

FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT

**Advice on Enforceability of possible
elements of the foreseen restriction
regarding:**

“CMR substances in childcare articles”

Final

Version		Adoption
1.0	The Forum advice is prepared based on the draft version of the investigation report that was placed on public consultation between 23 August and 29 September 2023	30.10.2023

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Advice of the Forum on the enforceability of possible elements of a foreseen Annex XVII restriction as set in the ECHA investigation report.

1. Preface

According to Article 2(4) of the Rules of Procedure for the Forum, the Forum may agree to advise on other issues related to enforceability of the REACH, CLP, PIC, POPs or the Biocidal Products Regulations.

In November 2022, the European Commission requested ECHA to support the Commission by preparing an investigation report in view of a restriction proposal for carcinogenic, mutagenic and toxic for reproduction (CMRs) substances in childcare articles in the basis of Article 68(2) of REACH¹.

The Commission requested that Forum should be consulted on the draft investigation report and its opinion on the enforceability of the enforceability of the possible elements of the restriction should be reflected in the final report.

The matter was discussed at Forum-44 and the Forum agreed to deliver the advice on enforceability of the possible elements of the foreseen restriction for CMRs in childcare articles based on the description on the ECHA's draft investigation report.

To do so, the Forum mandated the WG to develop the Forum advice on the possible elements of the anticipated restriction for CMRs in childcare articles based on the description in the ECHA's draft investigation report.

¹https://echa.europa.eu/documents/10162/17233/mandate_cmrs_childcare_articles_investigation_en.pdf/ccdf4a10-dea1-68e3-5ce2-5c210e8cd74d?t=1671606418803

2. Possible elements for the foreseen restriction

Brief title: The assessment of the presence of CMR substances in childcare articles

Forum has been asked to examine an investigation report, prepared to support the Commission to prepare a restriction proposal in accordance with the procedure in REACH Article 68 (2). The investigation report does not contain a restriction proposal, but rather suggestion of elements that could be part of the restriction.

Element #1 Scope: A ban of all substances with CMR 1A or 1B harmonised classification(s) in childcare articles

Element #2 Definition of childcare articles: A definition, which is clear, and commonly agreed and including an age limit if appropriate

Element #3 Derogations: (i) second-hand childcare articles, (ii) substances that are present in parts of childcare articles which are inaccessible to children in any form and (iii) articles that are covered by the Medical Devices or Cosmetic Products Regulations

Element #4 Concentration limits: to allow the practical and harmonised implementation of a restriction

Element #5 Transition period: to allow the practical implementation of a restriction.

The idea is to group the elements as follows:

Scope: Element #1

Conditions: Element #4 and #5

Definition of childcare articles: Element #2

Derogations: Element #3

3. Forum’s advice on the enforceability of the possible elements of the foreseen restriction

3.1 Abstract

The Forum has been asked to examine an investigation report, prepared by ECHA to support the Commission to prepare a restriction proposal in accordance with the procedure in REACH Article 68 (2). The investigation report does not contain a restriction proposal, but rather a suggestion of elements that could be part of the restriction. The foreseen restriction described in the investigation report aims to ban all substances with harmonised CMR 1A or 1B classification in childcare articles, with a generic concentration limit for most substances and specific concentration limits for a limited list of substances.

The Forum underlines that some articles in the scope of the intended restriction could be considered as toys and would also fall in the scope of the Toy safety directive. Interlinks between both regulations should be clarified for the purpose of enforcement.

The Forum appreciates the inclusion of the testing methodology and analytical statistics in the investigation report. It is also important that the Commission continues to support the development of analytical methods as new substances are added to the restriction.

Some suggestions for rewording and clarification are made, and provided that the legislation is clearly worded and that all substances can be analysed this restriction would be enforceable.

3.2 Scope of the foreseen restriction

The foreseen restriction described in the investigation report aims to ban all substances with harmonised CMR 1A or 1B classification in childcare articles. This means all substances currently listed in Annex VI of the CLP Regulation (1272/2008), but also those substances added in the future.

