



2023/0290(COD)

12.2.2024

OPINION

of the Committee on the Environment, Public Health and Food Safety

for the Committee on the Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council
Safety of toys and repealing Directive 2009/48/EC
(COM(2023)0462 – C9-0317/2023 – 2023/0290(COD))

Rapporteur for opinion (*): Sara Cerdas

(*) Associated committee – Rule 57 of the Rules of Procedure

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AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to take the following into account:

Amendment 1
Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) Children are a particularly vulnerable group. It is essential to ensure a high level of safety of children when playing with toys. Children should be adequately protected from possible risks stemming from toys, in particular from the chemical substances that toys may contain. At the same time, compliant toys should be able to move freely across the internal market without additional requirements.

Amendment

(2) Children are a particularly vulnerable group. It is essential to ensure a high level of safety of children when playing with toys. Children should be adequately protected from possible risks stemming from toys, in particular from the chemical substances that toys may contain ***in line with the precautionary principle as defined in the Article 191 of the Treaty on the Functioning of the European Union (TFEU)***. At the same time, compliant toys should be able to move freely across the internal market without additional requirements.

Amendment 2
Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

Amendment

(9 a) One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognises that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent and that actions to tackle threats to health have to take into account a complexity of health and environmental interrelations. Exposure to chemical pollution is linked to a wide range of health impacts, including chronic diseases, neurological disorders and

reduced fertility, as well as impacts on the environment, and the planet's biodiversity. Holistically recognising the interconnections between human health, animal health and the environment through integration of the One Health approach in policy making is defined as one of the enabling conditions to attain the priority objectives of the General Union Environment Action Programme to 2030^{1a} (8th EAP). Therefore, this Regulation should be implemented following the One Health approach.

^{1a} Decision (EU) 2022/591 of the European Parliament and of the Council

Amendment 3
Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

Amendment

(9 b) The 8th EAP also defines as one of its priority objectives the pursuit of zero pollution, including in relation to harmful chemicals, in order to achieve a toxic-free environment, including for air, water and soil. As one of the enabling conditions to attain the priority objectives, the 8th EAP aims to swiftly substituting substances of concern, including substances of very high concern, endocrine disruptors, very persistent chemicals, neurotoxins and immuno-toxicants, as well as tackling the combination effects of chemicals, nano-forms of substances and exposure to hazardous chemicals from products, assessing their impacts on health and the environment, including climate, and biodiversity, whilst promoting safe and sustainable by-design chemicals and materials and stepping up and coordinating efforts to promote the development and validation of alternatives to animal testing. The implementation of this Regulation should support the goals

Amendment 4
Proposal for a regulation
Recital 16

Text proposed by the Commission

(16) Chemicals that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR substances), chemicals that affect the endocrine system, the respiratory system or that are toxic to a specific organ are particularly harmful for children and should be specifically addressed in toys. Given the essential role of the endocrine system during human development, early exposure during critical periods, such as early childhood, to endocrine disruptors can lead to adverse effects even at very low doses and affect health at a later stage of life. Respiratory sensitisers can lead to an increase of childhood asthma and neurotoxic substances are particularly harmful to the developing brain of children, which is inherently more vulnerable to toxic injury than the adult brain. Children should also be adequately protected from allergenic substances and certain metals. The requirements for chemical substances set out in Directive 2009/48/EC need to be updated and strengthened. Toys are to comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council. In order to provide further protection of children, who are a vulnerable group of consumers, and other persons, that legal framework should be supplemented by generic prohibitions in toys covering certain hazardous chemicals, as classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council³³. Those generic prohibitions should apply to CMR substances, endocrine disruptors, respiratory sensitisers and substances

Amendment

(16) Chemicals that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR substances), chemicals that affect the endocrine system, the respiratory system or that are toxic to a specific organ ***or are mobile, persistent, bioaccumulative and toxic*** are particularly harmful for children ***and the environment*** and should be specifically addressed in toys. Given the essential role of the endocrine system during human development, early exposure during critical periods, such as early childhood, to endocrine disruptors can lead to adverse effects even at very low doses and affect health at a later stage of life. Respiratory sensitisers can lead to an increase of childhood asthma and neurotoxic substances are particularly harmful to the developing brain of children, which is inherently more vulnerable to toxic injury than the adult brain. ***Persistence and bioaccumulation lead to continuous exposure and therefore enhance the risk of adverse effects. Some toxic chemicals are also mobile in the environment.*** Children should also be adequately protected from allergenic substances and certain metals. The requirements for chemical substances set out in Directive 2009/48/EC need to be updated and strengthened. Toys are to comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council³³. In order to provide further protection of children, who are a vulnerable group of consumers, and other persons, that legal framework should be supplemented by generic prohibitions in toys covering

targeting a specific organ, **as soon as those substances** are classified as hazardous under Regulation (EC) No 1272/2008³⁴. In order to ensure toy safety, prohibited substances should be acceptable at trace levels but only if their presence at such levels is technologically unavoidable with good manufacturing practices and if the toy is safe.

certain hazardous chemicals, as classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council³⁴. Those generic prohibitions should apply to CMR substances, endocrine disruptors **for human health and the environment**, respiratory sensitisers and substances targeting a specific organ **or that are mobile, persistent, bioaccumulative and toxic that meet the criteria for classification or that** are classified as hazardous under Regulation (EC) No 1272/2008. In order to ensure toy safety, prohibited substances should be acceptable at trace levels but only if their presence at such levels is technologically unavoidable with good manufacturing practices and if the toy is safe.

