

CRIN Position Paper

No more harmful chemicals in toys:

How can the Toy Safety Regulation better uphold children's rights against hazardous substances?

The **Child Rights International Network (CRIN)** is a creative human rights organisation focused on children's rights. We challenge the status quo because the norms that dictate children and young people's place in society need radical change. We press for rights – not charity – and campaign for a genuine shift in how governments and societies view and treat under-18s.

CRIN is a non-governmental organisation registered under the EU Transparency Register (TR ID number: 392002349435-58).

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Executive Summary

As we write, many toys containing harmful chemicals are being sold in the European market, to end up in the hands and mouths of children. Exposure to those substances presents particularly damaging effects on foetuses, infants and children, and **there is no such thing as a tolerable intake of hazardous chemicals in toys.** Contamination due to their exposure causes severe children's rights infringements, including violations of their rights to health, play and physical integrity.

Children are worst affected by harmful substances, even at very low doses. All toys should be safe and hazard-free. Guaranteeing the highest level of safety in toys is the only way for the EU to effectively comply with its legally binding commitments under the UN and EU human rights frameworks.

We welcome the EU Commission's proposal for a Toy Safety Regulation¹ (TSR), revising the existing directive on the safety of toys in force since 2009.² To deliver on the Chemicals Strategy for Sustainability (CSS), a revision of this outdated directive is more than needed to reinforce children's rights protection in line with the latest scientific evidence. As appropriately proposed by the Commission, **the revision can better protect children not only against carcinogenic, mutagenic and reprotoxic (CMR) substances, but other hazard classes as well**. The TSR is the chance to finally tackle the combination of multiple chemicals and to restrict hazardous substances that were under the radar so far, though particularly damaging to children's health, such as known and suspected endocrine disrupting chemicals (EDCs).

The proposal is a great step toward a better protection of children against harmful chemicals. Nonetheless, **several of its provisions fall short in fully comprehending and upholding children's rights**. Among other issues, the long transition period as well as the risk to leave the door open to derogations for uses of the most harmful chemicals raise concerns and should be reconsidered.

The Council of the EU and the EU Parliament (particularly its responsible committees)³ can now contribute to refine this proposal so it can fully uphold children's rights. In the coming months of negotiations, the EU institutions must support this ambitious proposal and tweak the text, so **toy safety can be effectively guaranteed under a refined regulation which**:

- Better understands and upholds children's rights, by fully comprehending the links between exposure to hazardous substances and children's rights violations, as well as recognising children as independent rights holders.
- Bans both known and suspected categories of hazardous substances, including (but not limited to) CMRs and EDCs, under the generic approach to risk management.
- Updates limit values for chemicals in all toys, to protect all children below and above 3 years-old.
- Puts an end to unjustified derogations, moving away from the "safe use" misconception, and limits the transition period during which children will continue to be contaminated by hazardous substances.
- **Improves access to information, compliance and control**, by supporting effective market surveillance and customs including with the introduction of a Digital Product Passport and the reinforcement of the custom capacities.

² Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys. June 2009.

¹ European Commission, <u>Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing</u> <u>Directive 2009/48/EC</u>, July 2023.

³ European Parliament, Legislative Observatory, 2023/0290 (COD).



Acknowledgement: While our position paper focuses on chemicals, which is currently our main area of work at the EU, we also want to commend some suggested additions and improvements, particularly the extension of the concept of safety to mental health. A toy should not be considered safe if it poses foreseeable risks to 'psychological and mental health, well-being and cognitive development of children' (as tabled by the Commission's draft TSR). We encourage the decision makers to support, tweak and reinforce such provision as part of the product requirements.⁴

State of play of the EU Toy Safety Regulation

The proposal for a Toy Safety Regulation (TSR)⁵ published in July 2023 aims to revise the outdated 2009 Toy Safety directive (TSD)⁶ which established and enforced safety measures for children's toys sold in the EU. This directive only prohibits carcinogenic, mutagenic and reprotoxic (CMR) substances, and sets limit values for certain substances in toys intended for children under 36 months or intended to be put in the mouth. In 2020, **the TSD evaluation unveiled major shortcomings**⁷, **including on the protection against harmful chemicals**, as the TSD does not adequately respond to the latest scientific knowledge. In its Chemicals Strategy for Sustainability (CSS)⁸ published in the same year, the EU Commission committed to revise the TSD. Among other timely amendments, the Commission called to **extend the generic approach to risk management** (GRA, so-called hazard-based approach) already applying to CMRs to more hazardous substances including endocrine disrupting chemicals (EDCs), as well as to better take account of the combination effects of chemicals.

