INVESTIGATION REPORT

to support the Commission on the preparation of a restriction proposal for the use and presence of CMR 1A or 1B substances in childcare articles based on REACH Article 68(2)

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LIST OF ACRONYMS AND ABBREVIATIONS

Acronym/ abbreviation	Meaning
CCA	Childcare article
CL	Concentration Limit
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic, toxic for Reproduction
Forum	ECHA Forum for Exchange of Information on Enforcement
GCL	Generic Concentration Limit aka 'Generic Cut-off value' according to the CLP Regulation No 1272/2008. GCL indicates when the presence of a substance needs to be taken into account for the purpose of classification of a mixture containing that hazardous substance. GCL are given in Annex I to the CLP Regulation
LOD	Limit Of Detection: the smallest concentration of a substance that can be reliably detected by an analytical procedure
LOQ	Limit Of Quantification: the smallest concentration of a substance that can be reliably quantified by an analytical procedure
PAH	Polycyclic aromatic hydrocarbons
PFAS	Per- and polyfluoroalkyl substances
RAC	ECHA Committee for Risk Assessment
RSL	Restricted Substances List: Industry initiatives to list chemicals that are restricted or phased-out in consumer products/articles. The lists usually include substances with existing regulatory requirements, but not only. RSLs may be developed by industry groups, brands, or retailers, but also ecolabels, and can serve multiple purposes (e.g. compliance with various substance restricting laws in the EU and worldwide, enhancement of brand image, management of current and future chemical concerns throughout the supply chain and product life-cycle and avoid the costs of recalls, etc.).
SEAC	ECHA Committee for Socio-economic Analysis
SCL	Specific Concentration Limit according to the CLP Regulation No 1272/2008. SCL are given in Annex VI to the CLP Regulation where different from the GCL.

ABOUT THIS REPORT

REACH Article 68(2) provides a procedure, by which the Commission may propose to restrict substances that meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B on their own, in mixtures or in articles that could be used by consumers. The procedure differs from the standard restriction procedure prescribed in REACH Articles 69 to 73.

Although the Article 68(2) procedure does not foresee the development of an Annex XV dossier, nor a formal involvement of ECHA or its scientific committees, on 29 November 2022, the Commission sent a request to ECHA seeking support in the preparation of the Commission's restriction proposal. In that request, the Commission asks ECHA to prepare an investigation report and to collect available information on carcinogenic, mutagenic and toxic for reproduction substances in childcare articles.

According to the Commission request, the ECHA Forum for Exchange of Information on Enforcement (Forum) has been consulted on the draft report on the 28 August 2023 and its views on the enforceability of the possible elements of the foreseen restriction has been reflected in the final report.

The interested third parties were also consulted on the draft report from 28 August to 29 September 2023, and the comments received have been reflected as well in the final report.

The following seven deliverables were specified in the Commission's request to be part of the ECHA report:

1. Deliverable #1: A list of CMR 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) (see section 2.2)
2. Deliverable #2: Where available, information on tonnage, concentration ranges, frequency of finding in articles to be used as estimation of likelihood of exposure for further prioritisation (see sections 3.1 and 3.2)
3. Deliverable #3: Where available, information on release/exposure potential (see sections 3.3 and 4)
4. Deliverable #4: An inventory of existing Generic Concentration Limits (GCL)/Specific Concentration Limits (SCL) per substance or per groups of substances and further existing regulatory measures (see and sections 5.1 and 5.2)
5. Deliverable #5: Identification if deviation from GCL/SCL (content) limits is needed (see sections 5.2)
6. Deliverable #6: Summary of information on availability of analytical methods (see section 6)
7. Deliverable #7: An overview and summary of the stakeholder consultations (see section 7)

SUMMARY OF THE ANALYSIS AND MAIN CONCLUSIONS

The purpose of the current investigation and analysis is to support the Commission in the preparation of a restriction to protect children from exposure to CMR 1A or 1B substances in childcare articles.

The information included in this report shows that CMR 1A or 1B substances may be present in childcare articles (see section 2) and may lead to children exposure (see section 3). The likelihood of exposure does not take the form of a quantitative assessment but instead is presented through available evidence that children may be exposed to the substances in childcare articles during normal and reasonably foreseeable conditions of use.

Children may be particularly vulnerable to chemicals, and for genotoxic carcinogens no safe threshold can usually be established. CMR 1A or 1B substances are already banned in toys (Toys Safety Directive (2009)). In addition, many ecolabels, industry and distributors in the childcare sector have established voluntary limits for CMR 1A or 1B substances in their Restricted Substances Lists (RSLs) (see section 5).

This report was developed based on the assumption that a future restriction entry would consider the following elements:

> **Element #1.** Scope: A ban of all substances with CMR 1A or 1B harmonised classification(s) in childcare articles (see section 2.1).

Referring to all substances listed in Annex VI to the Classification, Labelling and Packaging (CLP) Regulation (EU, 2008) would allow a ban of substances currently classified as CMR 1A or 1B and added to the CLP Annex VI with such classification in future. This would also allow a faster regulation of substances with a harmonised classification as CMR 1A or 1B and contributes to avoiding regrettable substitution in a more efficient way than an approach based on a narrower closed list of substances.

Substances classified as CMR category 2 and substances self-classified as CMR in CLP notifications are not in the scope of this investigation report.

The ban would be applicable for CMR 1A or 1B substances (harmonised under Annex VI to CLP) in homogeneous materials of childcare articles. Entry 71 and 51 of REACH Annex XVII also establish limits in homogeneous materials, however, no definition of homogenous materials is covered under REACH or in these restriction entries. Therefore, ECHA proposes to consider a definition in line with the RoHS Directive (2011):

> *A homogeneous material is a material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes*.

> **Element #2.** Definition of childcare articles: A definition, which is clear, and commonly agreed and including an age limit if appropriate (see section 1.1)

The report considers the following definition of childcare articles, based on entry 51 and 52 of REACH Annex XVII and CEN/TC 252[1]:

> *Any product intended to facilitate seating, sleep, relaxation, hygiene such as bathing, changing and general body care, feeding, sucking, transportation and protection of children*.

No guidance or definition on age limit for children is available under REACH. However, when preparing this investigation report, it was also considered whether an age range may be specified in the definition of childcare articles (see section 1.1). On the one hand, the Toys Safety Directive (2009) applies an age limit for children of 14 years. On the other hand, the age limit for children recommended to be used for exposure assessments for biocidal products (ECHA, 2017) is below 12 years. Considering the similarity on the articles covered by the Toys Safety Directive (2009), aligning the age definition with the age as defined in this directive might be beneficial.

This report provides also an indicative list of examples of childcare articles which fall under the considered definition of a childcare article and which would therefore be in the scope of the restriction (see section 1.2), as well as some statistics regarding the occurrence of CMRs 1A or 1B substances in childcare articles (see section 2.2). Such an indicative list is aimed to help the authorities with the enforcement of the restriction.

The proposed definition for childcare articles is broad and may cover articles or parts of articles that are already regulated under other legislations (see section 1.3). Childcare articles or parts of it that are explicitly claimed to be covered under the Medical Devices Regulation (2017) are considered to be out of scope (see Element #3 below), because CMR 1A or 1B substances are already regulated for those (parts of) articles. Additionally, some childcare articles might also be covered by the Food Contact Material Regulation (2004), or Biocidal Products Regulation (EU, 2012) with sufficient protective conditions for children (see section 1.3). However, in other regulations (e.g. RoHS Directive (2011), see section 1.3) that may also concern childcare articles, only some CMR 1A or 1B substances are regulated and the defined limits are not considered sufficiently protective for children. Therefore, ECHA considers that childcare articles that would fall under these other regulations should meet the requirements with regard to the content of CMR 1A or 1B substances for childcare articles as considered in this report. Nevertheless, to define the concentration limits indicated in this report, ECHA considered the limits applied in other regulations (particularly for REACH restrictions) and those limits were proposed if considered sufficiently protective for children (see Figure 4).

> **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 including inhalation and (iii) articles that are covered by the Medical Devices Regulation (2017)(see section 1.3).

Similarly to REACH Annex XVII entries 47 and 72, it is considered to exclude second-hand childcare articles from the scope of a potential restriction. Indeed, if not explicitly excluded, once placed on the market (either with or without exchange of money) second-hand childcare articles would fall within the scope of the restriction. Though old childcare articles

[1] Child care articles technical committee of the European Committee for Standardization

may contain high level of CMR 1A or 1B substances such as phthalates (see section 3.2), enforcing second-hand market would be extremely difficult.

Similarly to the Toys Safety Directive (2009), it is also considered to exclude explicitly from the scope those substances in parts of childcare articles that are inaccessible to children in any form, including inhalation. Examples of inaccessible parts could be enclosed batteries (e.g. lead or lithium substances, or the metal bars of anchoring systems of children's car seats in the back of the seat).

For clarity, and to prevent double regulation of the same CMR substances in the same articles, it is also considered to explicitly exclude articles or part of articles covered by the Medical Devices Regulation (2017) from a future restriction on CMRs 1A or 1B in childcare articles (see section 1.3).

The Medical Devices Regulation (2017) specifies in Article 1(3.) that "*Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.*" Therefore, the non-medical part of a medical device (e.g. soother part of a soother with thermometer) would also need to fulfil the requirements for a childcare article.

Additionally, some childcare articles might also be covered by the Food Contact Material Regulation (2004), or Biocidal Products Regulation (EU, 2012) with sufficient protective conditions for children (see section 1.3). Therefore, the Commission should also consider if a derogation to this type of articles is appropriate.

> **Element #4.** Concentration limits: to allow the practical and harmonised implementation of a restriction (see sections 5.2 and 6).

As mentioned earlier, children may be particularly vulnerable to chemicals and for genotoxic carcinogens, no safe threshold can usually be established. Therefore, the presence of CMR 1A or 1B substances in childcare articles should be banned.

However, (i) to allow for non-intended presence of a small amount of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging (see section 2.2), which is technically unavoidable even in good manufacturing practices, and (ii) to allow a practical, efficient and harmonised enforcement of the restriction within Europe, a content concentration limit that can be determined by routine state of the art analytical methods needs to be defined for individual substances or groups of substances.

The GCLs defined in the CLP Regulation (EU, 2008) for all CMR 1A or 1B substances are either 1 000 (for carcinogenic and mutagenic substances) or 3 000 mg/kg (for reproductive toxic substances), SCLs are usually lower. Considering that CMR 1A or 1B substances also cover genotoxic carcinogens for which usually no safe threshold can be established, the GCL/SCLs may not be protective for children which are in the scope of this investigation. The GCLs/SCLs are used for classification purposes and are usually not based on substance-specific risk assessments. Moreover, GCLs/SCLs are defined for the classification of substances and mixtures.

Therefore, ECHA considers the need to deviate from the concentration limits defined in the CLP Regulation and to derive concentration limits in homogeneous materials of childcare articles linked to the Limit Of Quantification (LOQ) of commonly available sensitive and accurate analytical methods, preferably standard analytical methods.

It is expected that the current development of analytical methods allows for the quantification of almost any substance with an LOQ of at least 10 mg/kg (see section 5.2). Therefore, **ECHA considers a default concentration limit of 10 mg/kg in homogeneous materials (i.e. 0.001 % w/w) with derogation for substances for which different concentration limits were found to be more appropriate** (e.g. available regulatory limits (such as REACH restrictions) or available standard methods with lower or higher LOQ or concentration limits used by industry that justify higher or lower limits). Concentration limits deviating from 10 mg/kg are listed in section 5.2, Table 3. In this section, specific justifications on the proposed concentration limits are also provided. The general approach to define the concentration limits is presented in Figure 4. This approach can also be used to define concentration limits in childcare articles for CMR 1A or 1B substances which will be added to the CLP Annex VI in future.

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

The transitional period will be established during the decision-making process also considering the information provided in this investigation report.

ECHA notes that some companies already adhere to voluntary schemes that establish relatively strict concentration limits or bans for CMR 1A or 1B substances in materials used in childcare articles. Therefore, the implementation of the restriction will be in line with the common practice and procedures of several manufacturers of materials used for childcare articles.

In addition, ECHA notes that a 12-to-18-month transition period is de facto already granted for the new substances added to Annex VI of CLP as CMR 1A or 1B. Indeed, when new harmonised classification and labelling of hazardous substances are introduced through an 'Adaptation to Technical Progress (ATP)', the new/updated harmonised classification and labelling enter into force 20 days after publication in the official journal and apply usually 12 to 18 months from the publication of the ATP in the official journal.

Moreover, a specific question on the transition period needed for industry to adapt to the restriction was included in the consultation on the draft report, and only one comment on the transition period needed for a specific article where biocidal substances are used, was provided (see section 7).

Based on the above, for substances already listed in Annex VI of CLP, no transition period might be necessary as industry is, in most cases, already taking measures to ensure that those substances are not present in childcare articles. For substances added in the future to Annex VI of CLP, a transition period linked to the 12-to-18-month of entering into force of the classification is automatically granted and therefore, the need for a transition period might also not be necessary.

Elements of a potential draft restriction entry:

REACH Article 68(2) provides a procedure that differs from the standard restriction procedure prescribed in REACH Articles 69 to 73, it does not require the preparation of an Annex XV report. Therefore, the Commission's request (EU Commission, 2022a) did not include the drafting of a restriction entry as a deliverable, however to facilitate the Forum consultation, the potential elements of a restriction entry on CMRs in childcare articles (based on the elements described above) are indicated below. The final legal proposal, its

scope and wording (i.e. the REACH Annex XVII entry) will be proposed by the European Commission during the decision-making phase.

Scope: **Element #1**

Substances which are classified as carcinogen, germ cell mutagen or reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Conditions: **Element #4 and Element #5**

Substances under scope, shall not be placed on the market in childcare articles in a concentration equal or greater than 0.001 % by weight (10 mg/kg) of each homogeneous material.

By way of derogation, for substances listed in section 5.2, the relevant concentration limit shall be the one indicated in Table 3.

Definition of childcare articles and homogeneous materials: Element #1 and Element #2

'Childcare article' shall mean any product intended to facilitate seating, sleep, relaxation, hygiene such as bathing, changing and general body care, feeding, sucking, transportation and protection of children [under xx years of age].

'Homogeneous material' shall mean a material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

Derogations: Element #3

The restriction shall not apply to:

(a) Second-hand childcare articles

(b) Parts of the childcare article that are inaccessible to children in any form, including inhalation

(c) Parts of childcare article with a medical purpose that are regulated under the Medical Devices Regulation (2017)

Overall, based on the content of this report, and the views expressed by Forum[2], it is assumed that a restriction on CMR 1A or 1B in childcare articles as described above would be enforceable as the substances and articles in scope are clearly defined (including exemptions) using definitions commonly used in REACH Annex XVII. In addition, the considered concentration limits seem to be practicable and enforceable and, as indicated in the Forum's views, the listed analytical methods seem to be possible to be carried out with conventional equipment.

In section 6.2 of the report, a testing strategy to support the enforcement of a future restriction is described. In the Forum's views the testing strategy was recognised as useful tool to improve the practicability of a restriction covering such broad number of substances. Compliance of childcare articles with the foreseen restriction can be verified via paper or document-based enforcement which cover e.g. inventory records of childcare article producers such as purchased goods, source of supply, material composition, safety

[2] The views of the Forum were provided on the draft investigation report. ECHA took on board some of the Forum recommendations in the final version of the investigation report.

data sheets content, technical documentation. Moreover, the testing strategy may facilitate the targeting of analytical tests and therefore reduce the overall enforcement costs.

To conclude, based on the content of this report, and the views of the Forum , setting clear definitions, exemptions, and concentration limits for all CMR 1A or 1B substances (either 10 mg/kg or as defined in Table 3) will allow a practical, efficient and harmonised enforcement of the restriction within the EU.

In total 233 different stakeholders such as Member State Competent Authorities, NGOs, testing laboratories/organisations (ecolabels, public and private), associations (childcare product associations, trade associations, chemistry associations, consumer protection associations) and producers of childcare articles and toys were informed about the development of the investigation report and about the two calls for evidence and the draft report consultation. Relevant information about the presence of CMRs in childcare articles, suitable analytical methods and existing concentration limits was provided by stakeholders, not only during the calls for evidence and draft report consultation, but also by email and during individual meetings. In general, there was support from stakeholders to the report and no major concerns were raised regarding the implementation of the foreseen restriction.

REPORT

1. Scope of the investigation

1.1. Definition of childcare articles

Definition (see Element #2)

Childcare articles are a broad category of articles designated to ensure safety and well-being of children. The definition of childcare article for this report is described in the Commission's request:

1. intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children, as defined in entry 51 and 52 of Annex XVII of REACH.

2. designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, transportation and protection of young children, as defined within the remit of CEN/TC 252.

Stakeholders were consulted on the following wording of the definition during the first call for evidence, merging the REACH and CEN definitions*: "childcare article shall mean any product intended to facilitate (seating)[3], sleep, relaxation, hygiene such as bathing, changing and general body care, feeding, sucking, sleeping, transportation and protection of children*."

To be noted that only articles that are produced with the intention to be used by children are covered by this definition ("any product intended to"). Therefore, articles produced for adults but also used by children (e.g. mattress, water bottles, plates) are not covered by the definition.

No major proposals for amendment were received during the two calls for evidence or the draft report consultation. Therefore, and also considering that the REACH restrictions of Annex XVII entry 51 and 52 are already implemented and the CEN/TC standards are applied in the EU, it can be concluded that the definition is suitable and understandable by the stakeholders for the purpose of an intended restriction of CMR 1A or 1B substances in childcare articles.

In several REACH restrictions the scope is limited to substances in materials that are intended to come into contact with skin (e.g. Annex XVII entries 20, 43, 47, 50) or that can be placed in the mouth (entries 52, 63). ECHA notes that for childcare articles it would be more appropriate to broaden the scope to substances in all materials of a childcare article accessible to children in any form (including inhalation and migration) and to derogate instances where substances are in parts of childcare articles that are inaccessible to children e.g. by enclosure (see section 1.3). This would ensure that children would also be protected in case childcare articles are used in a non-intended or foreseeable way and in case those substances evaporate or migrate from materials that are not in direct contact with the skin or the mouth (see section 3.3). This approach would be in line with the current Toys Safety Directive (2009), however ECHA notes that in the proposal for the review of this directive, the derogation to inaccessible chemicals to children is narrowed

[3] 'seating' added later following a comment during the draft report consultation

and refers only to electric and electronic parts of childcare articles (EU Commission, 2023a).

ECHA notes that there might be overlaps and borderline cases between childcare article and toys, electric and electronic devices (e.g. baby phones), cosmetic products (e.g. baby wipes) or medical devices (e.g. soother with thermometer). Childcare articles that are explicitly claimed to be covered under the Medical Device Regulation are considered to be out of scope, because CMR 1A or 1B substances are already regulated. Additionally, some childcare articles might also be already covered by the Food Contact Material Regulation (2004), and Biocidal Products Regulation (EU, 2012) with sufficient children protection. However, in other legislations that may also concern childcare articles, only some CMR 1A or 1B substances are regulated. For example, electronic devices (e.g. baby dish steriliser, baby monitor) are regulated under the RoHS Directive (2011) and only a few CMR 1A or 1B substances (some metals and some phthalates) are restricted to 0.1 % (1 000 mg/kg). ECHA considers that childcare articles that would fall under other legislations (other than the Medical Device Regulation) should meet the requirements with regard to the content of CMR 1A or 1B substances for childcare articles as considered in this report.

For the purpose of this report, the packaging of childcare articles is not considered to fall under the definition of a childcare article.

Additionally, during the draft report consultation, EDANA (International association of nonwovens and related industries) commented that diapers might need to be exempted from a foreseen restriction on childcare articles. However, in the recent opinion on the proposed restriction of substances in single-use baby diapers (ECHA, 2021a), RAC concluded that substances in the scope of the restriction proposal might have the potential to induce adverse effects in children if present in diapers and their levels should therefore be as low as possible. RAC noted also that until the uncertainties/shortcomings concerning the restriction proposal on single-use baby diapers are resolved, the voluntary action by industry (the EDANA Stewardship Programme for Absorbent Hygiene Product (EDANA)) could further reduce the concentration of the substances in the scope of the proposed restriction (and also of other substances like phthalates, organotins, metals), in all single-use diapers placed on the European market. However, RAC did not accept that voluntary action is an effective risk management option should the risk from specific substances be demonstrated.

Age of the children

REACH Annex XVII entry 51 does not specify children's age range to whom the childcare articles are intended, while CEN TC 252 refers to children up to four years old. The EU Ecolabel for textile products refers to 'babies and children under three years old', the OEKO-TEX® (2023) Standard 100 to 'babies and children up to the age of 36 months'. Article 2 of Directive 2006/141/EC on infant formulae and follow-on formulae defines 'infants' as children under the age of 12 months and 'young children' as children aged between one and three years. For children, an age below 12 years is recommended to be used for exposure assessments for biocidal products (ECHA, 2017). However, the Toys Safety Directive (2009) covers products which are designed or intended, whether or not exclusively, for use in play by children under 14 years of age

Setting the age to cover articles intended to be used for babies and children up to the age of 36 months would cover most childcare articles such as diapers, prams, baby bottles or soothers. However, several articles, such as car seats, eating accessories, mattresses or beds are also used by older children. Therefore, aligning the age definition for a restriction of CMR 1A or 1B substances in childcare articles with the age as defined in the Toys Safety Directive (2009) i.e. 14 years, not only aligns the two regulations, but also ensures that

not only childcare articles for babies and small children are covered, but also for older children.

1.2. Categorisation of childcare articles

Table 1 provides an overview of the different categories and subcategories of childcare articles that may fall under the scope of the restriction proposal. This categorisation is based on the categorisation presented in the COM study (EU Commission, 2019) which follows the main categories as specified in standard CEN TC 252 on 'child use and care articles' but amends it with sub-categories and examples on specific articles/functions.

Table 1: Example of types of childcare articles that are in the scope of this investigation, sorted to main and sub-categories

Main category	Subcategory	Articles/function (examples)
1 Seating and body care	1-1 Toilet related articles	Baby changing mats/pads, baby changing tables, baby changing table mattresses, baby potties/ training seats, infant toilet seats
	1-2 Diaper and nappy related articles	Baby single-use diapers/nappies, baby reusable diapers/nappies, baby diaper accessories, baby wipes[4]
	1-3 Seating specific for eating and related articles	Highchairs, highchair (back) pads, (feeding) booster seats, table mounted chairs, hook on chairs
	1-4 Other seating related articles	Baby bouncing cradles/rocker seats (non-powered), baby bouncing cradles/rocker seats (powered), baby swings, infant bouncer seats, infant and toddler rockers, child safety seat, safety seat, children floor seats, children folding chairs
	1-5 Bathing and other body care related articles	Baby bath, baby bath safety products, baby bath chairs, baby bath cradles, infant bath slings, bath seats, bathtubs, bathers, bathtub seats, nail cutters, hairbrushes, bath thermometers, toothbrush, nail files
2 Sleeping, relaxation and lying down	2-1 Bed and mattress related articles	Baby carrycots/baskets/cradles, baby cot mattresses, baby cots/cot beds, baby/toddler beds, baby nests, carriers, crib mattress (with cover), crib mattress (without cover), carrycot mattresses, baby cribs, crib/co-sleepers, bedside sleepers, baby bassinets, baby mattresses, crib bumper, portable crib pads, full size cribs, non-full-size cribs, toddler beds, pee protectors, junior size mattresses, travel/folding cots
	2-2 Car seats	car/booster seats, car safety seats
3 Wheeled transportation	3-1 Pram, pushchair, buggy	Buggies, prams, pushchairs, strollers, carriages

[4] The impregnation fluid is covered by the Cosmetic Products Regulation (2009)

Main category	Subcategory	Articles/function (examples)
	3-2 Pram or pushchair accessories	Buggy/pram/pushchair/stroller accessories (such as rain cover, umbrella)
4 Early learning and protection	4-1 Transport/travel articles	Baby carriers, baby slings, frame infant carriers, handheld infant carriers, soft infant carriers
	4-2 Playing/walking articles	Baby playpens, baby play dens, baby walkers, crawling blankets, baby play rugs, stationary activity centers
	4-3 Child safety articles	Baby safety protection (non-powered), safety gates, baby monitors[5], cabinet safety locks and latches, expandable gates and enclosures, play yards, portable bed rails
	4-4 Miscellaneous furniture	Children and nursery furniture
5 Feeding, drinking, sucking and similar function	5-1 Bib	Bibs
	5-2 Feeding and drinking related articles[6]	Baby bottles, baby feeding products, baby and children's tableware/dishes (cutlery, plate, cup), sippy cups, feeding teats, food feeders, baby dishes sterilizer children water bottles
	5-3 Sucking related articles	Pacifiers/soothers/dummies/comforters, soother with thermometer[7], soother holders/chains[8], teethers, teething rings, baby rattles and teethers, soft and hard biters[9]
6 Other	6-1 Sleeping insulation article	Baby blankets, baby,children sleeping bags
	6-2 Sleeping support article	Crib wedges, mattress protector (such as covers, pads, pee protector), linens, cot bumpers, baby wedges, ergonomic mattresses, slopes, bed reducers, headrests

The following stakeholders provided comments on childcare article definition and categorisation: European Nursery Products Confederation (ENPC), World Association of Manufacturers of Bottles and Teats (WBT), EDANA, Vopak Terminal Europoort, Swedish Consumers' Association, National Institute for Public Health and the Environment of the Netherlands (RIVM), German Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal

[5] May be covered by the RoHS Directive (2011)

[6] Covered by Food Contact Material Regulation (2004), (EC) No 1935/2004

[7] Soother with thermometer may be declared as a medical device

[8] Soother holder chains without a playing function are childcare articles; soother holder chains with a playing function are covered by the Toys Safety Regulation (2009)

[9] Teethers, teething rings, baby rattles and teethers, soft and hard biters may be considered to be covered by the Toys Safety Directive (2009)

Institute for Occupational Safety and Health-Germany (BAUA)), French Agency for Food, Environmental and Occupational Health & Safety (ANSES), GROUP'HYGIENE, Chemservice, Taxation and Customs Union, Fédération française des industries Jouet Puériculture, Toys Industries of Europe and European Consumer Organisation (BEUC).

Based on the feedback received in the first call for evidence and during the draft report consultation, changes in the names of some sub-categories were made, and further articles/function types of childcare articles were added. The comments from stakeholders on the categorisation of childcare articles were consistent with keeping the main framework of the categorisation, which is in line with CEN TC 252 standards.