³³ **Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).**

³³ **Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).**

³⁴ **Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396,**

³⁴ **Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).**

30.12.2006, p. 1).

Amendment 5
Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) ***In order to provide for flexibility*** where the safety of children is not compromised and ***where it is necessary for making certain toys available on the market, it should*** be possible to ***derogate*** from the generic prohibitions of ***chemical*** substances in toys. ***Derogations to*** generic prohibitions permitting the use of prohibited substances should be of general application and should only be possible where the use of the relevant substance is considered safe for children, where there are no ***commercially*** viable alternatives for the substance and where the use of the substance is not prohibited in consumer articles under Regulation (EC) No 1907/2006. The assessment of ***the safety of the*** substance ***in toys*** should be carried out by the relevant scientific committees in the European Chemicals Agency (ECHA) in order to ensure consistency and efficient use of resources in the assessment of ***chemical*** substances in the Union.

Amendment 6
Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) Existing limit values for certain chemical substances and their corresponding test methods have proven to

Amendment

(17) Where the safety of children is not compromised and ***there are no suitable alternative substances or mixtures*** available ***it may*** be possible to ***exempt*** from the generic prohibitions of substances ***and mixtures*** in toys. ***Exemptions from*** generic prohibitions permitting the use of prohibited substances ***and mixtures*** should be ***time-limited***, of general application and should only be possible where the use of the relevant substance ***or mixtures*** is considered safe for children, where ***elimination or substitution of such prohibited substances via design changes or other materials or components is not technically possible***, where there are no ***technically*** viable alternatives for the substance ***or mixture***, ***where a substitution plan upon ECHA request has been submitted*** and where the use of the substance ***or mixture*** is not prohibited in consumer articles under Regulation (EC) No 1907/2006. The assessment of ***this*** substance should be carried out by the relevant scientific committees in the European Chemicals Agency (ECHA) in order to ensure consistency and efficient use of resources in the assessment of substances ***and mixtures*** in the Union.

Amendment

(21) Existing limit values for certain chemical substances and their corresponding test methods have proven to

be appropriate for the protection of children as regards those substances and should be maintained. In order to adapt to new scientific knowledge, the Commission should be empowered to revise those limit values where necessary. Limit values for arsenic, **cadmium, chromium VI, lead, mercury** and organic tin, which are particularly toxic and which should therefore not be intentionally used in toys, should be set out at half the values that are considered safe by the relevant scientific body, in order to ensure that only traces that are compatible with good manufacturing practice are present in the toy.

be appropriate for the protection of children as regards those substances and should be maintained. In order to adapt to new scientific knowledge, the Commission should be empowered to revise those limit values where necessary ***in line with the precautionary principle and the One Health approach***. Limit values for arsenic and organic tin, which are particularly toxic and which should therefore not be intentionally used in toys, should be set out at half the values that are considered safe by the relevant scientific body in order to ensure that only traces that are compatible with good manufacturing practice are present in the toy. ***Use of chromium VI, cadmium, mercury and lead, highly toxic elements, should not be allowed in toys, unless their presence is technically unavoidable under good manufacturing practice and their residues do not exceed the limit of detection in the homogenous material.***

Amendment 7
Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission

Amendment

(21 a) Lead is a naturally occurring toxic metal that may cause lung, brain, stomach, and kidney cancer in humans. It can enter drinking water when plumbing materials that contain lead corrode, especially where the water has high acidity or low mineral content that corrodes pipes and fixtures. The Directive (EU) 2020/2184^{1a} sets out provisions as regards lead content in water intended for human consumption. It can therefore not be excluded that toys produced with the use of water might contain minimal residues of lead due to the water used in the manufacturing process. Such residues should be considered as technically unavoidable under good manufacturing practice where it is not possible to

eliminate them via available filtering or absorption methods.

^{1a} Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), OJ L 435, 23.12.2020, p. 1–62

Amendment 8
Proposal for a regulation
Recital 22

Text proposed by the Commission

(22) Directive 2009/48/EC includes limit values for certain substances in toys intended for children under 36 months or intended to be put in the mouth. 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. These limit values should therefore apply to all toys. Since the adoption of the limit values for bisphenol A in Directive 2009/48/EC, new scientific data has emerged. The European Food Safety Authority (EFSA) re-evaluated the risks to public health from dietary exposure to bisphenol A in April 2023 concluding that exposure to bisphenol A is a health concern for consumers across all age groups. EFSA has established a new tolerable daily intake of bisphenol A which is significantly lower than the previous one. In view of *this scientific evidence, bisphenol A should fall under the generic prohibition for CMR substances in toys.*

Amendment

(22) Directive 2009/48/EC includes limit values for certain substances in toys intended for children under 36 months or intended to be put in the mouth. *In a family with more than one child, children under 36 months are likely to be attracted by the toys of their siblings that are older than 36 months, making it in practice impossible to completely shield children below 36 months from the toys of their elder siblings.* 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. These limit values should therefore apply to all toys. Since the adoption of the limit values for bisphenol A in Directive 2009/48/EC, new scientific data has emerged. The European Food Safety Authority (EFSA) re-evaluated the risks to public health from dietary exposure to bisphenol A in April 2023 concluding that exposure to bisphenol A is a health concern for consumers across all age groups. EFSA has established a new tolerable daily intake of bisphenol A which is significantly lower than the previous one. In view of *the structural similarities between different bisphenols leading to comparable risks for children, and to avoid regrettable substitution, toys should not contain any*

bisphenols.