In 2021, the **EU Parliament adopted a motion for a resolution urging for stronger legislation on toy safety, including restrictions of more hazardous substances**, such as EDCs as well as chemicals affecting the immune, neurological or respiratory systems and to chemicals toxic to a specific organ (STOT). The EU Parliament also contested the relevance of the 36 months threshold for setting limit values of certain chemicals.⁹

On 28 July 2023, the European Commission published the **long-awaited TSR proposal, relevantly turning the directive into a regulation, and including a ban on hazardous substances from toys, including known and suspected EDCs.**¹⁰ The proposal also specifies that, as part of the safety assessment, the manufacturer needs to consider the possible risks of the combined or cumulative presence of chemicals in the toy. Among other improvements, the Commission proposes to strengthen control and market surveillance, including by requiring all toys to have a Digital Product Passport.¹¹ These improvements are more than welcomed, as harmful substances in toys currently placed on the EU market irreversibly affect children's health and the enjoyment of their human rights. **The time is now to ban hazardous substances from toys**.

Harmful substances in toys irreversibly affect children's health

Exposure to dangerous substances via multiple routes, including toys, can have particularly damaging effects on children's health. Because of their smaller bodies, rapid growth and particular

- ⁶ European Commission, Toy Safety in the EU: The Toy Safety Directive 2009/48/EC.
- ⁷ European Commission, <u>Evaluation of the Toy Safety Directive</u>, November 2020.
- ⁸ European Commission, <u>Chemicals Strategy for Sustainability</u>, October 2020.

⁴ Proposal for a TSR, Article 5.2, Product requirements.

⁵ European Commission, Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC, July 2023.

⁹ European Parliament, <u>Report on the implementation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (Toy Safety Directive)</u>, December 2021.

¹⁰ <u>Annex II to the TSR proposal</u>, Particular Safety requirements, Part III Chemical Properties.

¹¹ Further detailed in the last section of this position paper.

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behavioural habits, children are worst affected by harmful substances, even at very low doses. Contamination can occur before birth, as **children can be born "pre-polluted"** due to exposure during the foetal development.¹² The foetal stage is a particularly critical period of life with increased vulnerability to exposure to hazardous chemicals. **Impacts can be irreversible and can even be passed down from one generation to the next**¹³, with long-term consequences on children's development, both during the prenatal and after-birth stages. Moreover, due to their **specific behavioural habits**, children are much more exposed to harmful chemicals, including in toys and other childcare articles. On account of their age, children might be **less able to evaluate and react to the risks**, for instance reading labels and adopting protective behaviours. **Children may be exposed to higher chemicals intake than adults**, as they for instance breathe more often per minute.¹⁵ They absorb substances more readily, and are less able to excrete them afterwards.

As mentioned by Senior Program Scientist and Zoologist Theo Colborn, "from the day of conception until an individual is born or hatched, the development of each stage of life is fully under the control of hormones. **Changes that happen during development are far less reversible [than those occurring in an adult]; you can't go back and rewire the brain**".¹⁶

Many harmful substances, including suspected and known EDCs, have been found in toys sold in the EU. In November 2018, Arnika found **significant levels of toxic brominated dioxins in plastic toys**¹⁷, including PBDEs and PBDDs/Fs which are EDCs that may impact children's hormone levels, affect brain development, damage the immune system and foetus, or induce carcinogenesis.

In 2021, the EU's Safety Gate rapid alert system found that, out of the 2,142 alerts it received, the **most notified product categories were "motor vehicles" and "toys"**. One of the main concerns for safety of toys pertained to the presence of hazardous chemicals. Similarly in 2022, 2,117 notifications were sent to the Safety Gate, and toys were still among the most notified product categories.¹⁸

In 2023, the Danish Consumer Council also found that bisphenols were present in 60% of 121 tested children's products, and **known or suspected EDCs were found in 11 out of 20 tested teething toys**.¹⁹ The same year, the Dutch organisation Tegengif analysed plastic toys placed on the Dutch market.²⁰ Several chemicals found in the tested toys are identified by ECHA as substances of **very high concern**, and associated with hormone disruption, reduced fertility and cancer. The study revealed that several phthalates, BHT and Triphenyl phosphate could be found in very popular toys. DEHtP and DINCH were present in exceeding concentration levels.

