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*Plenary sitting*

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**A9-0044/2024**

20.2.2024

**\*\*\*I**

## **REPORT**

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

Committee on the Internal Market and Consumer Protection

Rapporteur: Marion Walsmann

Rapporteur for the opinion of associated committee pursuant to Rule 57 of the  
Rules of Procedure:

Sara Cerdas, Committee on the Environment, Public Health and Food Safety

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

#### **Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

#### **Amendments by Parliament in the form of a consolidated text**

New text is highlighted in ***bold italics***. Deletions are indicated using either the ***■*** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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## **DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION**

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

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0462),
  - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0317/2023),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the opinion of the Committee on the Environment, Public Health and Food Safety,
  - having regard to the report of the Committee on the Internal Market and Consumer Protection (A9-0044/2024),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

## 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, ***including children with disabilities***, should be adequately protected from possible risks stemming from toys, ***including*** 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

### Proposal for a regulation

#### Recital 9

##### *Text proposed by the Commission*

(9) This Regulation should lay down essential requirements for toys to ensure a high level of protection of health and safety of children when playing with toys as well as the free movement of toys in the Union. This Regulation should be ***applied*** taking due account of the precautionary principle.

##### *Amendment*

(9) This Regulation should lay down essential requirements for toys to ensure a high level of protection of health and safety of children when playing with toys as well as the free movement of toys in the Union. This Regulation should be ***implemented*** taking due account of the precautionary principle.

## Amendment 3

### Proposal for a regulation

#### Recital 14

##### *Text proposed by the Commission*

(14) Relying on digital technologies has

##### *Amendment*

(14) Relying on digital technologies has

led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud in accordance with Directive 2014/53/EU of the European Parliament and of the Council<sup>30</sup>. Toys which include artificial intelligence are to comply with Regulation (EU) .../...[P.O. insert serial number for Regulation laying down harmonised rules on artificial intelligence]<sup>31</sup>. Therefore, particular safety requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys should *not be set out. However, protecting the health of children should not merely ensure the absence of disease or infirmity and relying on digital technologies may pose risks to children which go beyond their physical health. To ensure that children are protected from any risk coming from the use of digital technologies in toys, the general safety requirement should ensure the psychological and mental health, as well as the well-being and cognitive development, of children.*

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<sup>30</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

<sup>31</sup> PO: Please insert in the text the number of the Regulation and insert the number, date, title and OJ reference of that Regulation in the footnote.

led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud in accordance with Directive 2014/53/EU of the European Parliament and of the Council<sup>30</sup>. Toys which include artificial intelligence are to comply with Regulation (EU) .../...[P.O. insert serial number for Regulation laying down harmonised rules on artificial intelligence]<sup>31</sup>. Therefore, *such toys should comply with standards of safety, security and privacy by design.* Particular safety requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys should *be dealt with within the specific legislation.*

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<sup>30</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

<sup>31</sup> PO: Please insert in the text the number of the Regulation and insert the number, date, title and OJ reference of that Regulation in the footnote.

#### Amendment 4

**Proposal for a regulation**  
**Recital 14 a (new)**

*Text proposed by the Commission*

*Amendment*

***(14a) Under Regulation (EU) .../...[OJ insert serial number for Regulation laying down harmonised rules on artificial intelligence] toys containing AI systems as safety components are considered as high-risk AI. Furthermore, under the Cyber Resilience Act internet connected toys that have social interactive features (e.g. speaking or filming) or that have location tracking features are considered important products with digital elements (Class I). On the basis of those Regulations, such toys require a third party conformity assessment, unless the manufacturer has applied relevant harmonised standards.***

**Amendment 5**

**Proposal for a regulation**  
**Recital 14 b (new)**

*Text proposed by the Commission*

*Amendment*

***(14b) The safety assessment should take into account the health risk posed by digitally connected toys, where appropriate, including any risk posed to mental health. Therefore, when assessing the safety of digitally connected toys likely to have an impact on children, manufacturers should ensure that the products they make available on the market meet the highest standards of safety, security and privacy by design, in the best interests of children.***

**Amendment 6**

**Proposal for a regulation**  
**Recital 15**



(15) Toys should comply with physical and mechanical requirements that prevent children from getting physically injured when playing with toys and should not pose a risk of choking or suffocation to children. In order to protect children from the risk of impaired hearing, maximum values should be set out for both impulse noise and continuous noise emitted by toys. Toys or their parts and their packaging which can be reasonably expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use are subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>32</sup>. In addition, it is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys in food, since the association of a toy and food could cause a risk of choking which is distinct from the risks presented by the toy alone and which is, therefore, not covered by any specific measure at Union level. Toys should also ensure sufficient protection as regards flammability or electric properties, in particular to prevent burns or electric shocks. Moreover, toys should meet certain hygiene standards to avoid microbiological risks or other risks of infection or contamination.

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<sup>32</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(15) Toys should comply with physical and mechanical requirements that prevent children from getting physically injured when playing with toys and should not pose a risk of choking or suffocation to children. In order to protect children from the risk of impaired hearing, maximum values should be set out ***taking into account studies and the recommendations of medical experts*** for both impulse noise and continuous noise emitted by toys ***which are designed to emit a sound***. Toys or their parts and their packaging which can be reasonably expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use are subject to Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>32</sup>. In addition, it is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys in food, since the association of a toy and food could cause a risk of choking which is distinct from the risks presented by the toy alone and which is, therefore, not covered by any specific measure at Union level. Toys should also ensure sufficient protection as regards flammability or electric properties, in particular to prevent burns or electric shocks. Moreover, toys should meet certain hygiene standards to avoid microbiological risks or other risks of infection or contamination.

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<sup>32</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

## **Amendment 7**

### **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 Council<sup>33</sup>. Those generic prohibitions should apply to CMR substances, endocrine disruptors, respiratory sensitisers and substances targeting a specific organ, **as soon as those substances** are classified as hazardous under Regulation (EC) No 1272/2008<sup>34</sup>. In order to ensure toy safety, prohibited substances should be acceptable at trace

### *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 Council<sup>33</sup>. 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 Council<sup>34</sup>. Those generic prohibitions should apply to CMR

levels but only if their presence at such levels is technologically unavoidable with good manufacturing practices and if the toy is safe.

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.

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<sup>33</sup> *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).*

<sup>34</sup> *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).*

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<sup>33</sup> *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).*

<sup>34</sup> *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).*

**Proposal for a regulation**  
**Recital 20**

*Text proposed by the Commission*

(20) As batteries are regulated by Regulation (EU) .../[P.O. insert serial number for Regulation on batteries and waste batteries]<sup>35</sup>, the requirements regarding chemical substances in toys should not apply to the batteries included in toys. However, toys that include batteries should be designed in such a way that the batteries are difficult for children to access.

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<sup>35</sup> PO: Please insert in the text the number of the Regulation .... and insert the number, date, title and OJ reference of that Regulation in the footnote.

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

*Text proposed by the Commission*

*Amendment*

(20) As batteries are regulated by Regulation (EU) .../[P.O. insert serial number for Regulation on batteries and waste batteries]<sup>35</sup>, the requirements regarding chemical substances in toys should not apply to the batteries included in toys. However, toys that include batteries should be designed in such a way that the batteries are difficult for children to access. ***In situations where, due to the nature, size or form factor of the toy, or of the small electronics contained within, it would not be possible to design the toy in a way that the internal battery would be removable and replaceable by the end-user while also ensuring the safety of the child and the safe continued use of the toy, the toy could be designed in such a way as to make the battery removable and replaceable by independent operators.***

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<sup>35</sup> PO: Please insert in the text the number of the Regulation .... and insert the number, date, title and OJ reference of that Regulation in the footnote.

***(22a) 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 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 displayed efficiently, the manufacturer can add a QR-code that provides a link to the instruction in a digital format, but should always mark warnings on the toy, on an affixed label or on the packaging.***

## Amendment 11

### Proposal for a regulation Recital 25

#### *Text proposed by the Commission*

(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.

#### *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 ***clearly intelligible***, legible and visible.

## Amendment 12

### Proposal for a regulation Recital 25 a (new)

*Text proposed by the Commission*

*Amendment*

**(25a) To ensure awareness of any risks associated with the toy, especially in cases where the purchase is made through distance and online sales, it should be ensured that the warnings online are clearly legible and immediately visible.**

## Amendment 13

### Proposal for a regulation Recital 32

*Text proposed by the Commission*

*Amendment*

(32) Economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that the toys they place on the market do not **jeopardise** the safety and health of children under normal and reasonably foreseeable conditions of use, and that they make available on the market only toys which comply with the relevant Union legislation.

(32) Economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that the toys they place on the market do not **pose risks to** the safety and health of children under normal and reasonably foreseeable conditions of use, and that they make available on the market only toys which comply with the relevant Union legislation.

## Amendment 14

### Proposal for a regulation Recital 37

*Text proposed by the Commission*

*Amendment*

(37) **Economic operators** that either **place** a toy on the market under their own name or trademark or modify a toy in such a way that compliance with applicable requirements of this Regulation may be affected, should be considered to be **manufacturers** and should assume the

(37) **Any natural or legal person** that either **places** a toy on the market under their own name or trademark or modify a toy in such a way that compliance with applicable requirements of this Regulation may be affected, should be considered to be **manufacturer for the purposes of this**



obligations of *manufacturers*.

*Regulation* and should assume the obligations of *manufacturer*.

## Amendment 15

### Proposal for a regulation Recital 37 a (new)

*Text proposed by the Commission*

*Amendment*

***(37a) Online marketplaces play a crucial role in the supply chain, allowing economic operators to reach a large number of customers. Given their important role in intermediating the sale of toys between economic operators and customers, online marketplaces should take responsibility for addressing the sale of toys that do not comply with this Regulation and should cooperate with market surveillance authorities. Directive 2000/31/EC of the European Parliament and of the Council provides the general framework for e-commerce and lays down certain obligations for online platforms. Regulation (EU) 2022/2065 regulates the responsibility and accountability of providers of intermediary services online with regard to illegal content, including products that do not comply with this Regulation.***

## Amendment 16

### Proposal for a regulation Recital 38

*Text proposed by the Commission*

*Amendment*

(38) Ensuring traceability of a toy throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant toys

(38) Ensuring traceability of a toy throughout the whole supply chain, ***in accordance with Regulation 2023/988***, helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic

available on the market.

operators who made non-compliant toys available on the market.

## Amendment 17

### Proposal for a regulation Recital 39

#### *Text proposed by the Commission*

(39) In order to facilitate the assessment of conformity with the requirements of this Regulation it is necessary to provide for a presumption of conformity for toys which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>36</sup> and published in the Official Journal of the European Union.

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<sup>36</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

#### *Amendment*

(39) In order to facilitate the assessment of conformity with the requirements of this Regulation it is necessary to provide for a presumption of conformity for toys which are in conformity with ***the applicable*** harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>36</sup> and published in the Official Journal of the European Union.

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<sup>36</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

## Amendment 18

### Proposal for a regulation Recital 40

#### *Text proposed by the Commission*

(40) In the absence of relevant harmonised standards, the Commission

#### *Amendment*

(40) In the absence of relevant harmonised standards, the Commission



should be empowered to adopt **implementing acts** setting out common specifications for the essential requirements of this Regulation, provided that in doing so it duly respects the standardisation organisations' role and functions, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with the essential requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards.

should be empowered to adopt **delegated acts supplementing this Regulation** by setting out common specifications for the essential **safety** requirements of this Regulation, provided that in doing so it duly respects the standardisation organisations' role and functions, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with the essential requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards.

## Amendment 19

### Proposal for a regulation

#### Recital 42

##### *Text proposed by the Commission*

(42) Manufacturers should create a product passport to provide information on the compliance of toys with this Regulation and with any other Union legislation applicable to toys. **The** product passport should replace the EU declaration of conformity under Directive 2009/48/EC **and** include the elements necessary to assess the conformity of the toy with the applicable requirements and harmonised standards or other specifications. In order to facilitate checks on toys by market surveillance authorities and to allow the actors in the supply chain and consumers to access information on the toy, the information on the product passport should be provided digitally and in a directly accessible manner, through a data carrier affixed to the toy, its packaging or the accompanying documentation. Market surveillance authorities, customs authorities, economic operators and consumers should have immediate access to the information on the toy through the data carrier.

##### *Amendment*

(42) Manufacturers should create a **digital** product passport to provide information on the compliance of toys with this Regulation and with any other Union legislation applicable to toys. **They should keep the digital product passport up to date according to reasonable best efforts and make any necessary changes when required. The digital** product passport should replace the EU declaration of conformity under Directive 2009/48/EC, **Directive 2014/53/EU and any other Union legislation applicable to toys. It should also** include the elements necessary to assess the conformity of the toy with the applicable requirements and harmonised standards or other specifications **or elements**. In order to facilitate checks on toys by market surveillance authorities and to allow the actors in the supply chain and consumers to access information on the toy **and on communication channels**, the information on the **digital** product passport should be provided digitally and in a directly accessible manner, through a data carrier affixed to the toy, its packaging or the accompanying documentation.

***Depending on access rights***, market surveillance authorities, customs authorities, economic operators and consumers should have immediate access to the ***respective*** information on the toy through the data carrier.

## Amendment 20

### Proposal for a regulation Recital 43

#### *Text proposed by the Commission*

(43) To avoid duplication of investment into digitalisation by all actors involved, including manufacturers, market surveillance authorities and customs authorities, when other Union legislation requires a product passport for toys, a single product passport should be available containing the information required under this Regulation and the other Union legislation. In addition, the product passport should be fully interoperable with any product passport required under other Union legislation.

#### *Amendment*

(43) To avoid duplication of investment into digitalisation by all actors involved, including manufacturers, market surveillance authorities and customs authorities, when other Union legislation requires a product passport for toys, a single product passport should be available containing the information required under this Regulation and the other Union legislation. In addition, the ***digital*** product passport should be fully interoperable with any product passport required under other Union legislation.

