

ENPC and WBT represent the childcare articles (CCA) industries in Europe with the objectives to deliver an harmonized voice of our industry to European Institutions and National administrations and to participate actively in the relevant sector European policies.

We wish to comment on the regulation **on the restriction of CMR 1A/1B substances in childcare articles** (TRIS notification 2026/0059/SI - Slovenia) : <https://technical-regulation-information-system.ec.europa.eu/en/notification/27663>

The notified regulation is indicated as being part of a transitional period during which the EU is preparing a uniform restriction on CMR substances in childcare articles under REACH Article 68(2), which the European Commission has formally requested from ECHA (European Chemicals Agency).

Our sector welcomes initiatives aimed at supporting the safety of children. However, any initiative should be taken at EU level to avoid the fragmentation of the single market, and the modalities of application shall be proportionate, applicable and controllable. In this frame we believe this draft regulation represents a severe barrier to trade with economic impacts because if adopted it will ban in fact safe materials which are used in other sectors such as the toys sectors, and it is incompatible with EU law.

We call on the European Commission to present a detailed opinion, to extend the standstill period and to ask Slovenia to withdraw its draft regulation in order to follow the REACH restriction process which is under discussion.

According to the reading of this draft regulation, we understand that this draft regulation is based on the ECHA report when it comes to the generic limit and also the scope of the products that are considered.

We would like to highlight that there are several uncertainties mentioned in the ECHA report and we also want to alert the Commission that such regulation (if adopted) would ban definitively some materials (electrical or not), and therefore childcare article without adding safety.

1. GENERIC LIMIT OF 0.001 % (w/w) (10 mg/kg)

- There is uncertainty with regards to the potential presence of CMR 1A or 1B substances in childcare articles, their release from childcare articles, the potential for exposure of children to those substances and the consequent potential risk for children. Due to the large scope of this investigation, exposure and risk assessments could not be performed within this investigation report.
- There may be uncertainty for CMR 1A or 1B substances for which the default concentration limit of 10 mg/kg would be applicable and for which, no collection of information on existing regulations/available analytical methods was done. Due to the high number of substances under the scope of this report, it was not possible to collect this type of information for all CMR 1A and 1B substances.

Therefore, it is not certain that a limit of 10 mg/kg could be technically achievable for certain substances and materials, but we are sure that it will ban many CCA if the regulatory limit is by default at 10 mg/kg.

Finally, ECHA did not analyze regulatory migration value, and this 10 mg/kg limit has not been impact assessed.

For all above reasons the 10 mg/kg cannot be acceptable. Note that even the 100 mg/kg default limit which was under discussion within the toy regulation and indicated for the derogation of the Annex II, was also an issue as many materials, not exclusive to the toy sector or the CCA sector, contain non-intentional substances over this limit.

This proposed ban will be CCA sector specific: no other sector – food, cosmetics, stationary products, furniture, clothing, toys, etc. – would have the same ban, but materials used in CCA are also materials used in all these sectors.

The childcare articles manufacturers' suppliers will continue to work with the Safety Data Sheets (SDS) in the same way as they do for their others sectors customers with the applicable thresholds table 1.1 of the Annex: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0878&from=EN>

It means that for all the substances, the proposed ban will require manufacturers to perform tests (if achievable) for unintended trace-levels for many substances.

This proposal is extremely worrying:

- First, setting a trace level limit of 10 mg/kg (0,001%) will make it impossible for CCA manufacturers to comply with, and demonstrate compliance with the ban on CMRs.

As an example, the [Survey and investigation of migration of monomers in toy materials](#), indicates, for butadiene and acrylonitrile (used for the manufacturing of ABS) which are CMR1, that the residual levels are greater than 10 mg/kg whereas this study demonstrates that there is no hazard via migration : so a LOR (Limit Of Regulation) of 10 mg/kg means no more ABS in CCAs and this without improving the child safety. Moreover, it will force the manufacturer to use other materials that can be less strong, which means less durability and therefore less mechanical safety for children as well.

Subject to the childcare articles remain in conformity with the general safety requirement (no risk of adverse effects on human health due to exposure to the chemical substances or mixtures of which the Childcare articles are composed or which they contain), the non-intended presence of a CMR substances that stems from impurities of natural or synthetic ingredients, or from the manufacturing process and that is technically unavoidable in good manufacturing practice, is not permitted in this draft regulation.