The issue of unsafe toys sold in the EU market is widespread. While a considerable amount of unsafe toys are coming from non-EU countries selling toys via online platforms²¹, EU companies are

¹² Danish Protection Agency, 'Exposure of children and unborn children to selected chemical Substances', 2017,

¹³ HRC, <u>Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes</u>, <u>A/HRC/33/41</u>, August 2016, para. 2.

¹⁴ Govarts, E. et al., <u>Combined Effects of Prenatal Exposures to Environmental Chemicals on Birth Weight.</u> May 2016; Balbus J.M., et al. <u>Early-life prevention of non-communicable diseases</u>, December 2013.

¹⁵ Eleesha Lockett, Kirsten Nunez, medically reviewed by Carissa Stephens, <u>What Is a Normal Respiratory Rate for Adults and Children?</u>. Healthline, November 2022, Anthony Herbert et al., <u>Normal Percentiles for Respiratory Rate in Children-Reference Ranges Determined</u> from an Optical Sensor, October 2020.

¹⁶ <u>Theo Colborn's Letter to the president about chemicals disrupting our bodies</u>, December 2012.

¹⁷ Arnika, <u>Toxic Soup: Dioxins in Plastic Toys</u>, November 2018.

¹⁸ European Commission, Safety Gate: chemical substances top the annual list of health hazards for non-food products, March 2023.

¹⁹ Forbrugerrådet Tænks - Danish Consumer Council THINK Chemicals, <u>Bisphenols should be banned</u>, May 2023.

²⁰ Tegengif, <u>Populair kinderspeelgoed bevat giftige stoffen</u>, 2023.

²¹ BEUC, <u>Continued presence of dangerous products shows dire need to regulate online marketplaces</u>, March 2022.

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also responsible and too often erroneously presented as the 'frontrunners' or the 'safest sellers', while they also use hazardous substances in toys. Even when EU companies comply with the TSD, they still can use very harmful substances such as EDCs, or in case of derogations, even some CMRs that are usually banned under the TSD. Compliance with the existing legislation does not mean that EU companies effectively ensure the highest level of safety to children since this directive falls short in protecting children against several hazard classes.

From their early age and even before birth, children suffer from exposure to high levels of harmful substances. They are more sensitive to it, which makes them more vulnerable than adults. Continued exposure to dangerous substances, including in toys, impact children's rights that have been internationally recognised.²²

Why do harmful chemicals in toys affect children's rights?

Existing loopholes in the TSD have resulted in severe infringements of children rights enshrined in UN and EU frameworks. The TSR proposal is the chance for the EU to stand up and deliver on its commitments to international and EU children's rights binding frameworks.

International protection of child rights against harmful chemicals

The UN Convention on the Rights of the Child (UNCRC)²³ recognises the **right of all children to have the best possible start in life, to grow up healthy, and to develop to their full potential.**²⁴ Families and communities also need to be provided with the necessary support so that they can ensure children's wellbeing and development.²⁵ Article 31 enshrines the **right of the child to rest and leisure, to engage in play and recreational activities** appropriate to the age of the child and to **participate freely in cultural life and the arts.**

Such a right should be **enjoyed by all children**, **without the risk of being exposed to harmful substances while using toys.** Children's right to leisure and recreation also means the right to play safely. In 2013, the Committee on the Rights of the Child ("The Committee") outlined several issues stemming from the mass marketing and commercialisation of play. The Committee was concerned that many children and their families were exposed to increasing levels of unregulated marketing by toy and game manufacturers. They were pressured to purchase a growing number of products which may be harmful to their development or antithetical to creative play, for example (...) toys containing dangerous chemicals or parts.²⁶

In his report focusing on children's rights in 2016, former Special Rapporteur (SR) on human rights and toxics Baskut Tuncak provided a **full analysis of children's rights that are impacted by toxic chemicals, including the best interests of the child.**²⁷ He emphasised that the UNCRC makes it clear that States have an obligation to "prevent exposure to toxics by children, as well as by women of reproductive age". He reminded that businesses must ensure their products do not contain toxic or otherwise hazardous substances, stressing that **toys imported to Europe are regularly found to contain high levels of toxics**.

²⁷ Report of the Special Rapporteur on Toxics to the UN Human Rights Council on Rights of Child and Toxics, A/HRC/33/41, August 2016.

²² WHO, Don't pollute my future! The impact of the environment on children's health, 2017; Report of the Special Rapporteur on the right to food, A/HRC/34/48, January 2017.

²³ <u>UNCRC</u>, 1989.