Some stakeholders questioned the classification of certain articles as childcare articles, e.g. articles used by caretakers that are kept out of reach of children (e.g. baby monitors, dish sterilisers). Although, these articles are not intended to be used by children, they fall under the definition of childcare articles and can get in contact with children (baby monitor) or get in contact with articles that are used by children (dishes sterilised in the baby dish sterilisers). Therefore, the articles were kept in the childcare articles list.

Additionally, several comments were received regarding childcare articles that may fall under other legislations. Those childcare articles are indicated in Table 1 with a foot note. Although some childcare articles might fall under other legislations, the conditions set in other legislations except the Medical Devices Regulation (2017) are not sufficient to provide the level of children protection aimed to be achieved by the restriction on CMRs in childcare articles (e.g. CMRs not regulated or concentration limits not protective for children). Therefore, the foreseen restriction should take precedence over the other regulations.

1.3. Other legislations addressing CMR substances in childcare articles

Several REACH Annex XVII entries (5, 20, 23, 43, 47, 50, 51, 63, 72) are restricting certain CMR 1A or 1B substance in consumer articles. The concentration limits listed in those restriction entries are relevant for the current investigation report, especially in case the limits are in the range of the LOQ of standard analytical methods to ensure the absence of a substance in an article.

Also, several voluntary initiatives such as ecolabels and industry initiatives already request that CMR 1A or 1B substances are not present in childcare articles (see sections 5).

Additionally, ECHA notes the following impacts of the legislations on the preparation of the investigation report:

- The Toys Safety Directive (2009), 2009/48/EC (TSD) bans all CMR 1A, 1B or 2 substances in toys (except if the substances are inaccessible in any form). It applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age. For example, soother holders with play function are considered to fall under the definition of a toy, whereas soother holders without a play function would not. Teethers, and soft and hard biters are also considered as toys. However, for teethers without a toy function the definition of a childcare article seems to be applicable. In the Toys Safety Directive specific concentration limits are given, which are considered in the current report. The age limit for children specified in the Toys Safety Directive (under 14 years of age) is also important to be noted.
- Commission Directive (EU) 2019/1929 of 19 November 2019 amending Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council

for the purpose of adopting specific limit values for chemicals used in certain toys, provides specific limit values for formaldehyde.

- The Medical Devices Regulation (2017), (EU) 2017/745 (MDR), covers articles intended generally for a medical purpose. They can be used in prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the intended action of a medical device is not achieved by pharmacological, immunological or metabolic means. Baby soothers with thermometer, teethers or teething rings may be placed on the market in some countries as a medical device. Article 1.3. of this regulation specifies that *"devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements for both purposes*". According to the specifications set in Annex I to the Medical Devices Regulation regarding the general safety and performance requirement of medical devices, design and manufactures of medical devices *"shall only contain substances which are CMR 1A or 1B in concentration above 0.1% where justified"*.
- The Biocidal Products Regulation No 528/2012 (EU, 2012), regulates biocidal products which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. The active substance can be in some cases a CMR substance, that has been approved for a specific use by the authorisation process of the regulation. The childcare articles that are considered products in the scope of the regulation and for which the authorisation process is applicable and a risk assessment for children is performed could potentially be considered as exception from the restriction proposal. However, articles which are exempted from the authorisation process (i.e. see Chapter XIII of the Biocidal Products regulation) should be a part of the restriction proposal. During the consultation of the draft report, two examples of articles that could fall under the Biocidal regulation were provided by Industry (anti-mites micro capsules incorporated in mattresses and insect repellent bracelets).
- Food Contact Material Regulation (2004), (EC) No 1935/2004, applies to materials and articles intended to come into contact with food. Therefore, feeding and drinking-related childcare articles are also in the scope of this Regulation. During the draft report consultation BAUA commented that children feeding and drinking related articles are also covered by this regulation and explained that this regulation also takes children into consideration in their underling risk assessment and therefore these articles should be exempted from the foreseen restriction on CMRs in childcare articles. ECHA agrees that Food Contact Material Regulation also is protective of children, in particular, the related Regulation (EU Commission, 2011b) on plastic materials intended to come into contact with food, specifically considers the exposure of children. However, not all materials and CMR substances in them are clearly addressed taking into consideration specifically exposure to children. Moreover, the Food Contact Material Regulation sets migration limits and not content limits. Therefore, the Commission should consider if a derogation to this type of articles is appropriate.
- The Cosmetic Products Regulation (2009) (CPR), (EC) No 1223/2009 bans (prohibits) the presence of CMR 1A, 1B and 2 substances in cosmetics (listed in Annex II). In exceptional cases, CMR 1A or 1B substances may be used in cosmetics if these substances comply with food safety requirements, inter alia as a result of them naturally occurring in food, and that no suitable alternative substances exist. In such a case, the use of CMR 1A or 1B substances in cosmetic products would be authorised on the condition that such use has been found safe by the SCCS (Scientific Committee for Consumer Safety) and that the application is for a

particular use in a product category with a known exposure. According to the Cosmetic Products Regulation, the assessment by the SCCS of the use of substances classified as CMR 1A or 1B in cosmetic products should also take into account the exposure to those substances of vulnerable population groups. Children under three years of age fall under this vulnerable category.

The Cosmetic Products Regulation covers any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. Therefore, as commented by BAUA during the draft report consultation, the impregnation fluid present in baby wipes for cleaning falls under this regulation, but not the wipes. Commission Directive 93/11/EEC (EU Commission, 1993) concerning the release of the n-nitrosamines and n- nitrosatable substances from elastomer or rubber teats and soothers, specifies concentration limits from N-nitrosamines in rubber, which are relevant for this report.

- The RoHS Directive (2011), 2011/65/EU, regarding 'electrical and electronic equipment' (EEE) covers equipment which is dependent on electric currents or electromagnetic fields. There are also related Directives (2014/53/EU: Radio Equipment Directive, RED; 2014/30/EU: Electro Magnetic Compatibility, EMC; 2006/66/EC: Batteries; 2014/35/EU: Low Voltage) that may apply for childcare articles such as baby monitors or baby dishes sterilizer. The RoHS Directive (2011)covers inter alia consumer equipment, toys and medical devices. It intends to restrict hazardous substances (e.g. lead 0.1 %; mercury 0.1 %; cadmium 0.01 %; chromium VI 0.1 %; Bis(2-ethylhexyl) phthalate 0.1 %; butyl benzyl phthalate 0.1 %; dibutyl phthalate 0.1 %, diisobutyl phthalate 0.1 %) with specific technical functions in EEE. ECHA considers that materials of EEE that may come into direct contact with children may well be in the scope of this investigation.

  RoHS Directive (2011) does not affect the application of REACH, and vice-versa, with regard to the restriction of substances in EEE. When overlaps occur, the strictest restriction (i.e. the lowest maximum concentration) should apply. Furthermore, exemptions from the substance restrictions in RoHS Directive (2011) may not be granted if they result in a weakening of the environmental and human health protection afforded by REACH[10].

- Commission Implementing regulation (EU) no 321/2011 (EU Commission, 2011a) concerns the restriction of use of bisphenol A in plastic infant feeding bottles and Commission Regulation (EU) 2018/213 (EU Commission, 2018) on the use of bisphenol A in varnishes and coatings intended to come into contact with food, and amending regulation (EU) no 10/2011 as regards the use of that substance in plastic food contact materials. Childcare articles concerned by those regulations may be baby bottles, baby bottles nipples/teats or plates. The European Food Safety Authority (EFSA) provides scientific opinions on the risk of substances in food contact materials with specific migration limits for substances such as bisphenol A (EFSA Panel on Food Contact Materials et al., 2023) which are considered in the current investigation report.

- Furthermore, childcare articles are covered by the General Product Safety Directive (2002), 2001/95/EC. According to it, childcare articles placed on the EU market

[10] Synopsis of Questions to be Answered 20 (europa.eu)

must be safe. This directive contains a general safety requirement and does not address chemical substances in particular. However, Article 13 of this directive provides for the opportunity to adopt temporary 'emergency' measures which may include limit values for chemical substances in consumer products. Such measures had been adopted for phthalates in toys and childcare articles before the REACH restriction.

- Several EU standards are addressing childcare articles. CEN/TR 13387-2:2018 provides general safety guidelines on chemical hazards for child use and care articles. Furthermore, there are several specific standards related to child use and care articles, e.g.:
    - SFS-EN 14372 Child use and care articles - Cutlery and feeding utensils - Safety requirements and tests
    - SFS-EN 14350 Childcare articles - Drinking equipment. Safety requirements and test methods
    - SFS-EN 1400 + A2 Child use and care articles. Soothers for babies and young children. Safety requirements and test methods
    - SFS-EN 12586 + A1 Child use and care articles. Soother holder. Safety requirements and test methods
    - SFS-EN 14988 + A1 Children's highchairs. Requirements and test methods

2. Identification of CMRs 1A or 1B substances in childcare articles

2.1. CMR 1A and 1B substances (CMRs) (see also Element #1)

This investigation report covers all substances with CMR 1A or 1B classification(s) listed in Annex VI to CLP (ATP 18[11]), and also substances for which a CMR 1A or 1B harmonised classification have already been agreed by RAC (but are not yet published in Annex VI to the CLP), or are currently under discussion by RAC (i.e. CLH proposal submitted). The substances/entries covered in this investigation are listed in the excel file 'Appendix_A.2.1_CMRs_1A_1B'. CMR 2 substances and substances self-classified as CMR in CLP notifications are not in the scope of this investigation report.

CLP ATP 18 has 1 116 entries with CMR 1A or 1B harmonised classification, some of these entries are group entries with defined number of substances (e.g. entry with index number: 607-426-00-1 covers three phthalates) but others are 'open' group entries covering an undefined number of member substances (e.g. entry with index number 607-230-00-6 covers 2-ethylhexanoic acid and its salts without specifying the list of salts covered). All individual substances from the single and the defined group entries (1 188 substances) were considered on the searches to identify the presence of CMR 1A or 1B substances in childcare articles. Additionally, for the open group entries, some member substances were identified (108 substances) and also considered in the searches.

The foreseen restriction will potentially cover all substances with harmonised classification CMR 1A or 1B and will also potentially apply to any substance classified as such in the

[11] Eighteenth adaptation to technical and scientific progress (ATP-18) to the CLP Regulation that shall apply from 1 December 2023 (contains changes to the list of chemicals falling under Annex VI to the CLP Regulation) https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp

future. Therefore, in the searches were also considered substances for which a CMR 1A or 1B harmonised classification has been agreed by RAC (27 substances) or was under discussion in RAC (12 substances) by 27 January 2023.

2.2. CMRs in childcare articles

ECHA collected information on the presence of CMRs in childcare articles from 48 different sources, such as the 2019 COM study, literature search, reports/tests reports from authorities and other non-governmental organizations, databases, recalls/alerts information, REACH Restrictions, SCIP database, REACH Registration dossiers and Substance in Articles (SiA) notifications, industry Restricted Substances Lists and Ecolabels. More information on the sources and methodology to identify detected or suspected presence of CMR 1A or 1B substances in childcare articles is reported in00.

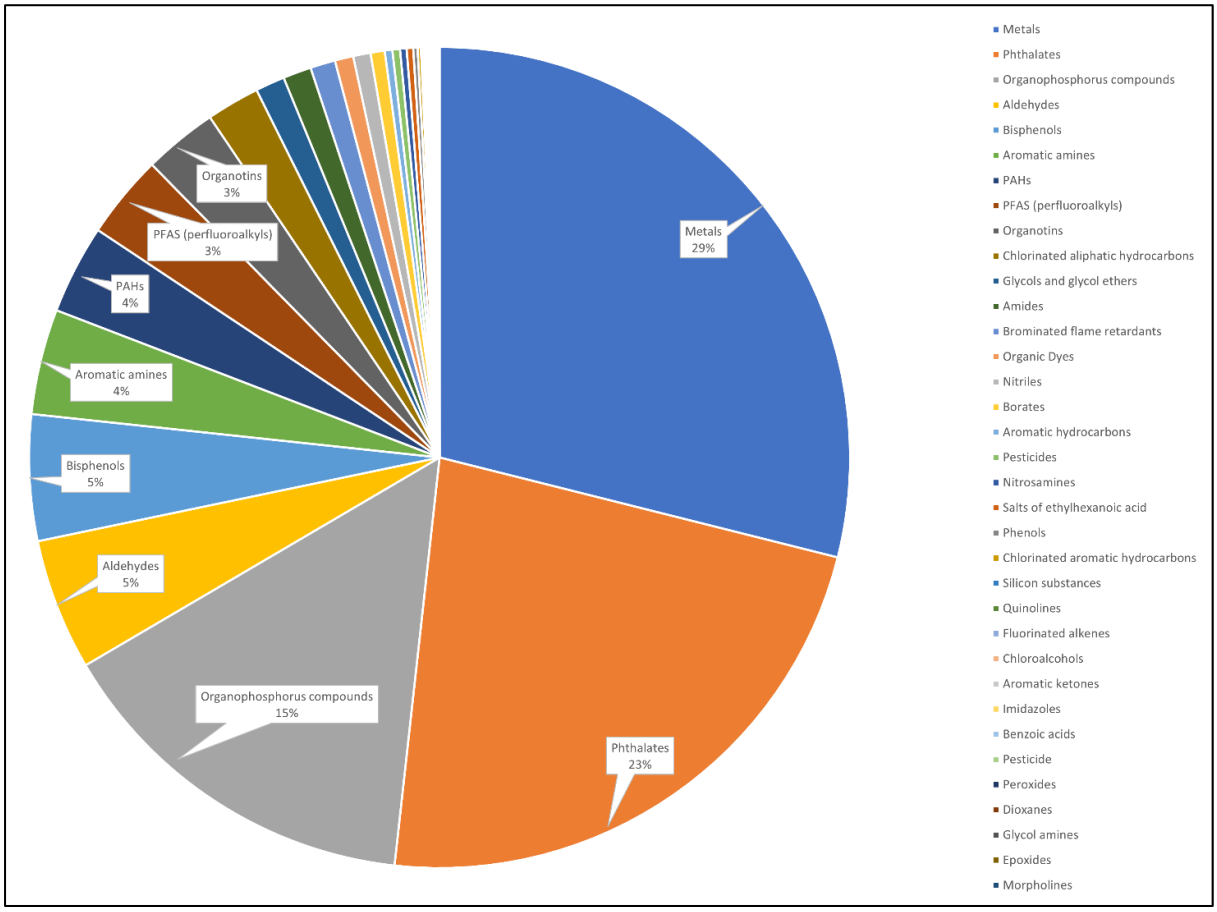

Figure 1: CMR 1A or 1B groups measured or suspected in childcare articles

The information collected in this report for CMR 1A or 1B substances (2 340 entries) that may be present in childcare articles is categorised in two ways: substances measured and/or substances suspected in childcare articles. Substances were considered suspected in childcare articles if information on their presence in materials commonly used in childcare articles (e.g. textile, synthetic polymers such as 'plastic', rubber) or in toys (due to the close link between toys and childcare articles) was collected.

65 CMR 1A or 1B substances were measured in childcare articles and for 116 substances their presence in childcare articles is suspected. The chemistry and function of these

substances is quite diverse. The substances can be divided in 35 different chemical groups (see

Figure 1), and their function in the materials is quite variable. The identified CMR 1A or 1B substances that may be present in childcare article are either intentionally added to a specific material to achieve a certain technical function in the article (e.g. dyes, plasticisers, stabilisers, flame retardants, water repellent coatings, pesticides) or are present in the article ('unintentionally') either as impurities (e.g. Polycyclic aromatic hydrocarbons (PAHs)) or residues from the production process (e.g. monomers, solvents). Some substances such as formaldehyde could be a residue from the production process (e.g. production of composite wood material used for baby and children furniture) but could also be used for wrinkle-free or easy-care textiles.

Based on the information collected, the CMR 1A or 1B substances most frequently detected in childcare articles are metals, being cobalt and lead the most reported followed by phthalates (e.g. di-(2-ethylhexyl)phthalate, di-n-butyl phthalate, butyl benzyl phthalate). Additionally, tris (2-chloroethyl) phosphate, formaldehyde and bisphenol A, were also within the substances most frequently measured in childcare articles. Regarding the substances only suspected in childcare articles, the majority are aromatic amines, metals, organotins, perfluoroalkyls and some phthalates.

With regards to the categories of childcare articles, CMR 1A or 1B substances were found in all sub-categories of childcare articles indicated in Table 1. The articles where CMR 1A or 1B substances were more often measured were car seats, bibs, toilet related articles, bed and mattresses related articles, diaper and nappy related articles and feeding and drinking related articles (see Figure 2).

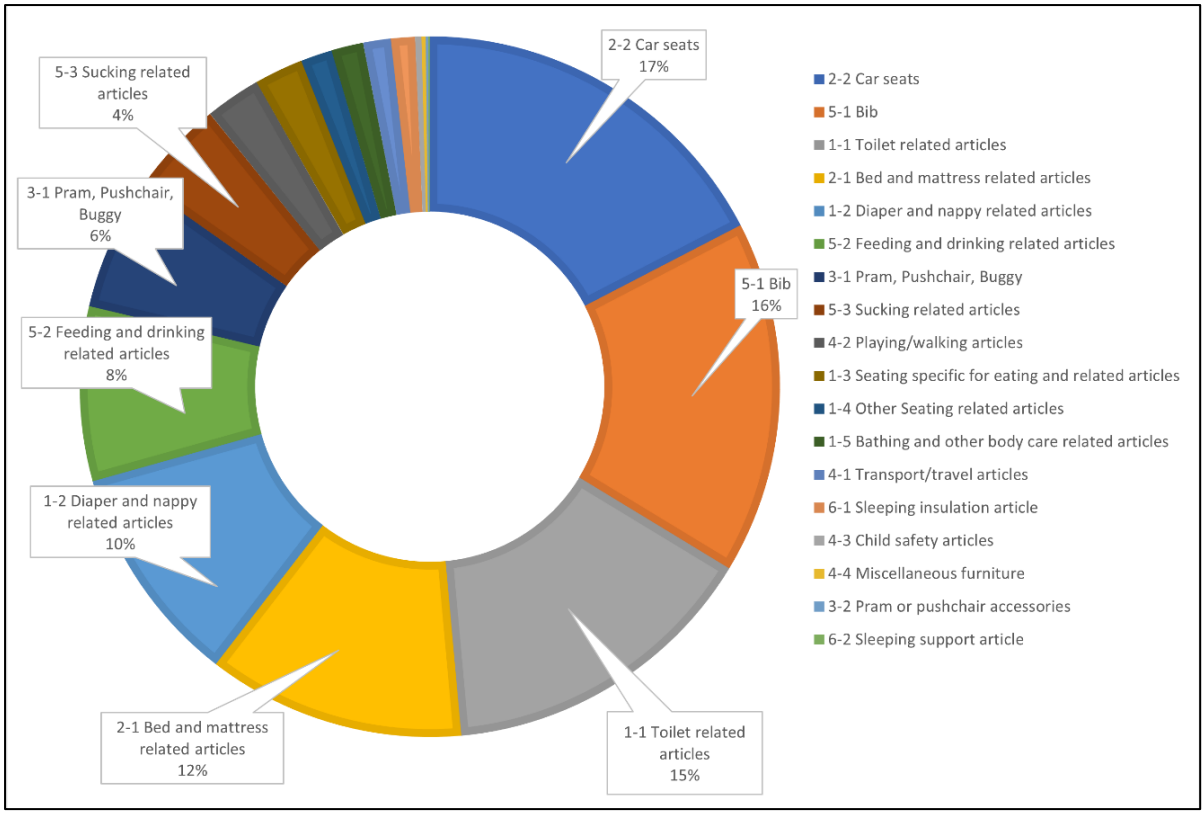

Figure 2: Categories of childcare articles where CMRs 1A or 1B were measured

Synthetic polymers and textiles are the materials where CMR 1A or 1B substances were more often measured in childcare articles, followed by metals and surface coatings (see Figure 3). Regarding the substances for which their presence in childcare articles is only suspected, most of them are suspected to be present in particular materials like textiles but also in synthetic polymers and leather.

The summary of the information collected for each individual substance (type of evidence, type of childcare article and material) is reported in the excel file and summarised in the excel file 'Appendix_A_Summary'.

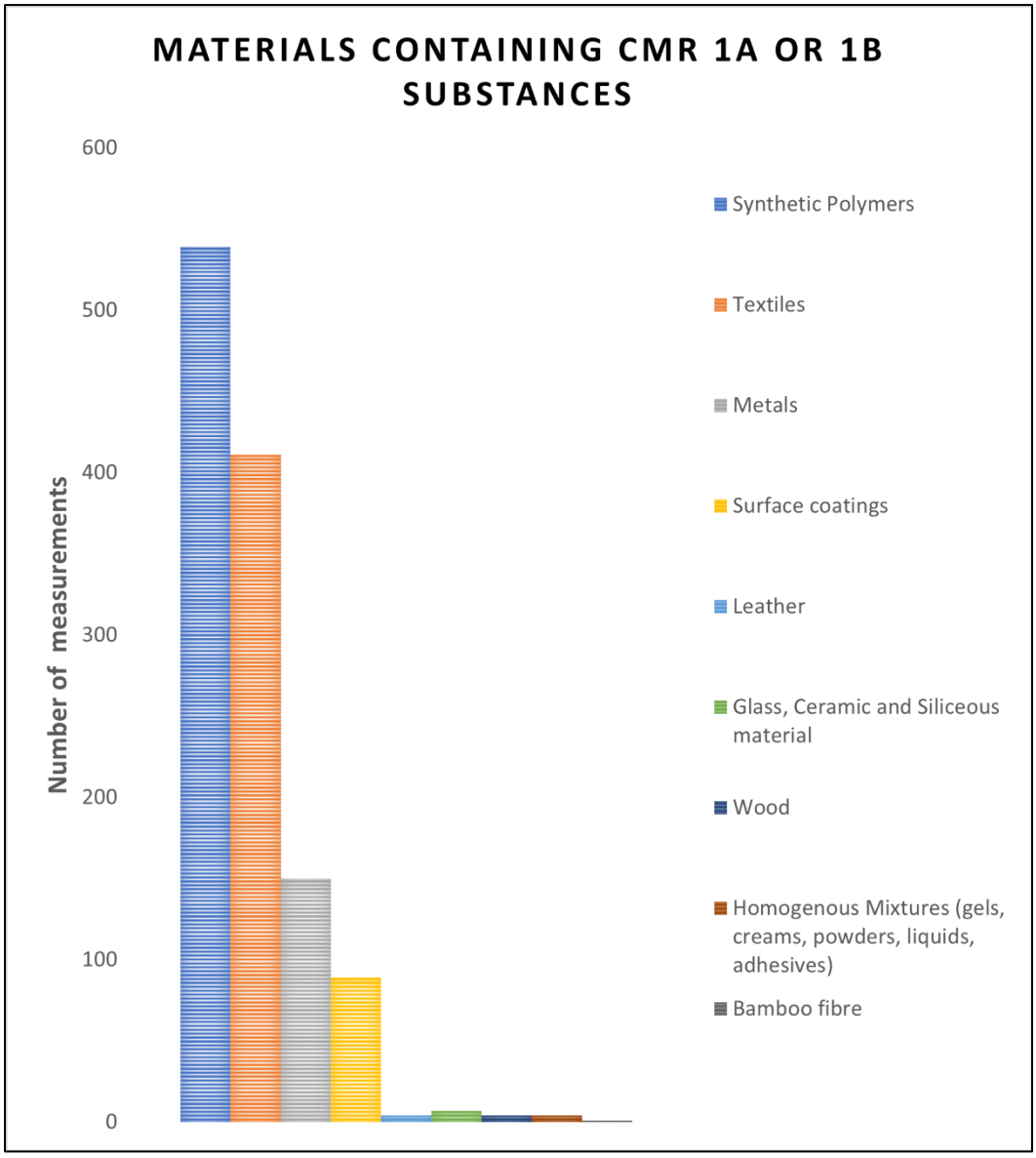

Figure 3: Type of materials where CMR 1A or 1B substances where measured

A matrix presenting the potential presence of individual substances in the different types of materials is reported in section 6.2 (Table 4).

Information on the potential presence of CMR 1A or 1B substances in childcare articles was collected mainly from literature search, reports/tests reports from authorities and other non-governmental organizations, from industry associations, databases recalls/alerts information and from the 2019 COM study (Appendix G1 'Final database on childcare articles').

The main sources of information on the suspected presence of CMR 1A or 1B substances in childcare articles were REACH restrictions, data from uses in REACH dossiers and industry RSLs as well as ecolabels.

Although the foreseen restriction will cover the EEA market, the sources of information collected were not only from EEA countries. Considering global/internet market, the information on articles produced outside of EEA was also considered as a source of

information to conclude on the presence of CMRs in childcare articles placed on the market and used in Europe.

From the information obtained during the interaction with different testing/enforcement laboratories (SGS France, TÜV SÜD PRODUCT SERVICE GMBH, KEMI, Tulli), the substances that are regularly tested in childcare articles are substances that are already regulated (substances of very high concern, restricted substances or substances listed in Appendix C of the Toys Safety Directive (2009)). Therefore, many CMR 1A or 1B substances that could be present in childcare articles might be missing from the data collected in this report as they are never detected because they are not yet regulated and therefore never tested.

3. Likelihood of exposure

It is to be noted that for a possible restriction following REACH Article 68(2), exposure of consumers is assumed by default and a specific exposure/release assessment, in line with Article 68(1) of REACH, is not required. Nevertheless, Commission requested ECHA to collect available information related to release and exposure potential.

As indicators for the likelihood of exposure for CMR 1A or 1B substances that may be present in childcare articles (measured or suspected) the following information was considered: (i) the tonnage of individual substances manufactured or imported, (ii) the concentration ranges and the number of measurements of substances in childcare articles, (iii) exposure potential based on physicochemical properties, type of inclusion of the substances in the matrix, type of contact to the material containing the CMR 1A or 1B substances, and frequency of potential exposure. Collecting information on all CMR 1A or 1B substances was not feasible due to the large number of such substances (> 1 000).

3.1. Tonnage

ECHA notes that there is no direct link between the tonnage of substances registered under REACH and the likelihood of children's exposure to CMR 1A or 1B substances from childcare articles. Therefore, it is not possible to draw any conclusion on the likelihood of exposure in childcare articles from the registered tonnage information. However, if a substance is registered at a high tonnage, the likelihood that the substance may be included in a childcare article is higher compared to a substance that would not be registered. Furthermore, substances used as intermediates (e.g. monomers) in the production of articles, may remain in articles as residues and any CMR 1A or 1B substance either registered or non-registered under REACH may be present in an imported article.