For the foreseen restriction, the investigation report states:

- a definition of childcare articles that is based on entries 51 and 52 of REACH Annex XVII as well as CEN/TC 252.
- a default concentration limit of 10 mg/kg in homogenous material, but with a derogation for substances where different concentration limits are found to be more appropriate.
- derogations for: (i) second-hand childcare articles, (ii) substances that are present in parts of childcare articles which are inaccessible to children in any form and (iii) articles that are covered by the Medical Devices or Cosmetic Products Regulations.
- a 12 to 18 months transition period when a new substance is classified as CMR 1A or 1B and added to CLP Annex VI².

Issues for enforceability related to the foreseen scope

In Forum's opinion, the development of the definition of childcare articles compared to the definition in entries 51 and 52 is a good approach. Forum recognises that the definition of a childcare article in CEN/TC 252 includes the wording "...and safely ensure". However, the use of "and safely ensure" in the definition might indicate that a risk assessment should be performed for an article to be in scope of the restriction.

The Forum also agrees that an age limit in the restriction is necessary. However, if the age limit of 14 years will be adopted, several items usually used by adults will be included and it could be difficult for enforcers to distinguish articles which are intended for

² It is a transition period related to CLP process and therefore when a substance is classified as CMR 1A or 1B, the classification is official only after 12-18 months giving time to the industry to adapt as well to restriction.

teenagers. The Forum understands the intention to align the restriction with the Toy Safety Directive (TSD) but recommends the Commission to take into consideration that in the Biocidal Products Regulation (528/2012), the age limit for children is 12 years³. An update of table 1 with examples of items for older children would be helpful.

As for the derogation “substances that are present in parts of childcare articles which are inaccessible to children in any form”, Forum has some concerns. To avoid unclarity, a better definition of this exemption is needed. It can be compared to the difficulties inspectors face with the various interpretations of the terms "skin contact" (entry 47), "prolonged skin contact" (entry 50), "direct and prolonged skin contact" (entry 27) etc. These terms often lead to a difference of opinion with the inspected companies so it is preferable that they can be avoided or clarified. In the TSD, the exemption for CMR in annex II, part III, paragraph 4b is currently expressed as follows: “these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2)”.

For products covered by two regulations (called “borderline products”), clarity should be provided to determine if both regulations are applicable or if one takes precedence over the other. For instance, a clear statement of the interlinks between the TSD and the proposed restriction is needed. Some of the examples in table 1 could fall under the definition of toy (baby play rug, activity centre, baby rattles). It is unclear which legislation would take precedence, especially if TSD becomes a regulation. Forum underlines that some guidance has been already published by the Commission on some specific categories of toys⁴, where a dual use occur (toy/non-toy). Additionally, several of the CMR substances that would be included in the scope of this restriction are already restricted under other entries of Annex XVII. For those situations all restrictions are applicable and all must be followed, i.e., the most stringent.

A clear definition of how homogenous material should be interpreted in this restriction would be helpful. A suggestion could be to use the definition in the RoHS Directive (2011/65/EC): one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different

³ The BPR defines children as young people under 12 years [Recommendation no.14 of the BPC Ad Hoc Working Group on Human Exposure “Default human factor values for use in exposure assessments for biocidal products”]

⁴ For example, the Commission has published a guidance on soother holders (Guidance document No 19 on the application of Directive 2009/48/EC on the safety of toys - Soother holders).

materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes, or differently.

3.3 Sampling, sample preparation and analysis of substances

The Forum acknowledges the efforts done in the investigation report to investigate the available analytical methods for CMR-substance likely to be found in childcare articles. The proposed analytical methods in the investigation report seem to be able to be carried out with conventional equipment.

Sampling of childcare articles is not foreseen to cause any problems. As for the sample preparation, some concerns are raised about multilayer materials and how to interpret homogenous materials. For some substances and materials, it seems like the intention of the investigation report is to have alternative limit values. For example, emission of formaldehyde from wood, migration and/or extraction of metals. Emission of formaldehyde would require specific expertise when it comes to sampling preparation.

The Forum supports the general idea of this investigation report to have same generic limit values for most substances in the restriction. This would facilitate enforcement. In table 7 of the investigation report deviating concentration limits are listed. Forum advises the Commission to make it clear in the legal text which substances are concerned by these deviating limit values as well as specify if the limit values only apply to certain materials (as seems to be the case with Cr VI for instance). The same clarity is needed for any grouping of substances (phthalates for example). In general, for enforcement purposes, a concentration limit is preferred over migration limits. By experience, when a concentration limit and migration limit exist side by side, enforcement will focus on concentration limits and leave the companies to show compliance via migration tests. For clarity, this responsibility of companies to prove compliance via migration tests when concentration limits are exceeded should be reflected in the restriction.

