals in childcare articles based on Article 68(2) of REACH

We would like to request ECHA to support the Commission by preparing a report in view of a restriction proposal for carcinogenic, mutagenic and toxic for reproduction (CMRs) substances in childcare articles on the basis of Article 68(2) of REACH.

Article 68(2) of REACH provides for a procedure which the Commission may use to restrict substances that meet the criteria for classification as CMRs, categories 1A and 1B on their own, in mixtures or in articles that could be used by consumers. Although Article 68(2) does not foresee the development of an Annex XV dossier nor a formal involvement of ECHA or ECHA's scientific committees, we still consider it necessary to get ECHA's support in particular as regards the issues listed below.

Document CA/89/2017¹ explains the process followed to prepare the preceding Article 68(2) restriction on CMRs in textiles, clothing and footwear (entry 72 to Annex XVII to REACH)². Learning from the experience of this particular restriction, the document also sets the main elements of the preparation of a new restriction based on Article 68(2).

Background and justification

Children are particularly vulnerable to the negative effects of exposure to hazardous chemicals. Due to particular developmental stage-specific behaviour patterns of children, their exposure to hazardous substances from articles is different compared to adults. For instance, children crawl on the ground where they can be exposed to chemicals present on

¹ Document CA/89/2017, 25th Meeting of Competent Authorities for REACH and CLP (CARACAL), 15-16 November 2017

² [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 \(europa.eu\)](#)

floors, soils, and in household dust. Also their hand-to-mouth behaviour increases the exposure to chemicals³.

Childcare articles were identified as a priority by the Member States during the discussion that followed up the application of Article 68(2) to CMRs in textiles, clothing and footwear. Subsequently, the Commission funded a study to gather evidence about the presence of CMRs in childcare articles. The aim of this study published in 2019⁴ was to use it as a basis to define the scope of a proposal to restrict CMR substances present in different categories of childcare articles under Article 68(2) or other possible risk management measures under REACH as appropriate, in order to limit the exposure of consumers, and in particular children, to those substances via articles.

Moreover, the Chemical Strategy for Sustainability of 14 October 2020 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, it 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) to provide the same level of protection as in toys, through the mandatory legal requirements of the General Product Safety Directive and restrictions in REACH.

Scope

Childcare articles are a broad category covering a range of very diverse products, including sleeping/transportation articles, relaxation tools, feeding and hygiene articles.

The scope of the report should cover:

1. articles under the definitions in entry 51 of Annex XVII of REACH⁵ :
 - any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
2. and/or articles within the remit of CEN TC 252:
 - any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, transportation and protection of young children.

Substances

The substances under scope are all CMRs with harmonised classification category 1A or 1B under Regulation 1272/2008 (CLP). Consideration should be given also to future updates of the restriction when additional substances will get harmonised classifications. For enforcement purposes and to help with the implementability of the restriction, the report should gather data on whether the substances are present in childcare articles, to establish a list of most relevant substances per group of articles, and the materials typically

³ See e.g. Study for the strategy for a non-toxic environment of the 7th Environment Action Programme, Sub-study c: Protection of children and vulnerable groups from harmful exposure to chemicals <http://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20c%20children%20vulnerable%20popul.%20NTE%20final.pdf>

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 Restriction on Bis (2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP) and Benzyl butyl phthalate (BBP)

used in the articles and where possible, if they either can be released from articles or lead to exposure of children.

The Commission will provide access to the raw data in the 2019 study mentioned above that already includes a good overview. Possible other information sources are also ECHA databases and industry voluntary initiatives.

The restriction is envisaged to propose a generic (content) limit in homogenous materials aligned with the generic concentration or specific concentration limits from CLP, unless it seems more appropriate to establish lower limits for all substances or only for specific cases. The report should then identify if lower limits are necessary.

Consultation

The preparation of the report should include a consultation to gather information with regard to:

- Identification of relevant (groups of) substances and types of articles and/or materials where they occur.
- Need for deviation from generic/specific CLP (content) limits.
- Availability of analytical methods for enforcement and implementation.
- Transitional periods.

The Forum should be consulted on the draft report and its opinion on the enforceability of the restriction should be reflected in the final report.

Deliverables and timing

The deliverable of this mandate is a report that should include:

- A list of CMRs substances with harmonised classification 1A or 1B that may be present in childcare articles (grouped per article types/material types, intentional vs unintentional if possible);
- Where available, information on tonnage, concentration ranges, frequency of finding in articles to be used as estimation of likelihood of exposure for further prioritisation;
- Where available, information on release/exposure potential ;
- An inventory of existing Generic Concentration Limits (GCL)/Specific Concentration Limits (SCL) per substance or per groups of substances and further existing regulatory measures;
- Identification if deviation from GCL/SCL (content) limits is needed;
- Summary of information on availability of analytical methods;
- An overview and summary of the stakeholder consultations.

Within 10 months from the receipt of this letter, ECHA should finalise the report and submit it to the Commission to support its decision on what action is necessary on a Union-wide basis to protect children from these substances in childcare articles.

Yours sincerely,

(e-signed)

Kristin Schreiber
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(e-signed)

Aurel Ciobanu-Dordea
DG Environment