As requested by the Commission, ECHA has collected registration information for the substances that may be present in childcare articles. The following information on the type of registrations and the tonnage of registered substances manufactured or imported was collected from REACH registrations: REACH Annex, cumulative tonnage, Article 10 registrations (active), intermediate registrations (active), inactive registrations, substances notified under the Notification of New Substances (NONS) scheme of Directive 67/548/EEC that was in place before REACH.

The collected information contains confidential data. To avoid disclosing confidential information, a conclusion is presented in column Q of the excel file 'Appendix_A_Summary'. Substances with full registrations with annual tonnages above 100 tonnes were flagged as 'high' tonnage (n = 70) and substances with registrations for lower tonnages for 'medium' tonnage (n = 20). Substances registered as intermediates and inactive registrations were flagged for 'low' tonnage (n = 9). For substances registered as intermediates production volumes might be high; however, it is assumed that such

intermediates might be present only as residues in the final article. Substances not registered under REACH, were indicated as 'not reg' (n = 38). For the following groups of substances, the information on the registration status was considered as not applicable ('n/a') due to the following reasons:

The aromatic amines included in the current investigations (n = 26) are cleavage products of certain azodyes. Azodyes should not be used in textiles and leather according to industry restricted substances lists and the EU ecolabel for textiles. Several of such aromatic amines released from azodyes are also restricted (REACH Annex XVII entry 43). The information provided in REACH registrations related to the production volumes of those aromatic amines may not be relevant for the production volume of the specific azodye from which it is cleaved. Therefore, the tonnage for aromatic amines cleaved from certain azodyes is marked as 'n/a'.

PAHs and N-nitrosamines may be detected e.g. in rubber and plastic materials. Also, articles made of recycled rubber may contain PAHs. Since PAHs and nitrosamines are residues and not intentionally manufactured, the information on tonnage is also marked as 'n/a'.

For some metals substances, for which the metal content is analysed, the information on the specific substance used in the childcare articles was not available. In such cases (n=2) the tonnage was also marked as 'n/a'.

Based on the information from REACH registrations high annual production volumes are reported specifically for substances used in the production of textiles and synthetic polymers, including solvents, (e.g. dimethylformamide, formaldehyde), monomers and/or precursors for synthetic polymers (e.g. formamide, N-ethyl pyrrolidone, bisphenols, vinyl chloride, 1,2-dichloroethane, benzyl chloride), plasticizers (e.g. phthalates), stabilisers (e.g. organotin compounds), dyes (e.g. several metals and their compounds), pesticides (e.g. diuron), and flame retardants (e.g. some brominated flame retardants).

3.2. Concentration ranges and frequency of findings

The information on concentration ranges of CMR 1A or 1B substances in childcare articles together with the number of measurements collected is presented in column N of the excel file 'Appendix_A_Summary'.

Some substances were measured in childcare articles outside the EU only. Examples are acetaldehyde, benzene, tetrabromobisphenol A, vinyl chloride, arsenic compounds, mercury, and cobalt, for which the highest number of measurements in childcare articles were reported. As already mentioned, considering the global/internet market, the articles produced outside of EEA should also be considered as a source of information to conclude the presence of CMRs in childcare articles used in Europe. Therefore, the measurements/concentration of the substances in those articles was also considered in this report.

ECHA collected 1 559 entries reporting measurements of CMR 1A or 1B substances in childcare articles. 39 % of the entries cover metals, being cobalt and lead compounds the most reported (373 and 164 entries, respectively). 21 % of the entries cover organophosphorus compounds (mainly tris(2-chloroethyl)phosphate), 15 % phthalates (mainly di-(2-ethylhexyl)phthalate, di-n-butyl phthalate, and butyl benzyl phthalate) and the other chemical groups/substances covered less than 10 % of the entries.

The measured concentrations of CMR 1A or 1B substances in homogeneous materials of childcare articles were usually below the CLP GCL or SCL. Exemptions with reported

concentrations higher than the CLP GCL/SCL were the flame retardants tetrabromobisphenol A (4/5 measurements > 1000 mg/kg; non-EU data only) and tris(2-chloroethyl)phosphate (9/310 measurements > 3 000 mg/kg), vinyl chloride (8/32 measurements > 1 000 mg/kg) and lead in textiles or synthetic polymers (6/106 measurements > 300 mg/kg), cobalt in coatings (3/194 measurements > 1 000 mg/kg; non-EU data only), and phthalates such as diisobutyl phthalate (2/9 measurements > 3 000 mg/kg), di-n-butyl phthalate (1/73 measurements > 3 000 mg/kg), and di-(2-ethylhexyl)phthalate (85/202 measurements > 3 000 mg/kg) in synthetic polymers.

High concentrations of phthalates were mainly reported in articles placed on the market before 2020 and/or in old articles (e.g. second hand), for which concentration even higher than 400 000 mg/kg were reported (Almroth and Slunge, 2022). Very high concentrations of eight different lead compounds were reported for a baby dish sterilizer in the SCIP database. However, it is not reported in which part of the sterilizer the lead substances are included and if the substances were inaccessible or in contact with the dishes to be later used by children.

For the substances listed above and for formaldehyde, some aromatic amines released from azo dyes in textiles, chromium (VI) compounds in leather, and metals in textiles and synthetic polymers, some reported concentrations were above existing concentration limit specified in REACH restrictions.

Even if substances are not registered under REACH, they may be present as impurity in other substances and in imported articles. An example provided by the Danish EPA (2016) is the flame retardant tris(2-chloroethyl)phosphate (TCEP) that was measured as impurity in other flame retardants[12], and in imported articles.

The available data do not allow a reliable conclusion related to the frequency of findings of CMR 1A or 1B substances in childcare articles, because information on 'negative' measurements is rarely available. However, based on the collected information on measured substances, it is possible to conclude on the substances that are more frequently measured in childcare articles.

Furthermore, the available data do also not allow to discriminate between childcare articles produced in the EU or outside the EU.

3.3. Exposure potential

Children can be exposed to CMR 1A or 1B substances contained in childcare articles either by inhalation (emission of volatile substances with high vapour pressure from the childcare article), dermal exposure following skin contact to the surface of the childcare article or by oral exposure by placing childcare articles in the mouth or licking at the childcare article.

[12] According to ECHA (2010a), TCEP is a reaction by-product in the manufacture of other commercial flame retardants in which TCEP is present as impurity (tris(2-chloro-1-methylethyl)phosphate (TCPP); tris[2-chloro-1-(chloromethyl)ethyl]phosphate (TDCP); 2,2-bis(chloromethyl)trimethylenebis(bis(2-hloroethyl)phosphate)]). Danish EPA (2016b) also states that it occurs at low levels in a flame retardant which has traditionally been traded under the name V6 or V66 (and may hence be present in articles).

Physico-chemical properties of substances

Exposure potential estimations were performed using physico-chemical properties (water solubility, log Know or log P, and vapour pressure) for the substances that are registered under REACH (n=107) and for which the tonnage (see section 3.1) was not considered as 'n/a'. Based on the identified physico-chemical properties, the exposure potential was estimated as described in Table 5.1 of the COM study (2019) which is presented in Table 2 below.

Table 2: Physico-chemical parameters and related thresholds used in the analysis

Property	Threshold value	Oral exposure potential	Dermal exposure potential	Inhalation exposure potential
Log Know (aka log P)	< 4	Tendency for low exposure	Tendency for low exposure	
	> 4	Tendency for medium exposure	Tendency for medium exposure	
	> 5	Tendency for high exposure	Tendency for high exposure	
Aqueous solubility	< 3 000 mg/L	Tendency for low exposure	Tendency for low exposure	
	3 000 < X < 20 000 mg/L	Tendency for low exposure	Tendency for high exposure	
	> 20 000 mg/L	Tendency for high exposure	Tendency for low exposure	
Vapour pressure	< 1 mmHg			Tendency for low exposure
	> 1 mm Hg			Tendency for high exposure

Source: COM Study (2019)

In the COM study (EU Commission, 2019) other parameters were indicated to be used for exposure estimation:

- Concentration detected only at trace level (0.01 % or 100 mg/kg) were concluded as potential 'low' exposure. However, ECHA analysed and concluded on concentration (ranges) of substances measured in childcare articles separately (see excel file 'Appendix_A_Summary').
- Presence of a physical barrier; however, it was noted that the gathered information was insufficient to conclude if there was a physical barrier and therefore it was assumed that there is no barrier. ECHA also did not have sufficient information to consider the possible presence of a barrier.
- The potential for transport into the body by mouthing (oral), inhalation (volatilisation/airborne particulates), or dermal contact was rated. This rating was linked to the physico-chemical properties. ECHA did this rating as explained above by concluding on 'high', 'medium' or 'low' exposure potential.

Based on this information the exposure estimation (to the substance once released from the childcare article) was concluded to be 'low', 'medium' or 'high' related to potential oral,

dermal and inhalation exposure. The overall conclusion, which reports the highest exposure potential estimation for a substance (based on physico-chemical properties), is presented in column R of the excel file 'Appendix_A_Summary'. Exposure potential was estimated as 'low' for 39 substances, 'medium' for 8 substances and 'high' for 59 substances.

Releases from articles

The release potential for substances from the matrix of the material is driven by the interaction between the substance properties, the properties of the matrix, the technical function of the substance and the conditions of use (temperature, radiation, abrasion, water contact). The design of the article may also impact on the release.

Substances acting as coupling agents or cross-linkers are meant to be reacted into the polymer matrix and, as such, are less likely to be released unless used under (highly) abrasive conditions. The same applies e.g. to the particular type of flame retardants that reacts into the matrix.

Interactions between substances and matrices may fundamentally differ between plastic/resin matrices, fibre matrices, foams, metal-grids and ceramic/glass matrices. In general, releases of substances present in inert matrices like glass or ceramics can be considered low (e.g. glass pigments). The release potential from metal matrices is highly dependent on the specific metal and the specific use (e.g. whether water contact exists, whether machining or abrasion is expected). For softer matrices like plastic, rubber, fabric or paper the potential for release is generally considered higher than from ceramic, glass or metal matrices.

Substances which are not covalently bound to the material can leak, migrate and/or evaporate from the article resulting in a higher potential for exposure, whereas for substances covalently bound to the matrix such as metals in metal alloys, the potential for exposure is most likely low. Certain functional additives in polymers such as plasticisers (e.g. phthalates) and the flame-retardant (e.g. tris (2-chloroethyl) phosphate) are not bound to the matrix and the likelihood of exposure is high. The flame retardant tetrabromobisphenol A may either be covalently or non-covalently bound to the matrix.

Physico-chemical properties indicative of low releases of substances from the matrix are high molecular weight and low water solubility. A high molecular weight is mostly associated with low vapour pressure, which makes it unlikely that the substance is released via the air-pathways, unless the use temperatures are high. Moreover, if included in plastic matrix, high molecular weight substances are unlikely to be released to a contact media (saliva, water, skin)[13]; an illustrative benchmark also used under FCM legislation and Drinking Water Directive for high molecular weight is 1000 Da. Though generally applicable, this benchmark is not fully reliable for organic molecules with very heavy elements, for example bromine (as the weight suggests the molecule been larger than it is in practice), or molecules with very compact structure as for example polyfluorinated substances. Also, low water solubility (often also a characteristic resulting from high molecular weight) is an indication for low releases from matrices. An illustrative

[13] Transformation products with lower molecular weight might be released; moreover, uses involving wear and tear and/or abrasion might result in releases as well.

benchmark of 0.01 mg/L can be used, below which release from the matrix is unlikely to happen (especially if in combination of high molecular weight)[14].

Uptake of substances from childcare articles

Children can be exposed to CMR 1A or 1B substances released from childcare articles by direct contact with skin or mouth, by inhalation of volatile substances emitted from the childcare articles or to particles from childcare articles to which the substances would be bound.

Mathematical models are available to assess and estimate the exposure and the uptake of substances from e.g. toys (RIVM, 2019). Existing default values and recommendations for exposure assessment are also provided by the Nordic exposure group project 2022 (Nordic exposure group, 2022). ECHA did not perform assessments of children's exposure to specific CMR 1A or 1B substances in childcare articles.

In several REACH restrictions the conditions for the restriction of substances apply to the materials that come into (direct as well as prolonged or short-term) contact with human skin (REACH Annex XVII, entries 20, 43, 47, 50) or the oral cavity (REACH Annex XVII, entries 52, 63; see also section 5.1).

In the Toys Safety Directive (2009)Article 10(2) it is specified that "*Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children*."

"*Bearing in mind the behaviour of children*", childcare articles may also be used by children in a not intended or foreseeable way. Furthermore, children may also be exposed to substances without direct contact, for example in case of substances emitting or migrating from a material such as mattress or through the textile coverage. Therefore, the conditions of a possible restriction may also be interpreted in a broader sense, covering all materials and parts of a childcare article and derogating instances where the parts including the CMR 1A or 1B substances are made inaccessible to children e.g. by enclosure. Such conditions are specified in the Toys Safety Directive (2009)in Annex II, section III, 13. Where the limit values for metals ('elements') "*shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2).*"

Duration and frequency of contact to childcare articles

It is assumed that the contact of children to childcare articles is prolonged and frequent. For example, the mean 'Object-to-Mouth Duration' was 11 to 13 minutes/hour for babies of 3 months and children < 3 years of age[15] For babies and toddlers (usually under 3 years of age) the contact is assumed to be for all identified types of childcare articles, whereas for children of 3 to 14 years of age the contact is assumed to be mainly to car seats, eating-related articles and mattresses.

[14] This value has been used as benchmark in the Plastic Additive Initiative for inorganics and organic pigments.

[15] CSEFH_HIGHLIGHTS (1).PDF

3.4. Conclusion on likelihood of exposure

The information included in this report indicates that CMR 1A or 1B substances that may be present in childcare articles (see section 2), can be released from childcare articles to different extend depending on the type of substance and the type of material of the article, and can be taken up by children. The likelihood of exposure does not take the form of a quantitative assessment but instead presents available evidence that **children may be exposed to the substances in childcare articles during normal and reasonably foreseeable conditions of use**.

Exposure of children to substances released from childcare articles requires first the release, emission or migration of the substance from the article and second the uptake by children (oral, dermal, inhalation) of the released substances.

The release of CMR 1A or 1B substances from childcare articles is more likely for substances that can be emitted from childcare articles (e.g. high vapour pressure) and that can be inhaled such as formaldehyde or benzene and for substances that are not covalently bound to the matrix of the article and can leach (and migrate), leading to dermal and/or oral uptake such as phthalates or tetrabromobisphenol A.

For 59 substances identified in this report with full registration under REACH ('medium' or 'high' tonnage), the physico-chemical properties indicate a medium or high exposure potential of the substances (without considering their inclusion in articles). Examples for medium or high exposure potential are formaldehyde, acetaldehyde, amides (formamide, acrylamide, dimethylformamide, N,N-dimethylacetamide, N-methylpyrrolidone, N-ethyl-2-pyrrolidone), acrylonitrile, benzene, an organic dye, the flame retardant trixylyl phosphate, benzoic acid, borates, brominated flame retardants (e.g. tetrabromobisphenol A), chlorinated aliphatic and aromatic hydrocarbons, glycol and glycol ethers, several metal and organotin compounds, phthalates, and salts of ethylhexanoic acids.

4. Available risk assessments

It is to be noted that for a possible restriction following REACH Article 68(2), a specific risk assessment is not required. Nevertheless, Commission requested ECHA to collect available information related to release and exposure potential (see section 3). Consequently, ECHA also collected available information with regards to risk assessments performed for some substances.

Children may be more vulnerable than adults to hazards presented by chemicals, due to physiological differences and unique behaviours. Risk assessment methodologies that specifically consider children are required to ensure that potential risks are addressed by OECD (2023).

For this report ECHA collected risk assessments performed in the EU on CMR 1A or 1B substances present in childcare articles or toys such as EU Risk Assessment Reports (EU RARs), RAC opinions, European Food Safety Authority (EFSA) opinions and assessments, Scientific Committee on Health and Environmental Risks (SCHER) reports or national reports. More detailed information is presented in Appendix 2 .

Risk assessments were identified for several substances such as formaldehyde, formamide, bisphenol A, tris(2-chloroethyl) phosphate (TCEP), tetrabromobisphenol A, metals, and phthalates. Assessments performed to derive occupational exposure limits were excluded due to the different route of exposure (mainly inhalation) and the population concerned (healthy workers). The assessments are summarised in listed Appendix 2. Several published risk assessments were the basis for legislative actions (e.g.

risk assessments performed by SCHEER on formaldehyde and metals in toys and by EFSA on bisphenol A).

The results of risk assessments were considered when proposing the of concentration or migration limits which are addressed in the following section.

5. Concentration limits

This section addresses the inventory of available concentration limits and the assessment on possible needs to deviate from CLP GCLs/SCLs.

5.1. Inventory of available concentration limits

Collecting information on all CMR 1A or 1B substances was not feasible due to the large number of such substances (> 1 000). A summary of the inventory of existing concentration limits for CMR 1A or 1B substances that may be present (measured or suspected) in childcare articles is presented in column V of the excel file 'Appendix_A_Summary'.

Sources of concentration limits included in the inventory are for example REACH restrictions (related to childcare articles or targeted to articles and/or materials that might be relevant for childcare articles), other EU legislation (e.g. the Toys Safety Directive (2009)), standards, ecolabels, and industry RSLs targeted to materials that are used in childcare articles. More detailed information on the sources is provided in the 1)a)i)(1)(a)(i)Appendix 3 . The defined concentration limits in the different sources are often linked to a specific analytical method or an existing legislative limit.

The inventory contains mainly content-related concentration limits; however, for certain substances (mainly bisphenol A and metals) other types of concentration limits are provided which are frequently used and referred to by industry. Those concentration limits are reflecting either 'extractable' and/or 'migration' of substances from materials of childcare articles and are also included in the inventory (column W). Concentration limits related to the 'emission' from wood is only included for formaldehyde due to its relevance e.g. for baby or children furniture; 'emission' values for other volatile organic compounds are not addressed.

All concentration limits addressed in this investigation report relate to a homogeneous material of a childcare article, not to the whole childcare article. Entry 71 and 51 of REACH Annex XVII also establish limits in homogeneous materials, however, no definition of homogenous materials is provided or covered under REACH. Therefore, ECHA proposes a definition in line with the RoHS Directive (2011): A homogeneous material is a material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes

ECHA notes that in the report underlying the restriction proposal on substances in single-use diapers (ANSES, 2019) and in the consequent restriction proposal, the concentration of substances in shredded whole diapers were analysed. Moreover, EDANA stated during the draft report consultation that *"disposable diapers should be considered as distinct homogeneous materials since they are multi-layered articles, where the different materials are mixed and/or fused and cannot be separated by mechanical actions"*. This statement was not verified, nor supported by relevant evidence. EDANA also suggested to consider the substances detected or suspected in disposable diapers (some are included in this report), and relative migration limits, listed in the EDANA Stewardship Program CODEX (EDANA), which have been included in EU Ecolabel criteria for absorbent hygiene products

(EU Commission, 2023b). Therefore, they recommend the EDANA CODEX test method (NWSP360) (see Appendix 4), which is currently under standardization by CEN, to test disposable baby diapers (CENELEC, 2023). However, these limits are migration limits only and for a very specific type of article (not a single type of homogeneous material) and therefore were not included in the inventory of concentration limits.

For metals such as arsenic (As), cadmium (Cd), cobalt (Co), lead (Pb), mercury (Hg), chromium (VI) (CrVI), for dioctyl tin (DOT) or dibutyl tin (DBT) compounds, for boron (B) and bromine (Br^-), the concentration limits (content, extractable content or migration) reflect the concentration of the species (atom or ion) analysed, and not the concentration of the substances that may be present in childcare articles. Therefore, for the concentration limits the species concerned is indicated, e.g. 10 mg As/kg in case of arsenic.

For 149 of the 180 substances identified in this investigation report that may be present in childcare articles (ca. 83 %) an existing concentration limit (either content and/or extraction and/or migration) was identified. For 91 substances (ca. 50%) legally binding concentration limits from REACH restrictions, the Toys Safety Directive or other legislations were identified.

5.2. Identification of the need to deviate from CLP GCL/SCL (see also Element #4)

All substances under the scope of this investigation are classified as CMR 1A or 1B or have that classification agreed or under discussion by RAC. The CLP GCL/SCL for CMR substances are values for classification purposes and are not based on substance-specific risk assessments (see CLP Annex I and Annex VI). CLP GCL for CMR 1A or 1B substances are either 1 000 mg/kg (for carcinogenic or mutagenic substances) or 3 000 mg/kg (for substances toxic to reproduction), SCL might be lower. Considering that CMR 1A or 1B substances also cover genotoxic carcinogens for which usually no safe threshold can be established, the GCL/SCL may not be sufficiently protective for children. The GCLs/SCLs are used for classification purposes and are usually not based on substance-specific risk assessments. Furthermore, GCL/SCLs are limits developed initially for substances and mixtures, not specifically for articles. In the Toys Safety Directive, these limits are considered as not enough protective for children.

Following this spirit, in an evaluation of the Toys Safety Directive (EU, 2020) it is noted that "*the prohibition in principle of chemicals that are carcinogenic, mutagenic or toxic for reproduction (CMR) has a derogation that tolerates their presence in concentrations too high to ensure effective protection according to current scientific knowledge.*".

Therefore, the presence of CMR 1A or 1B substances in childcare articles should be banned to ensure the protection of children. The ban of substances of concern is also applied in the Toys Safety Directive (2009). In this directive, the ban is linked to the CLP GCL/SCL (except for concentration limit listed for several substances). However, in the proposal for a review of this Directive (that is proposed to become a Regulation) (28 July 2023)[16], the link to the CLP concentration limit has been removed and replaced with a stricter prohibition. Only impurities that can't technically be avoided are permitted and only when toys remain in conformity with the general safety requirement. The Cosmetics Product Regulation (2009) bans substances listed in Annex II. For such substances, maximum

[16] Proposal for a Regulation on the safety of toys (europa.eu)

concentration limits are listed with '0 %'[17] and can be interpreted as below Limit Of Detection (LOD) or LOQ. Some ecolabels and RSLs indicate that substances or groups of substances are 'banned' (e.g. bluesign®, 2022), 'prohibited' (e.g. AFIRM, 2023; GOTS, 2023; Nordic Swan, 2017), 'not permitted' (e.g. Blue Angel textiles, 2023) and/or are requiring concentration limits which are in the range of the LOQ and to be considered as a practical 'ban'. In some standards (e.g. OEKO-TEX®, 2023) more strict concentration limits are required for babies and for material with direct skin contact. In several voluntary schemes, ecolabels or restricted substances lists no concentration limits are indicated. This indicates that industry has already phased out many CMR 1A or 1B substances from their products, on their own initiative and that minimising the content of those substances is not in principle technically challenging.

However, ECHA notes that even if CMR 1A or 1B substances shall not be used in a childcare article, it is possible that, as also considered in the Cosmetics Product Regulation (2009), non-intended presence of a small amounts of the substances, stemming from impurities of ingredients, the manufacturing process, storage, migration from packaging, can be present. **Moreover, to facilitate a practical, efficient, and harmonised enforcement of the restriction, it is helpful if specific analytical methods are available to measure the substances within the respective concentration limits set in the restriction.**

As indicated in the Commission request, ECHA identified the need to deviate from the **content** concentration limits of CLP and proposed other content limits that are more protective for children.

For CMR 1A or 1B substances that are to be banned in childcare articles, ECHA is therefore considering concentration limits close to the LOQs established for existing sensitive and accurate analytical methods (preferably standard methods) and which are normally already in use by authorities and industry to measure individual substances or groups of substances. With this approach the defined concentration limits are as low as reasonably feasible and accurately measurable to verify the compliance with the total ban in the restriction.

During the draft opinion consultation, some comments mentioned that the proposed concentration limits are only based on the performance of the analytical methods and not on the technical feasibility to minimise the presence of the substances. ECHA acknowledges that usually no information on the technical feasibility to reduce the presence of the substances is provided. However, the proposed limits take into consideration industry RSL that should already take that aspect into consideration. Moreover, during the two calls for evidence, no comments regarding technical problems on achieving the proposed concentration limits were provided.

For some cases, the proposed standard/common analytical methods have a LOQ that corresponds to the proposed concentration limit. In these cases, it might not be possible to quantify the substances in the homogeneous material with high accuracy and in particular it may not be possible to thoroughly conclude if detection below the LOQ and above the LOD is greater or smaller than the defined concentration limit. However, as the aim is to ban CMR 1A or 1B substances in childcare articles, a conservative approach should be taken by considering that substances detected with measurements between LOD and LOQ are considered present above the concentration limit (as there is sufficient

[17] cosmetics-prohibited-subs - ECHA (europa.eu)

high probability that the given measurement is over the limit/LOQ levels). For this scenario, only when the detected experimental concentration values are all below LOD, it should be considered the substance may be present below the concentration limit (as there is sufficient high probability that the given measurement is lower than the limit/LOQ levels). Valuable statistical methodologies to handle measurements between LOD and LOQ were collected and evaluated by EFSA for dietary exposure assessment of chemical substances (EFSA, 2010). Those approaches may be also used by enforcement authorities and Industry to control and monitor CMRs detected in traces close to the LOD of the applied analytical methods.

For several substances or groups of substances regulatory concentration limits may already exist to limit the concentration of such substances in articles (e.g. REACH restrictions, Toys Safety Directive). Considering the scope of the foreseen regulation on protecting a specific group of vulnerable consumers (babies and children) and based on concentration limits from standards, ecolabels, and industry RSLs, for some of those substances deviation from the regulatory concentration limit is considered. It is to be noted that the restriction on CMR substances in textiles (REACH Annex XVI, entry 72) is not specifically addressing children. However, existing regulatory limits which are in the same magnitude as the LOQ are considered not to be lowered.

This means that ECHA considers the need to deviate from the CLP GCL/SCL and also from some concentration limits specified in some REACH restrictions.

ECHA collected and analysed existing concentration limits and related analytical methods for all 181 substances identified as potentially present in childcare articles in this investigation report.

ECHA does not consider concentration limit(s) for the 11 PFAS (Per- and polyfluoroalkyl substances) included in this investigation report due to an on-going universal restriction proposal for PFAS. Furthermore, ECHA does not consider a content-related concentration limit for silicon carbide, since the harmonised classification Carc. 1B relates only to inhalation of silicon carbide fibres of a certain dimension and no hazard for the oral or dermal route was identified. Furthermore, its use in childcare articles is less likely and inhalation risk from abrasion of childcare articles is also considered less likely.