²⁴ See UNCRC Articles 6 and 24, and UNICEF's <u>Children Version of the UNCRC</u>.

²⁵ See UNCRC Preamble and Article 3, and UNICEF's <u>Children Version of the UNCRC</u>.

²⁶ Committee on the Rights of the Child, <u>General comment No. 17: The right of the child to rest, leisure, play, recreational activities, cultural life and the arts (Article 31)</u>, March 2013, para. 47, page 14.

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In its Resolution on the realisation of the rights of the child through a healthy environment²⁸, the UN Human Rights Council urged "States to ensure the right of the child to the enjoyment of the highest attainable standard of physical and mental health, by inter alia: [...] **Identifying and eliminating sources of exposure of children to indoor and outdoor air pollution and substances of high concern, such as (...) EDCs**".

Current SR on toxics and human rights Marcos Orellana emphasised in 2022 that "**children suffer a silent assault on their right to health, and often on their right to life, where plastic toys and other products contain toxic substances that leach and enter their bodies**". Use of plastic products exposes children to EDCs in toys or utensils. He called for better prioritising the protection of children, as well as securing people's access to environmental and health information.²⁹

In July 2022, the UN General Assembly (UNGA) adopted a resolution recognising the right to a clean, healthy and sustainable environment as a universal human right.³⁰ The UNGA called on States and businesses to scale up efforts to ensure a healthy environment for all. The resolution recognised that the **unsound management of chemicals and waste interferes with the enjoyment of a clean, healthy and sustainable environment**, and that **environmental damage has negative implications, both direct and indirect, for the effective enjoyment of all human rights**.

In August 2023, the Committee on the Rights of the Child released General Comment 26 on children's rights and the environment. According to the Committee, **States should consistently and explicitly consider the impact of exposure to toxic substances and pollution in early life**. They should "consider all factors required for children of all different ages to survive, develop and thrive to their fullest potential and design and **implement evidence-based interventions** that address a wide range of environmental determinants during the life course".³¹ It acknowledged that younger children are particularly susceptible to environmental hazards, and that the effects of environmental contaminants may even persist in future generations. According to the Committee, **States should consistently and explicitly consider the impact of exposure to toxic substances in early life**. They are asked to "closely regulate and eliminate, as appropriate, the production, sale, use and release of toxic substances that have disproportionate adverse health effects on children, in particular those substances that are developmental neurotoxins".³²

The UNCRC, which all EU Member States have ratified, must guide EU action. Harmful exposure via toys is a **silent assault** on children's rights, including their right to life and to health. In view of children's elevated susceptibility relative to adults, **the global human rights framework imposes enhanced obligations on States to safeguard them from harmful exposure**.

 ²⁸ Human Rights Council Resolution on realising the rights of the child through a healthy environment. A/HRC/RES/45/30, October 2020.
²⁹ OHCHR, Opening Remarks, United Nations Special Rapporteur on toxics and human rights, Marcos A. Orellana, at the 76th Session of the UN General Assembly, May 2022.

³⁰ UNGA Resolution A/76/L.75 "The human right to a clean, healthy and sustainable environment", July 2022.

³¹ Committee on the Rights of the Child, <u>General Comment No. 26 on children's rights and the environment, with a special focus on climate change</u>, CRC/C/GC/26, August 2023.

³² Committee on the Rights of the Child, <u>General Comment No. 26 on children's rights and the environment, with a special focus on climate change</u>, CRC/C/GC/26, August 2023, paragraph 65.

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EU commitments to protecting child rights

Charter of Fundamental Rights of the European Union

The Charter of Fundamental Rights of the EU was introduced by the Treaty of Lisbon. As such, it binds all EU Member states, with the same legal value as the EU Treaties. Article 24³³ guarantees and protects the rights and best interests of the child, including the right to protection and care, as well as to express views. In all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration.

More broadly, the Charter enshrines several human rights that can be impacted by the exposure to hazardous chemicals via toys. Article 1 protects human dignity. Article 2 the right to life and Article 3 the right to integrity of the person. The Charter guarantees equality before the law (Article 20), non-discrimination (Article 21), equality between women and men (Article 23), as well as the integration of persons with disabilities (Article 26). Many children severely impacted by exposure to harmful chemicals are already marginalised or discriminated against.³⁴ Resources are unjustly distributed across countries, regions and even localities. Communities impacted by oppressive patterns have access to less of their resources, and they often have to buy cheaper products, including toys, which often present more risks of non-compliance with the safety requirements. Moreover, exposure to harmful chemicals and their related impacts on health can create intergenerational effects that entrench marginalisation and socioeconomic disparities experienced by affected communities.³⁵

EU Strategy on the Rights of the Child

On 24 March 2021, the EU Commission unveiled the EU Strategy on the Rights of the Child³⁶, developed for children and with children. In this Strategy, the EU seeks to address persisting and emerging challenges, with concrete actions to protect, promote and fulfil children's rights. The EU strategy is child rights-based, and as such refers to the UNCRC.