## Amendment 21

### Proposal for a regulation Recital 44

#### *Text proposed by the Commission*

(44) In particular, Regulation (EU) .../... [P.O. insert serial number for the Regulation on ecodesign requirements for sustainable products] of the European Parliament and of the Council<sup>37</sup> also lays down requirements and technical specifications for a product passport, the establishment of a Commission central registry where passport information is stored and the interconnection of that registry with the customs IT systems. That

#### *Amendment*

(44) In particular, Regulation (EU) .../... [P.O. insert serial number for the Regulation on ecodesign requirements for sustainable products] of the European Parliament and of the Council<sup>37</sup> also lays down requirements and technical specifications for a ***digital*** product passport, the establishment of a Commission central registry where passport information is stored and the interconnection of that registry with the

Regulation may include toys within its scope in the medium term, thus requiring that a product passport is available for toys. Therefore, it should be possible in the future to include more precise information in the product passport, *in particular information related to environmental sustainability, such as the environmental footprint of a product, information useful for recycling purposes, the recycled content of a certain material, information about the supply chain, and other similar information.* The product passport for toys created under this Regulation should therefore comply with the same requirements and technical elements as those set out in Regulation (EU) .../... [P.O. insert serial number for the Regulation on ecodesign requirements for sustainable products], including the technical, semantic and organisational aspects of end-to-end communication and data exchange.

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<sup>37</sup> PO: Please insert in the text the number of the Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC.... and insert the number, date, title and OJ reference of that Regulation in the footnote.

## Amendment 22

### Proposal for a regulation Recital 45

#### *Text proposed by the Commission*

(45) As the product passport is to replace the EU declaration of conformity, it is crucial to make clear that by creating the product passport for a toy and by affixing the CE marking, the manufacturer declares that the toy is in compliance with the requirements of this Regulation and that the manufacturer takes full responsibility

customs IT systems. That Regulation may include toys within its scope in the medium term, thus requiring that a **digital** product passport is available for toys. Therefore, it should be possible in the future to include more precise information in the **digital** product passport. *The digital* product passport for toys created under this Regulation should therefore comply with the same requirements and technical elements as those set out in Regulation (EU) .../... [P.O. insert serial number for the Regulation on ecodesign requirements for sustainable products], including the technical, semantic and organisational aspects of end-to-end communication and data exchange.

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<sup>37</sup> PO: Please insert in the text the number of the Regulation establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC.... and insert the number, date, title and OJ reference of that Regulation in the footnote.

#### *Amendment*

(45) As the **digital** product passport is to replace the EU declaration of conformity, it is crucial to make clear that by creating the **digital** product passport for a toy and by affixing the CE marking, the manufacturer declares that the toy is in compliance with the requirements of this Regulation and that the manufacturer takes full

thereof.

responsibility thereof.

## Amendment 23

### Proposal for a regulation

#### Recital 46

##### *Text proposed by the Commission*

(46) Where other information than the elements required for the product passport is provided digitally, it is necessary to clarify that the different types of information need to be provided separately and clearly distinguished from each other but through a single data carrier. This will facilitate the work of market surveillance authorities but also provide clarity to consumers regarding the different types of information that are available to them in a digital format.

##### *Amendment*

(46) Where other information than the elements required for the **digital** product passport is provided digitally, it is necessary to clarify that the different types of information need to be provided separately and clearly distinguished from each other but through a single data carrier. This will facilitate the work of market surveillance authorities but also provide clarity to consumers regarding the different types of information that are available to them in a digital format.

## Amendment 24

### Proposal for a regulation

#### Recital 46 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

***(46a) The majority of toy manufacturers subject to the requirements of this Regulation are micro, small and medium sized enterprises (SMEs), for which drawing up a digital product passport is a significant challenge from an administrative and operational perspective. Therefore, the Commission should provide SMEs with additional support in order to assist them in complying with the new requirements set out in this Regulation. To this end, the Commission should publish practical guidelines and tailor-made guidance for SMEs. In particular a direct channel of communication with experts should be set up to help them perform safety***

*assessments and to set up a digital product passport for the toys they produce.*

## **Amendment 25**

### **Proposal for a regulation**

#### **Recital 48**

*Text proposed by the Commission*

(48) In addition to the framework of controls established by Chapter VII of Regulation (EU) 2019/1020, customs authorities should be able to automatically verify that a product passport exists for imported toys subject to this Regulation in order to strengthen the controls at the Union's external borders and prevent non-compliant toys from entering the Union market.

*Amendment*

(48) In addition to the framework of controls established by Chapter VII of Regulation (EU) 2019/1020, customs authorities should be able to automatically verify that a **digital** product passport exists for imported toys subject to this Regulation in order to strengthen the controls at the Union's external borders and prevent non-compliant toys from entering the Union market.

## **Amendment 26**

### **Proposal for a regulation**

#### **Recital 49**

*Text proposed by the Commission*

(49) When toys coming from third countries are placed under the customs procedure of release for free circulation, the reference to a product passport for those toys should be made available to the customs authorities by the economic operator. The reference to the product passport should correspond to a unique product identifier that is stored in the product passport registry established under Article 12 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for Sustainable Products] (the 'registry'). Customs authorities should carry out an automatic verification of the product passport presented for that toy, so as to ensure that only toys with a valid reference to a unique product identifier as

*Amendment*

(49) When toys coming from third countries are placed under the customs procedure of release for free circulation, the reference to a **digital** product passport for those toys should be made available to the customs authorities by the economic operator. The reference to the **digital** product passport should correspond to a unique product identifier that is stored in the product passport registry established under Article 12 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for Sustainable Products] (the 'registry'). Customs authorities should carry out an automatic verification of the product passport presented for that toy, so as to ensure that only toys with a valid reference to a unique

included in the registry are released for free circulation. To carry out that automatic verification, the interconnection between the registry and the customs IT systems as provided for in [Article 13 of Regulation (EU) .../... on ecodesign requirements for sustainable products] should be used.

product identifier as included in the registry are released for free circulation. To carry out that automatic verification, the interconnection between the registry and the customs IT systems as provided for in [Article 13 of Regulation (EU) .../... on ecodesign requirements for sustainable products] should be used.

## **Amendment 27**

### **Proposal for a regulation Recital 51**

#### *Text proposed by the Commission*

(51) The information included in the product passport allows customs authorities to enrich and facilitate risk management and enables more targeted controls at the Union's external borders. Therefore, customs authorities should have the possibility to retrieve and use the information included in the product passport and the registry for carrying out their tasks in accordance with Union legislation, including for risk management in accordance with Regulation (EU) No 952/2013.

#### *Amendment*

(51) The information included in the **digital** product passport allows customs authorities to enrich and facilitate risk management and enables more targeted controls at the Union's external borders. Therefore, customs authorities should have the possibility to retrieve and use the information included in the **digital** product passport and the registry for carrying out their tasks in accordance with Union legislation, including for risk management in accordance with Regulation (EU) No 952/2013.

## **Amendment 28**

### **Proposal for a regulation Recital 52**

#### *Text proposed by the Commission*

(52) It is appropriate to provide for the publication of a notice in the Official Journal of the European Union indicating the date when the interconnection between the registry and the EU Customs Single Window Certificates Exchange System referred to in Article 13 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for

#### *Amendment*

(52) It is appropriate to provide for the publication of a notice in the Official Journal of the European Union indicating the date when the interconnection between the registry and the EU Customs Single Window Certificates Exchange System referred to in Article 13 of [P.O. insert serial number for Regulation (EU) .../... on Ecodesign Requirements for

Sustainable Products] becomes operational in order to facilitate public access to that information.

Sustainable Products] becomes operational in order to facilitate public access to that information. ***Similar publication should be provided in case further EU customs IT systems become operational.***

## **Amendment 29**

### **Proposal for a regulation Recital 53**

#### *Text proposed by the Commission*

(53) The automatic verification by customs of the reference to the product passport for toys entering the Union market should not replace or modify the responsibilities of the market surveillance authorities but only complement the overall framework for controls on products entering the Union market. Regulation (EU) 2019/1020 should continue to apply to toys so as to ensure that market surveillance authorities carry out checks of the information contained in products passports, checks on toys within the market in accordance with that Regulation and, in case of suspension of release for free circulation by the authorities designated for controls at the Union's external borders, determine the compliance and risks of toys pursuant to Chapter VII of Regulation (EU) 2019/1020.

#### *Amendment*

(53) The automatic verification by customs of the reference to the ***digital*** product passport for toys entering the Union market should not replace or modify the responsibilities of the market surveillance authorities but only complement the overall framework for controls on products entering the Union market. Regulation (EU) 2019/1020 should continue to apply to toys so as to ensure that market surveillance authorities carry out checks of the information contained in products passports, checks on toys within the market in accordance with that Regulation and, in case of suspension of release for free circulation by the authorities designated for controls at the Union's external borders, determine the compliance and risks of toys pursuant to Chapter VII of Regulation (EU) 2019/1020.

## **Amendment 30**

### **Proposal for a regulation Recital 54 a (new)**

#### *Text proposed by the Commission*

#### *Amendment*

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



## Amendment 31

### Proposal for a regulation Recital 58

*Text proposed by the Commission*

(58) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, **it** should be presumed to comply with the corresponding requirements set out in this Regulation.

*Amendment*

(58) If a conformity assessment body demonstrates conformity **of the toy** with the criteria laid down in harmonised standards, **the toy** should be presumed to comply with the corresponding requirements set out in this Regulation.

## Amendment 32

### Proposal for a regulation Recital 67 a (new)

*Text proposed by the Commission*

*Amendment*

***(67a) Under Article 20 of the Regulation (EU) 2023/988 manufacturers are required to notify, through the Safety Business Gateway, of any occurrence of an injury as a result of using a product. On the basis of that information, the Commission should evaluate the need and the feasibility of a Pan-European injury database that could bring additional information and knowledge to economic operators, relevant stakeholders and experts, with a view to assessing the effectiveness of the specific Union regulatory framework for toys.***

## Amendment 33

### Proposal for a regulation Recital 69

*Text proposed by the Commission*

(69) In order to take into account technical and scientific progress as well as the level of digital readiness of market

*Amendment*

(69) In order to take into account technical and scientific progress as well as the level of digital readiness of market



surveillance authorities and of children and their supervisors, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should also be delegated to the Commission in respect of amending this Regulation with regard to the information that is to be included in the product passport and the information that is to be included in the product passport registry.

surveillance authorities and of children and their supervisors, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should also be delegated to the Commission in respect of amending this Regulation with regard to the information that is to be included in the **digital** product passport and the information that is to be included in the **digital** product passport registry.

## Amendment 34

### Proposal for a regulation Recital 71

#### *Text proposed by the Commission*

(71) When adopting delegated acts under this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>40</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>40</sup> OJ L 123, 12.5.2016, p. 1.

#### *Amendment*

(71) When adopting delegated acts under this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert **and stakeholder** level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>40</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>40</sup> OJ L 123, 12.5.2016, p. 1.

## Amendment 35

### Proposal for a regulation Recital 72

*Text proposed by the Commission*

(72) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to establish the detailed technical requirements for the product passport for toys, and to determine whether a specific product or group of products is to be considered a toy for the purposes of this Regulation. In exceptional cases where it is necessary in order to address new emerging risks that are not appropriately addressed by the particular safety requirements, the Commission should be empowered to adopt implementing acts setting out specific measures against toys or categories of toys made available on the market which present a risk for children. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>41</sup>.

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<sup>41</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

*Amendment*

(72) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to establish the detailed technical requirements for the **digital** product passport for toys, and to determine whether a specific product or group of products is to be considered a toy for the purposes of this Regulation. In exceptional cases where it is necessary in order to address new emerging risks that are not appropriately addressed by the particular safety requirements, the Commission should be empowered to adopt implementing acts setting out specific measures against toys or categories of toys made available on the market which present a risk for children. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>41</sup>.

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<sup>41</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

**Amendment 36**

**Proposal for a regulation**  
**Article 1 – title**

*Text proposed by the Commission*

Subject matter

*Amendment*

**Objective and** subject matter

**Amendment 37**

**Proposal for a regulation**  
**Article 1 – paragraph 1**

*Text proposed by the Commission*

This Regulation ***lays down rules on the safety of toys, ensuring*** a high level of protection of health and safety of children and other persons, ***and on the free movement of toys in the Union.***

*Amendment*

***The objective of*** this Regulation ***is to improve the functioning of the internal market while providing for a high level of consumer protection and*** a high level of protection of health and safety of children and other persons.

**Amendment 38**

**Proposal for a regulation**  
**Article 1 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***This Regulation lays down rules on the safety of toys and on the free movement of toys in the Union, contributing to strengthening of the internal market.***

**Amendment 39**

**Proposal for a regulation**  
**Article 2 – paragraph 1 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

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.

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, 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.

**Amendment 40**

**Proposal for a regulation**  
**Article 2 – paragraph 3**

*Text proposed by the Commission*

3. The Commission shall be empowered to adopt implementing acts determining whether or not specific products or categories of products fulfil the criteria set out in paragraph 1 of this Article and therefore can or cannot be considered toys within the meaning of this Regulation. Those implementing acts shall be adopted in accordance with the procedure set out in Article 50(2).

*Amendment*

3. The Commission shall, ***before the application of this Regulation pursuant to Article 56 and where necessary to address existing safety risks after the application of this Regulation***, be empowered to adopt implementing acts determining whether or not specific products or categories of products fulfil the criteria set out in paragraph 1 of this Article and therefore can or cannot be considered toys within the meaning of this Regulation. Those implementing acts shall be adopted in accordance with the procedure set out in Article 50(2).