Amendment 9
Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission

Amendment

(22 a) Per- and polyfluorinated alkyl substances (PFASs) are a large family of more 10,000 man-made chemicals. Since their emergence in the late 1940s, PFASs have been used in an increasingly wide range of consumer products. Exposure to the most studied PFASs has been associated with a range of adverse health effects, including thyroid disease, liver damage, obesity, diabetes and reduced response to routine vaccinations, as well as increased risk of breast, kidney and testicular cancer. Toys should not contain any per- and polyfluorinated alkyl substances (PFASs).

Amendment 10
Proposal for a regulation
Recital 23

Text proposed by the Commission

Amendment

(23) To ensure adequate protection from specific chemical substances in case of new scientific knowledge, the Commission should be empowered to adopt delegated acts establishing specific limit values for any chemical substance used in toys. If justified in cases of toys involving a higher degree of exposure, those delegated acts should set out specific limit values for toys ***intended for use by children under 36 months and*** in ***other*** toys intended to be put in the mouth, taking into account the requirements set out in Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food or articles from which risks may arise due to oral contact through their use

(23) To ensure adequate protection from specific chemical substances ***and mixtures*** in case of new scientific knowledge ***or technological developments***, the Commission should be empowered to adopt delegated acts establishing specific limit values for any chemical substance used in toys ***in line with the precautionary principle and the One Health approach. The Commission should act as swiftly as possible, when new knowledge of the risks of chemicals or new technological developments emerge.*** If justified in cases of toys involving a higher degree of exposure, those delegated acts should set out specific limit values for toys ***in general and especially*** in toys intended to be put in

as a food contact material. Fragrances in toys entail special risks for human health. Therefore, specific rules should be set out for the use of fragrances in toys and for the labelling of fragrances. The Commission should be empowered to adopt delegated acts to amend those rules to allow for adaptations to technical and scientific progress.

the mouth, taking into account the requirements set out in Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food or articles from which risks may arise due to oral contact through their use as a food contact material. ***In case the risk is not toy-specific, but related to any consumer product a child comes into contact with, restrictions through REACH Annex XVII should be prioritised in order to ensure better general protection of children and ensure a level-playing field.*** Fragrances in toys entail special risks for human health. Therefore, specific rules should be set out for the use of fragrances in toys and for the labelling of fragrances. The Commission should be empowered to adopt delegated acts to amend those rules to allow for adaptations to technical and scientific progress.

Amendment 11
Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission

Amendment

(23 a) In a clean circular economy, it is essential to boost the production and uptake of secondary raw materials and ensure that both primary and secondary materials and products are always safe. This requires a combination of actions upstream, to ensure that products are safe and sustainable by design, and downstream, to increase safety and trust in recycled materials and products. To move towards toxic-free material cycles and clean recycling, it is necessary to ensure that substances of concern in products and recycled materials are eliminated or minimised. In order to safeguard a level playing field, the same approach for hazardous substances should apply to virgin and recycled materials. Undeniably, producing cleaner materials without hazardous chemicals

makes recycling easier, preserves the environment and is key to making a circular economy work, while companies innovating and investing in safer alternatives also contribute to the competitiveness of European industry on the global market. Therefore, it is key to ensure that any toy manufactured from recycled material meets the same requirements as toys produced from virgin materials. Transparency on the chemical contents of all materials should be provided. At the same time, in accordance with the waste hierarchy, prevention takes priority over recycling and recycling should not, accordingly, justify the perpetuation of the use of hazardous legacy substances.

Amendment 12
Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) Where the hazards that a toy may present cannot be completely addressed by design, the residual risk should be addressed by product-related information directed at the supervisors of the children in the form of warnings, taking into account the capacity of those supervisors to take the necessary precautions.

Amendment

(24) Where the hazards that a toy may present cannot be completely addressed by design, the residual risk should be addressed by product-related information directed at the supervisors of the children in the form of warnings, taking into account the capacity of those supervisors to take the necessary precautions. ***In order to make sure the information is efficiently displayed, the manufacturer may add a QR-code with a link to the instruction in a digital format, but should always mark the health warnings on the physical label or packaging.***

Amendment 13
Proposal for a regulation
Recital 25

Text proposed by the Commission

(25) To prevent misuse of warnings to

Amendment

(25) To prevent misuse of warnings to

circumvent the applicable safety requirements, the warnings provided for certain categories of toy should not be allowed if they conflict with the intended use of the toy. To ensure that supervisors are aware of any risks associated with the toy, it is necessary to ensure that the warnings are legible and visible.