Exposure to hazardous chemicals via toys violates children's rights to live, learn and grow in a physical environment that facilitates health, play, and education, and is free from undue risk. Under this Strategy, the 2nd thematic area of EU actions aims to fight poverty and promote inclusive and child-friendly societies, health and education systems.³⁷ It mentions that all children have rights to education and health, as well as a right to a good standard of living. CRIN, together with other NGOs, supports that protecting children from exposure to hazardous chemicals, including those found in toys, is a cornerstone to deliver on the Strategy's promises.³⁸

Children are fully entitled to these rights the EU and Member States committed to uphold and protect. They committed to always take the child's best interests into primary consideration. That also means children should not be exposed to hazardous chemicals when they play and enjoy recreational activities.

³³ <u>Article 24 of the Charter of Fundamental Rights of the European Union</u>, December 2007.

³⁴ Johnston, J. and Cushing, L., Chemical exposures, health and environmental justice in communities living on the fenceline of industry, 2020.

³⁵ Shadaan; R. and Murphy, M., Endocrine-Disrupting Chemicals (EDCs) as Industrial and Settler Colonial Structures: Towards a Decolonial Feminist Approach, 2020. ³⁶ European Commission, <u>The EU Strategy on the Rights of the Child and the European Child Guarantee</u>, March 2021.

³⁷ European Commission, Thematic area 2, <u>Socio-economic inclusion, health and education</u>.

³⁸ EDC-Free Coalition, EU Strategy on the Rights of the Child to protect against harmful chemicals: time to deliver!, May 2021.



Toy Safety Regulation: Ensuring toys do not endanger children

The EU institutions and the Member States **committed to respect**, **enforce and protect children's rights**. The TSR is the opportunity to enhance provisions to adequately and fully guarantee children's rights, including their best interests, right to play and right to health.

1. A need for better recognition and protection of children as right holders

Children are rights holders: they are entitled to a range of human rights the EU and the Member States committed to respect, enforce and protect under both UN and EU treaties.³⁹ Efficiently upholding children's rights against exposure to harmful chemicals first requires for these rights to be fully comprehended and upheld under the EU chemicals legislation, including on toy safety. Children have all human rights.⁴⁰ Not because they are the "adults of tomorrow" or "the future", but because they are human beings today. Children are also more vulnerable than other people because of their young age and dependence on adults, so they have specific rights to protect them. For children's rights to be realised, they first have to be recognised. This requires developing strong legislation including on chemicals safety, and this includes warding off harmful, paternalistic and adult-centric narratives that prevent children being recognised as independent rights holders.

The 2021 motion for a resolution⁴¹ adopted by the EU Parliament reminded that "play is recognised as every child's right by the UNCRC, to which all EU Member States are signatories", that "**playing contributes to children's development, health and wellbeing and is an essential part of growing up**", and "studies show that toys can enrich play and keep children playing for longer". As such, the EU Parliament importantly recognised the interconnection between guaranteeing toy safety and safeguarding children's rights.

We regret that such mentions of children's rights, references to the UNCRC and acknowledgements of intersectionality between harmful chemicals and children's rights violations are not embedded in the TSR proposal. The draft only mentions that "**regarding fundamental rights, none of the policy options is expected to have significant impacts.** Policy option 1b⁴² should generally have a positive contribution to the overall rights of the child and to the possibility of children to play. Equality, including gender equality, is not significantly impacted by this initiative".

We disagree with the statement according to which "none of the policy options is expected to have significant impacts on fundamental rights, and that the initiative does not impact equality, including gender equality". This neglects and does not fully grasp the impacts hazardous chemicals can have on the most affected groups of children. While we agree policy option 1b can generally have a positive contribution to the overall rights of the child and to the possibility of children to play, we believe that **policy option 1c⁴³ would even better protect all children's rights**. **Granting no derogation for using the most harmful substances, the policy option 1c would truly prioritise children's best interests over other interests**, in line with the EU commitments to the UNCRC and the EU Charter, which require taking children's best interest into primary consideration.