There are also some concerns about the substances that will be included in the restriction in the future (i.e., when Annex VI of the CLP regulation is updated):

- It is unclear how the legislators will handle substances with Specific Concentration Limits (SCL) for substances added in the future. An alternative approach to setting limit values in the legal text could be to use the same method as when setting the

limit values for elicitation in CLP, i.e., the limit value of the restriction could be one tenth of the SCL or GCL (generic concentration limit).

- The intention seems to group certain substances (phthalates for instance). It is unclear how the legislators will amend these groups in the restriction if a group needs to be updated.

A restriction of CMR 1A and 1B would cover a vast number of substances and a large effort has been put into summarising available analytical methods for several prioritised substances. To be an enforceable restriction, it is important that analytical methods where LOQ is lower than the limit values are available. It is important that the Commission continues to support the development of analytical methods as new substances are added to the restriction.

The specific concentration limits suggested in the investigation report have been proposed based on LOQ. For enforcement it is important that this is also done in the future.

3.4 Wording of the restriction/elements

Recommendations on the wording to improve the enforceability.

As the intention of the investigation report seems to be to restrict the CMR substances in each homogenous material, a definition of “each homogenous material” is needed for harmonised enforcement.

To avoid unclarity and to align the restriction with the TSD it should be mentioned explicitly in the exemption that inhalation is to be taken into account, as it is done in TSD, i. e. “Parts of the childcare article that are inaccessible to children in any form, including by inhalation”.

To align with current entry 51, Forum suggests removing the phrase “safely ensure” from the definition of childcare articles: “childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene such as bathing, changing and general body care, feeding, sucking, sleeping, transportation and protection of children.”

The Forum suggests removing the example “wipes” from Element #3d, because substances in wipes for baby care are falling under the scope of the Cosmetic product regulation. Reference to the Cosmetic products regulation is sufficient.

The Forum suggests using the following wording if an exemption for second-hand articles is to be included in the restriction: "Shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before xxx".

3.5 Practicability/Enforceability

Enforceability:

Provided that the legislation is clearly worded and that all substances can be analysed this restriction would be enforceable. Since several of these CMR substances are restricted in other entries of Annex XVII, it also needs to be clarified which limit values will apply.

The Forum encourages the Commission to find coherence between the numerous existing Annex XVII entries and this restriction.

Practicability:

The testing methodology and analytical statistics described in the investigation report is a useful tool to improve the practicability of a restriction covering more than 1000 substances.

Enforcement costs

There is no indication of the enforcement costs in the investigation report.⁵ However, even with a risk-based approach and using the information in the investigation report (for instance the testing strategy suggested in the draft investigation report) it can be expected that the enforcement costs will be high.

Enforcement costs depends on the number of tested substances. For one complex article several substances in several types of materials need to be tested.

As a general comment, Forum considers that with more complex and broad restrictions like this one, the need for central European analytical laboratories is increasing, where samples collected from different Member States can be sent there for analysis. This would be a more feasible economic option to achieve on a long-term basis a harmonised approach on this and other restrictions. EU enforcement campaigns, through market surveillance

⁵ Article 68.2 does not require a cost or impact assessment.

mechanisms including Forum projects and CASP (Coordinated activities on the safety of products, run by the Commission) projects are also useful, but time limited.

3.6 *Miscellaneous*

It is not clear from the report and the indicative list of childcare articles if water bottles for elementary school children and teenagers are included or not.

Throughout the draft investigation report, the terms “inaccessible” and “enclosed” are both used, which could lead to confusion about the derogation “substances that are present in parts of childcare articles which are inaccessible to children in any form”.

Currently, in the TSD, the exemption for CMR in annex II, part III, paragraph 4b is expressed as follows: “these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2)”. The suggestion of the Forum is to align the exemption “substances that are present in parts of childcare articles which are inaccessible to children in any form” with this paragraph in the TSD or a possible new toys regulation. However, in the draft of the new Toy Safety regulation it seems like this exemption has been removed.