circumvent the applicable safety requirements, the warnings provided for certain categories of toy should not be allowed if they conflict with the intended use of the toy. To ensure that supervisors are aware of any risks associated with the toy, it is necessary to ensure that the warnings are legible and visible. ***Where the purchase is made through online or distance sales, warnings and the relevant pictograms for each category set out in Annex III should be marked on the first page next to the photo or the product in an immediately and clearly visible, easily legible and understandable and accurate manner.***

Amendment 14
Proposal for a regulation
Recital 54

Text proposed by the Commission

(54) Children are daily exposed to a wide range of different chemicals originating from various sources. Significant progress has been made to close some knowledge gaps on the impact of the combination effect of those chemicals. However, the safety of chemicals is usually assessed through the evaluation of single substances and in some cases of mixtures intentionally added for particular uses. In order to provide the highest protection for children, the most harmful substances should be generally banned in toys to ensure that there is no exposure to them in toys. The specific limit values for chemicals in toys should account for combined exposure from different sources to the same chemical substance. In addition, manufacturers should be required 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, as part of the assessment of chemical hazards, to consider known cumulative or synergistic effects of the

Amendment

(54) Children are daily exposed to a wide range of different chemicals originating from various sources ***that have negative effects as individual substances or mixtures, but also through combined exposure.*** Significant progress has been made to close some knowledge gaps on the impact of the combination effect of those chemicals. However, the safety of chemicals is ***currently*** usually assessed through the evaluation of single substances and in some cases of mixtures intentionally added for particular uses. ***Further efforts are needed to better understand the impact of the combination effect of chemicals.*** In order to provide the highest protection for children ***and the environment in general,*** the most harmful substances should be generally banned in toys to ensure that there is no exposure to them in toys. The specific limit values for chemicals in toys should account for combined exposure from different sources to the same chemical substance. In addition, manufacturers should be required

chemicals present in the toy, to ensure that risks from simultaneous exposure to multiple chemicals are taken into account. Furthermore, toys are to comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council; this Regulation does not modify the obligations for the assessment of the safety of the chemical substances or mixtures themselves that may be applicable in accordance with that Regulation.

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, as part of the assessment of chemical hazards, to consider known cumulative or synergistic effects of the chemicals present in the toy, to ensure that risks from simultaneous exposure to multiple chemicals are taken into account. Furthermore, toys are to comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council; this Regulation does not modify the obligations for the assessment of the safety of the chemical substances or mixtures themselves that may be applicable in accordance with that Regulation.

Amendment 15
Proposal for a regulation
Recital 54 a (new)

Text proposed by the Commission

Amendment

(54 a) In order to provide adequate expertise, support, and thorough scientific evaluations, an appropriate and stable funding for ECHA should be ensured.

Amendment 16
Proposal for a regulation
Recital 68

Text proposed by the Commission

Amendment

(68) In order to take into account technical and scientific progress or new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending this Regulation by adapting the specific warnings to be affixed on toys, adopting specific requirements concerning chemical substances in toys and granting

(68) In order to take into account technical and scientific progress or new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending this Regulation by adapting the specific warnings to be affixed on toys, adopting specific requirements concerning chemical substances in toys and granting ***exemptions***

derogations to include specific uses allowed in toys of substances subject to generic prohibitions.

to include specific uses allowed in toys of substances subject to generic prohibitions ***in line with the precautionary principle and the One Health approach.***

Amendment 17
Proposal for a regulation
Article 6 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The manufacturer shall mark warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them.

Amendment

The manufacturer shall mark warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them. ***The manufacturer may add a QR-code with a link to the instructions in a digital format, but shall always mark the health warnings on the physical label or packaging.***

Amendment 18
Proposal for a regulation
Article 6 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Warnings shall be clearly visible to the consumer before the purchase, including in cases where the purchase is made through distance sales. Warnings shall be of sufficient size to ensure their visibility.

Amendment

Warnings shall be clearly visible to the consumer before the purchase, including in cases where the purchase is made through distance sales. Warnings shall be of sufficient size to ensure their visibility. ***Where the purchase is made through online or distance sales, warnings and the relevant pictograms for each category set out in Annex III shall be marked on the first page next to the photo or the product in an immediately and clearly visible, easily legible and understandable and accurate manner.***

Amendment 19
Proposal for a regulation
Article 46 – paragraph 6

Text proposed by the Commission

6. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Part C of the Appendix to Annex II in order to permit a certain use in toys of a specific substance or mixture that is prohibited under Part III, point 4, of Annex II, or to limit a certain use that has been permitted.