**Amendment 41**

**Proposal for a regulation**  
**Article 2 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3a. This Regulation shall be implemented taking due account of the precautionary principle.***

**Amendment 42**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 4**

*Text proposed by the Commission*

*Amendment*

(4) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on that person’s behalf in relation to specified tasks;

(4) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on that person’s behalf in relation to specified tasks ***with regard to the manufacturer’s obligations under this Regulation***;

## Amendment 43

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 7

##### *Text proposed by the Commission*

(7) ‘fulfilment service provider’ means fulfilment service provider as defined in Article 2, point 11, of Regulation (EU) 2019/1020;

##### *Amendment*

(7) ‘fulfilment service provider’ means fulfilment service provider as defined in Article 3, point 11, of Regulation (EU) 2019/1020;

## Amendment 44

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 8

##### *Text proposed by the Commission*

(8) ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor and the fulfilment service provider;

##### *Amendment*

(8) ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor and the fulfilment service provider ***or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the market in accordance with this Regulation;***

## Amendment 45

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 9

##### *Text proposed by the Commission*

(9) ‘online marketplace’ means online ***marketplace as defined in*** Article 3, point (14), of Regulation (EU) 2023/988;

##### *Amendment*

(9) ‘***provider of an*** online marketplace’ means ***a provider of an intermediary service using an online interface which allows consumers to conclude distance contracts with traders for the sale of products according to*** Article 3, point (14), of Regulation (EU) 2023/988;

## **Amendment 46**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 11 a (new)**

*Text proposed by the Commission*

*Amendment*

***(11a) ‘intended for the use by’ means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group;***

## **Amendment 47**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 12 a (new)**

*Text proposed by the Commission*

*Amendment*

***(12a) ‘essential safety requirements’ means the ‘general safety requirement’ laid down in Article 5 (2) together with the particular safety requirements set out in Annex II;***

## **Amendment 48**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 13 a (new)**

*Text proposed by the Commission*

*Amendment*

***(13a) ‘digital product passport’ means a set of data specific to a product that includes the information specified in Annex VI and that is accessible via electronic means through a data carrier;***

## **Amendment 49**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 14**

*Text proposed by the Commission*

*Amendment*

(14) ‘data carrier’ means ***a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device;***

(14) ‘data carrier’ means ***data carrier as defined in Article 2 paragraph 1, point 30 of Regulation (EU) .../...*** [OJ insert serial number for Ecodesign Requirements for Sustainable Products];

## **Amendment 50**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 15**

*Text proposed by the Commission*

*Amendment*

(15) ‘unique product identifier’ means unique ***string of characters for the identification of toys that also enables a web link to the product passport;***

(15) ‘unique product identifier’ means unique ***identifier as defined in Article 2 paragraph 1, point 31 of Regulation (EU) .../...*** [OJ insert serial number for Ecodesign Requirements for Sustainable Products];

## **Amendment 51**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 16**

*Text proposed by the Commission*

*Amendment*

(16) ‘unique operator identifier’ means ***a unique string of characters for the identification of actors involved in the value chain of toys;***

(16) ‘unique operator identifier’ means unique ***operator identifier as defined in Article 2 paragraph 1, point 32 of Regulation (EU) .../...*** [OJ insert serial number for Ecodesign Requirements for Sustainable Products];

## **Amendment 52**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 20**

*Text proposed by the Commission*

*Amendment*

(20) ‘conformity assessment’ means the

(20) ‘conformity assessment’ means the

process demonstrating whether the essential requirements relating to a toy have been fulfilled;

process demonstrating whether the essential **safety** requirements relating to a toy have been fulfilled;

#### Amendment 53

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 28

*Text proposed by the Commission*

(28) ‘market surveillance authority’ means **a market surveillance** authority **as defined in Article 3, point (4),** of Regulation (EU) 2019/1020;

*Amendment*

(28) ‘market surveillance authority’ means **an** authority **designated by a Member State under Article 10** of Regulation (EU) 2019/1020 **as responsible for organising and carrying out market surveillance in the territory of that Member State;**

#### Amendment 54

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 28 a (new)

*Text proposed by the Commission*

*Amendment*

**(28a) ‘notifying authority’ means an authority designated by a Member State under this Regulation as responsible for the assessment and notification of conformity assessment bodies in the territory of that Member State;**

#### Amendment 55

##### Proposal for a regulation

##### Article 3 – paragraph 1 – point 29

*Text proposed by the Commission*

*Amendment*

(29) ‘functional toy’ means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and which may be a scale model of such product, appliance or

(29) ‘functional toy’ means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, **which brings the same level of risk as the product used by adults**



installation;

and which may be a scale model of such product, appliance or installation;

## **Amendment 56**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 32**

##### *Text proposed by the Commission*

(32) ‘chemical toy’ means a toy intended for the direct handling of chemical substances and mixtures;

##### *Amendment*

(32) ‘chemical toy’ means a toy intended for the direct handling of chemical substances and mixtures ***and which is used in a manner appropriate to a given age-group and under the supervision of an adult;***

## **Amendment 57**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 33**

##### *Text proposed by the Commission*

(33) ‘olfactory board game’ means a toy the purpose of which is to assist a child to learn to recognise different odours or flavours;

##### *Amendment*

(33) ‘olfactory board game’ means a toy the purpose of which is to assist a child to learn to recognise ***or combine*** different odours or flavours;

## **Amendment 58**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 35**

##### *Text proposed by the Commission*

(35) ‘gustative game’ means a toy the purpose of which is to allow children to make sweets or dishes through the use of food ingredients, including liquids, powders and aromas;

##### *Amendment*

(35) ‘gustative game’ means a toy the purpose of which is to allow children to make sweets or dishes through the use of food ingredients, including liquids, powders and aromas ***without using any heat source;***

## **Amendment 59**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 36**

*Text proposed by the Commission*

*Amendment*

**(36) ‘substance of concern’ means substance of concern as defined in Article 2, point (28), of Regulation (EU) .../... [on Ecodesign Requirements for Sustainable Products].**

**deleted**

**Amendment 60**

**Proposal for a regulation**  
**Article 4 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Member States shall not impede, for reasons relating to health and safety or other aspects covered by this Regulation, the making available on the market of toys which comply with this Regulation.

1. Member States shall not ***prohibit, restrict or*** impede, for reasons relating to health and safety or other aspects covered by this Regulation, the making available on the market of toys which comply with this Regulation.

**Amendment 61**

**Proposal for a regulation**  
**Article 5 – title**

*Text proposed by the Commission*

*Amendment*

***Product*** requirements

***Essential safety*** requirements

**Amendment 62**

**Proposal for a regulation**  
**Article 5 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

Toys shall not present a risk to the safety or health of users or third parties, ***including the psychological and mental health, well-***

Toys shall not present a risk to the safety or health of users or third parties, when they are used as intended or in a foreseeable

***being and cognitive development of children***, when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

way, bearing in mind the behaviour of children.

#### Amendment 63

##### Proposal for a regulation

##### Article 5 – paragraph 2 – subparagraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***When assessing the risk referred to in the first subparagraph, a manufacturer of digitally connected toys shall, where appropriate, according to reasonable best efforts, also take into account any risk posed to mental health, as well as the cognitive development, of children, that may arise when such toys are used in accordance with their intended use.***

#### Amendment 64

##### Proposal for a regulation

##### Article 5 – paragraph 2 – subparagraph 1 b (new)

*Text proposed by the Commission*

*Amendment*

***A manufacturer shall apply the second subparagraph in a manner that is proportionate to its capability in relation to adequately assessing those risks.***

#### Amendment 65

##### Proposal for a regulation

##### Article 6 – paragraph 1

*Text proposed by the Commission*

*Amendment*

1. Where necessary to ensure their safe use, toys shall bear a ***general*** warning specifying appropriate user limitations. The user limitations shall include at least the

1. Where necessary to ensure their safe use ***and the health of children***, toys shall bear a warning specifying appropriate user limitations. The user limitations shall

minimum *or maximum* age of the user and, where appropriate, the required abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

include at least the minimum age of the user and, where appropriate, the required abilities of the user, the maximum *weight* or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

## **Amendment 66**

### **Proposal for a regulation**

#### **Article 6 – paragraph 2 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

The *following* categories of toys *shall bear warnings in accordance with the rules for each category* set out in Annex III:

The categories of toys set out in Annex III *shall bear warnings*:

## **Amendment 67**

### **Proposal for a regulation**

#### **Article 6 – paragraph 2 – subparagraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

(a) *toys not intended for use by children under 36 months;*

*deleted*

## **Amendment 68**

### **Proposal for a regulation**

#### **Article 6 – paragraph 2 – subparagraph 1 – point b**

*Text proposed by the Commission*

*Amendment*

(b) *activity toys;*

*deleted*

## **Amendment 69**

### **Proposal for a regulation**

#### **Article 6 – paragraph 2 – subparagraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

(c) *functional toys;* *deleted*

#### **Amendment 70**

##### **Proposal for a regulation**

##### **Article 6 – paragraph 2 – subparagraph 1 – point d**

*Text proposed by the Commission*

*Amendment*

(d) *chemical toys;* *deleted*

#### **Amendment 71**

##### **Proposal for a regulation**

##### **Article 6 – paragraph 2 – subparagraph 1 – point e**

*Text proposed by the Commission*

*Amendment*

(e) *skater, roller skates, inline skates,* *deleted*  
*skateboards, scooters and toy bicycles;*

#### **Amendment 72**

##### **Proposal for a regulation**

##### **Article 6 – paragraph 2 – subparagraph 1 – point f**

*Text proposed by the Commission*

*Amendment*

(f) *aquatic toys;* *deleted*

#### **Amendment 73**

##### **Proposal for a regulation**

##### **Article 6 – paragraph 2 – subparagraph 1 – point g**

*Text proposed by the Commission*

*Amendment*

(g) *toys in food;* *deleted*

#### **Amendment 74**

**Proposal for a regulation**

**Article 6 – paragraph 2 – subparagraph 1 – point h**

*Text proposed by the Commission*

*Amendment*

**(h) imitations of protective masks and helmets;** **deleted**

**Amendment 75**

**Proposal for a regulation**

**Article 6 – paragraph 2 – subparagraph 1 – point i**

*Text proposed by the Commission*

*Amendment*

**(i) toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps;** **deleted**

**Amendment 76**

**Proposal for a regulation**

**Article 6 – paragraph 2 – subparagraph 1 – point j**

*Text proposed by the Commission*

*Amendment*

**(j) packaging for fragrances in olfactory board games, cosmetic kits and gustative games.** **deleted**

**Amendment 77**

**Proposal for a regulation**

**Article 6 – paragraph 3 – subparagraph 1**

*Text proposed by the Commission*

*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

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. Toys which are sold without packaging shall have

have appropriate warnings affixed to them.

appropriate warnings affixed to them *if the surface of the toy allows. If this is not possible, the warnings shall be placed on the label. The manufacturer may add a QR-code which provides a link to the instructions in a digital format, but shall always mark warnings on the toy, on an affixed label or on the packaging.*

## Amendment 78

### 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 **which determine the decision to purchase the toy** shall be clearly visible to the consumer before the purchase, including in cases where the purchase is made through distance **and online** sales. Warnings shall be of sufficient size to ensure **that they are also immediately visible and legible online. The Commission shall adopt implementing acts determining criteria related to the visibility and legibility of warnings, including for online sales, 12 months after the date of entry into force of this Regulation.**

## Amendment 79

### Proposal for a regulation

#### Article 6 – paragraph 4

##### *Text proposed by the Commission*

4. Labels and instructions for use shall draw the attention of children or their supervisors to the inherent hazards and risks to the health and safety of children **involved in using** the toys, and to the ways of avoiding such hazards and risks.

##### *Amendment*

4. Labels and instructions for use shall draw the attention of children or their supervisors to the inherent hazards and risks to the health and safety of children **considering the age group of children for which** the toys **are intended**, and to the ways of avoiding such hazards and risks.

## Amendment 80

### Proposal for a regulation

#### Article 7 – paragraph 2 – subparagraph 2 – point a

*Text proposed by the Commission*

*Amendment*

(a) create a product passport for the toy in accordance with Article 17;

(a) create a **digital** product passport for the toy in accordance with Article 17;

## Amendment 81

### Proposal for a regulation

#### Article 7 – paragraph 2 – subparagraph 2 – point b

*Text proposed by the Commission*

*Amendment*

(b) affix the data carrier **to the toy or to a label attached to the toy**, in accordance with Article 17(5);

(b) affix the data carrier in accordance with Article 17(5);

## Amendment 82

### Proposal for a regulation

#### Article 7 – paragraph 2 – subparagraph 2 – point d

*Text proposed by the Commission*

*Amendment*

(d) upload the unique product identifier and the unique operator identifier of the toy in the product passport registry referred to in Article 19(1), as well as any other additional information determined by a delegated act adopted in accordance with Article 46(2).

(d) upload the unique product identifier and the unique operator identifier of the toy in the **digital** product passport registry referred to in Article 19(1), as well as any other additional information determined by a delegated act adopted in accordance with Article 46(2).

## Amendment 83

### Proposal for a regulation

#### Article 7 – paragraph 3

*Text proposed by the Commission*

*Amendment*

3. Manufacturers shall keep the technical documentation and the product

3. Manufacturers shall keep the technical documentation **up to date** and the



passport for a period of 10 years after the **toy** covered by that documentation and product passport has been placed on the market.

**digital** product passport for a period of 10 years after the **last item of the toy model** covered by that documentation and **digital** product passport has been placed on the market.

## Amendment 84

### Proposal for a regulation

#### Article 7 – paragraph 4 – subparagraph 2

##### *Text proposed by the Commission*

When **manufacturers**, with regard to the risks presented by a toy, **consider it necessary** for the protection of health and safety of consumers, manufacturers shall, carry out sample testing of marketed toys.

##### *Amendment*

When **deemed appropriate** with regard to the risks presented by a toy, for the protection of health and safety of consumers, manufacturers shall, carry out sample testing of marketed toys.

## Amendment 85

### Proposal for a regulation

#### Article 7 – paragraph 6

##### *Text proposed by the Commission*

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal **and** electronic address at which they can be contacted on the toy or, where that is not **possible**, on its packaging or in a document accompanying the toy. Manufacturers shall indicate a single point at which they can be contacted.

##### *Amendment*

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal **or** electronic address at which they can be contacted on the toy or, where that is not **feasible**, on its packaging or in a document accompanying the toy **or in the digital product passport**. Manufacturers shall indicate a single point at which they can be contacted.

## Amendment 86

### Proposal for a regulation

#### Article 7 – paragraph 7

##### *Text proposed by the Commission*

7. Manufacturers shall ensure that the toy is accompanied by instructions and

##### *Amendment*

7. Manufacturers shall ensure that the toy is accompanied by instructions **for use**

safety information in a language or languages easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information shall be clear, understandable and legible.

and safety information in a language or languages easily understood by consumers and other end-users ***including persons with disabilities if feasible***, as determined by the Member State concerned. Such instructions and information shall be clear, understandable and legible.