⁴⁰ CRIN Archives, Children in vulnerable situations

³⁹ UN Convention on the rights of the child (UNCRC), 1989; Charter of Fundamental Rights of the European Union, 2007.

⁴¹ European Parliament, Report on the implementation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys (Toy Safety Directive), December 2021

⁴² TSR proposal, page 7: Policy option 1b would still **allow for derogations to the generic bans under certain conditions,** when the use of the substance in toys is considered to be safe by the relevant scientific committee in the ECHA and there are no alternatives.

⁴³ TSR proposal, page 7: Policy option 1c is the same as policy option 1b (generic bans for most harmful chemicals) but **without** derogations being possible to the generic bans.

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The assessment of the rights to be impacted by the different options on the table is poorly detailed, and the conclusions are inaccurate. The impact assessment (IA)⁴⁴ poorly comprehended children's rights, mentioning that "none of the policy options is expected to have significant impacts, but the first three policy options should generally assist in the rights of children and their possibility to play". Without fully assessing the rights to be impacted and by neglecting the many intersections between children's rights and exposure to harmful chemicals, the IA contributed to favouring a policy option which enables derogations without comprehending the negative effects this derogation process could ultimately have on children's rights.

Furthermore, the IA as well as the TSR proposal mainly focus on the achievement of the Sustainable Development Goals (SDGs). While SDGs are a relevant compass for international and EU action, they are only a piece of the broader human rights framework. The IA and the TSR proposal neglect an entire body of legally binding Conventions and Charters, such as the UNCRC. Not only should the TSR contribute to the realisation of SDGs but it should also - and first and foremost - ensure that the EU complies with its legal obligations regarding children's rights, as set out in the UNCRC and the EU Charter of Fundamental Rights.

2. Banning known and suspected hazardous substances from toys, with very limited derogations

Time to tackle both known and suspected hazardous substances

In the CSS, the European Commission committed to ensure that EDCs are banned in consumer products as soon as they are identified, and to extend the GRA to ensure that consumer products do not contain chemicals that cause problematic effects, including those affecting the endocrine system.

The TSR proposal adequately tables a ban on CMRs category (cat.) 1 and 2, EDCs cat.1 and 2 as well as STOT cat.1, either in single exposure or in repeated exposure, and respiratory sensitisation. **We welcome this GRA extension to more hazardous classes, including known and suspected EDCs.** EDCs present a similar level of concern as CMRs, if not higher. In light of the state of science and available test methods, the TSR relevantly adopts a precautionary approach. EDCs identified today as suspected EDCs (cat. 2) are very likely to get classified as known EDCs (cat.1) in the coming years.

Applying the precautionary principle is absolutely necessary, and the principle should be better embedded throughout the TSR proposal, not only in its recitals. As the European Society of Endocrinology adequately urged in 2021, "in order to safeguard human health and the environment, the EU Commission and the European Chemicals Agency (ECHA) **should strictly apply the precautionary principle, to avoid production, distribution and exposure to pesticides, biocides or consumer products containing suspected EDCs**".⁴⁵

The GRA extension will also help **avoiding regrettable substitutions.** With a substance-by-substance approach, the risk for a banned or restricted hazardous substance to be substituted by another one just as hazardous is much higher. For instance, TCEP used as a flame retardant in children's toys is an infamous case of regrettable substitution under the current TSD. Manufacturers used TCEP to replace other brominated flame retardants, even though this substance is classified as carcinogen cat. 2, toxic for reproduction cat. 1B and identified as a substance of very

⁴⁴ European Commission, <u>Staff working document: Impact assessment report</u>, SWD(2023) 269 final, July 2023.

⁴⁵ ESE White Paper "Hormones in European Health Policies: How endocrinologists can contribute towards a healthier Europe", May 2021.

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high concern to be included in the candidate list for authorisation.⁴⁶ The EU Commission had to drastically **reduce the maximum limit value for TCEP and its two alternatives**, TDCP and TCPP, to 5 mg/kg in toys for children up to the age of 3 years and in any toys intended to be placed in the mouth.⁴⁷

The GRA extension will **reinforce coherence with other legislative frameworks tackling, and planning to tackle, EDCs in the near future,** leading to more predictability and clarity for EU authorities and companies. In its fitness check of EU chemicals legislation, the Commission itself considered that there should be a coherent approach to the identification of EDCs across all relevant legislation, based on the broadly accepted WHO definition.⁴⁸ It also mentioned that attention will be paid to the **consistency and intensity of actions** to protect vulnerable population groups that are particularly sensitive to EDCs, such as the foetus or adolescents.