Amendment

6. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Part C of the Appendix to Annex II in order to permit ***for a specified period of time*** a certain use in toys of a specific substance or mixture that is prohibited under Part III, point 4, of Annex II, or to limit a certain use that has been permitted. ***While assessing the requests for exemption and its duration, the Commission shall take into account the availability of alternatives and any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant. Six months after the entry into force of this Regulation, the Commission shall adopt delegated acts in accordance with Article 47 to amend Part C of the Appendix to Annex II in regard to nickel, in order to set out the validity period for the exemption from the generic prohibition under Part III, point 4, of Annex II, for that substance. The Commission shall justify any exemption granted and make this publicly available in an easily accessible and user-friendly manner.***

Amendment 20
Proposal for a regulation
Article 46 – paragraph 7 – introductory part

Text proposed by the Commission

7. The use in toys of a substance or mixture prohibited under Part III, point 4, of Annex II ***may only*** be permitted ***when*** all of the following conditions are met:

Amendment

7. The use in toys of a substance or mixture prohibited under Part III, point 4, ***points (a), (b), (db), (dc), (dd) and (de)*** of Annex II ***shall not*** be permitted ***unless*** all of the following conditions are met:

Amendment 21
Proposal for a regulation
Article 46 – paragraph 7 – point a

Text proposed by the Commission

(a) it has been found to be safe by the European Chemicals Agency (ECHA), ***in particular in view of exposure, including the overall exposure from other sources, and*** taking particular account of the vulnerability of children;

Amendment

(a) it has been found to be safe by the European Chemicals Agency (ECHA) ***due to the absence of the possibility of exposure under reasonably foreseeable conditions of use in accordance with Article 5(2), first subparagraph,*** taking particular account of the vulnerability of children;

Amendment 22
Proposal for a regulation
Article 46 – paragraph 7 – point a (new)

Text proposed by the Commission

Amendment

(a a) elimination or substitution via design changes or the use of other materials or components without such substances or mixtures is not technically possible;

Amendment 23
Proposal for a regulation
Article 46 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. The use in toys of a substance or mixture prohibited under Part III, point 4, points (c), (d) and (da) of Annex II shall not be permitted unless all of the following conditions are met:

(a) it has been found to be safe by ECHA, in particular in view of exposure, including the overall exposure from all potential sources as well as any known additional hazards from combined exposure to the different substances and mixtures present in the toy, and taking particular account of the vulnerability of

children;

(b) elimination or substitution via design changes or the use of other materials or components without such substances or mixtures is not technically possible;

(c) there are no suitable alternative substances or mixtures available, as established by ECHA based on an analysis of alternatives;

(d) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

Amendment 24
Proposal for a regulation
Article 46 – paragraph 7 b (new)

Text proposed by the Commission

Amendment

7 b. Exemptions from the general prohibition in accordance with paragraphs 7 and 7a shall be time-limited. The validity period for each exemption shall be subject to a review and may be renewed, on a case-by-case basis for each substance or mixture.

Amendment 25
Proposal for a regulation
Article 46 – paragraph 9

Text proposed by the Commission

Amendment

9. For the purposes of paragraphs 6 **and 7**, the Commission shall systematically and regularly evaluate the occurrence of hazardous **chemical** substances or mixtures in toys. In those evaluations, the Commission shall take into account reports of market surveillance bodies and scientific evidence presented by Member States and stakeholders.

9. For the purposes of paragraphs 6, 7, **7a and 8**, the Commission shall systematically and regularly evaluate the occurrence of hazardous substances or mixtures in toys. In those evaluations, the Commission shall take into account reports of market surveillance bodies and scientific evidence presented by Member States and stakeholders.

Amendment 26

Proposal for a regulation
Article 46 – paragraph 9 a (new)

Text proposed by the Commission

Amendment

9 a. The Commission shall assess whether any substance or mixture prohibited under this Regulation requires further sectoral or horizontal restriction.

Amendment 27
Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission

Amendment

1. Requests for an assessment of a substance or mixture prohibited under Part III, point 4, of Annex II for the purposes of Article 46(6) shall be submitted to ECHA using the format and submission tools referred to in paragraph 3 of this Article.

1. Requests for an assessment of a substance or mixture prohibited under Part III, point 4, of Annex II for the purposes of Article 46(6) shall be submitted to ECHA using the format and submission tools referred to in paragraph 3 of this Article. ***The requests shall be made publicly available in an easily accessible and user-friendly manner.***

Amendment 28
Proposal for a regulation
Article 48 – paragraph 2

Text proposed by the Commission

Amendment

2. Any person submitting a request for assessment under paragraph 1 may request that certain information is not to be made publicly available. The request for confidentiality shall be accompanied by a justification as to why the disclosure of the information could be harmful to the commercial interests of the person submitting the request for assessment or of any other party concerned.

2. ***Without prejudice to the following subparagraph, any person submitting a request for assessment under paragraph 1 may request that certain confidential business information is not to be made publicly available in accordance with the relevant Union law.*** The request for confidentiality shall be accompanied by a justification as to why the disclosure of the information could be harmful to the commercial interests of the person submitting the request for assessment or of any other party concerned. ***The following information held by ECHA shall be made publicly available, free of charge, and in a***

user-friendly format:

(a) the name of the legal person making the request;

(b) the name of a substance or mixture for which there is a request for an exemption;

(c) type of toy or toy component;

(d) the substitution plan, where relevant;

Amendment 29
Proposal for a regulation
Article 48 – paragraph 3

Text proposed by the Commission

3. ECHA shall draw up and make publicly available a format and tools for the submission of requests for assessment referred to in paragraph 1 as well as technical and scientific guidance on how to submit such requests.

Amendment

3. ***Before ... [OP please insert the date = the first day of the month following 1 month after the date of entry into force of this Regulation],*** ECHA shall draw up and make publicly available a format and tools for the submission of requests for assessment referred to in paragraph 1 as well as technical and scientific guidance on how to submit such requests.