For all other 169 substances a concentration limit related to the **content** is considered, either reflecting the default concentration limit of 10 mg/kg in homogeneous materials, or a concentration limit deviating from this default limit (see below). For metals, **extractable content** limits are considered in addition to content limits taking into account available information. For bisphenol A and metals regulatory **migration** limits are available that are referred to but not further analysed.

For some groups of substances, a concentration limit for each substance and the total sum of all substances from the same group are in use e.g. by industry associations. The total sum of all substances of a group is useful to avoid additive effects in case more than one substance of a group can be present in a childcare article. ECHA is referring to this approach e.g. for nitrosamines, pesticides, and phthalates.

For substances of the same group with similar hazard profiles and analytical methods, the same concentration limit is applied.

Default content concentration limit of 10 mg/kg

ECHA considers a default concentration limit of 10 mg/kg with derogation for substances for which different concentration limits were found to be more appropriate (e.g. existing

regulatory limits in the range of the LOQ), see the flow-chart in Figure 4 for details about the criteria to define concentration limits.

The concentration limit of 10 mg/kg is based on the following considerations: the state-of-art analytical methods/techniques for the quantification of almost any type of substance guarantees LOQs below or at least of 10 mg/kg. Recent developments in analytical instrumental techniques have improved the detection sensitivities, quantitatively and qualitatively. The availability of multiple separation and detection combinations has expanded the analytical monitoring applications for almost all types of inorganic and organic compounds.[18] ECHA also notes that, in addition to advanced analytical methods that allow quantification of the content of a substance to proof conformity with a legislation at the highest level of accuracy, qualitative methods ('screening'), which are faster and cheaper, are available and frequently used. Such 'screening' methods are discussed in section 6.2 'Testing strategy'.

The default content concentration limit of 10 mg/kg is considered for 78 of 168 (46 %) of the substances identified in this investigation report with a concentration limit.

Substances not measured or suspected in childcare articles and new additions to Annex VI of CLP

The default concentration limit is also considered for all other CMR 1A or 1B substances for which no evidence of their presence in childcare articles was identified (measured or suspected). Those other CMR 1A or 1B substances may not be prioritised for enforcement actions, but their presence in childcare articles should also be restricted with defined concentration limits e.g. to prevent regrettable substitutions.

The default concentration limit of 10 mg/kg should also be considered for substances that will be covered by the restriction in the future (i.e. substances that will be classified as CMR 1A or 1B and included in Annex VI of the CLP regulation).

However, if evidence of the presence of these substances in childcare articles is identified and the substances become therefore a priority for enforcement actions the general approach to define the concentration limit presented in Figure 4 could be used.

Concentration limits (content) deviating from 10 mg/kg

The need to deviate from the default concentration limit considers the following criteria: (i) if a concentration limit from a REACH restriction is available, (ii) if there are technical reason to deviate from 10 mg/kg, (iii) the range of the LOQs for a substance and (iv) concentration limits used by industry (see flowchart in Figure 4).

The substances or groups of substances with a considered concentration limit (content) deviating from 10 mg/kg and/or with a different type of limit e.g. extractable content, are listed below in Table 3.

[18] Annual reviews (2022): Recent advances in analytical sciences: https://doi.org/10.1002/ansa.202200011

Concentration limits related to extractable amount of substances

Only for metals concentration limits related to an extractable amount of substances are considered (see Appendix 4 for the definition of 'extractable content').

In case an existing REACH restriction concentration limit reflects the LOQ of the standard methods (chromium (VI) compounds), this limit is considered. In case the REACH restriction limits are higher compared to the LOQs of the respective analytical methods and concentration limits reported by industry are lower, the lower concentration limits used by industry are considered (lead).

Extractable content limits for metals without existing REACH restriction limits are considered as proposed by industry, which are slightly higher than the respective LOQs (e.g. cadmium, cobalt, mercury).

All concentration limits related to extractable content considered are also listed in Table 3 and are explained further below. An overview of all considered concentration limits is presented in column X of the excel sheet 'Appendix_A_Summary'.

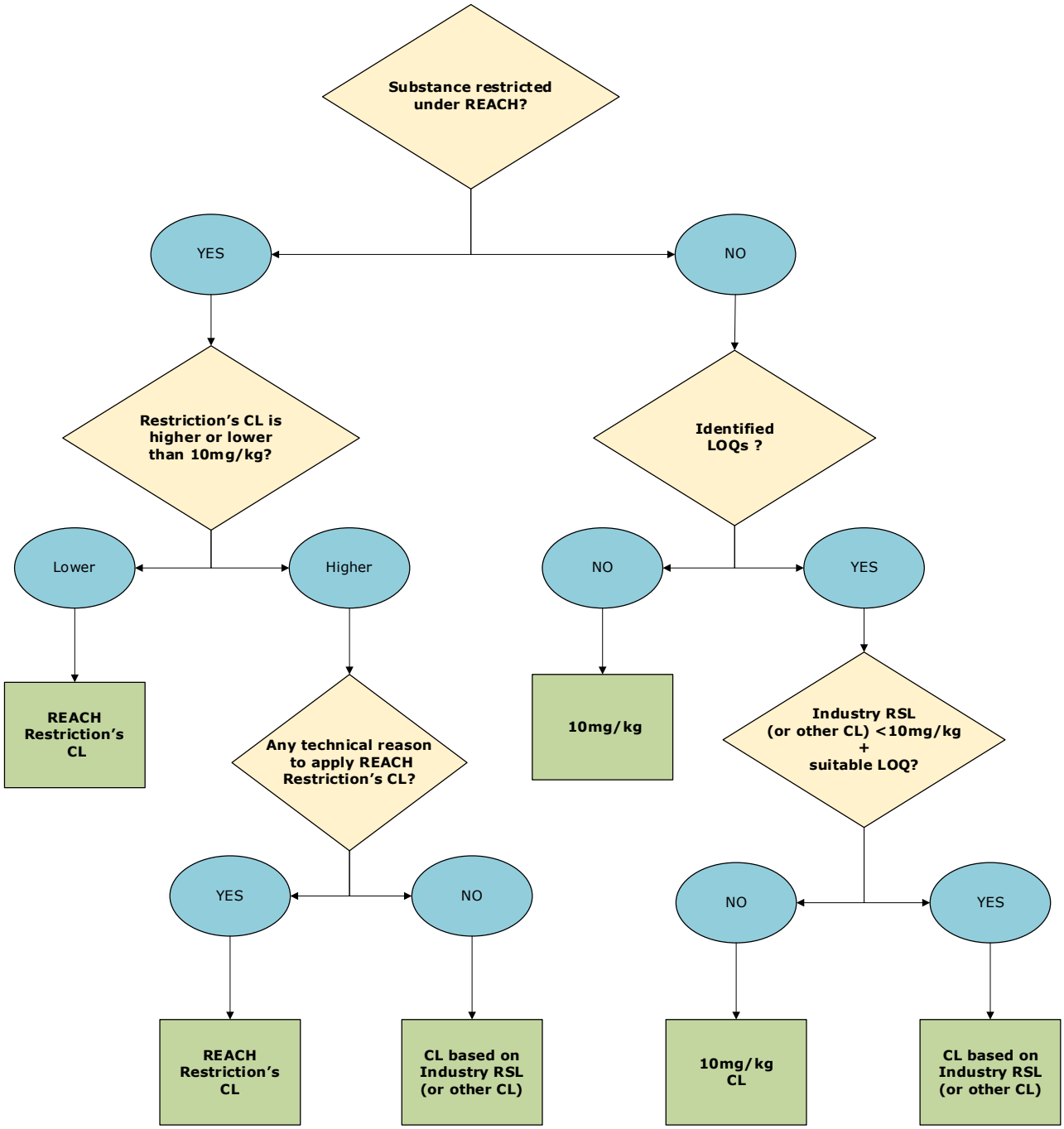

Figure 4: General criteria to define the proposed content concentration limits (CL)

Table 3: Substances or groups of substances with a considered concentration limit in homogeneous material different from 10 mg/kg (content) and/or with considered extractable-related concentration limits

Group	Substances	EC No	Existing REACH limit (content, unless specified)	Considered limit (content, unless specified)
Aldehydes	Formaldehyde	200-001-8	30 mg/kg (Dir 2019/1929/EU)	30 mg/kg (Wood 0.1 mg/m3 emission)
Aromatic amines (released from azo dyes)	Aromatic amines	(a)	30 mg/kg (REACH entry 43)	30 mg/kg
Aromatic hydrocarbons	Benzene	200-753-7	5 mg/kg (REACH entries 5, 72)	5 mg/kg
Bisphenols	Bisphenol A Bisphenol S Bisphenol AF	201-245-8 201-250-5 216-036-7	-	1 mg/kg
Chlorinated aromatic hydrocarbons	α,α,α-trichloro-toluene	202-634-5	1 mg/kg (REACH entry 72)	1 mg/kg
	α-chlorotoluene	202-853-6		
	α,α,α,4-tetra-chlorotoluene	226-009-1		
Metals	Arsenic (diarsenic trioxide)	215-481-4		10 mg As/kg (content)
			1 mg/kg (extract.; REACH entry 72	0.2 mg As/kg (extract.)
Metals	Cadmium and its compounds	231-152-8 (b)	100 mg/kg (content; REACH entry 23)	10 mg Cd/kg (content)
				0.1 mg Cd/kg (extract.)
Metals	Chromium VI compounds	(b)	Textiles: 1 mg CrVI/kg (extract.; REACH entry 72)	Textiles: 1 mg CrVI/kg (extract.)
			Leather: 3 mg CrVI/kg (extract.; REACH entry 47)	Leather: 3 mg CrVI/kg (extract.)
Metals	Cobalt and its compounds	231-158-0 (b)		10 mg Co/kg (content)
				1.0 mg Co/kg (extract.)

Group	Substances	EC No	Existing REACH limit (content, unless specified)	Considered limit (content, unless specified)
Metals	Lead and its compounds	200-755-8 (b)	500 mg/kg (content; REACH entry 63)	10 mg Pb/kg (content)
			1 mg Pb/kg (extract.; REACH entry 72)	0.2 mg Pb/kg (extract.)
Metals	Mercury	231-106-7		0.5 mg Hg/kg (content)
				0.02 mg Hg/kg (extract.)
Nitrosamines	N-nitrosamines and N-nitrosatable substances	(a)		0.5 mg/kg each, 5 mg/kg total N-nitrosatable substances
Organic dyes	Organic dyes	(a)	50 mg/kg (REACH entry 72)	50 mg/kg
Organotins	Organotin compounds	(a)	1 000 mg/kg (REACH entry 20)	1 mg DBT or DOT/kg
PAHs	PAHs	(a)	0.5 mg/kg (REACH entry 50)	0.5 mg/kg
Pesticides	Pesticides	(a)		0.5 mg/kg total pesticides
PFAS	PFAS	(a)		*See UPFAS*
Phthalates	Phthalates	(a)	1000 mg/kg (REACH entry 51)	50 mg/kg each, 100 mg/kg total phthalates
Quinolines	Quinoline	202-051-6	50 mg/kg (REACH entry 72)	50 mg/kg

Notes: (a): See EC list in the Appendix_A_Summary
(b): The limit also applies to the related metal compounds listed in Appendix A

Justifications for concentration limits for individual substances

Justifications for the selection of the considered concentration limit are provided below. For all substances, the content limits were defined based on the criteria presented in Figure 4.

Aldehydes

For acetaldehyde (EC 200-836-8) LOQs were identified with 1.8 and 30 mg/kg. ECHA considers that the default concentration limit of 10 mg/kg can be applied.

For formaldehyde (EC 200-001-8), ECHA considers a content concentration limit of 30 mg/kg, which is specified in Dir 2019/1929/EU related to textile and leather toy material based on a risk assessment by SCHER (EU, 2019) and which is also proposed by RAC for skin sensitising substances in textiles. This is only slightly higher than 16 mg/kg, which is the LOQ of the method EN ISO 14184-1:2011 for textiles and specified in the EU

Ecolabel for textile products (Commission Decision 2014/350/EU) (EU Commission, 2014) and is required in several RSLs, used by major stakeholders from the textile industry and testing laboratories. 75 mg/kg is specified in the restriction on CMR substances in textiles and footwear (REACH Annex XVII entry 72) and is proposed as a concentration limit by the ECHA Committee for Socio-economic Analysis (SEAC) for skin sensitising substances in textiles.

With regards to bamboo fibers, a stakeholder informed about the possibility to measure the content of formaldehyde with method EN ISO 14184-1.

With regards to the measurement of formaldehyde emission from wood or resin-bonded wood materials, ECHA is referring to the restriction for formaldehyde and formaldehyde releasers[19] (EU Commission, 2023c).

Amides

For acrylamide (EC 201-173-7) a usage ban with a concentration limit of 1 mg/kg is specified in the bluesign® (2022) RSL with an analytical method CEN/TS 13130-10:2005. No LOQs were provided during the second call for evidence.

For formamide (EC 200-842-0) a concentration limit of 200 mg/kg is specified in the Toys Safety Directive (2009).

For dimethylformamide (DMF, EC 200-679-5), N,N-dimethylacetamide (DMAC, EC 204-826-4) and N-methylpyrrolidone (NMP, EC 212-828-1) a concentration limit of 3 000 mg/kg is required in the restriction of CMR substances in textiles (REACH Annex XVII entry 72). For N-ethyl-2-pyrrolidone (NEP, EC 220-250-6) no restriction is yet applicable. For all those amides the same analytical methods apply (e.g. EN 17131:2019).

In the second call for evidence the following LOQs were reported: 5, 10, 40 mg/kg for formamide, 5, 40, 100 mg/kg for DMAC, 5, 40 mg/kg for NEP and 5, 10, 40 mg/kg for NMP. Based on those LOQs, ECHA considers the default concentration limit of 10 mg/kg to be applicable.

In the bluesign® (2022) RSL a usage ban for DMAC and DMF and is linked to a concentration limit of 5 mg/kg, the usage ban for NMP and NEP with 10 mg/kg. However, the following exemptions are specified. For articles produced by solvent coating, lamination or fiber manufacturing, the limit is 50 mg/kg for DMAC and DMF. For polyacrylonitrile (PAN) fibers, the limit is 10 mg/kg for DMAC; but not specified for DMF. The EU ecolabel for textile products requires for babies and children under 3 years of age 10 mg DMAC/kg for products containing elastane and acrylic. The OEKO-TEX® Standard 100 for textiles requires for DMAC and DMF 500 mg/kg and 1 000 mg/kg for materials made of acrylic (PAN), elastane (EL)/polyurethane, polyimide and aramids as well as coated (PU-, PVC-, PVC-plastisol, PVC-copolymer) textiles also for babies and children up to the age of 36 months.

Considering a usage ban and the fact that the available justification for higher concentration limits for specific conditions are inconsistent and no technical justification was received in the second call for evidence for having higher concentration limits, ECHA considers for all amides mentioned above the default concentration limit of 10 mg/kg. No

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1464

information was received from stakeholders to clarify if higher limits are technically needed for certain amides and certain materials.

Aromatic amines (released from azo dyes)

Several aromatic amines are listed that could be release from azo dyes (ECs 202-918-9, 202-974-4, 202-977-0, 203-401-0, 204-355-4, 204-358-0, 204-419-1, 205-282-0, 205-370-9, 221-627-8, 254-323-9, 209-030-0, 200-453-6, 210-406-1, 212-658-8, 201-963-1, 202-080-4, 202-109-0, 202-177-1, 202-199-1, 202-429-0, 202-441-6, 202-453-1, 202-591-2, 202-805-4, and CAS 21436-97-5).

For the detection of aromatic amines released from azo dyes, LOQs are provided with a range from 2 to 5 mg/kg. The Consumer Council at the Austrian Standards Institute (ASI, 2014) recommended that several aromatic amines shall not be present in accessible parts of child use and care articles with an action limit of 5 mg/kg. In the restriction on azocolourants and azodyes (REACH Annex XVII entry 43) a concentration limit of 30 mg/kg is specified for aromatic amines released from such dyes. It is important to note that the widely used standard methods EN ISO 14362-1 and EN ISO 14362-3 (for 4-amiazobenzene) for textiles, and EN ISO 17234-1 and EN ISO 17234-2 (for 4-aminoazobenzene) for leather, specify that a concentration above 30 mg/kg is necessary to state that the material has been treated using aromatic amine-releasing azo dyes (or 4-aminoazobenzene). With a concentration below or equal to 30 mg/kg a reliable statement on the use of such dyes is not possible and therefore the analyte should be reported as not detected. The reason given behind these statements is that the presence of small amounts of the aromatic amines can lead to false positives. Therefore, ECHA considers the existing REACH limit of 30 mg/kg appropriate to limit the intentional use of those substances.

Aromatic hydrocarbons

The LOQ of the standard methods ISO 22155:2016 referred to in the Forum Compendium of Analytical Methods to check compliance of REACH Annex XVII restrictions (ECHA, 2021b) is 0.2 mg/kg for benzene (EC 200-753-7). A concentration limit of 1 mg/kg is indicated in some restricted substances lists, whereas the restrictions on benzene in toys and parts of toys and on CMR substances in textiles (REACH Annex XVII entries 5 and 72) and the OEKO-TEX® Standard 100 specify a concentration limit of 5 mg/kg. Considering the small difference between 1 and 5 mg/kg and the high impact of changing a legal value, ECHA considers keeping 5 mg/kg.

Aromatic ketones

From the second call for evidence LOQs of 5 and 100 mg/kg were collected for benzophenone (EC 204-337-6). ECHA is considering the default LOQ of 10 mg/kg as no evidence of technical issues that could prevent from reaching this LOQ was provided.

Benzoic acids

No information on analytical methods to measure 4-tert-butylbenzoic acid (EC 202-696-3) in materials of childcare articles has been identified. Therefore, ECHA is considering the default LOQ of 10 mg/kg.

Bisphenols

Content

A reporting limit of 1 mg/kg is mentioned in the AFIRM (2023) restricted substance list for bisphenol A (EC 201-245-8), bisphenol S (EC 201-250-5) and bisphenol AF (EC 216-036-7) based on an in-house validated method. For Bisphenol A, LOQs collected from the call for evidence range from 0.1 to 3.33 mg/kg, with the possibility to go lower to 0.2 mg/kg with a concentration step for the latter. However, for bisphenol S and AF higher LOQs were reported (3.3 and 10 or 15 mg/kg) for in-house validated methods. SCCS (2020) established in its opinion on the safety of presence of bisphenol A in clothing articles a maximum amount of around 0.8 mg bisphenol A/kg textile to protect against systemic effects that bisphenol A may exert in humans when present in clothing. Therefore, also considering AFIRM limits, ECHA considers a concentration of 1 mg/kg for those bisphenols.

It is unclear if 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol (EC 204-327-1) should also be covered under bisphenols. This substance has other uses and a concentration limit of 1 000 mg/kg is reported in the OEKO-TEX® standard 100. LOQs reported are between 3.3 and 100 mg/kg. ECHA is also considering the default concentration of 10 mg/kg as no evidence of technical issues that could prevent from reaching this LOQ was reported.

Migration

Different legally binding migration values are available for bisphenol A (e.g. Food Contact Material Regulation, 2004; Toys Safety Directive, 2009 and EN 14350:2004). However, ECHA did not analyse those regulatory values further.

Borates

Boric acid (EC 233-139-2), diboron trioxide (EC 215-125-8) and disodium tetraborate (EC 215-540-4) release anionic boron species in solution that can interconvert depending on the pH conditions. In the second call for evidence stakeholders reported to quantify these species as total boron with an LOQ of 2.5 mg/kg. ECHA is therefore considering the default limit of 10 mg/kg as total boron content.

Brominated flame retardants

In the OEKO-TEX® standard 100 and some RSLs, a concentration limit of 10 mg/kg is reported for 2,2-bis(bromomethyl)propane-1,3-diol (EC 221-967-7), octabromodiphenyl ether (EC 251-087-9), and tetrabromobisphenol A (EC 201-236-9) with 50 mg/kg as limit for total brominated flame retardant content. In the second call for evidence LOQs of 1, 2, and 5 mg/kg for 2,2-bis(bromomethyl)propane-1,3-diol, 5 mg/kg for octabromodiphenyl ether and 1 and 5 mg/kg for tetrabromobisphenol A were reported.

For ammonium bromide (EC 235-183-8) an LOQ of 0.2 mg/kg was reported. ECHA notes that for sodium bromide (EC 231-599-9), which may also be used as flame retardant, a CLH report with a proposal for Repr. 1B was recently submitted and is not yet considered in this investigation report.

ECHA considers the default concentration limit of 10 mg/kg for each brominated flame retardant while for ammonium bromide ECHA considers a limit of 10 mg Br^-/kg as the quantification is limited to the bromide ion.

Chlorinated aliphatic hydrocarbons

For 1,1-dichloroethene (EC 200-864-0), 1,2-dichloroethane (EC 203-458-1), and trichloroethylene (EC 201-167-4), the OEKO-TEX® standard 100 requires a concentration limit of 1 mg/kg for each and 5 mg/kg in total, whereas for 1,2,3-trichloropropane (EC 202-486-1), the OEKO-TEX® standard 100 requires 10 mg/kg. For vinyl chloride (EC 200-831-0) 1 or 5 mg/kg are required in RSLs. LOQs for those substances range between 1 and 40 mg/kg. Based on those information ECHA considers that the default concentration limit of 10 mg/kg can be applied as no evidence of technical issues that could prevent from reaching this LOQ was reported.

Chlorinated aromatic hydrocarbons

The chlorinated aliphatic hydrocarbons α,α,α,4-tetrachlorotoluene (ECs 226-009-1, p-chlorobenzotrichloride), α,α,α-trichlorotoluene (EC 202-634-5, benzotrichloride), and α-chlorotoluene (EC 202-853-6, benzyl chloride) have a legally binding concentration limit of 1 mg/kg each (REACH Annex XVII entry 72) which is considered to be applied. The LOQs are 0.1 mg/kg.

Chloroalcohols

For 1,3-dichloropropan-2-ol (EC 202-491-9) LOQs were reported with 0.01 and 0.05 mg/kg. In the absence of further information on defined limits for this substance the default concentration limit of 10 mg/kg is applied.

Dioxanes

For 1,4-dioxane (EC 204-661-8) the LOQ for a standard method (EN ISO 16189:2021) is reported with 40 mg/kg (0.01% finished product). A RSL reports a concentration limit of 20 mg/kg. ECHA is considering the default concentration limit of 10 mg/kg as no evidence of technical issues that could prevent from reaching this LOQ was provided. No information was received from stakeholders to clarify if a higher limit would be required for a certain material.

Epoxides

For 1-chloro-2,3-epoxypropane (EC 203-439-8, epichlorohydrin) an LOQ of 100 mg/kg was reported for an in-house method suitable to measure the content. ECHA is considering the default concentration limit of 10 mg/kg as no evidence of technical issues that could prevent from reaching this LOQ was provided. No information was received from stakeholders to clarify if a higher limit would be required for a certain material.

Fluorinated alkenes

For tetrafluoroethylene (EC 204-126-9) a stakeholder reported an LOQ of 6 mg/kg for an in-house validated method. ECHA is considering the default concentration limit of 10 mg/kg.

Glycol amines

For ethanol, 2,2’-iminobis-, N-(C13-15-branched and linear alkyl) derivs. (EC 308-208-6) no LOQ was reported. ECHA is considering the default concentration limit of 10 mg/kg.

Glycols and glycol ethers

For several glycols and glycol ether such as 1,2-bis(2-methoxyethoxy)ethane (EC 203-977-3), 1,2-dimethoxyethane (EC 203-794-9), 2-ethoxyethanol (EC 203-804-1), 2-ethoxyethyl acetate (EC 203-839-2), 2-methoxyethanol (EC 203-713-7), 2-methoxyethyl acetate (EC 203-772-9), 2-methoxypropanol (EC 216-455-5), 2-methoxypropyl acetate (EC 274-724-2), and bis(2-methoxyethyl) ether (EC 203-924-4), OEKO-TEX® is requiring a concentration limit of 10 mg/kg by using thermodesorption and analysis by GC/MS of the enriched released substances. For standard analytical methods, the LOQ is 20 or 40 mg/kg for many substances. Only for 2-methoxypropoyl acetat an EPA-method provides an LOQ of 10 mg/kg. ECHA is considering the default concentration limit of 10 mg/kg as no evidence of technical issues that could prevent from reaching this LOQ was provided. No information was received from stakeholders to clarify if a higher limit would be required for a certain material.

Imidazoles

For 1-vinylimidazole (EC 214-012-0) no LOQ was reported. ECHA is considering the default concentration limit of 10 mg/kg.

Ketones

For 4,4'-bis(dimethylamino)benzophenon (Michlers Keton) (EC 202-027-5) no LOQ was reported. ECHA is considering the default concentration limit of 10 mg/kg.

Metals / arsenic (diarsenic trioxide)

Content: LOQs for measuring the content of arsenic (As) are 1, 20 and 100 mg As/kg. OEKO-TEX® specifies a concentration limit of 100 mg As/kg. ECHA is considering the default concentration limit (content) of 10 mg As/kg as no evidence of technical issues that could prevent from reaching this LOQ was provided. Stakeholders are invited to provide evidence in case a higher value would be required for a certain material.

Extractable: The LOQ for the extractable amount of arsenic is 0.1 mg As/kg. A concentration limit of 0.2 mg As/kg is required by several ecolabels (e.g. EU Ecolabel for textiles and shoes for children, OEKO-TEX®, GOTS), whereas REACH Annex XVII entry 72 specifies 1 mg As/kg in textiles. ECHA considers a concentration limit (extractable) of 0.2 mg As/kg as applicable specifically for babies and children below 3 years of age.

Migration: In the Toys Safety Directive migration limits for arsenic in different materials are specified. ECHA did not investigate further on migration limits.

Metals / cadmium and its compound:

Content: LOQs for measuring the content of cadmium (Cd) are 1, 2.5, 5, 10 mg Cd/kg. Concentration limits are reported with 10 mg Cd/kg (Versace RSL), 40, 45 or 50 mg Cd/kg for ecolabels and 100 mg Cd/kg in synthetic polymers (also referred to as 'plastic materials'; REACH entry 23). In this restriction entry plastic material that can be used by children is not considered specifically. Taking into account that small children may be more sensitive than adults and may be higher exposed (e.g. by mouthing of plastic material), ECHA is considering the default concentration limit (content) of 10 mg Cd/kg as applicable.