- In addition, many chemicals found in recycled materials are at an amount higher than this generic limit of 10 ppm. Beyond the fact that it will ban many materials, this means as well that this regulation will have a significant impact on the recycling industry and on brands' sustainability strategies.

- Finally, according to the COM mandate, this restriction was envisaged to propose a generic (content) limit in homogeneous materials aligned with the generic or specific concentration limits of the CLP Regulation, unless it seems more appropriate to establish lower limits for all substances or only for specific cases. The ECHA report did not determine whether lower limits were necessary.

In the light of these elements, **ENPC and WBT ask for the CLP thresholds to be applied as regulatory limits**, instead of setting the single limit of 10 mg/kg.

2. SCOPE

The draft regulation indicates that the *“Childcare articles are products intended to facilitate the sitting, sleeping, relaxation, hygiene, feeding, sucking, transport or protection of children up to the age of 14”*.

We assume that the intention was to cover products up to 4 and not up to 14.

Finally, the notification message indicates that teethingers are childcare articles. We want to remind that teethingers are toys covered by the 2009/48/EC directive and consequently they cannot be classified as childcare articles.

3. TIMELINE

This regulation shall enter into force on the 15th day following its publication in the Official Gazette of the Republic of Slovenia with an absence of transition period for substances already classified will leave no time for operators to adapt.

Beyond the fact that it will be just impossible within the timeline to change the global manufacturing process, this further demonstrates that the notified measure does not comply with the principle of proportionality.

4. BREACHES EU LAW

ENPC respectfully submits that the Slovenian proposed regulation goes against the principles of free movement laid down both under REACH (articles 128 and 129).

The spirit of REACH is to have restrictions of substances harmonized at the level of the European Union and not by individual Member States.

Article 128 REACH provides that *“Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a mixture or in an article, falling within the scope of this Regulation”*.

The same article however provides that *“nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonize the requirements on manufacture, placing on the market or use.”*. The latter exception does however not apply in this specific case, since this regulation does harmonize manufacture, placing on the market and use of CMR substances.

Therefore, if Slovenia wishes to restrict the use of CMR in childcare articles, it should have opted for the safeguard procedure described in article 129, REACH : *“Where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a mixture or in an article, even if satisfying*

the requirements of this Regulation, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.”

By not activating the safeguard procedure, the Slovenian government has also failed to comply with the provisions of Article 129 (1) of the REACH Regulation.

Finally, Article 2.2 seems to exempt products manufactured in other EU Member States and Turkey, but in reality only does so if there is an ‘*equivalent level of protection*’ from CMR substances offered by *national legislation*. In reality, no case can be made that other Member States have such legislation. Furthermore, there is no option to show such ‘*equivalent level of protection*’ using EU-level legislation. This conflicts with the supremacy of EU Regulations like REACH.

5. ENPC and WBT CALL ON THE EC TO ISSUE A DETAILED OPINION REQUESTING SLOVENIA TO

- Postpone the adoption of the draft Regulation for 12 months, consistently with the Single Market safeguards and the ongoing preparation of the REACH restriction.
- Refrain from adopting any national legislation running against EU legislation and the Treaties.
- Provide justifications to deviate from the principle of free movement of goods in the internal market.
- Change their draft regulation to address the above-mentioned concerns, such as proportionality, compliance with EU rules, achievable and applicable limit values, longer implementation deadlines and clarify the scope of this measure, and not to wait one year after the entry into force of this regulation, to assess the justification, implementation and effects of the measures set out in this regulation.

About ENPC : The European Nursery Products Confederation (ENPC) is the trade association for childcare product manufacturers in Europe. It is composed of national associations representing small and medium-size enterprises (SMEs) and large companies playing a key role in the European single market. ENPC was established in May 2011 in Brussels with the aim of speaking with a united voice and guaranteeing an active participation of its members in European policy developments.

About WBT : World Association of Manufacturers of Bottles and Teats is a trade association of manufacturers of baby bottles and teats. Since its founding by several leading manufacturers in 1991 in Paris, the association has provided a platform for its members to come together with a single voice and exchange information about and give input into key policies that affect our industry. This involves working closely with other trade associations, and being actively involved in the development of European and International child care articles standards.