Amendment 30
Proposal for a regulation
Article 49 – paragraph 1

Text proposed by the Commission

1. For the purposes of Article 46(6), ECHA shall provide opinions to the Commission on the use in toys of substances or mixtures that are prohibited under Part III, point 4 of Annex II, where a request for an assessment is submitted to it in accordance with Article 48(1). ECHA shall assess in its opinions whether the criteria set out in Article **46(6), second subparagraph, points (a) and (b)**, are met for a specific use.

Amendment

1. For the purposes of Article 46(6), ECHA shall provide opinions to the Commission on the use in toys of substances or mixtures that are prohibited under Part III, point 4 of Annex II, where a request for an assessment is submitted to it in accordance with Article 48(1). ECHA shall assess in its opinions whether the criteria set out in Article **46(7) and Article 46(7a)**, are met for a specific use.

Amendment 31
Proposal for a regulation

Article 49 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. The European Commission shall issue guidelines as to how this assessment shall be conducted, in particular as regards the availability of alternative substances or mixtures and how to address the combined exposure effects under this Regulation.

Amendment 32

Proposal for a regulation

Article 49 – paragraph 2

Text proposed by the Commission

Amendment

2. ECHA may request the person submitting the request for assessment or any third party to submit additional information within a specified period. ECHA shall take into account any information submitted by third parties.

2. ECHA may request the person submitting the request for assessment or any third party to submit additional information within a specified period. ECHA shall take into account any information submitted by third parties. ***When ECHA considers it necessary for the determination of an adequate validity period for the exemption, it may also request the person submitting the request for assessment to submit a substitution plan.***

Amendment 33

Proposal for a regulation

Article 49 – paragraph 3

Text proposed by the Commission

Amendment

3. The opinions referred to in paragraph 1 shall be sent to the Commission within a period of 12 months from the receipt of the request for an assessment.

3. The opinions referred to in paragraph 1 shall be sent to the Commission ***and made publicly available in an easily accessible and user-friendly manner*** within a period of 12 months from the receipt of the request for an assessment.

Amendment 34

Proposal for a regulation

Article 49 – paragraph 6

Text proposed by the Commission

6. The Commission shall request an opinion from ECHA on the use in toys of substances or mixtures listed in Part C of the Appendix to Annex II as soon as new scientific information that may affect the permitted use of a specific substance or mixture in toys becomes known to the Commission.

Amendment

6. The Commission shall request an opinion from ECHA on the use in toys of substances or mixtures listed in Part C of the Appendix to Annex II as soon as new scientific information **or technical developments** that may affect the permitted use of a specific substance or mixture in toys becomes known to the Commission.

Amendment 35

Proposal for a regulation

Article 49 – paragraph 7

Text proposed by the Commission

7. For the purposes of Article 46(7), the Commission may request an opinion from ECHA on the safety of a specific substance or mixture in toys, **which shall take into consideration the overall exposure to the substance or mixture from other sources and the vulnerability of children.**

Amendment

7. For the purposes of Article 46(7), **(7a) and (8)**, the Commission may request an opinion from ECHA on the safety of a specific substance or mixture in toys

Amendment 36

Proposal for a regulation

Article 49 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. ECHA shall be provided with the adequate resources to support its work.

Amendment 37

Proposal for a regulation

Annex II – Part II – point 2 – point a – point 5

Text proposed by the Commission

Amendment

(5) hazard classes 3.9 **and 3.10**;

(5) hazard classes 3.9, **3.10 and 3.11**;

Amendment 38
Proposal for a regulation
Annex II – Part II – point 2 – point a – point 6

Text proposed by the Commission

(6) hazard class 4.1;

Amendment

(6) hazard class 4.1, **4.2, 4.3 and 4.4**;

Amendment 39
Proposal for a regulation
Annex II – Part III – point 2

Text proposed by the Commission

2. Toys that are themselves substances or mixtures shall comply also with Regulation (EC) No 1272/2008 .

Amendment

2. Toys that are themselves substances or mixtures shall comply also with Regulation (EC) No 1272/2008 **as well as with the labelling requirements laid down in Regulation (EC) No 1223/2009.**

Amendment 40
Proposal for a regulation
Annex II – Part III – point 4 – introductory part

Text proposed by the Commission

4. The use in toys, components of toys or micro-structurally distinct parts of toys, of substances or mixtures classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the following categories is prohibited:

Amendment

4. The use in toys, components of toys or micro-structurally distinct parts of toys, of substances or mixtures **meeting the criteria laid down in Article 57 and being identified in accordance with Article 59(1) of Regulation (EC) No 1907/2006,** classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 **or meeting the criteria for classification** in any of the following categories is prohibited:

Amendment 41
Proposal for a regulation
Annex II – Part III – point 4 – point b

Text proposed by the Commission

(b) endocrine disruption category 1 or 2;

Amendment

(b) endocrine disruption category 1 or 2, **for human health and the environment,**

Amendment 42
Proposal for a regulation
Annex II – Part III – point 4 – point d a (new)

Text proposed by the Commission

Amendment

(d a) skin sensitisation category 1;

Amendment 43
Proposal for a regulation
Annex II – Part III – point 4 – point d b (new)

Text proposed by the Commission

Amendment

(d b) persistent, bioaccumulative and toxic;

Amendment 44
Proposal for a regulation
Annex II – Part III – point 4 – point d c (new)

Text proposed by the Commission

Amendment

(d c) very persistent, very bioaccumulative;

Amendment 45
Proposal for a regulation
Annex II – Part III – point 4 – point d d (new)

Text proposed by the Commission

Amendment

(d d) persistent, mobile and toxic;

Amendment 46
Proposal for a regulation
Annex II – Part III – point 4 – point d e (new)

Text proposed by the Commission

Amendment

(d e) very persistent, very mobile.