Extractable: The LOQ for the extractable amount of cadmium is 0.05 mg Cd/kg. A concentration limit of 0.1 mg Cd/kg is required by several ecolabels (e.g. EU Ecolabel for textiles and shoes for children, OEKO-TEX®, GOTS), whereas REACH Annex XVII entry 72

specifies 1 mg Cd/kg in textiles. ECHA considers a concentration limit (extractable) of 0.1 mg Cd/kg as applicable specifically for babies and children below 3 years of age.

Migration: In the Toys Safety Directive migration limits for cadmium in different materials are specified. ECHA did not investigate further on migration limits.

Metals / chromium VI compounds:

Content: no methods are available to analyse the total content of the chromium VI ion (CrVI) in articles through acid digestion of the material without losing the +VI oxidation state.

Extractable: REACH Annex XVII entry 72 specifies a limit of 1 mg CrVI/kg for textiles, REACH Annex XVII entry 47 a limit of 3 mg CrVI/kg in leather with skin contact. LOQs are 0.5 mg CrVI/kg in textiles and 3 mg CrVI/kg in leather. ECHA considers the REACH limits (extractable) as applicable.

Migration: In the Toys Safety Directive migration limits for chromium VI in different materials are specified. ECHA did not investigate further on migration limits.

Metals / cobalt and its compounds:

Content: LOQs for measuring the content of cobalt (Co) are 1, 2.5, 5, 10 mg/kg. No content-related concentration limits are reported. ECHA is considering the default concentration limit (content) of 10 mg Co/kg.

Extractable: The LOQs for the extractable amount of cobalt are 0.05, 0.1, 0.5 mg Co/kg. A concentration limit of 1.0 mg Co/kg is required by several ecolabels (e.g. EU Ecolabel for textiles and shoes for children, OEKO-TEX®, GOTS). ECHA considers a concentration limit (extractable) of 1.0 mg Co/kg as applicable.

Migration: In the Toys Safety Directive migration limits for cobalt in different materials are specified. ECHA did not investigate further on migration limits.

Metals / lead and its compounds:

Content: LOQs for measuring the content of lead (Pb) are 1, 2.5, 5, 10 mg Pb/kg. A RSL (Versace) specifies a limit of 40 mg Pb/kg, GOTS 50 mg Pb/kg and other ecolabels or RSLs 90 mg/kg. REACH Annex XVII entry 63 specifies a limit of 500 mg Pb/kg for consumer articles with release rates > 0.05 µg Pb/cm^2 and articles < 5 cm with mouthing my children. ECHA notes that RAC indicated in its opinion on lead in consumer articles (ECHA, 2014) that blood lead levels in children already exceeded the benchmark dose level assessed by EFSA (2013)[20] and that RAC agreed to limit additional exposure of children from consumer articles as much as possible to 500 mg/kg. ECHA is considering the default concentration limit of 10 mg Pb/kg as no evidence of technical issues that could prevent from reaching this LOQ was provided.

Extractable: The LOQs for the extractable amount of lead are 0.05, 0.1, 0.5 mg Pb/kg. A concentration limit of 0.2 mg Pb/kg is required by several ecolabels (e.g. EU Ecolabel for textiles and shoes for children, OEKO-TEX®, GOTS). REACH Annex XVII entry 72 specifies

[20] Scientific Opinion on Lead in Food (wiley.com)

a limit of 1 mg Pb/kg. ECHA considers a concentration limit (extractable) of 0.2 mg Pb/kg as applicable, specifically for babies and children below 3 years of age.

Migration: In the Toys Safety Directive migration limits for lead in different materials are specified. ECHA did not investigate further on migration limits.

Metals / lithium (lithium hydroxide)

Content: LOQs for measuring the content of lithium (Li) are 0.1 and 100 mg Li/kg. ECHA is considering the default concentration limit (content) of 10 mg Li/kg.

Extractable: no information on LOQs for the measurement (extraction) of lithium in materials of childcare articles was identified.

Metals / mercury

Content: LOQs for measuring the content of mercury (Hg) are 0.1, 0.4, 2, 5 mg Hg/kg. Concentration limits range from 0.2 mg Hg/kg in diapers, to 0.5 mg Hg/kg (OEKO-TEX® and RSLs) to 1 mg Hg/kg. ECHA is considering a concentration limit (content) of 0.5 mg Hg/kg.

Extractable: The LOQs for the extractable amount of cobalt are 0.01, 0.02, 0.1 mg Hg/kg. A concentration limit of 0.02 mg Hg/kg is required by several ecolabels (e.g. EU Ecolabel for textiles and shoes for children, OEKO-TEX®, GOTS). ECHA considers a concentration limit (extractable) of 0.02 mg Hg/kg.

Migration: In the Toys Safety Directive migration limits for mercury in different materials are specified. ECHA did not investigate further on migration limits.

Metals / vanadium (divanadium pentaoxide)

Content: LOQs for measuring the content of vanadium (V) are 2.5 and 100 mg V/kg. ECHA is considering the default concentration limit (content) of 10 mg V/kg.

Extractable: no information on LOQs for the measurement (extraction) of vanadium in materials of childcare articles was identified.

Morpholines

For 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (List 404-360-3) no LOQ was reported. ECHA considers the default concentration limit of 10 mg/kg.

Nitriles

For acrylonitrile (EC 203-466-5) LOQs of 2 and 30 mg/kg were reported. ECHA considers the default concentration limit of 10 mg/kg applicable as no evidence of technical issues that could prevent from reaching this LOQ was provided.

Nitrosamines

Content: OEKO-TEX® specifies a content limit of 0.5 mg/kg each and 5 mg/kg for total N-nitrosatable substances[21], which is also considered by ECHA as concentration limit (content). LOQs are provided with 0.1 and 0.5 mg/kg.

Migration: For nitrosamines released from N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers, Dir 93/11/EEC specifies a migration limit of 0.01 mg in total of N-nitrosamines released/kg and 0.1 mg in total nitrosatable substances/kg. ECHA did not investigation further on this or related migration limits.

Organic dyes and quinoline

For quinoline LOQs were provided by different stakeholders in a range from 2.5 to 10 mg/kg, for organic dyes from 2 to 15 mg/kg. The Consumer Council at the Austrian Standards Institute (ASI, 2014) recommended that several colourants shall not be present in accessible parts of child use and care articles with an action limit of 10 mg/kg. The restriction on CMR substances in textiles (REACH Annex XVII entry 72) specifies concentration limits of 50 mg/kg for quinoline and some organic dyes (ECs 208-953-6, 219-603-7, 209-321-2). It is important to note that the standard method DIN 54231 for quinoline and organic dyes, which is also indicated in the legal text, states that the use of a dye is considered proven if the dye has been identified above 50 mg/kg. Therefore, ECHA considers the existing REACH concentration limits of 50 mg/kg applicable.

Recently, the Swedish Chemicals Agency (KEMI, 2022) has performed a RMOA of quinoline in textiles and concluded that 50 mg/kg may pose a risk to consumers and therefore proposed to lower the concentration limit for quinoline required in REACH Annex XVII, entry 72. However, KEMI did not calculate a concentration limit that may not pose a risk to consumers.

Organophosphorus compounds

For the flame retardants tris(2-chloroethyl)phosphate (EC 204-118-5) and trixylyl phosphate (EC 246-677-8), the concentration limit specified in OEKO-TEX® is 10 mg/kg. LOQs are 1 and 5 mg/kg. No information on LOQs was received for dimethyl propylphosphonate (EC 242-555-3) and diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC 278-355-8).

ECHA considers the default concentration limit of 10 mg/kg applicable for all the above-mentioned organophosphorus compounds.

Organotin compounds

Organotin compounds identified during this investigation that may be present in childcare articles are dioctyl tin (DOT) or dibutyl tin (DBT) compounds. DOT compounds include 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (EC 239-622-4), dioctyltin dilaurate (EC 222-883-3), and stannane, dioctyl-, bis (coco acyloxy) derivs (EC 293-901-5). DBT compounds include dibutylbis(pentane-2,4-dionato-O,O')tin (EC 245-152-0), dibutyltin bis (2-ethylhexanoate) (EC 220-481-2), dibutyltin di(acetate)

[21] WEB_New_Regulations_2020_STANDARD_100_EN.pdf (oeko-tex.com)

(EC 213-928-8), dibutyltin dichloride (EC 211-670-0), dibutyltin dilaurate (EC 201-039-8), dibutyltin hydrogen borate (EC 401-040-5), dibutyltin maleate (EC 201-077-5).

REACH Annex XVII entry 20 specifies a concentration limit of 1 000 mg/kg in mixtures or articles. OEKO-TEX® and the EU Ecolabel for shoes report a concentration limit of 1 mg DOT or DBT/kg. LOQs for the detection of DOT or DBT ions are reported between 0.04 and 0.5 mg DOT or DBT/kg. ECHA notes that the justification for the restriction of organotin compounds in consumer articles, particularly the risk for children from mouthing PVC toys have been identified, and a concentration limit was set with 0.1 % (1 000 mg/kg). The European Association of Flexible Polyurethane Foam Blocks Manufacturers (EUROPUR) stated during the draft report consultation that in their CertiPUR certification program a limit of 1 mg/kg for DBT in PU foam, which was considered to be higher than the LODs of their test methods, was initially proposed. However, this limit proved to lead to false positive results and for this reason the limit was raised to 15 mg/kg for DBT. Still, considering the low LOQs ≤ 0.5 mg/kg and the concentration limit in the ecolabels of 1 mg/kg, ECHA considers a concentration limit of 1 mg DOT or DBT/kg as applicable to effectively enforce a ban of organotin compounds in plastic materials.

PAHs

The current regulatory value of 0.5 mg/kg for each PAH (REACH Annex XVII entry 50) is considered. This value is specifically set in the restriction for toys and childcare articles. However, there are slightly different approaches measuring more and slightly different PAHs. For example, in the OEKO-TEX® Standard 100 the same concentration limit of 0.5 mg/kg for each PAH is required and in addition below 5 mg/kg for the sum of 24 PAH. As also mentioned in the comments provided by BEUC, BAUA requires that for 15 PAHs the concentration for each PAH should be lower than 0.2 mg/kg and the sum below 1 mg/kg for materials intended for children up to three years to be placed in the mouth or with prolonged dermal contact (BAuA, 2020). Considering that REACH Annex XVII entry 50 already defines a limit specifically for childcare articles, that the two limits have similar magnitude and the high impact of changing the legal value, ECHA is proposing not to deviate from the REACH limit and keep 0.5 mg/kg as limit for each PAH.

Peroxides

For bis(α,α-dimethylbenzyl) peroxide (EC 201-279-3) an LOQ of 2 mg/kg is reported. ECHA considers the default concentration limit of 10 mg/kg applicable.

Pesticides

Hexachlorobenzene (EC 204-273-9), captafol (EC 219-363-3), and dinoseb (EC 201-861-7) have concentration limits of 0.5 mg for total pesticides (e.g. OECO-TEX®). LOQs reported are between 0.1 and 10 mg/kg. ECHA considers for all pesticides that may be present in childcare articles including also diuron (EC 206-354-4) and 1,2-dibromoethane (EC 203-444-5) a concentration limit of 0.5 mg for total pesticides.

PFAS

Due to the ongoing universal restriction for PFAS (UPFAS), no concentration limit for PFAS is considered within this report.

Phenols

For **2,4,6-tri-tert-butylphenol** (EC 211-989-5) an LOQ is reported with 5 mg/kg. ECHA considers the default concentration limit of 10 mg/kg applicable.

Phthalates

In total 15 phthalates have a harmonised CMR 1A or 1B classification. The CLP generic concentration limits for those phthalates are 3 000 mg/kg based on category 1B for reproductive toxicity. For phthalates also identified with endocrine disrupting properties for human health (e.g. REACH Annex XIV) a GCL for endocrine disruptor may apply which is e.g. 0.1 % for category 1 endocrine disruptors (1 000 mg/kg) following the new hazard classes and related GCL of CLP. Eight of those phthalates are restricted: REACH Annex XVII, entry 51 lists four phthalates restricted in toys and childcare articles marketed after 7 July 2020 (DEHP, EC 204-211-0; DBP, EC 201-557-4; BBP, EC 201-622-7; and DIBP, EC 201-553-2) and entry 72, Appendix 12, five further phthalates restricted in textiles (ECs 201-559-5, 204-212-6, 205-017-9, 210-088-4, 276-158-1). The concentration limits for the eight phthalates specified in the restrictions are 1 000 mg/kg for each substance individually or in total. Those concentration limits were based on a risk assessment (ECHA, 2012) that indicated no risk for 2-year-old children from articles. DEHP shows endocrine effects, however, the endocrine effect was not specifically considered in the risk assessment.

ECHA identified an LOQ of 50 mg/kg for all 15 phthalates with harmonised CMR 1A or 1B classification. For several phthalates also lower LOQs (e.g. 10 mg/kg) and for some phthalates LOQs also above 100 mg/kg were identified, depending on the analytical method.

The lowest concentration limit identified in a RSL was 50 mg/kg (total) for children. The Ecolabel GOTS specified a concentration limit of 100 mg/kg (total) in textiles and 500 mg/kg (total) for additional fibres and accessories. OEKO-TEX® lists 100 mg/kg each and 250 mg/kg total for textiles used for babies. For shoes and coatings, the concentration limits identified are often higher e.g. 500 mg/kg. The Danish Executive order BEK No 947 of 20/06/2020 requires 500 mg/kg for all phthalates except the phthalates restricted under REACH. Some RSLs require 500 mg/kg each phthalate and 1 000 mg/kg total phthalates.

Considering the intention to ban CMR 1A or 1B substances in childcare articles, ECHA is considering a concentration limit of 50 mg/kg for each phthalate, which reflects the LOQ, and 100 mg/kg for total phthalates. No information was received from stakeholders to clarify if higher limits are technically needed for certain phthalates in certain materials.

Salts of ethylhexanoic acid

The following salts of ethylhexanoic acid were considered: 2-ethylhexanoic acid, iron salt (EC 243-169-8), barium bis(2-ethylhexanoate) (EC 219-535-8), cobalt bis(2-ethylhexanoate) (EC 205-250-6), potassium 2-ethylhexanoate (EC 221-625-7), strontium bis(2-ethylhexanoate) (EC 219-536-3), tin bis(2-ethylhexanoate) (EC 206-108-6) and zinc bis(2-ethylhexanoate) (EC 205-251-1). No information on LOQs was received. ECHA considers the default concentration limit of 10 mg/kg for 2-ethylhexanoate anion.

Silicon substances

Silicon carbide (EC 206-991-8) is suspected to be present in textiles and rubber (synthetic polymers) from REACH registration dossiers information. Publicly available sources (Britannica, 2023) report that the substance is synthetically manufactured and it is used for its hardness and fracture characteristics in grinding wheels and abrasive paper and cloth products, for its high thermal properties as a refractory, and for its electrical properties as a semiconductor. based on this information, ECHA considers that it is unlikely for this substance to be used in childcare articles. Furthermore, the harmonised classification Carc 1B relates to the inhalation route (i.e.silicon carbide fibres with diameter

< 3 µm, length > 5 µm and aspect ratio ≥ 3:1), which is the only route of concern as specified in the RAC opinion (ECHA, 2018a) A potential remaining risk from inhalation from a material abrased from childcare articles is considered very low (if any). Since no carcinogenic risk is to be considered for the oral and dermal route, ECHA considers that no specific content concentration limit in childcare articles would be applicable to this substance. In case this substance would be identified in childcare articles, a specific concentration limit related to inhalation of abrased material would need to be set.

6. Inventory of available analytical methods

All the collected analytical methods suitable to detect the CMR 1A and 1B substances measured or suspected in homogeneous materials present in childcare articles are reported in the excel sheet 'Inventory' of the excel file 'Appendix_A.6.1_Analytical_methods'. Detailed information on the methodology, including information from stakeholders' consultations, and description of the table structure is provided in Appendix 4 .

As requested by the Commission, the analytical methods should be suitable to quantify the substance content according to the indicated substance content limits. However, for some substances, migration, emission, and extractable content limits are mentioned in some legislative frameworks. For this reason, migration methods for bisphenol A and Nitrosamines, emission methods for formaldehyde in wood and extractable content method for metals and metals substances have also been collected (see 1)a)i)(1)(a)(i)Appendix 4 for more details).

The considerable amount of information collected suggest the feasibility to analyse the listed substances. For the majority of the substances identified in this investigation report that may be measured or suspected in childcare articles, well-established standard analytical methods are available. For all the remaining substances that lacked information on analytical methods it was possible to indicate analytical methods that would need to be validated in-house by testing laboratories. Collecting information on analytical methods for all CMR 1A or 1B substances was not feasible due to the large number of such substances (>1 000).

6.1. Summary of most relevant analytical methods

Since many analytical methods were collected for each of the substances in different materials, a summary of the most relevant analytical methods was created (sheet 'Summary' in the excel file 'Appendix_A.6.1_Analytical_methods'). These methods, selected from the listed methods on the excel sheet 'Inventory', were considered the most well-established and easily implementable, and often also the cheapest, analytical methods, suitable to detect the substances according to the considered concentration limits.

The most relevant methods were chosen by prioritising standard analytical methods from European standardization bodies (e.g. CEN, DIN) and the International Organization for Standardization (ISO), followed by US governmental agencies' methods (e.g. EPA, CPSC). Stakeholders' consultations (individual meetings and the dedicated call for evidence) and information from RSLs also allowed to verify which methods were the most well-established, cheapest, and most often used by testing laboratories. For the substances with little to no information available, focus was put on trying to select the cheapest and easily implementable methods, giving priority to routinely used analytical techniques such as GC-MS and therefore excluding methods with more sophisticated techniques.

6.2. Potential Testing strategy

Due to the large scope of articles and different materials and substances, a testing strategy could support the practical implementation, and in particular the enforcement, of a future restriction. Moreover, the testing strategy may facilitate the targeting of tests and therefore reduce the overall enforcement costs.

The purpose of this investigation report is not to elaborate a detailed and comprehensive testing strategy at this stage (the final scope and condition of a restriction are not decided), but to give a flavour on how a step-by-step testing strategy could look like and could be later elaborated by the Forum. This investigation report therefore presents a potential testing strategy based on the different deliverables collected and described in this investigation report:

1. **Identify if an article falls under the definition of a childcare article** also using the categorisation table (Table 1).

2. **Identify the different materials present in the childcare article** that are **accessible** to children to the substances of concern by direct contact or potential migration or emission of substances from the materials (via skin, mouth, or inhalation) (see Figure 5: Example of materials exposed to children in a car seat).

Figure 5: Example of materials exposed to children in a car seat

3. **Consider which substances need to be tested for identified material(s).** Table 4: Testing matrix: testing priorities for CMR 1A or 1B substances in different materials ('Testing Matrix') presents an overview of the substances potentially present in different materials. This table is based on the AFIRM[22]

[22] The Apparel and Footwear International RSL Management (AFIRM) Group is a member-driven organization of (43 well recognised) apparel and footwear companies collaborating to promote chemicals management in the global supply chain. Since its founding, AFIRM's focus has been the continuous advancement of chemicals management including phasing out or limiting restricted substances to established limits in apparel, footwear, and accessories. The testing priorities are based on a broad understanding of global supply chain operations, and from nearly two decades of managing restricted substances across a wide range of materials. https://afirm-group.com/about/#steeringcommittee substances to established limits in apparel, footwear, and accessories. https://afirm-group.com/about/#steeringcommittee

(2023) Testing Matrix, however the reported testing priorities are modified based on the data collected in this investigation report. Dark red flags (1*) are for substances measured in childcare articles. Red flags (1) are for substances suspected in childcare articles and indicated as priority 1 by the AFIRM Testing Matrix (high risk of being present in the specified materials). Orange flags (2) are for all other substances suspected in childcare articles. When available, additional information is provided: e.g. "dyed" applicable for dyed/coloured materials; "synthetic" for textiles containing (also) synthetic materials; "PU foam".

After identifying the substances to be tested, suitable analytical methods can be identified in the excel file Appendix_A.6.2_Testing strategy'. The excel provides a dedicated excel sheet for each material that allows to find a targeted analytical method (and a screening method, if available) to accurately quantify each substance at the considered concentration limit. In case any of the listed analytical methods is not available to the testing laboratory, alternative methods are provided and can be consulted in the sheet 'Inventory' of the excel file 'Appendix_A.6.1_Analytical_methods'.

4. **Perform a screening analytical test if available** to exclude the need for further investigation. The screening method will provide certainty of conformity (analytes well below the applicable concentration limit) or indication of concentration levels potentially above the concentration limit. For some substances in specific materials, the screening can be performed by using portable devices. This is the case for metals (As, Cd, Co, Cr, Pb, V) that can be determined with portable Energy dispersive X-ray fluorescence (ED-XRF), and total phthalate content in synthetic polymers (mainly PVC) that can be determined with portable FT-IR devices. It is important to note that technological advances in the field of portable devices might allow to extend the scope of this type of testing for childcare articles in the future. (Duan et al., 2022)

5. **Perform targeted analytical tests.** If step 4 is not applicable/appropriate or if the analytical screening performed following step 4 gives indication of the presence of the substance at levels potentially above the defined concentration limit, the target methods should be applied to confirm the content of the substance in the article.

To complement the laboratory testing enforcement, paper or document-based enforcement could be performed at childcare articles' manufacturing sites, at childcare article importers' offices or at childcare distributor/retailer location (shops or website). This could include verification of inventory records such as purchased goods, sold goods, source of material supplies, materials composition that should provide information on the composition of the materials and on the conformity of that composition with different regulations that apply to childcare articles. Documented unconformities could be the trigger to move to laboratory testing.

ECHA also investigated if the Combined Nomenclature (CN)[23] codes could be used to support enforcement in identifying childcare articles. The information received from the

[23] Combined nomenclature codes is a tool for classifying goods when they are declared at the customs in EU

Directorate-General for Taxation and Customs Union (TAXUD) indicates that the CN codes are very generic and cannot be used for that purpose. The only exception is the CN code *871500* that applies to 'Baby carriages and parts thereof'.

Table 4: Testing matrix: testing priorities for CMR 1A or 1B substances in different materials

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
Aldehydes	Formaldehyde	200-001-8	1	1*	1*	1*	1*	1*	1*		
	Acetaldehyde	200-836-8		1*		1*					
Amides	Acrylamide	201-173-7			2						
	Formamide	200-842-0			2	2					
	Dimethylformamide	200-679-5		1	1*	1	1				
	N,N-Dimethyl-acetamide	204-826-4		1	2	2	2				
	N-Methyl-pyrrolidone	212-828-1		1*	2	2	2				
	N-Ethyl-2-pyrrolidone	220-250-6		2							
Aromatic amines	N,N-Dimethyl-p-toluidine	202-805-4		2	2						
	4-Aminoazobenzene	200-453-6	1 (dyed)	1* (dyed)							
	2-Aminotoluene	202-429-0	1 (dyed)	* (dyed)	1*						
	4-Methyl-m-phenylene diamine	202-453-1	1 (dyed)	1* (dyed)	1*						
	4,4'-Methylene-bis[2-chloroaniline]	202-918-9	1 (dyed)	1 (dyed)	2						
	3,3'-Dimethoxy-benzidine	204-355-4	1 (dyed)	1* (dyed)							
	4,4'-Bi-o-toluidine	204-358-0	1 (dyed)	1* (dyed)							
	4-Chloroaniline	203-401-0	1 (dyed)	1* (dyed)							
	Benzidine	202-199-1	1 (dyed)	1* (dyed)							

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
	Further 17 substances		1 (dyed)	1 (dyed)							
Aromatic hydrocarbons	Benzene	200-753-7		1*	1*	2	1*				
Aromatic ketones	Benzophenone	204-337-6			2						
Benzoic acids	4-tert-Butyl-benzoic acid	202-696-3			2						
Bisphenols	Bisphenol A	201-245-8	1	1	1*						
	Bisphenol AF	216-036-7	1	1	1*						
	Bisphenol S	201-250-5	1	1	1 (polycarbo nate), 2 (others)						
	6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol	204-327-1		1*	1*						
Borates	Boric acid	233-139-2	2 (FR)	2 (FR)	2 (FR)						
	Diboron trioxide	215-125-8	2 (FR)	2 (FR)	2 (FR)						
	Disodium tetraborate	215-540-4	2 (FR)	2 (FR)	2 (FR)	2 (FR)		2 (FR)			
Brominated flame retardants	Tetrabromobisphenol A	201-236-9		1* (FR)	1* (FR)	2 (FR)	2 (FR)	2 (FR)			
	2,2-Bis(bromo-methyl)propane-1,3-diol	221-967-7		2 (FR)	2 (FR)	2 (FR)	2 (FR)	2 (FR)			
	Diphenylether; octabromo derivate	251-087-9		2 (FR)	2 (FR)	2 (FR)	2 (FR)	2 (FR)			

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
	Ammonium bromide	235-183-8		2 (FR)							
Chlorinated aliphatic hydrocarbons	Vinyl chloride	200-831-0		1*	1*	1*					
	1,1-Dichloroethene	200-864-0		2	2	2	1				
	1,2,3-Trichloropropane	202-486-1		2	2						
	1,2-Dichloroethane	203-458-1		2	2	2	1				
	Trichloroethylene	201-167-4		2	2	2	1				
Chlorinated aromatic hydrocarbons	α,α,α,4-Tetra-chlorotoluene	226-009-1		2							
	α,α,α-Trichlorotoluene	202-634-5		2							
	α-Chlorotoluene	202-853-6		2							
Chloro-alcohols	1,3-Dichloropropan-2-ol	202-491-9		1*							
Dioxanes	1,4-Dioxane	204-661-8			2						
Epoxides	1-Chloro-2,3-epoxypropane	203-439-8			2						
Fluorinated alkene	Tetrafluoroethylene	204-126-9		2							

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
Glycol amines	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	308-208-6			2						
Glycols and glycol ethers	1,2-Bis(2-methoxy-ethoxy)ethane	203-977-3	2	2	2					2	
	1,2-Dimethoxy-ethane	203-794-9	2	2	2						
	2-(2-Methoxy-ethoxy)ethanol	203-906-6		2							
	2-Ethoxyethanol	203-804-1		1*			1*				
	2-Methoxyethanol	203-713-7	2	1*	2		1*				
	2-Methoxyethyl acetate	203-772-9	2	2	2						
	2-Methoxypropanol	216-455-5	2	2	2						
	2-Methoxypropyl acetate	274-724-2	2	2	2						
	2-Ethoxyethyl acetate	203-839-2		2	2						
	bis(2-methoxy-ethyl) ether	203-924-4		2	2						
Imidazoles	1-vinylimidazole	214-012-0		2							
Ketones	4,4'-Bis(dimethyl-amino)benzo-phenon (Michlers Keton)	202-027-5		2							
Metals	Arsenic(diarsenic trioxide)		1	1*	1*	1*	2			1*	
	Cadmium and its compounds		1	1*	1*	1	2			1	1