## Amendment 87

### Proposal for a regulation

#### Article 7 – paragraph 8 – subparagraph 1

##### *Text proposed by the Commission*

Where manufacturers consider, or have reason to believe, that a toy which they have placed on the market is not in conformity with this Regulation, they shall immediately take the corrective measures necessary to bring that toy into conformity, withdraw it or recall it, as appropriate.

##### *Amendment*

Where manufacturers consider, or have reason to believe, ***on the basis of the information in that manufacturer's possession***, that a toy which they have placed on the market is not in conformity with this Regulation, they shall immediately take the corrective measures necessary to bring that toy into conformity, withdraw it or recall it, as appropriate.

## Amendment 88

### Proposal for a regulation

#### Article 7 – paragraph 8 – subparagraph 2 – introductory part

##### *Text proposed by the Commission*

Where manufacturers consider, or have reason to believe, that a toy presents a risk, they shall immediately provide information thereof to:

##### *Amendment*

Where manufacturers consider, or have reason to believe, ***on the basis of the information in that manufacturer's possession***, that a toy presents a risk, they shall immediately provide information thereof to:

## Amendment 89

### Proposal for a regulation

#### Article 7 – paragraph 8 – subparagraph 2 – point a

*Text proposed by the Commission*

(a) the market surveillance authorities of the Member States in which they have made the toy available, via the Safety Business Gateway referred to in Article 26 of Regulation (EU) 2023/988, giving details, in particular, of any non-compliance and of any corrective measures taken; and

*Amendment*

(a) the market surveillance authorities of the Member States in which they have made the toy available, via the Safety Business Gateway referred to in Article 26 of Regulation (EU) 2023/988, giving details, in particular, of any non-compliance and of any corrective measures taken ***and if available, of the quantity, by Member State, of the toys still circulating on the market;*** and

**Amendment 90**

**Proposal for a regulation  
Article 7 – paragraph 10**

*Text proposed by the Commission*

10. Manufacturers shall ensure that other economic operators, the economic operator referred to in Article 4(1) of Regulation (EU) 2019/1020, and online marketplaces, in the supply chain concerned, are kept informed in a timely manner of any non-conformity that the manufacturers have identified.

*Amendment*

10. Manufacturers shall ensure that other economic operators, the economic operator referred to in Article 4(1) of Regulation (EU) 2019/1020, and ***providers of*** online marketplaces, in the supply chain concerned, are kept informed in a timely manner of any non-conformity that the manufacturers have identified.

**Amendment 91**

**Proposal for a regulation  
Article 7 – paragraph 11**

*Text proposed by the Commission*

11. Manufacturers shall make publicly available a telephone number, an electronic address, a dedicated section of their website ***or another communication channel***, allowing consumers or other end-users to ***file*** complaints concerning the safety of toys and to inform the manufacturers of any accident or safety issue they have experienced with such toys.

*Amendment*

11. Manufacturers shall make publicly available ***communication channels such as*** a telephone number, an electronic address, a dedicated section of their website, allowing consumers or other end-users to ***submit*** complaints concerning the safety of toys and to inform the manufacturers of any accident or safety issue they have experienced with such toys.

In doing so, the manufacturers shall take into account the accessibility needs for persons with disabilities.

In doing so, the manufacturers shall take into account the accessibility needs for persons with disabilities. ***The communication channel shall include a link to the section of the Safety Gate Portal referred to in Article 34(3) of Regulation 2023/988 for the transmission of information about toys that may present a risk to the health and safety of consumers.***

## Amendment 92

### Proposal for a regulation Article 8 – paragraph 1

#### *Text proposed by the Commission*

1. A manufacturer may appoint an authorised representative by written mandate.

#### *Amendment*

1. A manufacturer may appoint an authorised representative by written mandate. ***When manufacturers terminate the mandate of their authorised representative, they shall inform the market surveillance authority. A manufacturer established in the Union may also appoint an authorised representative.***

## Amendment 93

### Proposal for a regulation Article 8 – paragraph 3 – point a

#### *Text proposed by the Commission*

(a) keep the technical documentation at the disposal of national surveillance authorities and ensure that the product passport is available, in accordance with Article 17(2), for a period of 10 years after the **toy** covered by those documents has been placed on the market;

#### *Amendment*

(a) keep the technical documentation at the disposal of national surveillance authorities and ensure that the **digital** product passport is available, in accordance with Article 17(2), for a period of 10 years after the **last item of the toy model** covered by those documents has been placed on the market;

## Amendment 94

**Proposal for a regulation**

**Article 8 – paragraph 3 – point b**

*Text proposed by the Commission*

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;

*Amendment*

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy ***in an official language, which can be understood, by that authority***;

**Amendment 95**

**Proposal for a regulation**

**Article 8 – paragraph 3 – point c**

*Text proposed by the Commission*

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.

*Amendment*

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate ***in an effective manner*** the risks posed by toys covered by the ***written*** mandate.

**Amendment 96**

**Proposal for a regulation**

**Article 8 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

***(ca) inform the competent national authorities about any action taken to eliminate the risks posed by toys covered by their mandate through a notification in the Safety Business Gateway, where the information has not been already provided by the manufacturer or upon instruction of the manufacturer.***

**Amendment 97**

## Proposal for a regulation

### Article 9 – paragraph 2 – subparagraph 1 – point b

*Text proposed by the Commission*

(b) the toy is accompanied by instructions **of** use and safety information in accordance with in Article 7(7) in a language or languages which can be easily understood by consumers or other end-users, as determined by the Member State concerned;

*Amendment*

(b) the toy is accompanied by instructions **for** use and safety information in accordance with in Article 7(7) in a language or languages which can be easily understood by consumers or other end-users, as determined by the Member State concerned;

## Amendment 98

## Proposal for a regulation

### Article 9 – paragraph 2 – subparagraph 1 – point c

*Text proposed by the Commission*

(c) the manufacturer has created a product passport for the toy in accordance with Article 7(2);

*Amendment*

(c) the manufacturer has created a **digital** product passport for the toy in accordance with Article 7(2);

## Amendment 99

## Proposal for a regulation

### Article 9 – paragraph 2 – subparagraph 1 – point d

*Text proposed by the Commission*

(d) **the toy bears** a data carrier in accordance with Article 17(5);

*Amendment*

(d) a data carrier **is affixed** in accordance with Article 17(5);

## Amendment 100

## Proposal for a regulation

### Article 9 – paragraph 2 – subparagraph 1 – point e

*Text proposed by the Commission*

(e) the relevant information in the product passport has been included in the product passport registry in accordance with Article 19(1);

*Amendment*

(e) the relevant information in the **digital** product passport has been included in the **digital** product passport registry in accordance with Article 19(1);

## Amendment 101

### Proposal for a regulation

#### Article 9 – paragraph 2 – subparagraph 2

##### *Text proposed by the Commission*

Where importers consider, or have reason to believe, that a toy is not in conformity with the essential safety requirements, they shall **not place** the toy on the market until it has been brought into conformity.

##### *Amendment*

Where importers consider, or have reason to believe, ***on the basis of the information in that importer's possession***, that a toy is not in conformity with the essential safety requirements, they shall ***inform the manufacturer and refrain from placing*** the toy on the market until it has been brought into conformity ***by the manufacturer***.

## Amendment 102

### Proposal for a regulation

#### Article 9 – paragraph 2 – subparagraph 3 – introductory part

##### *Text proposed by the Commission*

Where importers consider, or have reason to believe, that the toy presents a risk, they shall immediately provide information thereof to:

##### *Amendment*

Where importers consider, or have reason to believe, ***on the basis of the information in that importer's possession***, that the toy presents a risk, they shall immediately provide information thereof to:

## Amendment 103

### Proposal for a regulation

#### Article 9 – paragraph 2 – subparagraph 3 – point c

##### *Text proposed by the Commission*

(c) ***consumers or other end-users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, or both.***

##### *Amendment*

***deleted***

## Amendment 104

**Proposal for a regulation**  
**Article 9 – paragraph 6 – subparagraph 2**

*Text proposed by the Commission*

Where importers consider, or have reason to believe, that a toy that they have placed on the market presents a risk to health and safety of consumers and other end-users, they shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

*Amendment*

Where importers consider, or have reason to believe, that a toy that they have placed on the market presents a risk to health and safety of consumers and other end-users, they shall immediately inform the ***manufacturer and the*** competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken ***and inform consumers or other end-users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, or both.***

**Amendment 105**

**Proposal for a regulation**  
**Article 9 – paragraph 7**

*Text proposed by the Commission*

7. Importers shall, for a period of 10 years after the ***toy*** has been placed on the market, keep the unique product identifier of the toy at the disposal of the market surveillance authorities and ensure that the technical documentation referred to in Article 23 can be made available to those authorities, upon request.

*Amendment*

7. Importers shall, for a period of 10 years after the ***last item of the toy model*** has been placed on the market, keep the unique product identifier of the toy at the disposal of the market surveillance authorities and ensure that the technical documentation referred to in Article 23 can be made available to those authorities, upon request.

**Amendment 106**

**Proposal for a regulation**  
**Article 9 – paragraph 9**

*Text proposed by the Commission*

9. Importers shall verify whether the manufacturer has made ***a*** communication ***channel*** as referred to in Article 7(11)

*Amendment*

9. Importers shall verify whether the manufacturer has made communication ***channels*** as referred to in Article 7(11)



publicly available to consumers or other end-users, allowing them to present complaints concerning the safety of toys and provide information on any accident or safety issue they have experienced with the toy. If **a** communication **channel is** not available, importers shall provide for **such a channel**, taking into account accessibility needs for persons with disabilities.

publicly available to consumers or other end-users, allowing them to present complaints concerning the safety of toys and provide information on any accident or safety issue they have experienced with the toy. If communication **channels are** not available, importers shall provide for **them**, taking into account accessibility needs for persons with disabilities.

## **Amendment 107**

### **Proposal for a regulation**

#### **Article 9 – paragraph 10 – subparagraph 2**

##### *Text proposed by the Commission*

Importers shall keep the manufacturer, distributors and, where relevant, online marketplaces informed in a timely manner of the investigation performed and of the results of the investigation.

##### *Amendment*

Importers shall keep the manufacturer, distributors and, where relevant, **providers of** online marketplaces informed in a timely manner of the investigation performed and of the results of the investigation.

## **Amendment 108**

### **Proposal for a regulation**

#### **Article 10 – paragraph 2 – subparagraph 1 – point a**

##### *Text proposed by the Commission*

(a) the toy is accompanied by instructions and safety information in a language or languages which can be easily understood by consumers or other end-users as determined by the Member State in which the toy is to be made available on the market;

##### *Amendment*

(a) the toy is accompanied by instructions **for use** and safety information in a language or languages which can be easily understood by consumers or other end-users as determined by the Member State in which the toy is to be made available on the market;

## **Amendment 109**

### **Proposal for a regulation**

#### **Article 10 – paragraph 2 – subparagraph 2**

*Text proposed by the Commission*

Where distributors consider, or have reason to believe, that a toy is not in conformity with the essential safety requirements, they shall ***not make*** the toy available on the market until it has been brought into conformity.

*Amendment*

Where distributors consider, or have reason to believe, ***on the basis of the information in that distributor's possession***, that a toy is not in conformity with the essential safety requirements, they shall ***inform the manufacturer and refrain from making*** the toy available on the market until it has been brought into conformity ***by the manufacturer***.

**Amendment 110**

**Proposal for a regulation**

**Article 10 – paragraph 2 – subparagraph 3 – introductory part**

*Text proposed by the Commission*

Where distributors consider, or have reason to believe, that the toy presents a risk, they shall immediately provide information thereof to:

*Amendment*

Where distributors consider, or have reason to believe, ***on the basis of the information in that distributor's possession***, that the toy presents a risk, they shall immediately provide information thereof to:

**Amendment 111**

**Proposal for a regulation**

**Article 10 – paragraph 2 – subparagraph 3 – point c**

*Text proposed by the Commission*

***(c) consumers or other end-users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, or both.***

*Amendment*

***deleted***

**Amendment 112**

**Proposal for a regulation**

**Article 10 – paragraph 4 – subparagraph 1**

*Text proposed by the Commission*

Where distributors consider, or have reason

*Amendment*

Where distributors consider, or have reason

to believe, that a toy which they have made available on the market is not in conformity with this Regulation, they shall ensure that the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate, are taken.

to believe, ***on the basis of the information in that distributor's possession***, that a toy which they have made available on the market is not in conformity with this Regulation, they shall ensure that the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate, are ***immediately*** taken.

## Amendment 113

### Proposal for a regulation

#### Article 10 – paragraph 4 – subparagraph 2

##### *Text proposed by the Commission*

Where distributors consider, or have reason to believe, that a toy that they have made available on the market presents a risk, they shall immediately inform the market surveillance authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

##### *Amendment*

Where distributors consider, or have reason to believe, that a toy that they have made available on the market presents a risk, they shall immediately inform ***the manufacturer or the importer, as applicable and*** the market surveillance authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken ***and inform consumers or other end-users, in accordance with Article 35 or 36 of Regulation (EU) 2023/988, or both.***

## Amendment 114

### Proposal for a regulation

#### Article 11 – title

##### *Text proposed by the Commission*

Cases in which obligations of manufacturers apply to ***importers and distributors***

##### *Amendment*

Cases in which obligations of manufacturers apply to ***other persons***

## Amendment 115

### Proposal for a regulation

#### Article 11 – paragraph 1

*Text proposed by the Commission*

***An importer or a distributor*** shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 7, where such ***importer or distributor*** places a toy on the market under its name or trademark or modifies a toy already placed on the market in such a way that compliance with the applicable requirements of this Regulation may be affected.

*Amendment*

***A natural or legal person*** shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 7, where such ***a natural or legal person*** places a toy on the market under its name or trademark or modifies a toy already placed on the market in such a way that compliance with the applicable requirements of this Regulation may be affected.