Amendment 47
Proposal for a regulation
Annex II – Part III – point 4 a (new)

Text proposed by the Commission

Amendment

(4 a) The use in toys, components of toys or micro-structurally distinct parts of toys, of per- and polyfluoroalkyl substances (PFAS) and of bisphenols is prohibited. Toys intended for use by children under 36 months or other toys intended to be placed in the mouth shall not contain any fragrances.

Amendment 48
Proposal for a regulation
Annex II – Part III – point 8

Text proposed by the Commission

Amendment

8. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Regulation (EC) No 1223/2009 of the European Parliament and of the Council⁴³.

8. Cosmetic toys, such as play cosmetics for dolls **or children, slime, finger-paint or modelling clay** shall comply with the compositional and labelling requirements laid down in Regulation (EC) No 1223/2009 of the European Parliament and of the Council⁴³.

⁴³ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

⁴³ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

Amendment 49
Proposal for a regulation
Annex II – Part A – point 1 a (new)

Text proposed by the Commission

Amendment

1 a. Toys shall not contain chromium VI, cadmium, mercury and lead, unless their presence is technically unavoidable under good manufacturing practice and does not exceed the limit of detection in the homogeneous material.

Amendment 50
Proposal for a regulation
Annex II – Part A – point 2

Text proposed by the Commission

2. Nitrosamines and ***nitrosable*** substances are prohibited in ***toys intended for use by children under 36 months or in other toys intended to be placed in the mouth where*** the migration of those substances ***is equal to or higher than*** 0,01 mg/kg for nitrosamines and 0,1 mg/kg for ***nitrosable*** substances.

Amendment

2. Nitrosamines and ***nitrosatable*** substances are prohibited in ***all toys***. The migration of those substances ***from toys, components of toys or micro-structurally distinct parts of toys, shall not exceed*** 0,01 mg/kg for nitrosamines and 0,1 mg/kg for ***nitrosatable*** substances.

Amendment 51
Proposal for a regulation
Annex II – Part A – point 4 – introductory part

Text proposed by the Commission

4. Toys shall not contain the following fragrance allergens unless their presence in the toy is technically unavoidable under good manufacturing practice and does not exceed ***100 mg/kg***:

Amendment

4. Toys shall not contain the following fragrance allergens unless their presence in the toy is technically unavoidable under good manufacturing practice and does not exceed ***the respective limit of detection***:

Amendment 52
Proposal for a regulation
Annex II – Part B – point 1 – introductory part

Text proposed by the Commission

1. The names of the following fragrance allergens shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, as well as in the product passport, if those allergens are added to a toy, where they are present in the toy or any component thereof at concentrations exceeding ***100 mg/kg***:

Amendment

1. The names of the following fragrance allergens shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, as well as in the product passport, if those allergens are added to a toy, where they are present in the toy or any component thereof at concentrations exceeding ***10 mg/kg***

Amendment 53
Proposal for a regulation

Annex II – Part B – point 2 – paragraph 1 – point a

Text proposed by the Commission

(a) **the** fragrances are clearly labelled on the packaging of the toy, and the packaging contains the warning referred to in point 11 of Annex III;

Amendment

(a) **those** fragrances are clearly labelled on the packaging of the toy, and the packaging contains the warning referred to in point 11 of Annex III;

Amendment 54 Proposal for a regulation

Annex II –Part A – table

Text proposed by the Commission

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped off toy material
Aluminium	2250	560	28130
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18750
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,053
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	2,0	0,5	23
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

Amendment

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped off toy material
Aluminium	2250	560	28130
Antimony	45	11,3	560

Arsenic	3,8	0,9	47
Barium	1 500	375	18750
Boron	1 200	300	15 000
<i>Deleted</i>			
Chromium (III)	37,5	9,4	460
<i>Deleted</i>			
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
<i>Deleted</i>			
Manganese	1 200	300	15 000
<i>Deleted</i>			
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

Amendment 55

Proposal for a regulation

Annex II – Part C – introductory part

Text proposed by the Commission

Amendment

The names and the classification of the following substances and mixtures shall be listed on the toy, on an affixed label or on the packaging, as well as in the product passport. In addition, this information may be included in the accompanying leaflet.

Amendment 56

Proposal for a regulation

Annex II –Part C – table

Text proposed by the Commission

Substance or mixture	Classification	Permitted use
Nickel	Carc 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric

		current.
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Amendment

Substance or mixture	Classification	Permitted use	<i>Dates of applicability</i>
Nickel	Carc 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric current.	