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
	Chromium (VI) compounds		1*	2							
	Cobalt and its compounds		1	1*	1*	1*	2			1*	1*
	Lead and its compounds		1	1*	1*	1*	2			1*	2
	Mercury		1	1*	1*	1	2			1	
	Lithium (lithium hydroxide)	215-183-4		2							
	Vanadium (divanadium pentaoxide)	215-239-8			2						
Morpholines	2-Benzyl-2-dimethylamino-4'-morpholino-butyrophenone	404-360-3				1*					
Nitriles	Acrylonitrile	203-466-5		1*	1*						
Nitrosamines	Nitrosodipropyl-amine	210-698-0			2						
	Dimethylnitroso-amine	200-549-8		1*	1*						
	4-Nitroso-morpholine	627-564-6			2						
	2,2'-(Nitrosoimino) bisethanol	214-237-4		2							
Organic Dyes	9 Substances			1 (dyed)							
Organo-phosphorus compounds	Tris(2-chloroethyl) phosphate	204-118-5	2 (FR)	1* (FR)	1* (FR)	1* (FR)	2 (FR)	2 (FR)			
	Trixylyl phosphate	246-677-8	2 (FR)	2 (FR)	2 (FR)	2 (FR)	2 (FR)	2 (FR)			

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
	Diphenyl(2,4,6-trimethyl-benzoyl) phosphine oxide	278-355-8		2 (FR)	1* (FR)						
	Dimethyl propyl-phosphonate	242-555-3			2 (FR)						
Organotins	Dioctlytin (DOT) compounds		2	1 (synthetic leather), 2 (others)	1	1	1				
Organotins	Dibutyltin (DBT) compounds		2	1 (synthetic leather), 2 (others)	1*	1	1				
PAHs	Benzo(a)pyrene	200-028-5		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Benzo[a]anthracene	200-280-6		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Benzo[e]ace-phenanthrylene	205-911-9		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Benzo[e]pyrene	205-892-7		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Benzo[j]fluoranthene	205-910-3		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
	Benzo[k]fluoranthene	205-916-6		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Chrysene	205-923-4		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Dibenz[a,h]anthracene	200-181-8		2	1*	1 (rubber or black materials), 2 (others)	1 (rubber or black materials), 2 (others)				
	Benzo(r,s,t)pentaphene	205-877-5			2						
	Dibenzo[b,def]chrysene	205-878-0			2						
	Dibenzo[def,p]chrysene	205-886-4			2						
Peroxides	Bis(α,α-dimethyl-benzyl) peroxide	201-279-3			2						
Pesticides	Hexachlorobenzene	204-273-9		2	1*						
	Captafol	219-363-3		2							
	Dinoseb	201-861-7		2							
	Diuron	206-354-4			2						
	1,2-Dibromoethane	203-444-5		2							
PFAS	10 Substances		1	1*	1	1	1				

Chemical group	Substance name	EC number	Leather (natural)	Textiles	Synthetic polymers	Surface coatings	Homo-genous mixtures	Wood, compo-site wood	Bamboo-resin	Metals	Glass
Phenols	2,4,6-Tri-tert-butylphenol	211-989-5		1*	1*						
Phthalates	Dicyclohexyl phthalate	201-545-9		1	1*	1	1				
	Diisobutyl phthalate	201-553-2		1*	1*	1	1				
	Di-n-butyl phthalate	201-557-4		1*	1*	1*	1	1*			
	Butyl benzyl phthalate	201-622-7		1*	1*	1*	1				
	Dihexyl phthalate	201-559-5		1*	1*	1	1				
	Di-(2-ethylhexyl) phthalate	204-211-0		1*	1*	1*	1				
	Bis(2-methoxyethyl) phthalate	204-212-6		1	1*	1	1				
	Diisopentylphthalate	210-088-4		1	1*	1	1				
	Di-n-pentyl phthalate	205-017-9		1	1*	1	1				
	Further 6 phthalates			1	1	1	1				
Quinoline	Quinoline	202-051-6		2 (dyed)							
Salts of ethyl-hexanoic acid	7 Substances				2						

Abbreviations: FR: flame retardant

.

7. Stakeholder consultations

ECHA identified different relevant stakeholders consisting of Member State Competent Authorities, NGOs, testing laboratories/organisations (ecolabels, public and private), producers of childcare articles, associations (childcare product associations, trade associations, chemistry associations, consumer protection associations). In total 233 different stakeholders were informed about the preparation of this investigation report, and about the launch of the two calls for evidence and draft report consultation. Mostly national authorities and manufacturers/importers of childcare articles, but also many testing laboratories and associations were informed (see Figure 6). Given the strong synergy between toys and childcare articles sectors, the Toys Industry Europe (TIE) association and some toys' producers were also informed and invited to provide input at the various steps of the investigation.

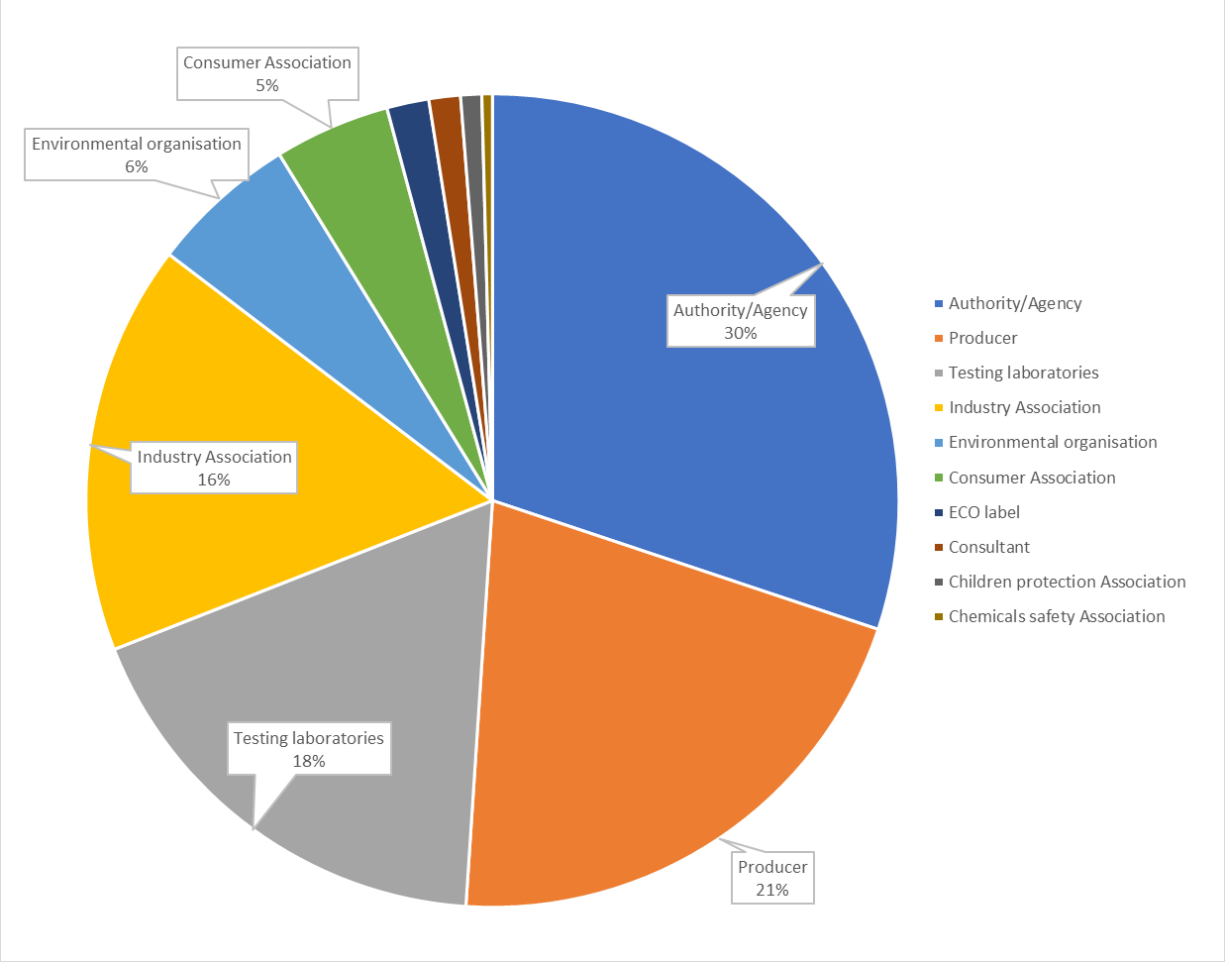

Figure 6: Type of stakeholders contacted during the investigation

86 % of the stakeholders were from the European Economic Area (EEA) (203 stakeholders) but also some stakeholders from UK, Canada and US were informed and provided some input to the investigation report. Below, Figure 7 shows the number of stakeholders per EEA country that were informed about this investigation report.

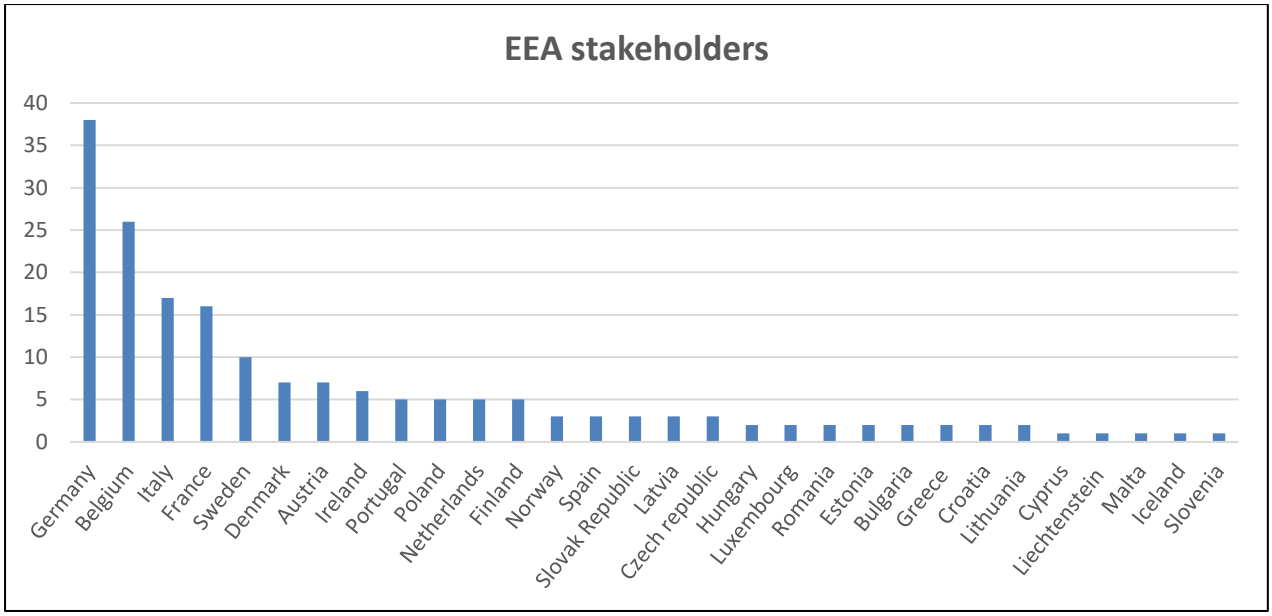

Figure 7: Number of EEA stakeholders per country

On 7 February 2023, ECHA reached out to 110 stakeholders via email to inform about Commission's request to ECHA, the forthcoming call for evidence, and to ask for relevant stakeholder information.

The first call for evidence was carried out from 15 February to 31 March 2023 and announced on the ECHA webpage. In the call for evidence, ECHA provided the list of substances under scope of the investigation (all CMR 1A or 1B substances as described in section 2.1) and also the considered categorisation of childcare articles. ECHA also provided a list of CMR 1A or 1B substances for which evidence of their presence in childcare articles was already collected.

The purpose of the first call for evidence was to receive input on:

1. Verification, complementation and/or correction of the categorisation of childcare articles.
2. Verification, complementation and/or correction of the information compiled by ECHA on the presence or absence of individual CMR 1A or 1B substances in childcare articles, type of article and material analysed, technical function and measured concentration.
3. Information on existing certification schemes, standards, company or sector specific 'restricted list of substances' in childcare articles.
4. Information related to the intentional or unintentional presence of CMR 1A or 1B substances in childcare articles.
5. Information on available analytical methods to measure CMR 1A or 1B substances in childcare articles and on foreseen challenges to detect and verify the presence of such CMR substances in childcare articles.
6. Information on existing risk assessments targeted to the exposure of children to CMR 1a or 1b substances in childcare articles.
7. Any other relevant information.

The Forum was informed about the investigation on CMR 1A or 1B substances in childcare articles, the call for evidence and the future Forum consultation on the draft investigation report regarding enforceability by a presentation that was held at the ECHA Forum enforcement meeting on 16 March 2023.

To increase Member States awareness the first call for evidence was announced in the informal Risk Management and Evaluation (RIME+) platform bulletin, on 14 February 2023, and a presentation was held at the RIME+ meeting on 20 March 2023.

ECHA also informed Competent Authorities for REACH and CLP (CARACAL) on 28 March 2023 about Commission's request and the first call for evidence and requested information and their collaboration on sharing the call for evidence with competent authorities and other national relevant bodies.

During the first call for evidence, 27 stakeholders provided information (eight industry associations, eight national authorities/agencies, four consumer associations, three producers, one consultant, one testing laboratory, one environmental organisation and one ECO label). Particularly, stakeholders provided comments on the categorisation of the childcare articles (details in section 1.2), on the presence of CMR substances in childcare articles, on existing certification schemes and on suitable analytical methods to measure CMR substances in different materials.

A second call for evidence was organised between 10 May 2023 and 7 June 2023 to collect information on suitable analytical methods to measure CMR 1A or 1B substances in childcare articles. More specifically, ECHA requested input on:

1. Suitability, availability, and costs of analytical methods already identified by ECHA to detect some of the measured or suspected substances in childcare articles at defined concentration limits.
2. Information on available analytical methods for all the other measured or suspected CMR 1A or 1B substances for which no method was identified by ECHA.
3. Feasibility of the considered default concentration limit of 10 mg/kg for all CMR 1A or 1B substances, in childcare articles, and possible other generic concentration limits.

The second call for evidence was announced on ECHA's webpage and 223 stakeholders were notified about it via email. 11 stakeholders (six testing laboratories, three national authorities and two industry associations) replied to the call for evidence and provided relevant input on the analytical methods considered by ECHA, provided information on additional analytical methods suitable to measure many substances and commented on the default concentration limit considered by ECHA. More details on the input provided by the stakeholders can be found in Appendix 4

In addition to the call for evidence, to promote further stakeholder engagement in the preparation of the investigation report, some stakeholders were approached for further collaboration. Consequently, ten meetings were held individually with the Environment Protection Agency of Austria, with a worldwide childcare articles manufacturer, the European Consumer Organisation BEUC and Danish Consumer Council (THINK), the Finnish Customs Laboratory (TULLI), the Swedish Chemicals Agency (KEMI), the Norwegian Environment Agency, the European Committee for Standardization (CEN), and TÜV SÜD Product Service GMBH, SGS. After the meetings the different stakeholders provided relevant information for this investigation report, particularly on the presence of CMR substances in childcare articles and on analytical methods suitable to measure CMR substances in different materials.

As a summary, 233 stakeholders were informed about this investigation report and 41 stakeholders provided relevant input to the investigation report via the two calls for evidence or via individual meetings. The type of stakeholders that provided relevant input in the and their region is presented in Figure 8.

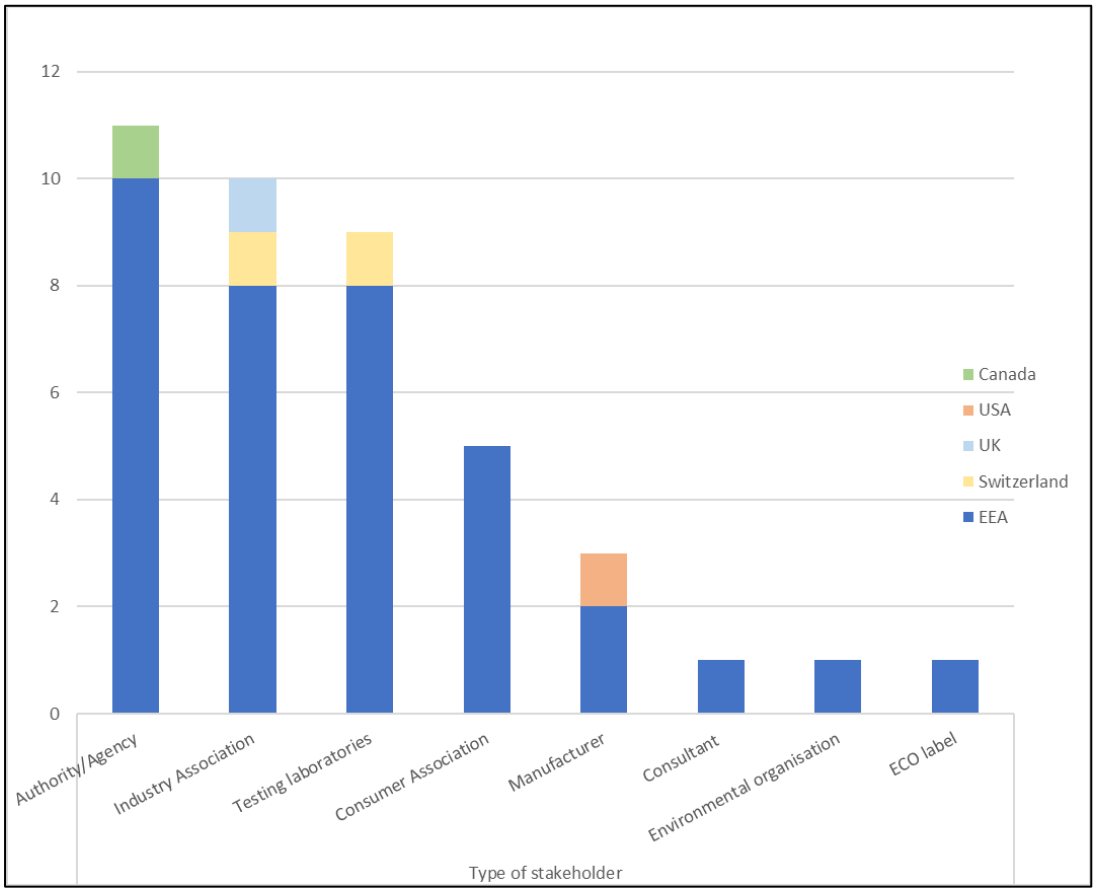

Figure 8: Type and region of stakeholders contributing to the investigation report

The final consultation on the draft investigation report took place between 23 August and 29 September 2023. At the same time the draft investigation report was also shared with the Forum to collect their views on the possible elements of the foreseen restriction.

The draft Forum views concluded that based on the information collected in the investigation report, a restriction on CMR 1A or 1B substances in childcare articles would be enforceable provided that the final legislation is clear, and all substances can be analysed. Moreover, it concludes that the testing strategy is a useful tool to improve the practicability of a restriction covering a broad number of substances and indicates that the listed analytical methods seem to be possible to be carried out with conventional equipment. The Forum also supports the proposed approach to define the concentration limits. Additionally, Forum also recommended amendments and clarifications regarding the wording used in the definition of childcare articles, the proposed age limit, the definition of homogeneous material, the wording regarding derogations, how to address substances covered by other regulations and how to address substances that will be covered by the restriction in the future. ECHA amended the report and added further clarifications reflecting the Forum recommendations.

The consultation on the draft investigation report was announced in the ECHA website and 233 stakeholders were notified about it via email. During the consultation 15 comments

were submitted (8 from Industry 2 from NGOs, 1 from Individuals, 1 from a Consumer association (BEUC) and 3 from member state competent authority (BAUA, ANSES and the Norwegian Environmental Agency). Most comments were originated from the EEA and only two comments from non-EEA Industry were received (US and UK). The most prominent topics covered in the comments received are summarised below:

- Links to other regulations: ANSES and BAUA commented that children feeding and drinking related articles are also covered by the Food Contact Material Regulation (2004). BAUA further indicated that these articles should be exempted from the foreseen restriction on CMRs in childcare articles. Additionally, BAUA also commented on the fact that baby wipes are only partially covered by the Cosmetics regulation, as this regulation only covers mixtures and substances and therefore, it only covers the impregnated liquid and not the wipe (see section 1.3).

- Adult articles used by children: Several comments raised that children, particularly older children, also use articles that are produced for adults and therefore, the scope of restriction on the childcare articles is not clear. ECHA acknowledges that children might use articles produced for adults, however, the definition of childcare articles (section 1.1) covers only articles that are produced with the clear intention to be used by children.

- Transition period: One comment specific for an article containing biocidal substances, indicated that industry would need 5-10 years to find suitable alternatives however, another comment from an NGO suggested that the transition period should be as short as possible considering that the harmful effects of the substances are already known for a long time. Additionally, BEUC suggested that the transition period should be align with the transition time of the entry into force of new harmonized classification (12-18 months).

- Content limits: Some comments challenged the reasoning behind proposing content limits. ECHA clarified in section 5.2 that the report proposes manly content limit because this was indicated in the Commission request.

- Concentration limits: For organotins (DBT), one comment from Industry challenged the proposed concentration limit. However, based on the concentration limits present in ecolabels (EU Ecolabel, OEKO-TEX®), RSLs and the LOQs of available analytical methods, ECHA kept the initially proposed concentration limit (section 5.2). Additionally, BEUC commented on the proposed limits for bisphenols and PAHs, suggesting lower concentration limits based on scientific opinions. ECHA considered the concentration limit for bisphenol A in the report. However, for PAHs ECHA considers that the legal limit of REACH Annex XVII entry 50 as more appropriate (see section 5.2).

- LOQ approach: The Norwegian Environmental Agency commented that the indicated concentration limits based on LOQ will be outdated in the future, as LOQs tend to be lowered with the development of better analytical methods. ECHA acknowledges that the current LOQs might be lowered in the future, but current LOQs must be considered to ensure the enforceability of a potential restriction. Moreover, ECHA notes that the Commission has the possibility to review restriction entries based on technical progress and therefore the concentration limits of the foreseen restriction could be review in the future based on lower LOQs.

- Technical feasibility vs concentration limits: Some comments mentioned that the proposed concentration limits are based on the performance of the analytical methods and not on the technical possibilities to minimise the presence of the

substances. Although no information on manufacturing process technical possibilities is provided, the proposed limits take into consideration industry RSL and moreover, no comments regarding technical problems on achieving the indicated concentration limits were provided by industry.

- Diapers: EDANA stated that no CMR substance is intentionally added to disposable diapers and therefore these articles should be exempted from the foreseen restriction. If disposable baby diapers are to remain in the scope of the foreseen restriction EDANA requested that they would be considered as a homogeneous material and advised on the use of their analytical method developed specifically to analyse diapers. However, there is no scientific assessment available considering diapers as chemically safe for children and moreover ECHA considers that diapers are not made of a single homogeneous material (see section 5.1 and Appendix 4).

- Reasoning for the ban: Two comments mention that ECHA justifies the ban of CMRs in childcare articles based on the fact that usually genotoxic carcinogens are considered non-threshold substances. The comments raised that, however some substances are only reprotoxic and therefore have a threshold mode of action and additionally the non-threshold characteristics of carcinogens is currently being challenged. ECHA acknowledges these comments, but notes that the proposal to ban CMRs is not only linked to the non-threshold characteristics of carcinogens, but also to the fact that the foreseen regulation aims to protect the most vulnerable part of the population from hazardous CMRs and therefore, the limits imposed should be as low as possible.

- Link between the Commission's Chemicals Strategy for Sustainability and REACH Article 68(2): One NGO commented on the Since the generic approach to consumer protection is a key commitment of this strategy, the report could be clearer on the reasoning behind the generic approach to risk management done under REACH Article 68(2).

- Second-hand articles: BEUC also commented that the second-hand childcare articles should be covered by the future restriction. ECHA acknowledges the comment but to be in line with already existing restrictions and to facilitate enforcement, ECHA considers that second hand article should be outside the scope of the future restriction.

8. Assumptions and uncertainties

This section describes the uncertainties identified during the development of the investigation report. The identified uncertainties do not impact (i) the main conclusion of this report which confirms the need to ban all CMR 1A and 1B substances from childcare articles, neither (ii) the potential future restriction itself. The analysis of uncertainties in this report could be used to support the practical implementation and enforcement of a potential future restriction.

ECHA identified seven key uncertainties (see Table 5) and analysed their impact on the conclusions of the report. The analysis of uncertainties was based on the EFSA's guidance on uncertainty analysis and the communication of uncertainty in scientific assessment (EFSA, 2018).

Most of the identified uncertainties are related to gaps on the collected information. To reduce the impact of these uncertainties, several stakeholders were engaged during the development of the report, through both public consultations and individual meetings, to

gather additional information related to the identified gaps. Detailed information on the uncertainties and related mitigation measures are presented below Table 5.

Table 5: Main identified uncertainties

Relevant section of the report	Identified uncertainties		
	No.	Description of uncertainty	Source of uncertainty
2.2. CMRs in childcare articles	1	Uncertainty regarding the completeness of the list of CMR 1A or 1B substances identified as potentially present in childcare articles	Input data
	2	Uncertainty regarding representativeness of findings and the share of childcare articles that may contain CMR 1A or 1B substances	Input data
3. Likelihood of exposure	3	Uncertainty regarding potential releases of CMRs from articles and consequent exposure and risk for children	Input data
5. Concentration limits	4	Uncertainty regarding if some concentration limits would be suitable in certain materials	Input data
	5	Uncertainty if the default concentration limit of 10 mg/kg would be applicable for all CMRs for which no concentration limits and analytical methods were collected.	Analysis not carried out
6. Inventory of available analytical methods	6	Uncertainty regarding the applicability of the identified analytical methods for some of the substances measured and/or suspected to be present in childcare articles.	Input data
	7	Uncertainty regarding the availability of analytical methods for CMRs 1A or 1B substances not measured and/or suspected in childcare articles, for which the default concentration limit of 10 mg/kg is indicated.	Analysis not carried out

Uncertainties regarding the presence of CMR 1A or 1B substances in childcare articles

1) Some CMR 1A or 1B substances that might be present in childcare articles may not have been identified in this report. Testing in childcare articles is not done routinely by authorities because there is at the moment no regulation covering childcare articles. Therefore, the data available on substances present specifically on childcare articles is not abundant.