There is no such thing as a tolerable intake of hazardous substances

There is no time to waste and the transition efforts must happen now. A **30-month transition period is excessively long,** considering that during this period, children will continue to be exposed to hazardous substances with short, medium and long term adverse effects on their health. The **transition period should be reevaluated and limited as much as possible.**

Moreover, **the TSR should not leave the derogation tap open.** Opportunities for the manufacturers to obtain derogations to the ban of the most harmful chemicals should be **extremely limited both in time and scope**. But to fully uphold children's rights as requested in EU and UN legally binding frameworks, they should not even exist. We deplore the existence of derogations to the generic bans in the TSR. According to the proposal, derogations would be possible where the safety of children is not compromised, but this aspect is difficult to assess and the proposal very unclear, where alternatives are not available, and where the substance is not restricted under REACH. The EU Regulatory Scrutiny board itself raised concerns and called for clarification regarding the derogation process, considering that "**the report does not provide sufficient information** about the process to grant derogations for the most harmful chemicals under the preferred option. **It does not explain how this process will ensure that children's safety is not compromised**" and that "it does not explain sufficiently why granting derogations does not have any impact on the expected health benefits".⁴⁹

We are concerned to see the notion of "safe use" being included in the proposal. **The EU must move away from the "dose makes the poison" misconception.** The most harmful chemicals should be restricted as much as possible, everywhere, and especially in products intended for children's uses. There is a misconception that very low doses can have less of a harmful effect. However, the dose does not make the poison, as several substances demonstrated harmful effects even at very low doses, for instance when they present endocrine disrupting properties.⁵⁰ The notion of "safe use" should be disregarded as it does not reflect the current state of science, and the existence of derogations in the proposal contradicts the *raison d'être* of the toy safety legislation itself.

With the possibility for derogations, some companies could continue using the most hazardous substances as long as alternatives do not exist, continuing their harmful business as usual.

- ⁴⁹ European Commission, <u>SEC(2023)297 Opinion of the Regulatory Scrutiny Board</u>, July 2023.
- ⁵⁰ Laura N. Vandenberg, When the dose doesn't make the poison: low dose effects and endocrine disrupting chemicals; Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses, June 2012.

⁴⁶ ECHA, <u>Substance Infocard on Tris(2-chloroethyl) phosphate</u>.

⁴⁷ DG GROW, <u>TCEP (Tris(2-chloroethyl) phosphate and similar flame retardants strictly limited in toys</u>, June 2014.

⁴⁸ European Commission, <u>Fitness Check of the most relevant chemical legislation (excluding REACH)</u>, April 2020.

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Furthermore, as explained in the section on "Proportionality", one of the rationales for such derogations is that "by allowing for derogations to these generic bans under limited circumstances, it will limit the costs for industry from introducing such bans in those cases where the safety of children is not compromised".⁵¹ Safety of children is compromised as soon as they are exposed to those hazardous chemicals. Trading off children's health in favour of companies' profits is unacceptable. Under the existing TSD, derogations related to CMR knowingly enabled the industry to circumvent its obligation and responsibility to ensure the highest protection of all children. Only a sweeping ban of the most hazardous chemicals under GRA with very little to no derogation can fully and effectively protect children's rights and their health.

And there is no such thing as a tolerable age for being exposed to harmful chemicals

Under the existing TSD, the limit values on certain chemicals apply only for toys for children under 36 months, and for toys intended to be placed in the mouth. As relevantly stressed in the TSR proposal, "those substances have shown to also pose a risk to older children, as they could be equally exposed to such chemicals via skin contact or inhalation".⁵²

The draft TSR proposes to apply these limit values to all toys, no matter the age of their users. **The limit values extension to all toys intended for all age groups is much welcome**. It will contribute to better upholding rights of children (as specifically defined by the proposed regulation, i.e. under 14 years-old).⁵³

Introducing a long-overdue assessment and management of combination effects

The TSR proposal makes major progress in better addressing the combination effects of chemicals, as it not only mentions that the most harmful substances should be generally banned in toys but also that the specific limit values for chemicals in toys should account for combined exposure from different sources to the same chemical substance. It asks the manufacturers to carry out an analysis of the various hazards that the toy may present and an assessment of the potential exposure to such hazards and to consider known cumulative or synergistic effects of the chemicals present in the toy.