**ANNEX: ENTITIES OR PERSONS
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

The rapporteur has received input from the following entities or persons in the preparation of the opinion:

Entity and/or person
Toy Industries of Europe (TIE)
The Lego Group
European Balloon and Party Council
Globetrade
SES Creative
Amazon
The International Chemical Secretariat (ChemSec)
European Chemicals Agency
European Commission
Federation of European Publishers
EuroCommerce
APOFAB – Associação Portuguesa de Fabricantes de Brinquedos
Mattel Portugal
Creative Toys Portugal
Concentra
SRS Legal
European Writing Instrument Manufacturer's Association (EWIMA)
Industrieverband Schreiben, Zeichnen, Kreatives Gestalten e.V. (ISZ e.V.).
European Committee for Electrotechnical Standardization (CENELEC)
European Committee for Standardization (CEN)
CHEM Trust
The European Consumer Organisation (BEUC)
Client Earth

The list above is drawn up under the exclusive responsibility of the rapporteur.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Safety of toys and repealing Directive 2009/48/EC
References	COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)
Committee responsible Date announced in plenary	IMCO 19.10.2023
Opinion by Date announced in plenary	ENVI 19.10.2023
Associated committees - date announced in plenary	19.10.2023
Rapporteur for the opinion Date appointed	Sara Cerdas 24.10.2023
Discussed in committee	6.11.2023
Date adopted	24.1.2024
Result of final vote	+: 72 -: 0 0: 5
Members present for the final vote	Catherine Amalric, Maria Arena, Hildegard Bentele, Michael Bloss, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Mohammed Chahim, Nathalie Colin-Oesterlé, Esther de Lange, Christian Doleschal, Bas Eickhout, Helène Fritzon, Malte Gallée, Catherine Griset, Martin Häusling, Anja Hazekamp, Martin Hojsík, Jan Huitema, Karin Karlsbro, Ska Keller, Petros Kokkalis, Peter Liese, Javi López, César Luena, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Lydie Massard, Liudas Mažylis, Marina Measure, Silvia Modig, Dolors Montserrat, Alessandra Moretti, Ville Niinistö, Ljudmila Novak, Nikos Papandreou, Francesca Peppucci, Stanislav Polčák, Jessica Polfjärd, Erik Poulsen, Nicola Procaccini, Frédérique Ries, Manuela Ripa, María Soraya Rodríguez Ramos, Maria Veronica Rossi, Silvia Sardone, Günther Sidl, Ivan Vilibor Sinčić, Maria Spyradi, Edina Tóth, Achille Variati, Petar Vitanov, Alexandr Vondra, Mick Wallace, Emma Wiesner, Michal Wiezik
Substitutes present for the final vote	Asger Christensen, Christophe Clergeau, Margarita de la Pisa Carrión, Billy Kelleher, Sara Matthieu, Dace Melbārde, Idoia Villanueva Ruiz
Substitutes under Rule 209(7) present for the final vote	Mazaly Aguilar, Katarina Barley, Daniel Buda, Ana Collado Jiménez, Marie Dauchy, Matthias Ecke, Paola Ghidoni, Peter Jahr, Thierry Mariani, Nora Mebarek, Sara Skyttedal, Michaela Šojdrová, Thomas Waitz, Stefania Zambelli

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

72	+
ECR	Mazaly Aguilar, Margarita de la Pisa Carrión, Alexandr Vondra
ID	Marie Dauchy, Catherine Griset, Thierry Mariani
NI	Edina Tóth
PPE	Hildegard Bentele, Daniel Buda, Nathalie Colin-Oesterlé, Ana Collado Jiménez, Christian Doleschal, Peter Jahr, Esther de Lange, Peter Liese, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Liudas Mažylis, Dace Melbārde, Dolors Montserrat, Ljudmila Novak, Francesca Peppucci, Stanislav Polčák, Jessica Polfjård, Sara Skytvedal, Michaela Šojdrová, Maria Spyraki, Stefania Zambelli
Renew	Catherine Amalric, Pascal Canfin, Asger Christensen, Martin Hojsík, Jan Huitema, Karin Karlsbro, Billy Kelleher, Erik Poulsen, Frédérique Ries, María Soraya Rodríguez Ramos, Emma Wiesner, Michal Wiezik
S&D	Maria Arena, Katarina Barley, Delara Burkhardt, Sara Cerdas, Mohammed Chahim, Christophe Clergeau, Matthias Ecke, Heléne Fritzon, Javi López, César Luena, Nora Mebarek, Alessandra Moretti, Nikos Papandreou, Günther Sidl, Achille Variati, Petar Vitanov
The Left	Anja Hazekamp, Petros Kokkalis, Marina Measure, Silvia Modig, Idoia Villanueva Ruiz, Mick Wallace
Verts/ALE	Michael Bloss, Bas Eickhout, Malte Gallée, Martin Häusling, Ska Keller, Lydie Massard, Sara Matthieu, Ville Niinistö, Manuela Ripa, Thomas Waitz

0	-

5	0
ECR	Nicola Procaccini
ID	Paola Ghidoni, Maria Veronica Rossi, Silvia Sardone
NI	Ivan Vilibor Sinčić

Key to symbols:

+ : in favour

- : against

0 : abstention