   To mitigate this lack of information, the report also covers CMR 1A or 1B substances that are present in materials commonly used in childcare articles (e.g. textile, synthetic polymers such as 'plastic', rubber) or in toys (due to the close link between toys and childcare articles). These substances were considered as suspected in childcare articles. This approach minimises the risk of missing substances that might be present in childcare articles. However, ECHA also noted that the substances that are tested in articles/materials are usually always the same substances that have legal requirements in e.g. REACH restrictions or the Toys Safety Directive. Therefore, other substances might have been missed because they are never tested in articles.

   To further mitigate the risk of having missed relevant information on the presence of CMR 1A or 1B substances in childcare articles, several meetings were held with stakeholders (industry, authorities and laboratories) and also during the call for

evidence, and the consultation on the draft investigation report, third parties had the possibility to submit information missing from the report. The information received from the stakeholders did not identify additional substances, but more evidence of the presence of the substances in childcare articles or materials used in childcare articles was provided.

Although there is the risk of having missed the identification of some CMR 1A or 1B substances that could be present in childcare articles, this report confirms the need to ban all CMR 1A and 1B substances from childcare articles and not only substances identified as potentially present in childcare article. Therefore, this uncertainty does not have a major impact on the reported conclusions.

2) There is uncertainty about the representativeness of findings and the share of childcare articles that may contain CMR 1A or 1B substances. Most often, only 'positive' results are reported (but not the total number of tested articles). Some investigations from consumer protection organisations (such as Stiftung Warentest or Ökotest) are testing a certain number of articles and are reporting the findings, which may provide some insight of the frequency of positive findings. However, those reports cannot provide sufficient certainty to conclude on the share of childcare articles containing certain CMR 1A or 1B substances. Furthermore, as indicated above, the substances that are tested in articles are usually the same that have legal requirements. Therefore, the collected evidence of measured and/or suspected CMR 1A and 1B on childcare articles cannot be used to determine the frequency of the presence of CMR substance in childcare articles.

   Although it is not possible to estimate the share of childcare articles containing CMR 1A or 1B substances, the findings presented in this investigation report confirm the potential presence of CMR 1A or 1B substances in childcare articles and the need for enforcement actions to confirm compliance. Moreover, in case of toys, there are sufficient indicators that a very high number of toys are non-compliant, in particular, in the context of online sales as described in the updated proposal for the Toys Safety Directive. No such information is available for childcare articles, but similar concerns could be assumed.

Uncertainties regarding releases, exposure and risk

3) There is uncertainty with regards to the potential presence of CMR 1A or 1B substances in childcare articles (see uncertainty 1), 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. Furthermore, a potential restriction proposal from the Commission addressing CMR 1A or 1B substances in articles according to REACH Article 68(2) does not require to demonstrate an unacceptable risk. However, examples of substances were provided for which releases from certain materials is expected to be high, potential exposure was estimated for REACH registered substances using physico-chemical properties and the results of available risk assessment were reported.

Uncertainties regarding concentration limits

4) There is uncertainty if some proposed concentration limits would be suitable in certain materials (e.g. due to unavoidable background content), even if the LOQ allow the substance to be measured. For example, for the amides, DMF and DMAC the default concentration limit of 10 mg/kg is proposed (which is in the range of the LOQ), whereas industry concentration limits may indicate the need for higher concentration limits for

certain e.g. coated materials. Further information was requested in the consultation of the draft investigation report, but no information was submitted to clarify this uncertainty.

5) 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 applicable for certain substances and materials (see uncertainty 7 below) and/or if the toxicity of the substances would require a lower concentration limit. ECHA acknowledges this uncertainty, but considering the information collected for the other substances, 10 mg/kg should be for most substances, a concentration limit sufficient to address its toxicity. Moreover, having a concentration limit of 10 mg/kg already provides a higher protection for children compared to the CLP GCL/SCL.

Uncertainties regarding analytical methods

6) There is uncertainty regarding the applicability of some of the analytical methods indicated for some of the substances measured and/or suspected to be present in childcare articles. In some cases, information on standard analytical methods for a substance and specific materials was missing. ECHA carried out a Call for Evidence dedicated to analytical methods to address the issue but, despite all the useful information gathered, it was still not possible to indicate a method for all these substances. ECHA therefore indicated methods for which a standard operating procedure (SOP) would need to be developed by testing laboratories. In some cases, standard methods suitable for some substances were extended to substances in the same chemical group, and in other cases standard methods developed for a particular material (e.g. textiles) were extended for other materials that were deemed similar (e.g. synthetic polymers). When extending the scope of existing standard methods was not possible, ECHA considered EPA methods, which are usually developed for more complex matrices such as environmental matrices (e.g. soil, wastewater etc.) but give a good indication of the possible applicable techniques and sample preparations. Internal expert advice was taken into consideration to assess the feasibility of the indicated analytical methods, however, for all these cases there might be issues on validation parameters (e.g. linearity, stability, recovery, matrix effects etc.) that cannot be predicted without proper testing and method validation by laboratories. To mitigate this uncertainty, a specific question about this issue was asked both to the Forum and during 3rd party consultations. Although more research and development is necessary to ensure the testing of these substances, there was no concern raised by stakeholders during the last consultation. Overall, there are well-established analytical methods for the majority of the substances measured or suspected in childcare articles and useful information has been collected to fill the information gaps for the remaining substances. Therefore, the impact of this uncertainty in the collection of suitable analytical methods is limited.

7) There is uncertainty regarding the availability of analytical methods for the CMR 1A or 1B substances for which 10 mg/kg limit was proposed but no collection of such methods was done. Due to the high number of substances under the scope of this report, it was not possible to collect analytical methods for all CMR 1A or 1B substances, ECHA collected analytical methods only for the substances measured or suspected in childcare articles. For the other substances, the default concentration limit of 10 mg/kg was based on the assumption that suitable and widely available analytical methods exist to measure these substances with LOQs down to 10 mg/kg. However,

there is some uncertainty on the availability of these methods. To mitigate this uncertainty a specific question on this topic was included in the call for evidence targeting analytical methods. Some stakeholders raised the concern that for some substances (e.g. complex mixtures and reaction masses classified as CMR 1A and/or 1B) standard analytical methods might not be available and more refined methods would need to be applied or developed. However, for the majority of the substances, no concern was raised by stakeholders. Therefore, ECHA concludes that for most substances widely analytical methods are probably available and this uncertainty has impact only on a small number of substances.

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APPENDICES

Appendix 1 CMR in childcare articles data collection (see below)

Appendix 2 Available risk assessments (see below)

Appendix 3 Inventory of available concentration limits (see below)

Appendix 4 Inventory of available analytical methods additional information (see below)

SEPARATE EXCEL FILES:

Appendix_A_Summary

Appendix_A.2.1_CMRs_1A_1B

Appendix_A.6.1_Analytical_methods

Appendix_A.6.2_Testing strategy

Appendix 1 CMR in childcare articles data collection

The information on the presence of CMR 1A or 1B substances in childcare articles (n = 2 338 entries) was collected from 48 different sources such as the 2019 COM study, literature search, reports/tests reports from authorities and other non-governmental organizations (many received via the call for evidence), databases, recalls/alerts information, REACH Restrictions, SCIP database, REACH Registration dossiers and Substance in Articles (SiA) notifications, industry Restricted Substances Lists and Ecolabels.

1. COM study (EU Commission, 2019)

   The COM study covered all substances with harmonised classification 1A, 1B and 2 and as well substances with 'potential' CMR hazards. ECHA analysed the Appendix G1 ('Final database on childcare articles') of the COM study and extracted only the entries correspondent to substances with harmonised classification CMR 1A or 1B and also substances for which a CMR 1A or 1B harmonised classification have already been agreed or is under discussion by RAC. 784 entries were extracted covering 40 different substances. The sources reported in the COM study are databases, scientific papers, reports from authorities and other non-governmental organizations and recalls/alerts. A large percentage of data was from the Washington Children Safe Products Act database (Washington State Department of Ecology, 2008), with data collected between 2012 and 2018.

2. Literature search

   Google Scholar was initially used for a systematic search of evidence in scientific publications. The search was limited to the years 2018 to 2023, as it was considered that the COM study (EU Commission, 2019) covered all literature published until 2018. The keywords used in the search were: 'cmr', 'childcare', 'articles'. Only two publications (Almroth and Slunge, 2022, Harrad et al., 2010) containing evidence on the presence of CMRs in childcare articles could be identified.

   Additionally, the database 'Science Citation Index Expanded' (SCI-EXPANDED) in the platform 'Web Of Science' was used to do literature search using the same type of keywords as in Google Scholar. The function NEAR/0 was used to limit the research to consecutive words, e.g. 'childcare' NEAR/0 article*, where it was possible to search exact terms between quotation marks and include singular and plural terms using the wildcard '*'. The search was refined further by selecting the relevant categories and excluding irrelevant results from fields such as medicine, pedagogy, paediatrics and others. Relevant papers were selected considering the title and abstract. A total of 12 new scientific articles published from 2017 to 2023 were found. However, only six scientific articles (Li et al., 2022, Mohammed et al., 2020, Negev et al., 2018, Nyamukamba et al., 2023, Wu et al., 2018, Wu and Venier, 2023) were identified to contain evidence of CMR 1A or 1B substances in childcare articles, mainly outside the EU.

   Findest IGOR^{AI} technology scouting tool research tool was also employed for the search, but it did not find additional relevant publications.

   Finally, two other relevant scientific articles were collected via the call for evidence (Balanzá-Martínez et al., 2021, Viñas et al., 2012).

3. Reports/test reports

Reports and test reports on the presence of concern substances in childcare articles, toys or materials that are commonly present in childcare articles (e.g. textile, plastic) were analysed to extract information on CMR 1A or 1B substances. Some were investigation reports and others were enforcement or consumer associations test reports (few not published). Most of these reports were shared by stakeholders via the call for evidence. The reports were mostly from authorities (e.g. Danish Environmental Protection Agency, German Member State authorities, KEMI Sweden, KEMI Denmark, ECHA (ECHA, 2016)) but also from consumer protection associations (e.g. ALHem, Serbia; Öko-Test and Stiftung Warentest, Germany). The published reports that were analysed were the following:

- Cry game (Safer Chemicals Alternative (ALHem), 2019)
- Bisphenol A in Beruhigungssaugern (BfR, 2009)
- Survey and Health Assessment of the exposure of 2 year-olds to chemical substances in Consumer Products (Danish EPA, 2009)
- Cyclical Enforcement Project 2019-2020: Consumer Products Containing Lead Regulations (Government of Canada, 2020)
- Rapport 4/21: Kartläggning av farliga kemiska ämnen i textil (KEMI SE, 2021)
- Kemitest: Bæreseler og vikler (KEMI DK, 2020)
- Öko-Test reports (Öko-Test, 2023)
- Stiftung Warentest reports (Stiftung Warentest, 2023) for more details)

4. Databases

Three databases were used to collect information on the presence of CMR 1A or 1B substances in childcare articles, the Danish database 'Vannmiljø' (Miljø-direktoratet, 2023), the US database 'High Priority Chemicals Data System' (HPCDS) and the ECHA 'SCIP' database for information on substances of concern in articles as such or in complex objects (Products).

The Danish database 'Vannmiljø' was created based on an enforcement project in 2016 where different childcare articles were tested for several chemicals of concern. Information collected from this database was received via the first call for evidence by the Norwegian competent authority.

The High Priority Chemicals Data System (The Interstate Chemicals Clearinghouse, 2023) is an online database that collects information on the presence of chemicals of concern in children's products as required by the Oregon Toxic-Free Kids Act (Government of Oregon, 2023) and the Washington Children's Safe Products Act. The Washington Children Safe Products Act and the Oregon Toxic-Free Kids Act database requires producers to report chemicals of concern present in their children's products sold in the state of Washington or Oregon, respectively. In order to complement the information already reported in the COM study (EU Commission, 2019) ECHA searched for evidence from this database reported from January 2019 to 4 April 2023. This database covers many child articles that are not childcare articles as defined in this report (e.g. cosmetics, clothes, games) and substances that do not have CMR 1A or 1B classification. Only entries covering articles and substances relevant for this report were considered.

The SCIP database (ECHA, 2023c) collects information (since January 2021) submitted by companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1 % weight by weight (w/w) on the EU market. The SCIP database ensures that the information on articles containing Candidate List substances is available to waste operators and

consumers. In the SCIP database there is no article category specifically covering childcare articles, therefore the search in the SCIP database was done by checking if any of the CMR 1A or 1B substances were reported in categories covering article material types used in childcare articles (e.g. SCIP category 'Textile articles' or 'Other articles of plastics'). The CMR 1A or 1B substances reported under those categories were considered suspected in childcare articles. Additionally, a search was performed on entries submitted by childcare article producers and the entries related to childcare articles with CMR 1A or 1B substances were collected.

5. Recalls/alerts

   Most of the information obtained from recalls was collected from the 'Safety Gate: the EU rapid alert system for dangerous non-food products' (EU Commission, 2022b), previously called 'RAPEX'. The COM study (EU Commission, 2019) already collected information from this source covering the entries reported up to 2018; therefore, only entries from January 2019 to 4 April 2023 were analysed. The search was performed selecting the Risk type 'Chemical'; the Product category 'Childcare articles and children's equipment'; the Notifying country 'All'; the Country of Origin 'All'; the Alert Type 'All'; the Product user 'All' and the Year: 2019, 2020, 2021, 2022, 2023. Only entries covering the CMR substances relevant for this report were considered.

   Few additional entries from non-EU recalls were collect based on information provided by stakeholders in the first call for evidence.

6. Regulations

   Several REACH Annex XVII restriction entries (e.g. 5, 20, 23, 43, 47, 50, 51, 63, 72) address chemicals of concern that are used in textiles and/or leather (ECHA, 2023b). As textile and leather are commonly used in childcare articles, the substances covered by those entries can be considered as potentially present in childcare articles.

   Considering that toys have a close link to childcare articles, the materials used to produce both type of articles are probably similar and containing the same type of substances. The Toys Safety Directive restricts all CMR 1A or 1B substances and for some of the substances specifies concentration limits. ECHA considered relevant to target these substances in the foreseen restriction and to consider the concentration limits for those substances. Therefore, the CMR 1A or 1B substances listed in accordance with points 8 and 13, Part III, and Appendices A and C of Annex II (Particular Safety Requirements) to Directive 2009/48/EC on toy safety were considered as suspected in childcare articles (Toys Safety Directive, 2009).

7. REACH data

   Registrations

   Information on the uses of all registered substances under the scope of this investigation was collected from REACH registration dossiers.

   The substances with article service life reported uses, that specify plastic, textile, rubber, or leather type of articles, were considered as suspected in childcare articles.

Additionally, for some UVCB substances[24] the classification is related to specific constituents (e.g. substance with list number 648-002-00-6 is only classified if it contains benzene in its composition). Therefore, the concern is related to a specific constituent and not to the substance as such. The related constituents of concern are already targeted in this investigation report as substances suspected or present in childcare articles, therefore, these UVCB substances were not considered as suspected in because the concern with those substances is already covered.

Substances in Articles (SiA) notifications

Producers and importers must submit a notification to ECHA if a Candidate list substance is present in their articles above one tonne per year and in a concentration above 0.1% weight by weight. The notifications related to CMR 1A or 1B substances were screened to collect information on reported childcare articles or materials used in childcare articles. No specific notification reporting childcare articles was found, only materials that are used in childcare articles.

8. RSLs

Industry restricted substance lists are industry initiatives to ban the presence of some substances in the products/articles they are placing on the market. ECHA collected information on CMR 1A or 1B substances in several RSLs that may apply to childcare articles such as AFIRM (2023), ALDI (2021), bluesign® (2022), NIKE INC (2022), Cradle To Cradle™ (2021) and VERSACE (2018). The substances listed with restricted concentration limits in materials commonly used in childcare articles (textile, leather, or synthetic polymers) were considered suspected in childcare articles.

9. Ecolabels

ECHA also collected information from different ecolabels such as EU ecolabel for textile products and footwear, OEKO-TEX® (2023), GOTS (2023), Nordic Swan (2017) and Blue Angel textiles (2023). The CMR 1A or 1B substances covered by those ecolabels were already identified in previous sources, except for Acrylamide that the only evidence of its potential presence in childcare articles was found from the Blue Angel ecolabel (reported as being present in plastic).

10. Other

The restriction proposal for substances in single-use baby diapers (ECHA, 2021d) was also considered to identify CMR 1A or 1B substances in diapers.

Additionally, all azo dyes with CMR 1A or 1B classification were considered as suspected in textile as their use in fabric is well known.

Finally, ECHA also reviewed Article 69(2) screening reports covering CMR 1A or 1B substances to collect information on uses, however, no additional information was collected from those reports. (ECHA, 2023a)

[24] Substances of unknown or variable composition, complex reaction products or of biological materials

Appendix 2 Available risk assessments

Methodology and collected information

Searches for available risk assessments were performed with the intention to find specific information related to the exposure of children to (childcare) articles or toys.

By performing a general search in internet using the terms 'child' and 'risk assessment' several generic risk assessment methodologies for children were identified such as:

- OECD (2013) Assessing the risk of chemicals to children's health: an OECL-wide survey. Series on Testing and Assessment No. 192
- OECD (2019) Considerations when assessing children's exposure to chemicals from products. Series on Testing and Assessment No. 310
- OECD (2021) Assessing the risk of chemicals to Children's Health: OECD-wide survey 2021. Survey Report. Series on Testing and Assessment No. 376
- RIVM (2008) Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements. RIVM report 320003001/2008
- Danish EPA (2015) CMR Substances in Toys – Market Surveillance and Risk Assessment. Survey of Chemical Substances in Consumer Products 141, 2015

In the OECD (2019) report several examples for child-specific differences compared to adults are presented. Table 6 is extracted from OECD (2019) summarising the main differences between children and adults.

Table 6: Child-specific characteristics and related exposure factors per route of exposure causing differences in exposure of children compared to adults

Child-specific difference and effect in exposure scenario	Related exposure factors
Inhalation	
Higher breathing rate and surface area for absorption (relative to body weight) resulting in higher internal exposure via inhalation (per kg bw)	Vapour pressure of a chemical
Crawling behaviour or lower body height resulting in a lower personal breathing zone if stratification is expected in room air (air intake at lower position, possibly closer to surface)	Emission from product, Semi-Volatile Organic Compounds (SVOCs)
Exposure pattern, e.g. a child generally spends more time indoors leading to a higher magnitude, duration, or frequency of exposure to indoor air. Smoking behaviour in older children.	Presence in specific buildings (home, day-care, school), etc.
Oral	
Higher intake (relative to body weight) leading to a higher exposure via the oral route (per kg bw)	
Oral exploration and mouthing resulting in additional, or higher exposure via the oral route	Leaching from products
Dermal	
Crawling behaviour, larger surface area (relative to body weight) and relative bigger head, all leading to higher exposure via the dermal route (per kg bw)	Ability of migration to skin, contact to textile, clothing, flouring, etc.

Child-specific difference and effect in exposure scenario	Related exposure factors
Exposure pattern, e.g. a child lays/plays more on the grass or ground, sleeps longer in bed, all leading to higher magnitude, duration, or frequency of exposure via the dermal route (per kg bw) high use of cosmetics and personal care products in older children.	Ability of migration to skin, contact to textile, matrasses, ground, grass, flouring, etc.

Source: OECD (2019)

Risk assessments that may cover exposure of children to specific substances or groups of substance in articles are summarised below. Documents were retrieved by searches via ECHA (e.g. PACT) and from searches in internet using terms such as 'child' 'childcare' 'articles', 'toys', 'risk assessment' and the name of specific substances.

Aldehydes / formaldehyde

- Commission Directive (EU) 2019/1929: based on a scientific opinion risk assessment performed by SCHER, concentration limits of 30 mg/kg for formaldehyde in toys of (in textile and leather toy material) were implemented (EU, 2019). This concentration limit is also considered applicable for formaldehyde in childcare articles except for wood-based articles and furniture (see below).
- Commission Regulation (EU) 2023/1464 of 14 July 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers (EU Commission, 2023c) specifies for formaldehyde and formaldehyde-releasing substances concentration limits e.g. of ≤ 0.062 mg/m^3 for wood-based articles and furniture. Those are relevant e.g. for childcare articles which are wood-based or furniture. The related risk assessment is published in the ECHA opinion (ECHA, 2020) from RAC and SEAC.
- SAGCS (2021) Statement on Formaldehyde "SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)" The following paragraphs are cited from this document:
    - The tolerable daily intake (TDI) for formaldehyde was set at 0.15 mg/kg body weight per day by the World Health Organisation (WHO) in their guidelines for drinking water quality (WHO, 1993) and has been confirmed by the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) of the European Food Safety Authority (EFSA, 2006).
    - Given that toys are not the only source of chemical exposure in children, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) released an opinion in 2004, in which they set the maximum permitted contribution from toys as 10 % of the tolerable daily intake (TDI) (CSTEE, 2004). This percentage was confirmed twice by the Scientific Committee on Health and Environmental Risks (SCHER) in 2010 in its opinion on 'Risk from organic CMR substances in toys' and its opinion on 'Evaluation of the migration limits for chemical elements in toys'.
    - The SCHER Committee has also stated that CMR substances should not be present in toys and therefore levels should be as low as reasonably practicable (ALARP) (SCHER, 2007).

- A report performed by the Danish Environmental Protection Agency (Danish EPA, 2015) on CMR substances in toys provides exposure scenarios and derived no-effect levels (DNELs) for substances migrating from toys (e.g. formaldehyde from wooden puzzles). No content limit for the articles is specified.

Aromantic amines

- REACH Annex XVII entry 43 restricts the use of azocolourants and azodyes, which may release aromatic amines (listed in Appendix 8 of REACH Annex XVII) in detectable concentrations i.e. above 30 mg/kg (0.003 % by weight) from articles (such as textiles, footwear, or textile or leather toys) or from the dyed parts thereof. The respective test methods are listed in Appendix 10 of REACH Annex XVII. The specified concentration limit is based on the lowest concentration technical feasibility (see also section 5.2), not on risk assessment.

Amides / formamide

- ANSES published an opinion related to formamide in children's foam puzzle mats (ANSES, 2011). Formamide was assumed to be either used as plasticiser or as a substance associated with a blowing agent in the production of objects formed by foam. The data collected by ANSES revealed concentrations between 20 and 1 300 mg/kg in puzzle mats and an expert assessment indicated that exposure of children and adults occurs almost exclusively by inhalation, whereas the ingestion exposure route (mouthing, direct ingestion of pieces) is negligible. The risk assessment performed by ANSES was based on maximum concentrations (emission into the air, migration in water) measured in three puzzle mats with highest concentration among 32 puzzle mats analysed. Results based on a conservative exposure scenario indicated a risk for children. A second, more detailed calculation, taking into account the variability of exposure parameters, showed a possible risk with a probability lower than 5 % in children from 0 to 2 years old. ANSES concluded that formamide emissions from puzzle mats may not exceed 20 $\mu g/m^3$ measured 28 days after unpacking and following a specific protocol. No content-related concentration limit was provided.

- German Federal Institute for Occupational Safety and Health (2012) published a proposal for identification of a substance as CMR Cat 1A or 1B, PBT, vPvB or a substance of and equivalent concern. It was noted that formamide may be used as solvent, plasticiser and other unknown sources in consumer products. As formamide was measured in consumer products and probable exposure is indicated, it was concluded that consumers might be at risk.

Bisphenols / Bisphenol A

- In the EU Risk assessment report for bisphenol A (EU RAR, 2003) potential consumer exposure was considered to arise only under conditions where residual monomer in the polymer matrix becomes available for exposure or where breakdown of the polymer occurs, to generate additional bisphenol A monomer. For polycarbonate food contact applications, estimates of daily ingestion of bisphenol A were derived for infants exposed via feeding bottles and for young children (1.5 - 4.5 years) exposed via tableware. Intake values of 0.035 mg/day (1 - 2 month baby), 0.05 mg/day (4 - 6 month baby) and 0.01 mg/day (young children) were derived. For epoxy resin food contact applications, estimated intake values of 0.1 mg/day for adults, 0.2 mg/day for young children and 0.04 mg/day for infants (6 - 12 months) were derived. It was concluded that further information

is required in relation to the potential for bisphenol A to produce adverse effects on development.

- EFSA did a comprehensive re-evaluation of bisphenol A (BPA) in 2015 (EFSA, 2015) paper) and reduced the 'tolerable daily *intake'* (*TDI*) for bisphenol A from 50 µg/kg of bw/day to 4 µg/kg of bw/day. In a recent re-evaluation (EFSA Panel on Food Contact Materials et al., 2023), a TDI of 0.2 nanograms (0.2 billionths of a gram) per kilogram of body weight per day, was established which is around 20 000 times lower. However, the European Medicines Agency (EMA) is not in agreement with the change of the temporary TDI to the TDI currently revised by EFSA (EMA, 2023) and the German federal institute for risk assessment (BfR) published an opinion document where they state their disagreement with this new TDI (BfR, 2023).
- The Scientific Committee on Consumer Safety SCCS (2020) published an opinion on the presence of bisphenol A in clothing articles. Referring to the TDI of 4 µg/kg bw/day, SCCS established a maximum amount of around 0.8 mg bisphenol A/kg textile.

Brominated flame retardants / tetrabromobisphenol A

- An EU Risk Assessment Report (EU RAR, 2006) risk assessment was performed with regards to nephrotoxicity for infants with exposure to tetrabromobisphenol A via breast milk concluding on sufficient MOS (1.7×10^6). However, this report does not provide information with regards to the risk for babies from the content of the substance in articles such as baby bottles which would be relevant in the context of this investigation report. Furthermore, the carcinogenic (and endocrine) mode of action is not considered, for which the Norwegian Environmental Agency (2020) submitted a CLH report with the proposal for Harmonised Classification for tetrabromobisphenol A Carc 1B.