**Amendment 116**

**Proposal for a regulation  
Chapter II a (new) – Article 12 a (new)**

*Text proposed by the Commission*

*Amendment*

***Chapter IIa***

***Obligations of online marketplaces***

***Article 12a***

***For the purposes of this Regulation, providers of online marketplaces shall comply with the requirements set out in Article 22 of Regulation (EU) 2023/988.***

**Amendment 117**

**Proposal for a regulation  
Article 13 – title**

*Text proposed by the Commission*

*Amendment*

Presumption of conformity

Presumption of conformity ***of toys***

**Amendment 118**

**Proposal for a regulation  
Article 14 – paragraph 2 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

The Commission may, by means of ***implementing acts***, establish common specifications for the essential safety requirements where the following conditions are fulfilled:

*Amendment*

The Commission may, by means of ***delegated acts supplementing this Regulation***, establish common specifications for the essential safety requirements ***only*** where the following conditions are fulfilled:

**Amendment 119**

**Proposal for a regulation**

**Article 14 – paragraph 2 – subparagraph 1 – point a**

*Text proposed by the Commission*

(a) ***there is no harmonised standard covering*** those requirements ***the reference of which is published in the Official Journal of the European Union or the standard does not satisfy the requirements it aims to cover;***

*Amendment*

(a) ***the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft or revise European standards for*** those requirements ***and:***

(i) ***the request has not been accepted;***  
***or***

(ii) ***the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or***

(iii) ***the harmonised standards do not comply with the request; and***

**Amendment 120**

**Proposal for a regulation**

**Article 14 – paragraph 2 – subparagraph 1 – point b – introductory part**

*Text proposed by the Commission*

(b) ***the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft or to revise European standards for*** those

*Amendment*

(b) ***no reference to harmonised standards covering the product requirements has been published in the Official Journal of the European Union in accordance with Regulation (EU) No***

requirements *and either* of the *following conditions is fulfilled*:

*1025/2012 and no such reference is expected to be published within a reasonable period.*

#### **Amendment 121**

##### **Proposal for a regulation**

##### **Article 14 – paragraph 2 – subparagraph 1 – point b – point 1**

*Text proposed by the Commission*

*Amendment*

**(1) *the request has not been accepted by any of the European standardisation organisations to which the request was addressed;*** ***deleted***

#### **Amendment 122**

##### **Proposal for a regulation**

##### **Article 14 – paragraph 2 – subparagraph 1 – point b – point 2**

*Text proposed by the Commission*

*Amendment*

**(2) *the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:*** ***deleted***

**(a) *have not been adopted within the deadline set in the request;***

**(b) *do not comply with the request; or***

**(c) *do not satisfy the requirements they aim to cover.***

#### **Amendment 123**

##### **Proposal for a regulation**

##### **Article 14 – paragraph 2 – subparagraph 2**

*Text proposed by the Commission*

*Amendment*

***Those implementing acts shall be adopted in accordance with the examination*** ***deleted***

*procedure referred to in Article 50(3).*

#### **Amendment 124**

##### **Proposal for a regulation**

##### **Article 14 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. When preparing the delegated act referred to in paragraph 2, the Commission shall take into account the views of the relevant bodies and expert groups.**

#### **Amendment 125**

##### **Proposal for a regulation**

##### **Article 14 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. When references of a harmonised standard are published in the Official Journal of the European Union, the Commission shall assess whether the **implementing** acts referred to in paragraph 2 of this Article which cover the same essential safety requirement need to be repealed or amended.

3. When references of a harmonised standard are published in the Official Journal of the European Union, the Commission shall assess whether the **delegated** acts referred to in paragraph 2 of this Article which cover the same essential safety requirement need to be repealed or amended.

#### **Amendment 126**

##### **Proposal for a regulation**

##### **Chapter IV – title**

*Text proposed by the Commission*

*Amendment*

PRODUCT PASSPORT

**DIGITAL** PRODUCT PASSPORT

#### **Amendment 127**

##### **Proposal for a regulation**

##### **Article 17 – title**

*Text proposed by the Commission*

*Amendment*

Product passport

**Digital** Product passport

## Amendment 128

### Proposal for a regulation Article 17 – paragraph 1

*Text proposed by the Commission*

*Amendment*

1. Before placing a toy on the market, manufacturers shall **create a** product passport for that toy. The product passport shall meet the requirements laid down in this Article and Article 18.

1. Before placing a toy on the market, manufacturers shall **draw up a digital** product passport for that toy. The **digital** product passport shall meet the requirements laid down in this Article and Article 18 **and other relevant Union harmonised legislation requiring an EU declaration of conformity and it shall replace all EU declarations of conformity required.**

## Amendment 129

### Proposal for a regulation Article 17 – paragraph 2 – introductory part

*Text proposed by the Commission*

*Amendment*

2. The product passport shall:

2. The **digital** product passport shall:

## Amendment 130

### Proposal for a regulation Article 17 – paragraph 2 – point b

*Text proposed by the Commission*

*Amendment*

(b) state that compliance of the toy with the requirements set out in this Regulation and, in particular, the essential safety requirements, has been demonstrated;

(b) state that compliance of the toy with the requirements set out in this Regulation and **in other Union harmonised legislation requiring an EU declaration of conformity**, in particular, the essential safety requirements, has been



demonstrated;

## Amendment 131

### Proposal for a regulation

#### Article 17 – paragraph 2 – point f

*Text proposed by the Commission*

(f) be accessible to consumers or other end-users, market surveillance authorities, customs authorities, notified bodies, the Commission and other economic operators;

*Amendment*

(f) ***depending on access rights***, be accessible to consumers or other end-users, market surveillance authorities, customs authorities, notified bodies, the Commission and other economic operators ***in accordance with paragraph 2a and taking into account the need to protect confidential business information and trade secrets in accordance with Directive (EU) 2016/943***;

## Amendment 132

### Proposal for a regulation

#### Article 17 – paragraph 2 – point g

*Text proposed by the Commission*

(g) be available for a period of 10 years after the **toy** is placed on the market, also in cases of insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created the product passport;

*Amendment*

(g) be available for a period of 10 years after the ***last item of the toy model*** is placed on the market, also in cases of insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created the ***digital*** product passport;

## Amendment 133

### Proposal for a regulation

#### Article 17 – paragraph 2 – point i

*Text proposed by the Commission*

(i) fulfil the specific and technical requirements laid down pursuant to paragraph 10.

*Amendment*

(i) fulfil the specific and technical requirements laid down pursuant to paragraph 10 ***in order to facilitate the***

*verification of product compliance by competent national authorities.*

## **Amendment 134**

### **Proposal for a regulation**

#### **Article 17 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. The access rights referred to in paragraph 2, point (f) of this Article shall comprise:**

**(a) information accessible to consumers or other end-users listed in points (c), (d), (i), (j), (ja), (jb) and (jc) of Part I of Annex VI and, where applicable, points (a) and (b) of Part II of Annex VI;**

**(b) information accessible only to market surveillance authorities, customs authorities, notified bodies, and the Commission listed in points (a) to (j) of Part I of Annex VI and, where applicable, points (a) and (b) of Part II of Annex VI.**

## **Amendment 135**

### **Proposal for a regulation**

#### **Article 17 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. In addition to the information referred to in paragraph 2, the product passport may contain the information set out in Part II of Annex VI.

3. In addition to the information referred to in paragraph 2, the **digital** product passport may contain the information set out in Part II of Annex VI.

## **Amendment 136**

### **Proposal for a regulation**

#### **Article 17 – paragraph 4**

*Text proposed by the Commission*

4. By creating the product passport, the manufacturer shall assume responsibility for the compliance of the toy with this Regulation.

*Amendment*

4. By creating the **digital** product passport, the manufacturer shall assume responsibility for the compliance of the toy with this Regulation **and with any other Union legislation applicable to toys**.

**Amendment 137**

**Proposal for a regulation  
Article 17 – paragraph 5**

*Text proposed by the Commission*

5. The data carrier shall be physically present on the toy or on a label attached to the toy, in accordance with the implementing act adopted in accordance with paragraph 10. In the case of small toys and toys consisting of small parts, the data carrier **may alternatively** be affixed to its packaging. It shall be clearly visible to the consumer before any purchase and to market surveillance authorities, including in cases where the toy is made available through distance sales.

*Amendment*

5. The data carrier shall be physically present on the toy or on a label attached to the toy, in accordance with the implementing act adopted in accordance with paragraph 10. In the case of small toys and toys consisting of small parts, the data carrier **shall** be affixed to its packaging. It shall be clearly visible to the consumer before any purchase and to market surveillance authorities, including in cases where the toy is made available through distance sales.

**Amendment 138**

**Proposal for a regulation  
Article 17 – paragraph 7**

*Text proposed by the Commission*

7. Where other Union legislation applying to toys requires a product passport, a single product passport shall be created for toys containing the information required under this Regulation as well as any other information required for the product passport by that other Union legislation.

*Amendment*

7. Where other Union legislation applying to toys requires a **digital** product passport, a single **digital** product passport shall be created for toys containing the information required under this Regulation as well as any other information required for the **digital** product passport by that other Union legislation.

## Amendment 139

### Proposal for a regulation Article 17 – paragraph 8

*Text proposed by the Commission*

*Amendment*

8. *By way of derogation from paragraph 2, point (c), where information requirements relating to substances of concern in toys are established in a delegated act adopted in accordance with Article 4 of Regulation .../... [OP please insert: the Ecodesign for Sustainable Products Regulation], the information referred to in Part I, point (k), of Annex VI to this Regulation is no longer required.*

*deleted*

## Amendment 140

### Proposal for a regulation Article 17 – paragraph 10 – subparagraph 1 – introductory part

*Text proposed by the Commission*

*Amendment*

The Commission *shall* adopt *implementing acts* determining the *specific* and technical requirements related to the product passport for toys. Those requirements shall cover in particular the following:

The Commission *is empowered to* adopt *delegated acts in accordance with Article 47 to supplement this Regulation by* determining the *basic* technical requirements related to the *digital* product passport for toys *by.....[12 months after the entry into force of this Regulation]*. Those requirements shall cover in particular the following:

## Amendment 141

### Proposal for a regulation Article 17 – paragraph 10 – subparagraph 1 – point d

*Text proposed by the Commission*

*Amendment*

(d) the actors that may introduce or update the information in the product passport, including where needed the

(d) the actors that may introduce or update the information in the *digital* product passport, including where needed

creation of a new passport, including manufacturers, notified bodies, competent national authorities, and the Commission, or any organisation acting on their behalf, and the types of information they may introduce or update.

the creation of a new passport, including manufacturers, notified bodies, competent national authorities, and the Commission, or any organisation acting on their behalf, and the types of information they may introduce or update.

#### **Amendment 142**

##### **Proposal for a regulation**

##### **Article 17 – paragraph 10 – subparagraph 2**

###### *Text proposed by the Commission*

Those **implementing** acts shall be adopted in accordance with the procedure set out in Article **50(3)**.

###### *Amendment*

Those **delegated** acts shall be adopted in accordance with the procedure set out in Article **46 (2)**.

#### **Amendment 143**

##### **Proposal for a regulation**

##### **Article 18 – title**

###### *Text proposed by the Commission*

Technical design and operation of the product passport

###### *Amendment*

Technical design and operation of the **digital** product passport

#### **Amendment 144**

##### **Proposal for a regulation**

##### **Article 18 – paragraph 1**

###### *Text proposed by the Commission*

1. The product passport shall be fully interoperable with product passports required by other Union legislation in relation to the technical, semantic and organisational aspects of end-to-end communication and data exchange.

###### *Amendment*

1. The **digital** product passport shall be fully interoperable with **digital** product passports required by other Union legislation in relation to the technical, semantic and organisational aspects of end-to-end communication and data exchange.

#### **Amendment 145**

**Proposal for a regulation**  
**Article 18 – paragraph 2**

*Text proposed by the Commission*

2. All information included in the product passport shall be based on open standards developed with an interoperable format **and** shall be machine readable, structured and searchable.

*Amendment*

2. All information included in the **digital** product passport shall be based on open standards developed with an interoperable format, **including for the purpose of transmitting information via the Safety Business Gateway and the Safety Gate Portal referred to in Articles 27 and 34 of Regulation 2023/988. It** shall be machine readable, structured and searchable **in accordance with the essential requirements set out in Regulation .../... [Ecodesign Regulation for Sustainable Products]. The digital product passport shall be designed and operated in an accessible manner, and incorporate the principle of security and privacy by design.**

**Amendment 146**

**Proposal for a regulation**  
**Article 18 – paragraph 3**

*Text proposed by the Commission*

3. Consumers or other end-users, economic operators and other relevant actors shall have access to the product passport free of charge.

*Amendment*

3. Consumers or other end-users, economic operators and other relevant actors shall have access **on the basis of their respective access rights in accordance with Union legislation** to the **digital** product passport free of charge.

**Amendment 147**

**Proposal for a regulation**  
**Article 18 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

**3a. Consumers shall not be requested to download and install any software,**

*register, or to provide a password to access the digital product passport.*

## Amendment 148

### Proposal for a regulation Article 18 – paragraph 4

*Text proposed by the Commission*

4. The data included in the product passport shall be stored by the economic operator responsible for its creation or by operators authorised to act on their behalf.

*Amendment*

4. The data included in the **digital** product passport shall be stored by the economic operator responsible for its creation or by operators authorised to act on their behalf.

## Amendment 149

### Proposal for a regulation Article 18 – paragraph 5

*Text proposed by the Commission*

5. Where the data included in the product passport is stored or otherwise processed by an operator authorised to act on behalf of the economic operators placing the toy on the market, that other operator shall not be allowed to sell, re-use or process such data, in whole or in part, beyond what is necessary for the provision of the relevant storing or processing services.

*Amendment*

5. Where the data included in the **digital** product passport is stored or otherwise processed by an operator authorised to act on behalf of the economic operators placing the toy on the market, that other operator shall not be allowed to sell, re-use or process such data, in whole or in part, beyond what is necessary for the provision of the relevant storing or processing services.

## Amendment 150

### Proposal for a regulation Article 18 – paragraph 6

*Text proposed by the Commission*

6. Economic operators **may** not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the information on

*Amendment*

6. Economic operators **shall** not track, analyse or use any usage information for purposes other than what is absolutely **and strictly** necessary for providing the

the product passport online.

information on the **digital** product passport online.