Introducing better assessment and management of combined chemicals (so-called cocktail effect) is a long-overdue measure to effectively protect children against exposure to hazardous substances. Children are exposed to many hazardous chemicals via a wide range of exposure routes, including the use of toys but also other consumer uses, such as hygiene and cosmetic products, as well as in food and water.⁵⁴ We welcome the Commission's more holistic approach in assessing and managing chemicals, **contributing to a move away from the outdated and isolating evaluation of single substances.**

3. Ensuring efficient control and enforcement of the safety requirements

The evaluation of TSD found severe shortcomings in market surveillance. The draft TSR proposes to improve the evaluation and market surveillance, including via the introduction of a Digital Product

⁵¹ TSR Proposal, p.4, "Proportionality", July 2023.

⁵² TSR proposal, p. 19, point (22), July 2023.

⁵³ TSR proposal, July 2023: "This Regulation applies to products which are designed or intended, whether or not exclusively, for use in play by children under 14 years of age ('toys'). For the purposes of this Regulation, a product shall be considered to be intended for use in play by children under 14 years of age, or by children of any other specific age group below 14 years, where a parent or supervisor can reasonably assume, by virtue of the functions, dimensions and characteristics of that product, that it is intended for use in play by children of the relevant age group."

⁵⁴ Chemtrust, Report: Why you should know about 'the mixture effect, March 2022.



Passport (DPP) for all toys. The DPP would contain information on compliance with the TSR and importers would have to provide a DPP for all toys at EU borders, including those sold online. Imposing the DPP can help authorities to access crucial information on toys and better control products sold online. The DPP can contribute to increase transparency on chemicals in toys, as well as facilitating communication across the entire supply chain. In that regard, **we welcome the requirement to mention "any substance of concern that is present in the toy"** in the DPP.

Moreover, the TSR proposal must be refined and provisions about the DPP should be further detailed. To fully uphold the right to information for both children and their parents, the DPP should be freely accessible to the public. Information must be clear and easily available, so they can make informed decisions before buying a toy, and it is crucial for the TSR to ensure that information, including on the substances of concern, is accessible to people (including children) with disabilities. While digitalisation can in some extent improve access to information, some groups of the population do not have the devices required to access it (e.g. smartphones). As such, the QR code is a good tool but it should not be the only way to access information. Overall, the DPP is a great measure but cannot alone tackle non-compliant toys. It should come together with a reinforcement of the customs capacities, including an increase in the number of custom officers.

Concluding remarks

Children are fully entitled to their rights that the EU and Member States committed to promote, guarantee and protect. Exposure to harmful substances in toys directly impacts several children's rights guaranteed by the UN Convention on the Rights of the Child as well as in the EU Charter of Fundamental Rights. Under the Charter, the EU committed to always take children's best interest into primary consideration. So far, the EU and its Member States fall short in guaranteeing their best interest and upholding their rights. Exposure to harmful chemicals found in toys severely infringes children's rights such as the rights to play, physical integrity and health.

The TSR can address existing shortcomings regarding toy safety, including the presence of hazardous substances. Enough data is available to know there is a need for action. High-quality independent scientific research demonstrated the risks stemming from children's exposure to harmful chemicals, including the wide range of hazardous substances found in toys placed on the EU market. To live up to its ambition to "**build the best possible life for children in the EU**", the EU institutions must adopt all preventive measures necessary to protect children from exposure to harmful chemicals. The **proposed TSD revision is a pivotal step to drastically reduce children's exposure to harmful chemicals, including EDCs**. Focusing on improving compliance with existing limit values set under the existing TSD is not enough. The TSR must be ambitious as a whole and step up children's protection, both in terms of safety requirements and controlling the enforcement and compliance with those requirements.

The TSR is the chance for the EU to lead by example for a better protection of children against harmful chemicals worldwide. Measures to globally ensure toy safety are needed more than ever, as independent tests found for instance that several toys imported by the United States from China contained asbestos fibres.⁵⁵ The EU can be an influential player globally and incentivise countries to improve toy safety - but only by first improving its own legislation first.

For more information on CRIN's work:

- CRIN, <u>Who We Are and Our Code</u>
- CRIN's Work on protecting children from harmful chemicals in the EU
- CRIN's <u>Work on toxics</u> (international level)

⁵⁵ Povtak, T., <u>Are Children Safe from Asbestos Lurking in Their Crayons, Toys2</u>, The Mesothelioma Center, October 2015.