Metals / cadmium

- Restriction Annex XVII, entry 23 requires mixtures and articles produced from synthetic organic polymers (referred to as 'plastic material') shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0.01 % by weight of the plastic material (100 mg/kg). In the Annex XV report (ECHA, 2015) it is noted that e.g. a material containing 160 mg Cd/kg gave non-detectable results in a wiping test with moist filters to simulate skin contact. Wiping or extraction was reported not to be done when the content of cadmium in the products was less than 100 ppm (0.01% or 100 mg/kg). It is also noted that leaching of cadmium is very much dependent on many factors such as particle size of the material containing cadmium, acidity of the extracting solution, duration and temperature of exposure.

- (WHO, 2019) notes that inexpensive jewellery, toys and plastics can be significant sources of exposure to cadmium, especially for children and that many countries have restricted or banned cadmium in such products.

Metals / cobalt

- The SCHEER (SCHEER, 2023) evaluated the safety of the use of cobalt in toys. For the oral exposure, the SCHEER calculated new migration limits for cobalt in toys. However, due to the uncertainties regarding the carcinogenic properties for cobalt after oral exposure, the SCHEER recommended reducing migration limits to the lowest technically achievable levels. The SCHEER did not propose content related limits.

Metals / lead

- In a voluntary Risk Assessment Reports for lead and its compounds (LDAI, 2008) a need for limiting the risks with regards to e.g. lead in children's toys and jewellery, as well as deteriorating lead-based paint in older residential housing was mentioned.

- SCHEER (2009), in its opinion on the Voluntary Risk Assessment Report on lead and lead compounds concluded on a 'practical' NOAEL of 50 µg/L for effects on the central nervous system in children also noting that the methods were not sufficiently sensitive to identify effects at this blood lead level.

- The RAC and SEAC opinion (ECHA, 2014) supported the risk assessment of EFSA (2013), in which a benchmark dose level (BMDL (01)) of 0.5 µg Pb/kg bw per day, was derived as a dose descriptor for the potential adverse effects of lead in children. This corresponds to a change in blood level of 12 µg Pb/L and an IQ loss of 1 point. EFSA (2013) observed that children in the age group of 1 - 3 years have mean background lead exposures of between 1.3 and 6.4 µg/kg bw per day (e.g. from the diet and background environmental exposure), which exceeds the BMDL(01) level of 0.5 µg Pb/kg bw per day. Therefore, EFSA concluded that any additional lead exposure would on average be expected to further increase a child's typical exposure. RAC considered that chronic exposure of children as a result of their mouthing behaviour is most relevant to justify the restriction on lead and its compounds in consumer articles. To limit additional exposure of children to lead from consumer articles as much as possible, RAC agreed on a lead concentration limit in articles of 500 ppm (500 mg/kg or 0.05 %) to be sufficiently protective, irrespective of the material. Should children mouth these articles (or parts thereof) for 1 hr, the IQ impact would in that case be limited to a reduction of 0.1 point. The proposed restriction would also cover risks presented after a single exposure from swallowing lead containing articles. A similar approach was taken by RAC for the aforementioned lead in jewellery restriction. The migration data submitted for brass alloys justifies a limit value of 0.5 % in these materials. The restriction of lead in consumer articles is implemented in REACH Annex XVII entry 63.

Metals / mercury

- (WHO, 2010) published a report on children's exposure to mercury compounds. Sources for exposure from articles are for example broken mercury-containing equipment such as thermometers. No exposure to any other kind of childcare article was mentioned.

- REACH Annex XVII, entry 18a restricts placing on the market of mercury e.g. in fever thermometers. The related justification is published in the RAC and SEAC opinion (ECHA, 2011).

Organophosphorous compounds / tris(2-chloroethyl) phosphate

- An EU Risk Assessment report is available (EU RAR, 2009). This report concludes that risk reduction measures are required for babies with respect to sucking on toys.

- ECHA (2018b) has published a draft screening assessment in 2018 whether TCEP, TCPP, and TDCP should be restricted. The screening assessment identified a risk for children from exposure to the flame retardants TCEP, TCPP and TDCP in flexible polyurethane (PUR) foams in childcare articles and residential upholstered

furniture. Therefore, ECHA recommended that a restriction proposal should be prepared. Due to the migration of TCEP from textile and foam, dermal exposure was considered to be the main route of exposure, followed by exposure from mouthing.

Organotin compounds

- According to REACH Annex XVII, entry 20 the use and placing on the market of organostannic (organotin) compounds is restricted with a concentration limit of 0.1 % (1 000 mg/kg;). The Commission (EU, 2009) noted that di-substituted organotin compounds, including in particular dibutyltin compounds (DBT) and dioctyltin compounds (DOT), are widely used in consumer articles where they function either as a stabilizer or as a catalyst. Furthermore, it was noted that the use of organotin compounds in consumer articles has been found to pose a risk to human health, particularly for children. The specific risks to the health of children and adults from various consumer articles have been identified in a risk assessment (EU, 2015), and have been confirmed by the Commission's Scientific Committee on Health and Environmental Risks (SCHER) in its opinion of 30 November 2006. Specifically, the risk from mouthing of PVC toys was indicated.

Phthalates

- In the EU Risk Assessment Report on DEHP (EU RAR, 2008) concerns for children were identified with regard to testicular effects, fertility, and toxicity to kidneys, on repeated exposure as a consequence of oral exposure from toys and child-care articles, and multiple routes of exposure.
- REACH Annex XVII, entry 51 specifies that the specified four phthalates (DEHP, DBP, BBP, DIBP) shall not be placed on the market in toys or childcare articles, individually or in combination of the first three phthalates listed in column 1 of the entry, in a concentration equal to or greater than 0.1 % (1 000 mg/kg) by weight of the plasticised material. In the RAC opinion (ECHA, 2012) it is specified that the risk characterisation ratios (RCRs) for 2-year-old children from articles were calculated with 0.05 for a realistic scenario and 0.14 for realistic worst case scenario.
- ANSES (2016) published an opinion on plastic toys and children's equipment intended for children under three years of age and concluded that PVC is one of the most widely used plastics in the area of toys. The plasticisers used most often in PVC are phthalates. Phthalates such as bis(2-ethylhexyl) isophthalate (DOIP), and their substitutes have therefore been targeted in this report. With regard to DOIP, the health risk could not be assessed due to the absence of data on the substance's hazards.
- EFSA (2019) re-evaluated its risk assessment on phthalates from 2005 on the phthalates DBP, BBP, DEHP, DINP, and DIDP. The review of the toxicological data focused mainly on reproductive effects. The CEP Panel derived the same critical effects and individual tolerable daily intakes (TDIs) (mg/kg bw per day) as in 2005 for all the phthalates, i.e. reproductive effects for DBP (0.01), BBP (0.5), DEHP (0.05), and liver effects for DINP and DIDP (0.15 each).

Quinoline

- The Swedish Chemical Agency (KEMI) has performed a Risk Management Option Analysis for quinoline (KEMI, 2022). In a recent survey conducted by KEMI, quinoline was detected in 12 out of 35 textile articles. The presence of quinoline in clothes on the Swedish market has been demonstrated in several other studies.

The risk assessment performed in the RMOA shows that exposure to quinoline when present in textile at 50 mg/kg may pose a risk to consumers (considering a cancer risk level of 10^{-6}). Even lower concentrations of quinoline detected in the KEMI survey resulted in an exposure that exceeded by far the DMEL concentration. KEMI proposed to amend the current REACH restriction entry 72 to lower the concentration limit of 50 mg/kg for quinoline.

Appendix 3 Inventory of available concentration limits

Table 7 lists REACH restrictions and other legislations are listed in Table 8. The related concentration limits considered for the current investigation are also reported in the tables.

Table 7: Existing REACH restrictions that may be relevant for restricting CMR 1A or 1B substances in childcare articles

Article(s) and/or substance(s) concerned	REACH	Specification
Benzene in toys	REACH Annex XVII, Entry 5	1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy.
Organostannic compounds in articles for general public	REACH Annex XVII, Entry 20	5. Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin. 6. Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin: (only relevant examples provided) - textile articles intended to come into contact with the skin - childcare articles - nappies
Cadmium and its compounds in synthetic organic polymers	REACH Annex XVII, Entry 23	Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.
Colourants in textiles and leather	REACH Annex XVII, Entry 43	1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as — clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags, — footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck, — textile or leather toys and toys which include textile or leather garments, — yarn and fabrics intended for use by the final consumer.

Article(s) and/or substance(s) concerned	REACH	Specification
Chromium VI in leather articles	REACH Annex XVII, Entry 47	5. & 6. Leather articles / Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3 mg/kg (0,0003 % by weight) of the total dry weight of the leather / that leather part.
PAHs in rubber or plastic	REACH Annex XVII, Entry 50	6. Toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reason- ably foreseeable conditions of use, contain more than 0.5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs.
Phthalates (DEHP, DBP, BBP, DIBP) in plasticized material	REACH Annex XVII, Entry 51	1. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0,1 % by weight of the plasticised material
Lead	REACH Annex XVII, Entry 63	7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foresee- able conditions of use, be placed in the mouth by children That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or un- coated, does not exceed 0,05 µg/cm 2 per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable condi- tions of use of the article. For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.
CMR 1A or 1B substances in textile products	REACH Annex XVII, Entry 72	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

Article(s) and/or substance(s) concerned	REACH	Specification
		homogeneous material, equal to or greater than that specified for that substance in Appendix 12.

Table 8: Other legislation than REACH that may be relevant for a restriction of CMR 1A or 1B substances in childcare articles (CCAs)

CCAs and/or substance concerned	Legislation	Specification
Toys	Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Toys Safety Directive, 2009)	Ban of CMR substances; Specific concentration limits for many substances (see excel sheet 'Appendix_A_Summary')
Rubber teats and soothers	Commission directive 93/11/EEC of 15 March 1993 concerning the release of the n-nitrosamines and n- nitrosatable substances from elastomer or rubber teats and soothers (EU Commission, 1993)	— 0.01 mg in total of N-nitrosamines released/kg (of the parts of teat or soother made of elastomer or rubber), — 0.1 mg in total of N-nitrosatable substances/kg (of the parts of teat or soother made of elastomer or rubber
Bisphenol A in plastic infant feeding bottles	Commission implementing regulation (EU) no 321/2011 of 1 April 2011 amending regulation (EU) no 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (EU Commission, 2011a)	Not to be used for the manufacture of polycarbonate infant feeding bottles
Bisphenol A used as varnishes and coatings in plastic food contact materials	Commission regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol a in varnishes and coatings intended to come into contact with food and amending regulation (EU) no 10/2011 as regards the use of that substance in plastic food contact materials (EU Commission, 2018)	SML of 0.05 mg of BPA per kg of food (mg/kg)

Several **EU standards** for child use and care articles are addressing childcare articles (see Table 9). Currently, a standard addressing other childcare articles is under preparation (prEN 17826:2022). The EU standards are focussing on safety and testing but general safety requirements for chemical hazards may also be provided. The report 'Chemical requirements for child use and child care' by The Consumer Council at the Austrian Standards Institute (ASI, 2014) concluded that the standards are mainly addressing requirements concerning migration of elements (metals) but also further requirements for child use and care articles that are used directly in the mouth of babies and young children, i.e. products such as soothers, baby bottles, and cutlery and feeding utensils. ECHA notes that the EU standards addressing chemical hazards are mainly referring to existing legal

requirements specified e.g. in REACH restrictions and in the Toys Safety Directive and may also be aligned with future requirements of the intended restriction on CMR 1A or 1B substances in childcare articles.

Furthermore, some chemical requirements have been established by standards for textile childcare articles (see Table 9). However, details on concentration limits are not available.

Table 9: Standards for child use and care articles (CCAs)

CCAs and/or substance concerned	Legislation	Specification
Soothers	DIN EN 1400:2018-11: Child use and care articles. Soothers for babies and young children. SFS-EN 1400 + A2 Child use and care articles. Soothers for babies and young children.	Safety requirements and test methods (details not available)
Soother holder	DIN EN 12586:2011-04 Child care articles - Soother holder SFS-EN 12586 + A1 Child use and care articles. Soother holder.	Safety requirements and test methods (details not available)
Cutlery and feeding utensils	DIN EN 14372:2004-11: Child use and care articles - Cutlery and feeding utensils - SFS-EN 14372 Child use and care articles - Cutlery and feeding utensils	Safety requirements and test methods (details not available)
Drinking equipment	SFS-EN 14350 Child care articles - Drinking equipment.	Safety requirements and test methods (details not available)
High chairs	SFS-EN 14988 + A1 Children's high chairs.	Requirements and test methods (details not available)
Childcare articles (with exemption of the articles above)	prEN 17826:2022 Child care articles - Chemical hazards	Requirements and test methods (details not available)
Cot bumpers	EN 16780	
Children's sleep bags for use in a cot	EN 16781	

Additionally, the following **ecolabels** were analysed to collect concentration limits:

- EU Ecolabel for textile products (Commission Decision 2014/350/(EU)) (EU Commission, 2020b),
- EU Ecolabel for footwear (Commission Decision (EU) 2016/1349) (EU Commission, 2020a),
- OEKO-TEX® (2023),

- Global Organic Textile Standard, GOTS (2023),
- Nordic Swan Ecolabelling of Baby products with textile (Nordic Swan, 2017),
- Blue Angel textiles (2023).

Finally, the following **RSLs** and standards were also analysed:

- Apparel and Footwear International RSL Management group (AFIRM, 2023),
- ALDI (2021),
- Amazon (2020),
- American Apparel & Footwear Association (AAFA, 2023),
- Bed Bath & Beyond (2022),
- bluesign® (2022),
- Cradle To Cradle™ (2021),
- EDANA (2023),
- GreenScreen Certified™ Standard for Textile Chemicals (GreenScreen Certified™, 2022),
- H&M Group (2023),
- NIKE INC (2022),
- Philips (2023),
- SATRA (2023),
- SGS (2022),
- VERSACE (2018),
- ZDHC Manufacturing Restricted Substances List (MRSL) & ZDHC Gateway (ZDHC, 2023).

It is to be noted that no specific RSLs for childcare articles could be identified. However, since several childcare articles contain textiles and the materials used for footwear (e.g. synthetic polymers and leather), those RSLs are considered applicable also for materials used in childcare articles.

ECHA also considered existing concentration limits for 'Chemicals of high concern' from several US States including Washington, Maine, Vermont and Oregon. Producers have to report products for children under 12 years of age containing one or more chemicals considered of concern to children. The listed concentration limits (e.g. Bed Bath & Beyond, 2022) are often much lower than the LOQs reported for commonly available standard analytical methods (e.g. formaldehyde 5 mg/kg; LOQ 16 mg/kg). To ensure that the considered concentration limits will be implementable with available methods frequently used, ECHA did not take such concentration limits into account.

Appendix 4 Inventory of available analytical methods additional information

Methodology

Appropriate analytical methods are necessary to effectively monitor the presence of hazardous substances in childcare articles and to ensure the enforceability of the restriction. Standard analytical methods are testing procedures published by national and international standardization bodies that are used to perform accurate and reproducible analytical measurements. They have been extensively validated, which means their performance parameters (accuracy, precision, linearity, LOD, LOQ, selectivity, recovery, and robustness) have been assessed by complying with an official validation norm. In addition, accredited testing laboratories can also validate their own analytical operating procedures in-house following an official validation norm. On the other hand, analytical methods published in scientific literature are subject to scientific review but are usually not validated following an international recognised norm.

ECHA decided to prioritise available standard methods and to consider analytical methods based on already published standard methods, or on EPA methods, that would need to be validated in-house by the testing laboratories. In addition, in-house validated analytical methods found in the consulted sources or used in research activities and published in scientific literature have been taken into account, for the substances for which analytical methods where difficult to find, as those can be further validated by accredited laboratories. It is important to point out that independently of the type of analytical method used (standard or in-house), chemical analyses for enforcement purposes should, normally, be carried out in accredited laboratories (ISO 17025).

The Commission's mandate specified the need for the identification of content related concentration limits and consequentially analytical methods to assess substance content in the materials present in childcare articles. However, while collecting the available information, different types of methods (e.g. screening, extractable content, migration, emission) were found to be relevant for some substances and therefore, information on these methods was also collected and reported in the Inventory. In particular, migration methods were collected for bisphenol A in synthetic polymers and for Nitrosamines and N-nitrosatable substances (e.g. dimethyl nitrosamine) in rubber of soothers, while emission methods were collected for formaldehyde in wood. Since for metals (and metal compounds) legislations (e.g. REACH restrictions, Toys Safety Directive), ecolabels (e.g. EU ecolabel) and RSLs, refer mainly to extractable content, both extractable and total content concentration limits and analytical methods were considered. For chromium VI in leather and textiles, only extractable content limits and related methods were identified as they allow identification of the oxidation state.

Three substances, dibutyltin bis (2-ethylhexanoate), dibutyltin hydrogen borate and cobalt bis(2-ethylhexanoate), can be classified under two different chemical groups and therefore quantification methods for both were indicated.

Finally, due to the ongoing universal restriction for PFAS (UPFAS), no analytical methods (or concentration limits) for PFAS were collected.

To compile the inventory of analytical methods the following sources were consulted:

- The Forum Compendium of Analytical Methods to check compliance of REACH Annex XVII restrictions (ECHA, 2021b) was consulted to identify analytical methods available for the substances restricted under REACH. The Forum has developed a

methodology (ECHA, 2021c) to recommend analytical methods based on the performance requirements of the methods. Many of the reported analytical methods in the compendium have been developed internally by the consulted laboratories, from existing standard methods (in-house validated methods). However, only the referenced standard methods are collected in this investigation report, as the in-house validated methods are laboratory-specific and do not provide sufficient information on the methods' performance.

- RSLs by AFIRM (2023), Versace (2018), Bed Bath & Beyond (2022), NIKE INC (2022), H&M Group (2023), bluesign® (2022), ALDI (2021), CRADLE TO CRADLE CERTIFIED™ (2021), AAFA (2023), Phillips (2023).

- Certifications and labels: EU Ecolabel for textiles.

- Analytical methods recommended in the Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

- Web databases for standard methods: ISO and EN websites, iTeh Standards database and EPA methods collection were used for finding standard methods directly by searching the name of the substance or the substance group (e.g. 'phthalates') (ISO Standards, European Standards s.r.o., iTeh Inc Standards, EPA test methods). Standard methods for which the LOQ or the complete list of target substances were not visible in the preview where purchased.

- Literature research: Findest IGOR^{AI} technology scouting tool was employed to research possible analytical methods in literature for substances or substances in matrices for which standard analytical methods or internal methods were not found in the consulted sources. The search function 'action' + 'object', in addition to keywords to specify the 'environment', was used. 'Action' comprised verbs such as 'measure', 'identify', 'analyse', 'quantify' and similar, 'object' was the name of the substance and the 'environment' included keywords to specify the material. Each search was individually optimised by changing the Boolean operators on the search function and the keywords depending on the search results.

Information was also collected through stakeholders' consultations. In the first call for evidence the following relevant comments about analytical methods were given:

1. Norway and Germany suggested the Toys Safety standard EN 71 part 3 (Migration of certain elements), 9 (Organic chemical compounds – Requirements), 10 (Organic chemical compounds – Sample preparation), 11 (Organic chemical compounds – Methods of analysis), and 12 (N-Nitrosamines and N-nitrosatable substances) to assess the presence of CMR substances in toys and childcare articles. However, Norway pointed out that parts 9, 10, and 11 have not been included in OJEU yet.

2. Germany suggested DIN EN 12868:2017 and DIN EN 1400:2018 for testing the presence of N-nitrosamines and N-nitrosable substances in pacifiers (rubber teats). ISO 8124-6:2018 was mentioned for detecting phthalates in toys and children's products.

3. ANEC and BEUC provided a list of substances, which included formaldehyde, dimethylformamide, formamide, aromatic amines, bisphenols, lead, organic dyes, organophosphorus compounds, PFAS, phthalates, PAHs, and relative testing methods utilised to assess their presence in childcare articles.

4. ANSES stressed the importance of reporting the type of essay (migration, emission, content and composition) that is carried out for each substance. Examples of studies on nappies composition and substance's migration from nappies with urine simulants were provided, as well as emission and migration measurements for formamide.

Finally, in addition to individual meetings with stakeholders, a second call for evidence dedicated entirely to analytical methods was organised. Hohenstein Textiles Testing Institute, Eurofins ATS, IKEA of Sweden testing laboratory, EDANA (International association of nonwovens and related industries), Formcare, Centexbel, Thueringer Landesamt fuer Verbraucherschutz (TLV), SGS, and the Croatian Institute of Public Health replied to the call for evidence, while TÜV SÜD Product Service, SGS and Tulli provided information through meetings and via e-mail. All the comments and information gathered be summarized as follows:

1. Suitability, availability, and costs of analytical methods already identified by ECHA to detect some of the measured or suspected substances in childcare articles at defined CLs:

   Overall, the identified methods were considered suitable, available, and reasonably cheap by the stakeholders that responded to the call for evidence. Eurofins stated that the final cost of the analysis is also dependent upon the complexity of the article. Specific observations and suggestions have been taken into consideration in the Inventory, including suggested method that were not already present. TLV pointed out that some standards methods are difficult to obtain and expensive and that, due to the high demand of quality assurance, costs of analyses have risen sharply. They also stressed the lack of reference materials to check the methods.

   For some substances and class of substances, Stakeholders provided higher LOQs than the found method's LOQs and/or the considered concentration limits. Each case is discussed in section 5.2. above.

   EDANA provided information on their test method NWSP360 for the analysis of substances in disposable baby diapers (absorbent hygiene products (AHPs)). In the method, AHP material is homogenized by using a mechanical mill, soaked in liquid extraction solution (e.g. urine simulant) and the migrated substances analysed using LC-MS, GC-MS or ICP-MS. The method covers only some of the CMR 1A and 1B substances measured or suspected in childcare articles but the scope could be potentially extended. However, the method has not been included in the Inventory of analytical methods as it focuses only on migration measurements and not on content measurements. Moreover, it is applicable only to a specific category of articles (considered as homogeneous materials, see section 5.1), while ECHA is considering disposable diapers as containing different materials such as "synthetic polymers" and/or "textiles", which have analytical methods available for the determination of the content of the relevant substances. EDANA finally added that none of the CMR 1A and 1B measured or suspected that ECHA listed are intentionally added (have a functional use) in AHPs.

2. information on available analytical methods for all the other measured or suspected CMR 1A or 1B substances for which no method was identified by ECHA:

   Stakeholders indicated potential challenges for some of the CMR 1A and 1B substances in childcare articles that are not routinely analysed and therefore lack information on analytical methos. TLV stated that there is a lack of published, validated methods. However, Hohenstein Textiles Testing Institute, Formcare, SGS,

and TÜV SÜD provided methods for some of the substances in this category and their suggestions were taken into consideration. ECHA identified analytical methods that would need to be developed internally by the testing laboratories (see below).

EDANA stated that the substances in the list could potentially be included in the scope of their NWSP360 method provided further development work is carried out.

3. Feasibility of the considered default concentration (content) limit of 10 mg/kg for all CMR 1A or 1B substances, in childcare articles, and possible other generic concentration limits:

Hohenstein Textile Testing Institute states that some CMR 1A and 1B substances are distillate fractions and reaction masses and therefore they are challenging to analyse. They also state that a generic limit encompassing all substances and all materials is not sensible as limits depend on the use of the substances. Eurofins states that LOQ depends on the tested matrix and other concentration limits might be considered if a global risk assessment which takes the matrix into account is performed. On the other hand, Centexbel and the Croatian Institute of Public Health stated that the concentration limit of 10 mg/kg is reasonable.

EDANA stresses that some substances with CMR 1A or 1B classification are complex mixtures with variable composition and insufficient characterization, they are not relevant for AHPs and their determination is too challenging. It was once again reinforced that these substances are not intentionally added to AHPs.

SGS, Thueringer Landesamt fuer Verbraucherschutz – TLV, Formcare and IKEA of Sweden testing laboratory did not comment on the issue.

Inventory table structure

All the collected information is reported in the excel file 'Appendix_A.6.1_Analytical_methods'. The sheet 'Inventory' covers all the CMR 1A or 1B substances measured or suspected in childcare articles (column B), their respective chemical group (column A), the Index No (Annex VI CLP) (column C), the EC/list number (column D) and the CAS number (column E). As it is fundamental to identify methods that are suitable to detect the substance in accordance with the considered concentration limits identified in this investigation, they are reported in column F in addition to the type of concentration limit (content, extractable content, migration or emission), reported in column G. The childcare article's material in which the substance was measured or is suspected to be present is reported in column H. In column I 'Analytical method', the standard method name was recorded. In case the method was developed as an internal method, it is reported as 'in-house validated method' and, if it comes from literature, as 'Research method'. In column J 'Reference', the reference for in-house validated methods, for sources and literature sources is indicated. The analytical methods main characteristics, analytical technique and sample preparation, are then reported in columns K, L, respectively. The meaning of all the abbreviations can be found in the sheet 'Abbreviations' in the same excel file.

For each method, the type of measurement was identified (column M):

- Screening: methods that are used in a first step to assess the content of a substance in a semi-quantitative or qualitative way or methods that might be relevant (widely used) but not appropriate for the considered concentration limit (LOQ too high) and can therefore be used as screening methods. These methods

can be used to decide whether to carry out more targeted or precise quantitative measurements (see Testing Strategy).

- Substance content: methods that quantify the total amount of a substance in the homogeneous material in accordance to the considered concentration limits.

- Extractable content: methods that quantify the substance content that can be extracted from the material in determined extraction conditions. They are usually carried out by shredding or pulverizing the material and using acid artificial sweat solutions or other bland extraction solutions.

- Migration content: methods that determine the amount of substance that is released from the material, usually kept integral, in food simulants or similar environments for a long period of time.

- Emission: methods that measure the amount of a volatile substance released in the air from a source.

Additional notes about the methods have been added in column N 'Notes'. Finally, in column O 'Comment' each method was defined 'Suitable for content', 'Suitable for screening', 'Suitable for extractable content', 'Suitable for migration' or 'Suitable for emission' based on the previously reported type of measurements, on the information found in the consulted source and on the characteristics of the method. For the substances that lacked information on available standard analytical methods, ECHA identified possible analytical methods or considered to extend the scope of standard methods. For these substances, a standard operating procedure (SOP) needs to be developed internally by the testing laboratories for the methods to be validated, and therefore 'in-house SOP to be developed' is reported. For research methods found in literature, 'Research method' is indicated in this column. By using column P 'Selected for the testing strategy', it is possible to filter the Targeted and Screening analytical methods reported for the Testing strategy (see section 6.2).