## Amendment 151

### Proposal for a regulation Article 19 – title

*Text proposed by the Commission*

Product passport registry

*Amendment*

**Digital** product passport registry

## Amendment 152

### Proposal for a regulation Article 19 – paragraph 1

*Text proposed by the Commission*

1. Before placing a toy on the market, economic operators shall upload, in the registry established under Article 12(1) of Regulation (EU) .../... [**PO** insert serial number for Ecodesign Requirements for Sustainable Products] (the ‘registry’), the unique product identifier and unique operator identifier for that toy.

*Amendment*

1. Before placing a toy on the market, **and following the adoption of delegated acts in accordance with Article 17(10) of this Regulation**, economic operators shall upload, in the registry established under Article 12(1) of Regulation (EU) .../... [**OJ** insert serial number for Ecodesign Requirements for Sustainable Products] (the ‘registry’), the unique product identifier and unique operator identifier for that toy.

## Amendment 153

### Proposal for a regulation Article 19 – paragraph 2

*Text proposed by the Commission*

2. The Commission, market surveillance authorities and customs authorities shall have access to the information stored in the registry referred to in paragraph 1 for carrying out their duties pursuant to this Regulation.

*Amendment*

2. The Commission, market surveillance authorities and customs authorities shall have **efficient** access to the information stored in the registry referred to in paragraph 1 for carrying out their duties pursuant to this Regulation.



## Amendment 154

### Proposal for a regulation Article 20 – title

*Text proposed by the Commission*

Customs controls relating to the product passport

*Amendment*

Customs controls relating to the **digital** product passport

## Amendment 155

### Proposal for a regulation Article 20 – paragraph 7

*Text proposed by the Commission*

7. Customs authorities may retrieve and use the information on toys included in the product passport and in the registry for carrying out their duties pursuant to Union legislation, including for risk management in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

*Amendment*

7. Customs authorities may retrieve and use the information on toys included in the **digital** product passport and in the registry for carrying out their duties pursuant to Union legislation, including for risk management in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

## Amendment 156

### Proposal for a regulation Article 20 a (new)

*Text proposed by the Commission*

*Amendment*

#### **Article 20a**

#### **Assistance for SMEs**

***1. The Commission shall provide comprehensive assistance, in cooperation with the relevant national authorities, to SMEs that are required to establish a digital product passport for toys, by providing them with tailor-made guidance on how to efficiently set up and operate a digital product passport for toys and an automatic translation tool for the languages referred to in Article 17(2)***

*point (e).*

*This support, referred to in the first subparagraph, shall be provided no later than ....[12 months after the entry into force of this Regulation].*

*2. The Commission shall evaluate the possibility of setting up an online tool to provide SMEs with the basic information and functions necessary to establish a digital product passport for their products.*

## Amendment 157

### Proposal for a regulation Article 21 – paragraph 1

#### *Text proposed by the Commission*

1. In order to demonstrate that a toy complies with the essential safety requirements, manufacturers shall, before placing a toy on the market, carry out a safety assessment *including an analysis of the hazards that the toy may present, as well as an assessment of* the potential exposure to such hazards.

#### *Amendment*

1. In order to demonstrate that a toy complies with the essential safety requirements, manufacturers shall, before placing a toy on the market, carry out a safety assessment *which shall at least the following:*

*(a) cover all the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards and the potential exposure to such hazards;*

*(b) in relation to chemical hazards, take account of the possible exposure to individual chemicals, and any known additional hazards from combined exposure to the different chemicals present in the toy, taking into account the obligations under Regulation (EC) No 1907/2006 and the conditions set out therein;*

*(c) be updated whenever additional relevant information is available.*

*The safety assessment shall be included in the technical documentation referred to in Article 23.*

## Amendment 158

### Proposal for a regulation

#### Article 21 – paragraph 2

*Text proposed by the Commission*

*Amendment*

**2. The safety assessment shall in particular :**

***deleted***

**(a) cover all the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards and the potential exposure to such hazards;**

**(b) in relation to chemical hazards, take account of the possible exposure to individual chemicals, and any known additional hazards from combined exposure to the different chemicals present in the toy, taking into account the obligations under Regulation (EC) No 1907/2006 and the conditions set out therein;**

**(c) be updated whenever additional relevant information is available.**

**The safety assessment shall be included in the technical documentation referred to in Article 23.**

## Amendment 159

### Proposal for a regulation

#### Article 22 – paragraph 3 – point c

*Text proposed by the Commission*

*Amendment*

**(c) where one or more of the harmonised standards referred to in point (a) has been published with a restriction;**

**(c) where one or more of the harmonised standards referred to in point (a) has been published with a restriction, *in the event that the restriction is relevant to the toy in question*;**

## Amendment 160

**Proposal for a regulation**  
**Article 26 – paragraph 4**

*Text proposed by the Commission*

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, nor shall they offer or provide consultancy services on a commercial or competitive basis.

*Amendment*

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, nor shall they offer or provide consultancy services on a commercial or competitive basis, ***however the notifying authority shall provide information to the economic operators about the procedures for the assessment and the conformity assessment bodies if requested to do so.***

**Amendment 161**

**Proposal for a regulation**  
**Article 26 – paragraph 6**

*Text proposed by the Commission*

6. A notifying authority shall have a sufficient number of competent personnel at their disposal for the ***proper*** performance of their tasks.

*Amendment*

6. A notifying authority shall have a sufficient number of competent personnel ***and adequate resources*** at their disposal for the ***efficient*** performance of their tasks.

**Amendment 162**

**Proposal for a regulation**  
**Article 28 – paragraph 6 – subparagraph 3**

*Text proposed by the Commission*

A conformity assessment body shall have the ***means*** necessary to perform the technical and administrative tasks connected with the conformity assessment activities ***in an appropriate manner*** and shall have access to all necessary equipment or facilities.

*Amendment*

A conformity assessment body shall have the ***resources*** necessary to ***efficiently*** perform the technical and administrative tasks connected with the conformity assessment activities and shall have access to all necessary equipment or facilities.

**Amendment 163**

**Proposal for a regulation**  
**Article 28 – paragraph 7 – point b**

*Text proposed by the Commission*

(b) **satisfactory** knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

*Amendment*

(b) **in-depth** knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

**Amendment 164**

**Proposal for a regulation**  
**Article 28 – paragraph 7 – point c**

*Text proposed by the Commission*

(c) **appropriate** knowledge and understanding of the requirements set out in this Regulation, of the applicable harmonised standards referred to in Article 13 of this Regulation and the common specifications referred to in Article 14 of this Regulation;

*Amendment*

(c) **in-depth** knowledge and understanding of the requirements set out in this Regulation, of the applicable harmonised standards referred to in Article 13 of this Regulation and the common specifications referred to in Article 14 of this Regulation;

**Amendment 165**

**Proposal for a regulation**  
**Article 28 – paragraph 10**

*Text proposed by the Commission*

10. The personnel of a conformity assessment body shall **observe** professional secrecy with regard to all information obtained in carrying out their tasks under Annex IV, except in relation to the competent authorities of the Member State in which its activities are carried out. Intellectual property rights shall be protected.

*Amendment*

10. The personnel of a conformity assessment body shall **respect** professional secrecy with regard to all information obtained in carrying out their tasks under Annex IV, except in relation to the competent authorities of the Member State in which its activities are carried out. Intellectual property rights **and trade secrets, in accordance with Directive (EU) 2016/943**, shall be protected.

**Amendment 166**

**Proposal for a regulation**  
**Article 41 – title**

*Text proposed by the Commission*

***Procedure for dealing with toys  
presenting a risk at national level***

*Amendment*

National ***measures concerning toys which  
are not compliant with the particular  
safety requirements***

**Amendment 167**

**Proposal for a regulation**  
**Article 41 – paragraph 1 – subparagraph 1**

*Text proposed by the Commission*

Where the market surveillance authorities of one Member State have sufficient reason to believe that a toy covered by this Regulation presents a risk to the health or safety of ***persons***, they shall carry out an evaluation in relation to the toy concerned covering all the requirements laid down in this Regulation. The relevant economic operators shall cooperate, as necessary, with the market surveillance authorities for that purpose.

*Amendment*

Where the market surveillance authorities of one Member State have sufficient reason to believe that a toy covered by this Regulation presents a risk to the health or safety of ***children***, they shall carry out an evaluation in relation to the toy concerned covering all the requirements laid down in this Regulation. ***They shall immediately inform the relevant economic operator, in accordance with Article 4(1) and (2) of Regulation (EU) 2019/1020, of the procedure they have initiated and of the possible risk they have identified in the toy, and give the economic operator the opportunity to react.*** The relevant economic operators shall cooperate, as necessary, with the market surveillance authorities for that purpose.

**Amendment 168**

**Proposal for a regulation**  
**Article 41 – paragraph 9**

*Text proposed by the Commission*

9. The information referred to in paragraphs 2, 4, 6 and 8 of this Article shall be communicated through the information and communication system

*Amendment*

9. The information referred to in paragraphs 2, 4, 6 and 8 of this Article shall be communicated through the information and communication system

referred to in Article 34 of Regulation (EU) 2019/1020. That communication shall not affect the obligation on market surveillance authorities to notify measures taken against products presenting a serious risk in accordance with Article 20 of Regulation (EU) 2019/1020.

referred to in Article 34 of Regulation (EU) 2019/1020. That communication shall not affect the obligation on market surveillance authorities to notify measures taken against products presenting a serious risk in accordance with Article 20 of Regulation (EU) 2019/1020 ***and strictly enforce Article 19 of that Regulation given the vulnerability of children to defective, unsafe or counterfeit products.***

## **Amendment 169**

### **Proposal for a regulation**

#### **Article 43 – paragraph 1 – point c**

*Text proposed by the Commission*

(c) the product passport has not been drawn up in accordance with Article 17;

*Amendment*

(c) the ***digital*** product passport has not been drawn up in accordance with Article 17;

## **Amendment 170**

### **Proposal for a regulation**

#### **Article 43 – paragraph 1 – point d**

*Text proposed by the Commission*

(d) the data carrier through which the product passport is accessible has not been affixed in accordance with Article 17(5);

*Amendment*

(d) the data carrier through which the ***digital*** product passport is accessible has not been affixed in accordance with Article 17(5);

## **Amendment 171**

### **Proposal for a regulation**

#### **Article 46 – paragraph 1**

*Text proposed by the Commission*

1. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex VI as regards the information to be provided in the

*Amendment*

1. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex VI as regards the information to be provided in the

product passport, in order to adapt it to technical and scientific progress and to the level of digital readiness of market surveillance authorities and of users and their supervisors.

**digital** product passport, in order to adapt it to technical and scientific progress and to the level of digital readiness of market surveillance authorities and of users and their supervisors.

## Amendment 172

### Proposal for a regulation

#### Article 46 – paragraph 2 – subparagraph 2 – point b

##### *Text proposed by the Commission*

(b) the need to allow for the verification of the authenticity of the product passport;

##### *Amendment*

(b) the need to allow for the verification of the authenticity of the **digital** product passport;

## Amendment 173

### 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 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. ***When developing such delegated acts, the Commission shall take into account the availability of viable alternative substances or mixtures and any potential adverse impact that such a delegated act could have on innovation and on relevant manufacturers.***

## Amendment 174

### 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 175**

**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 176**

**Proposal for a regulation**

**Article 46 – paragraph 7 – point a a (new)**

*Text proposed by the Commission*

**Amendment 177**

**Proposal for a regulation**

**Article 46 – paragraph 7 a (new)**

*Text proposed by the Commission*

*Amendment*

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

*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*

**(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*

**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 the 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 into account, in particular, 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 the 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 178**

### **Proposal for a regulation Article 46 – paragraph 9**

*Text proposed by the Commission*

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.

## **Amendment 179**

### **Proposal for a regulation Article 47 – paragraph 2**

*Amendment*

9. For the purposes of paragraphs 6 - **8**, 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.

*Text proposed by the Commission*

2. The power to adopt delegated acts referred to in Article 46 shall be conferred on the Commission for ***an indeterminate period of time***.

*Amendment*

2. The power to adopt delegated acts referred to in Article 46 shall be conferred on the Commission for ***five years from ... [the date of entry into force of the Regulation]. The Commission shall draw up a report in respect of the delegation of power no later than 9 months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.***

**Amendment 180**

**Proposal for a regulation  
Article 47 – paragraph 4**

*Text proposed by the Commission*

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

*Amendment*

4. Before adopting a delegated act, the Commission shall consult ***relevant stakeholders and*** experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

**Amendment 181**

**Proposal for a regulation  
Article 47 – paragraph 6**

*Text proposed by the Commission*

6. Delegated acts adopted pursuant to Article 46 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of ***two*** months of notification of that act to the European

*Amendment*

6. Delegated acts adopted pursuant to Article 46 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of ***three*** months of notification of that act to the European

Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *two* months at the initiative of the European Parliament or of the Council.

Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by *three* months at the initiative of the European Parliament or of the Council.

**Amendment 182**  
**Proposal for a regulation**  
**Article 48 – paragraph 1**

*Text proposed by the Commission*

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.

*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.  
***The requests shall be made publicly available in an easily accessible and user-friendly manner.***

**Amendment 183**  
**Proposal for a regulation**  
**Article 48 – paragraph 2**

*Text proposed by the Commission*

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.

*Amendment*

2. ***Without prejudice to the second subparagraph of this paragraph,*** 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 the 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 the 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 184**  
**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 ... [the first day of the month following 1 month after the date of entry into force of this Regulation], the*** 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 185**  
**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 186**  
**Proposal for a regulation**  
**Article 49 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**1a. The 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 187**  
**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. The ECHA may request the person submitting the request for assessment or any third party to submit additional information within a specified period. The ECHA shall take into account any information submitted by third parties.  
***When the 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 188**  
**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 189**  
**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 190**  
**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 191**  
**Proposal for a regulation**  
**Article 49 – paragraph 8 a (new)**

*Text proposed by the Commission*

*Amendment*

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

**Amendment 192**

**Proposal for a regulation**  
**Article 51 – paragraph 1 – introductory part**

*Text proposed by the Commission*

1. Competent national authorities, notified bodies and the Commission shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation:

*Amendment*

1. Competent national authorities, notified bodies, ***the ECHA*** and the Commission shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation:

**Amendment 193**

**Proposal for a regulation**

**Article 51 – paragraph 1 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) the effective implementation of this Regulation, in particular for the purpose of investigations, inspections or audits.***

**Amendment 194**

**Proposal for a regulation**

**Chapter IX a (new) – Article 52 a (new)**

*Text proposed by the Commission*

*Amendment*

***Chapter IXa***

***AMENDMENTS***

***Article 52a***

***Amendment to Directive 2014/53/EU***

***In Article 10(3) of the Directive 2014/53/EU the following text is added:***

***‘If the radio equipment is in a toy, the digital product passport established by Regulation (EU) 2024/... of the European Parliament and of the Council of..... on the safety of toys includes also the elements set out in Annex VI and Annex VII of this Directive.’***



## Amendment 195

### Proposal for a regulation Article 54 – paragraph 1

*Text proposed by the Commission*

1. Toys placed on the market in conformity with Directive 2009/48/EC before ... [OP please insert the date = the first day of the month following 30 months after the date of entry into force of this Regulation] may continue to be made available on the market until ... [OP please insert the date = the first day of the month following **42** months after the date of entry into force of this Regulation].

*Amendment*

1. Toys placed on the market in conformity with Directive 2009/48/EC before ... [OP please insert the date = the first day of the month following 30 months after the date of entry into force of this Regulation] may continue to be made available on the market until ... [OP please insert the date = the first day of the month following **50** months after the date of entry into force of this Regulation].

## Amendment 196

### Proposal for a regulation Article 54 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***1a. Toys placed on the market in conformity with Directive 2009/48/EC and compliant with this Regulation shall not be considered non-compliant solely due to the absence of a digital product passport, provided that the same information contained in the passport is made available by the manufacturer upon the request of the parties entitled to have access to the digital product passport under this Regulation.***

## Amendment 197

### Proposal for a regulation Article 54 – paragraph 2

*Text proposed by the Commission*

2. Chapter VII of this Regulation shall apply mutatis mutandis instead of Article

*Amendment*

2. Chapter VII of this Regulation shall apply mutatis mutandis instead of Article

42, 43 and 45 of Directive 2009/48/EC to toys which were placed on the market in conformity with that Directive before ... [PO insert date: the first day of the month following 30 months after the date of entry into force of this Regulation], including toys for which a procedure has already been initiated under Article 42 or 43 of Directive 2009/48/EC before ... [**PO insert date:** the first day of the month following **30** months after the date of entry into force of this Regulation].

## Amendment 198

### Proposal for a regulation Article 54 – paragraph 3

#### *Text proposed by the Commission*

3. EC type-examination certificates issued in accordance with Article 20 of Directive 2009/48/EC shall remain valid until ... [**PO insert date:** the first day of the month following **42** months after the date of entry into force of this Regulation], unless they expire before that date.

## Amendment 199

### Proposal for a regulation Article 55 – paragraph 1

#### *Text proposed by the Commission*

1. By ... [**OP please insert the date** = the first day of the month following **60** months after the date of entry into force of this Regulation] and every 5 years thereafter, the Commission shall carry out an evaluation of this Regulation. The Commission shall submit a report to the European Parliament and to the Council on the main findings.

42, 43 and 45 of Directive 2009/48/EC to toys which were placed on the market in conformity with that Directive before ... [PO insert date: the first day of the month following 30 months after the date of entry into force of this Regulation], including toys for which a procedure has already been initiated under Article 42 or 43 of Directive 2009/48/EC before ... [the first day of the month following **50** months after the date of entry into force of this Regulation].

#### *Amendment*

3. EC type-examination certificates issued in accordance with Article 20 of Directive 2009/48/EC shall remain valid until ... [the first day of the month following **50** months after the date of entry into force of this Regulation], unless they expire before that date.

#### *Amendment*

1. By ... [the first day of the month following **68** months after the date of entry into force of this Regulation] and every 5 years thereafter, the Commission shall carry out an evaluation of this Regulation. The Commission shall submit a report to the European Parliament and to the Council on the main findings. **The report shall assess:**

**1) whether this Regulation, and in particular the provisions in Chapter IV,**

*achieved the objective of ensuring a high level of protection of health and safety of children and shall assess the possibility to include adaptive toys in the scope of this Regulation;*

*2) the Regulation's effect on the safety of toys' users and the proper functioning of the internal market, as well as a detailed summary of the effects on businesses, including costs of operations and competitiveness, in particular for SMEs;*

*3) the presence of chromium, cadmium, mercury and lead in toys and their effect on the safety of toys' users.*

## Amendment 200

### Proposal for a regulation

#### Article 56 – paragraph 3

*Text proposed by the Commission*

However, Articles 17(10), 24 to 40, and 46 to 52, shall apply from ... [OP: please insert the date of entry into force of this Regulation].

*Amendment*

However, Articles **2(3)**, 17(10), 24 to 40, and 46 to 52, shall apply from ... [the date of entry into force of this Regulation].

## Amendment 201

### Proposal for a regulation

#### Annex I – Part II – point 3

*Text proposed by the Commission*

3. sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg;

*Amendment*

3. sports equipment, including roller skates, inline skates, and ***other means of transport, such as*** skateboards ***and scooters*** intended for children with a body mass of more than 20 kg;

## Amendment 202

### Proposal for a regulation

#### Annex I – Part II – point 5

*Text proposed by the Commission*

*Amendment*

**5. scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;**

**deleted**

## **Amendment 203**

### **Proposal for a regulation Annex I – Part II – point 14**

*Text proposed by the Commission*

*Amendment*

14. electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels;

14. electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals **or components**, unless the electronic equipment or the associated peripherals **or components** are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels;

## **Amendment 204**

### **Proposal for a regulation Annex I – Part II – point 19 a (new)**

*Text proposed by the Commission*

*Amendment*

**19a. Books intended for children older than 36 months, that are made entirely of paper or cardboard, without additional materials or components.**

## **Amendment 205**

### **Proposal for a regulation Annex II – Part I – point 9**

*Text proposed by the Commission*

9. Toys shall be designed and manufactured in such a way, in terms of the maximum values for impulse noise and continuous noise, that the sound from them is not able to impair children's hearing.

*Amendment*

9. Toys ***that are designed to emit a sound*** shall be designed and manufactured in such a way, in terms of the maximum values for impulse noise and continuous noise, that the sound from them is not able to impair children's hearing. ***The limit values shall be set through a delegated act, while the maximum values shall not exceed those set in Directive 2003/10/EEC.***

**Amendment 206**

**Proposal for a regulation**

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

*Text proposed by the Commission*

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

*Amendment*

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

**Amendment 207**

**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 208**

**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

*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 of this***

1272/2008 in any of the following categories is prohibited:

***Regulation 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 209**  
**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 210**  
**Proposal for a regulation**  
**Annex II – Part III – point 4 – point d a (new)**

*Text proposed by the Commission*

*Amendment*

(da) ***skin sensitisation category 1***;

**Amendment 211**  
**Proposal for a regulation**  
**Annex II – Part III – point 4 – point d b (new)**

*Text proposed by the Commission*

*Amendment*

(db) ***persistent, bioaccumulative and toxic***;

**Amendment 212**  
**Proposal for a regulation**  
**Annex II – Part III – point 4 – point d c (new)**

*Text proposed by the Commission*

*Amendment*

(dc) ***very persistent, very bioaccumulative***;

**Amendment 213**  
**Proposal for a regulation**  
**Annex II – Part III – point 4 – point d d (new)**

*Text proposed by the Commission*

*Amendment*

**(dd) persistent, mobile and toxic;**

**Amendment 214**  
**Proposal for a regulation**  
**Annex II – Part III – point 4 – point d e (new)**

*Text proposed by the Commission*

*Amendment*

**(de) very persistent, very mobile.**

**Amendment 215**  
**Proposal for a regulation**  
**Annex II – Part III – point 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**(4a) 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 216**  
**Proposal for a regulation**  
**Annex II – Part III – point 7 – point c**

*Text proposed by the Commission*

*Amendment*

**(c) toy components necessary for electronic or electric functions of the toy where the substance or mixture is fully inaccessible to children, including by inhalation.**

**(c) toy components necessary for electronic or electric functions of the toy where the substance or mixture is fully inaccessible to children, including by inhalation, *when the toy is used as specified in the first subparagraph of Article 5(2).***

**Amendment 217**  
**Proposal for a regulation**  
**Annex II – Part III – point 8**

*Text proposed by the Commission*

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 Council<sup>43</sup>.

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<sup>43</sup> 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*

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 Council<sup>43</sup>.

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<sup>43</sup> 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 218**

**Proposal for a regulation**  
**Annex II – Part IV – point 1 – paragraph 2**

*Text proposed by the Commission*

Internal voltages shall not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk for health and safety or any electric shock, even when the toy is broken.

*Amendment*

Internal voltages shall not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk for health and safety or any ***harmful*** electric shock, even when the toy is broken.

**Amendment 219**

**Proposal for a regulation**  
**Annex II – Part V – point 2**

*Text proposed by the Commission*

2. A toy intended for use by children under 36 months shall be designed and manufactured in such a way that it can be

*Amendment*

2. A toy intended for use by children under 36 months ***or intended to be put in the mouth*** shall be designed and



cleaned. A textile toy shall, to this end, be washable, except if it contains a mechanism that may be damaged if soaked. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

manufactured in such a way that it can be cleaned. A textile toy shall, to this end, be washable, except if it contains a mechanism that may be damaged if soaked. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

## Amendment 220

### 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. **N-nitrosamines and N-nitrosatable** substances are prohibited in toys where the migration of those substances is equal to or higher than:

<b>PRODUCT TYPE</b>		
	<b><i>N-nitrosamines mg/kg</i></b>	<b><i>N-nitrosatable substances mg/kg</i></b>
<b><i>a) toys intended for use by children under 36 months and intended or likely to be placed into the mouth</i></b>	<b><i>0,01</i></b>	<b><i>0,1</i></b>
<b><i>b) toys intended for use by children under 36 months not covered by a)</i></b>	<b><i>0,05</i></b>	<b><i>1</i></b>
<b><i>c) toys intended for use by children of 36 months and over and intended to be placed into the mouth</i></b>	<b><i>0,05</i></b>	<b><i>1</i></b>
<b><i>d) balloons</i></b>	<b><i>0,05</i></b>	<b><i>1</i></b>
<b><i>e) finger paints</i></b>	<b><i>0,02</i></b>	<b><i>1</i></b>

## Amendment 221

## 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 **10 mg/kg**:

## Amendment 222

## 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 **digital** 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 223

## Proposal for a regulation

### Annex III – point 1 – paragraph 2 – introductory part

*Text proposed by the Commission*

All warnings shall be preceded by the word ‘Warning’ or, alternatively, by a generic pictogram such as the following:

*Amendment*

All warnings shall be preceded by the word ‘Warning’ or, alternatively, by a generic pictogram such as the following **pictogram, which shall be displayed in a prominent way**:

## Amendment 224

## Proposal for a regulation

### Annex III – point 2 – paragraph 3

*Text proposed by the Commission*

These warnings shall be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

*Amendment*

***The pictogram shall be at least 10 mm diameter in size and shall contain a red circle with a white background and with the text and face in black colour.*** These warnings shall be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

**Amendment 225**

**Proposal for a regulation**

**Annex III – point 8 – paragraph 2 – introductory part**

*Text proposed by the Commission*

***Toys contained in*** food or co-mingled with ***food*** shall bear the following warning:

*Amendment*

***Packaging of food containing toys or packaging of*** food or co-mingled with ***toys*** shall bear the following warning:

**Amendment 226**

**Proposal for a regulation**

**Annex IV – Part I – point 4 – introductory part**

*Text proposed by the Commission*

4. CE marking and product passport

*Amendment*

4. CE marking and ***digital*** product passport

**Amendment 227**

**Proposal for a regulation**

**Annex IV – Part I – point 4 – point 4.2**

*Text proposed by the Commission*

4.2. The manufacturer shall draw up the product passport for a toy model and ensure that together with the technical documentation, it remains available for 10 years after the ***product*** has been placed on

*Amendment*

4.2. The manufacturer shall draw up the ***digital*** product passport for a toy model and ensure that together with the technical documentation, it remains available for 10 years after the ***last item of the toy model***

the market. The product passport shall identify the toy for which it has been drawn up.

has been placed on the market. The **digital** product passport shall identify the toy for which it has been drawn up.

#### Amendment 228

##### Proposal for a regulation Annex IV – Part II – point 9

###### *Text proposed by the Commission*

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the **toy** has been placed on the market.

###### *Amendment*

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the **last item of the toy model** has been placed on the market.

#### Amendment 229

##### Proposal for a regulation Annex IV – Part III – title

###### *Text proposed by the Commission*

III Conformity to type based on internal production control

###### *Amendment*

III **Module C:** Conformity to type based on internal production control

#### Amendment 230

##### Proposal for a regulation Annex IV – Part III – point 3 – introductory part

###### *Text proposed by the Commission*

3. CE marking and product passport

###### *Amendment*

3. CE marking and **digital** product passport

#### Amendment 231

##### Proposal for a regulation Annex IV – Part III – point 3 – point 3.2

*Text proposed by the Commission*

3.2. The manufacturer shall create a product passport for a toy model and ensure that it remains available for 10 years after the **toy** has been placed on the market. The product passport shall identify the toy for which it has been drawn up.

*Amendment*

3.2. The manufacturer shall create a **digital** product passport for a toy model and ensure that it remains available for 10 years after the **last item of the toy model** has been placed on the market. The **digital** product passport shall identify the toy for which it has been drawn up.

**Amendment 232**

**Proposal for a regulation**  
**Annex V – point 5**

*Text proposed by the Commission*

(5) Copies of documents that the manufacturer has submitted to any notified body,

*Amendment*

(5) Copies of documents that the manufacturer has submitted to any notified body, **where relevant;**

**Amendment 233**

**Proposal for a regulation**  
**Annex VI – subheading 1**

*Text proposed by the Commission*

PRODUCT PASSPORT

*Amendment*

**DIGITAL** PRODUCT PASSPORT

**Amendment 234**

**Proposal for a regulation**  
**Annex VI – Part I – title**

*Text proposed by the Commission*

I Information to be included in the product passport

*Amendment*

I Information to be included in the **digital** product passport

**Amendment 235**

**Proposal for a regulation**  
**Annex VI – Part I – point d**

*Text proposed by the Commission*

(d) object of the passport  
(identification of toy allowing traceability,  
*including a colour image of sufficient  
clarity to enable the identification of the  
toy;*

*Amendment*

(d) object of the passport  
(identification of toy allowing traceability);

**Amendment 236**

**Proposal for a regulation**  
**Annex VI – Part I – point j a (new)**

*Text proposed by the Commission*

*Amendment*

*(ja) the communication channel as  
provided for in Article 7(11);*

**Amendment 237**

**Proposal for a regulation**  
**Annex VI – Part I – point j b (new)**

*Text proposed by the Commission*

*Amendment*

*(jb) if the toy includes radio equipment  
the information provided for in Annex VI  
of Directive 2014/53/EU of the European  
Parliament and of the Council;*

**Amendment 238**

**Proposal for a regulation**  
**Annex VI – Part I – point j c (new)**

*Text proposed by the Commission*

*Amendment*

*(jc) a link to the Safety Business  
Gateway and to the section of the Safety  
Gate Portal referred to in Articles 27 and  
34(3) of Regulation 2023/988 for the  
transmission of information about toys*

*that might present a risk to the health and safety of consumers.*

#### **Amendment 239**

##### **Proposal for a regulation Annex VI – Part I – point k**

*Text proposed by the Commission*

*Amendment*

*(k) any substance of concern that is present in the toy.*      *deleted*

#### **Amendment 240**

##### **Proposal for a regulation Annex VI – Part II – title**

*Text proposed by the Commission*

*Amendment*

II Information that may be included in the product passport

II Information that may be included in the **digital** product passport

#### **Amendment 241**

##### **Proposal for a regulation Annex VI – Part II – point b a (new)**

*Text proposed by the Commission*

*Amendment*

*(ba) image or drawing of the toy.*

## EXPLANATORY STATEMENT

The EU single market for safe toys has been a major achievement for the protection of children while removing the barriers to the free movement of toys within the Union to the benefits of companies, which are mostly constituted by small and medium sized enterprises.

While it must be recognized that the framework built by Directive 2009/48/EC - the ‘Toy Safety Directive’ - has made the EU the safest place for toys in the world, new challenges have arisen, for example, from the changes in the purchasing habits brought by online marketplaces and from new technologies. Greater efforts must be undertaken to overcome these challenges, and reduce the number of unsafe toys circulating in the single market (toys are still amongst the most notified categories of products in the EU Safety Gate system for non-food dangerous products).

The current Toy Safety Directive should therefore be revised to ensure that consumers can count on a high level of safety for all products and that this safety is effectively monitored. This revision should also prioritise the removal of potential barriers to the development of disruptive technologies, as stated by the European Parliament in its resolution of 25 November 2020 on addressing product safety in the single market (2019/2190(INI)). Furthermore, the Parliament called for a broader approach for this revision through its resolution of 16 February 2022 on the implementation of the Toy Safety Directive (2021/2040(INI)), in order to enhance its effectiveness and efficiency and avoid implementation inconsistencies among Member States and market fragmentation.

The rapporteur is satisfied that the Commission has chosen a Regulation on toy safety to replace the Directive. This will not just strengthen the level of protection of children from possible risks but will also strengthen a harmonised protection system while providing for a level playing field between toys manufactured in the EU and abroad.

The key principle of the Rapporteur in drafting the report was therefore the protection of children as the most vulnerable consumers. With this perspective, the Rapporteur welcomes the ban on CMRs and endocrine disruptors, and, with regard to other chemicals, suggests a proportionate approach if children are not exposed to them.

With regard to the obligations for the economic operators, the rules for manufacturers, importers and distributors need to be coherent with currently adopted legislation, in particular the General Product Safety Regulation. Further to that, administrative burdens should be avoided, since they might create barriers to market access and will not help to improve toy safety. Additionally, SMEs need more help to comply with the future new set of rules set out by the Regulation. In particular, the product passport might cause an administrative burden to SMEs. The Rapporteur therefore suggests for the Commission to provide SMEs with tailor-made guidance on how to set up a product passport for their toys and also an automatic translation tools for the different languages of the Member States in which the SMEs want to make available their toys.

Issues may arise due to the fact that the new Ecodesign for sustainable products Regulation is not yet adopted, while this proposal refers to that Regulation when it comes to the use of the



digital product passport. In any case, even if the uncertainties concerning the digital product passport are addressed, the relevant information requirements in the context of the toy safety regulation should be applied only with regard to toy safety related matters and should not cover other elements, such as those related to the substances of concern. The specific environmental issues are subject to other pieces of legislation. Therefore, overlapping should be avoided, to allow legal certainty in the interest of consumers, companies and market surveillance authorities who will have to enforce the new rules.

Within this context, the product passport is an interesting solution as an effective tool for the market surveillance of products, including products entering the territory of the Union, but it could also do more than that. The Rapporteur has identified four specific aspects with regard to the product passport:

- a) it should allow consumers to get the information needed in case they want to complain about the safety of a product;
- b) it should replace all declarations of conformity, also the one foreseen in radio equipment directive;
- c) it should be organised in different sections with different access rights for market surveillance authorities and consumers, since sensitive commercial information and trade secrets should be protected;
- d) its technical specifications should be set out through delegated acts and at least 12 months after the entry into force of the legislation, to give the toy industry 18 months to adapt to the new system.

Furthermore, in general, industry needs enough time to adapt to new legislation, in particular because of the standards that need to be updated, the possible derogations and transitional period. The transitional period therefore should be modified.

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

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur declares that she has received input from the following entities or persons in the preparation of the report, until the adoption thereof in committee:

Entity and/or person
DG Internal Market, Industry, Entrepreneurship and SMEs, Bioeconomy, Chemicals, Cosmetics (European Commission)
HASBRO Spieleverlag
Deutscher Verband der Spielwarenindustrie e.V. (DVSI)
Toy Industries of Europe (TIE)
DEKRA
Deutscher Verband der Spielwarenindustrie e. V.
European Balloon & Party Council (EBPC)
The European Consumer Organisation (BEUC)
Verbraucherzentrale Bundesverband (VZBV)
The European consumer voice in standardisation (ANEC)
Independent Retail Europe
Permanent Representation Germany
HEJ Support International
Client Earth
Bundesamt für Risikobewertung
TÜV
Independent Retail Europe
Child Rights International Network (CRIN)
Handelsverband Deutschland (HDE)
Börsenverein des Deutschen Buchhandels e.V.
LEGO
Deutsches Institut für Normung (DIN)

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

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

### 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)**

**(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<sup>1a</sup> (8th EAP). Therefore, this Regulation should be implemented following the One Health approach.**

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**<sup>1a</sup> Decision (EU) 2022/591 of the European Parliament and of the Council**

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

**(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 of the 8th EAP.*

**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

*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***

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 Council<sup>33</sup>. Those generic prohibitions should apply to CMR substances, endocrine disruptors, respiratory sensitisers and substances targeting a specific organ, **as soon as those substances** are classified as hazardous under Regulation (EC) No 1272/2008<sup>34</sup>. 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.

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<sup>33</sup> **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).**

**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 Council<sup>33</sup>. 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 Council<sup>34</sup>. 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.

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<sup>33</sup> **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**

<sup>34</sup> *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).*

*Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).*

<sup>34</sup> *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).*

## 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*

(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 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 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.

*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 ***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<sup>1a</sup> 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.*

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*<sup>1a</sup> 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

*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.

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*.

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 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.

(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 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

*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.

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 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.

*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. ***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

*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

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 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.

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 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*

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

*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 ***exemptions*** 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 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*

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.

**Amendment 26**  
**Proposal for a regulation**  
**Article 46 – paragraph 9 a (new)**

*Text proposed by the Commission*

*Amendment*

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.

**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*

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.

*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.  
**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*

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.

*Amendment*

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 31**

**Proposal for a regulation**

**Article 49 – paragraph 1 a (new)**

*Text proposed by the Commission*

**Amendment 32**

**Proposal for a regulation**

**Article 49 – paragraph 2**

*Text proposed by the Commission*

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.

*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*

**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*

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*

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.

*Amendment*

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*

*Amendment*

(6) hazard class 4.1;

(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*

*Amendment*

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

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*

*Amendment*

4. The use in toys, components of toys or micro-structurally distinct parts of toys, of substances or mixtures classified in Part

4. The use in toys, components of toys or micro-structurally distinct parts of toys, of substances or mixtures **meeting the**

3 of Annex VI to Regulation (EC) No 1272/2008 in any of the following categories is prohibited:

***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 Council<sup>43</sup>.

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 Council<sup>43</sup>.

<sup>43</sup> 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).

<sup>43</sup> 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*

*Amendment*

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.

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*

*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 ***100 mg/kg***:

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
<b>Cadmium</b>	<b>1,3</b>	<b>0,3</b>	<b>17</b>
Chromium (III)	37,5	9,4	460
<b>Chromium (VI)</b>	<b>0,02</b>	<b>0,005</b>	<b>0,053</b>
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700

<b>Lead</b>	<b>2,0</b>	<b>0,5</b>	<b>23</b>
Manganese	1 200	300	15 000
<b>Mercury</b>	<b>7,5</b>	<b>1,9</b>	<b>94</b>
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*

<b>Element</b>	<b>mg/kg in dry, brittle, powder-like or pliable toy material</b>	<b>mg/kg in liquid or sticky toy material</b>	<b>mg/kg in scraped off toy material</b>
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
<b>Deleted</b>			
Chromium (III)	37,5	9,4	460
<b>Deleted</b>			
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
<b>Deleted</b>			
Manganese	1 200	300	15 000
<b>Deleted</b>			
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.

*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:

<b>Entity and/or person</b>
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

<b>Title</b>	Safety of toys and repealing Directive 2009/48/EC						
<b>References</b>	COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)						
<b>Committee responsible</b> Date announced in plenary	IMCO 19.10.2023						
<b>Opinion by</b> Date announced in plenary	ENVI 19.10.2023						
<b>Associated committees - date announced in plenary</b>	19.10.2023						
<b>Rapporteur for the opinion</b> Date appointed	Sara Cerdas 24.10.2023						
<b>Discussed in committee</b>	6.11.2023						
<b>Date adopted</b>	24.1.2024						
<b>Result of final vote</b>	<table> <tr> <td>+: </td><td>72</td></tr> <tr> <td>–: </td><td>0</td></tr> <tr> <td>0: </td><td>5</td></tr> </table>	+:	72	–:	0	0:	5
+:	72						
–:	0						
0:	5						
<b>Members present for the final vote</b>	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, Hélène 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 Spyraiki, Edina Tóth, Achille Variati, Petar Vitanov, Alexandr Vondra, Mick Wallace, Emma Wiesner, Michal Wiezik						
<b>Substitutes present for the final vote</b>	Asger Christensen, Christophe Clergeau, Margarita de la Pisa Carrión, Billy Kelleher, Sara Matthieu, Dace Melbārde, Idoia Villanueva Ruiz						
<b>Substitutes under Rule 209(7) present for the final vote</b>	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 Skyttedal, 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, Hélène Fritzson, 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



## PROCEDURE – COMMITTEE RESPONSIBLE

<b>Title</b>	Safety of toys and repealing Directive 2009/48/EC
<b>References</b>	COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)
<b>Date submitted to Parliament</b>	28.7.2023
<b>Committee responsible</b> Date announced in plenary	IMCO 19.10.2023
<b>Committees asked for opinions</b> Date announced in plenary	ENVI 19.10.2023
<b>Associated committees</b> Date announced in plenary	ENVI 19.10.2023
<b>Rapporteurs</b> Date appointed	Marion Walsmann 5.9.2023
<b>Discussed in committee</b>	28.11.2023      24.1.2024
<b>Date adopted</b>	13.2.2024
<b>Result of final vote</b>	+:                    37 –:                    0 0:                    0
<b>Members present for the final vote</b>	Andrus Ansip, Pablo Arias Echeverría, Alessandra Basso, Brando Benifei, Vlad-Marius Botoș, Anna Cavazzini, Dita Charanzová, Deirdre Clune, Sandro Gozi, Maria Grapini, Svenja Hahn, Virginie Joron, Eugen Jurzyca, Arba Kokalari, Marcel Kolaja, Andrey Kovatchev, Maria-Manuel Leitão-Marques, Morten Løkkegaard, Antonius Manders, Beata Mazurek, Leszek Miller, Anne-Sophie Pelletier, René Repasi, Christel Schaldemose, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Róza Thun und Hohenstein, Kim Van Sparrentak, Marion Walsmann
<b>Substitutes present for the final vote</b>	Claude Gruffat, Francisco Guerreiro, Petra Kammerevert, Antonio Maria Rinaldi, Kosma Złotowski
<b>Substitutes under Rule 209(7) present for the final vote</b>	César Luena, Tonino Picula
<b>Date tabled</b>	20.2.2024

## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

<b>37</b>	<b>+</b>
ECR	Eugen Jurzyca, Beata Mazurek, Kosma Złotowski
ID	Alessandra Basso, Virginie Joron, Antonio Maria Rinaldi
PPE	Pablo Arias Echeverría, Deirdre Clune, Włodzimierz Karpiński, Arba Kokalari, Andrey Kovatchev, Antonius Manders, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Marion Walsmann
Renew	Andrus Ansip, Vlad-Marius Botoș, Dita Charanzová, Sandro Gozi, Svenja Hahn, Morten Løkkegaard, Róza Thun und Hohenstein
S&D	Brando Benifei, Maria Grapini, Petra Kammerevert, Maria-Manuel Leitão-Marques, César Luena, Leszek Miller, Tonino Picula, Christel Schaldemose
The Left	Anne-Sophie Pelletier
Verts/ALE	Anna Cavazzini, Claude Gruffat, Francisco Guerreiro, Marcel Kolaja, Kim Van Sparrentak

<b>0</b>	<b>-</b>

<b>0</b>	<b>0</b>

Key to symbols:

+ : in favour

- : against

0 : abstention