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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC - Analysis of the final compromise text with a view to agreement

I. INTRODUCTION

1. On 28 July 2023, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC[1].

2. The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) and aims at further improving the protection of children from potential risks in toys, in particular from harmful chemicals, and strengthening enforcement, by requiring, among other things, that all toys to have a Digital Product Passport.

[1] ST 12234/23 + ADD 1-5

3. On 5 September 2023, the European Parliament's Committee on Internal Market and Consumer Protection (IMCO) appointed Marion Walsmann (EPP, DE) as rapporteur for the proposal. The Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament delivered its opinion on the proposal on 12 February 2024. IMCO voted on its final report on the proposal on 13 February 2024, which was adopted in the plenary on 13 March 2024.

4. The European Economic and Social Committee gave an opinion on the proposal on 13 December 2023[2].

5. The Working Party on Technical Harmonisation (Safety of Toys) started the examination of the proposal on 3 October 2023 under the Spanish Presidency. Since then, 19 additional Working Party meetings have taken place under the Spanish, Belgian, Hungarian and Polish presidencies.

6. Following the examination of the text under the Belgian Presidency, the Permanent Representatives Committee (hereafter 'Committee') adopted the Council's mandate on 15 May 2024.

7. The interinstitutional negotiations started with the first trilogue on 20 November 2024 under the Hungarian Presidency. Second and third trilogues took place on 18 March and 10 April 2025 respectively. In addition, 17 interinstitutional technical meetings were held.

8. The Committee was debriefed on the outcome of the last trilogue on 16 April 2025.

9. With a view to agreement on the Regulation on the safety of toys in an early second reading between the Council and the European Parliament, the Presidency submits to the Committee the outcome of the final trilogue in the form of a consolidated text of the draft Regulation.

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[2] ST 17090/23

II. ANALYSIS OF THE FINAL COMPROMISE TEXT WITH A VIEW TO AGREEMENT

10. The main elements of the provisional agreement are set out below.

11. The compromise text includes detailed provisions on the obligations of fulfilment service providers and online marketplaces. These provisions are in line with other Union acts like Construction Products Regulation and Digital Services Act.

12. The provisions on Digital Product Passport (DPP) are aligned with the Regulation on ecodesign requirements for sustainable products. The Commission is tasked to provide assistance to the SMEs in order to assist them in complying with the new requirements linked with the DPP. Furthermore, where the DPP includes all relevant information required under certain sectoral product legislation, the manufacturers are deemed to comply with the obligation to draw up an EU declaration of conformity under those sector specific rules.

13. The mental health aspect was deleted from the essential safety requirements. The co-legislators agreed to insert into Article 21 a requirement that the safety assessment must take into account the vulnerabilities of children, when the assessment is made on toys falling under the AI Act, the Cybersecurity act or the Radio Equipment Directive.

14. In addition, the provisional agreement includes a diluted reference to the precautionary principle in Article 1.

15. On chemicals provisions:

    a) the co-legislators agreed to prohibit the use of certain chemicals in toys:

        i) skin sensitizers category 1A;

        ii) per- and polyfluoroalkyl substances (PFAS) until the general restrictions under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or the Regulation on classification, labelling and packaging of substances and mixtures (CLP) will come into force;

iii) certain allergenic fragrances;

iv) ten bisphenols, which were added to a new Part D of the Appendix of Annex II. This Part D will also be under the Commission's empowerment to amend the Appendix by a delegated act;

v) nitrosamines and nitrosatable substances where the migration of those substances is higher than the migration limits set out in the provisional agreement;

b) migration limits were established for four additional monomers (vinyl chloride, acrylonitrile, styrene, butadiene);

c) the migration limits for four heavy metals (chromium VI, cadmium, lead and mercury) were kept as in the Commission proposal;

d) the Commission is empowered to amend the parts A, B and D of the Appendix of Annex II, including the provisions on nitrosamines and on the four heavy metals. It was agreed to spell out these delegated powers of the Commission in separate paragraphs for nitrosamines and the heavy metals, obliging the Commission to request an opinion from the European Chemicals Agency (ECHA) first.

16. The co-legislators agreed with the implementing acts for the establishment of common specifications, and with the delegated acts for the establishment of technical requirements for the digital product passport. The provisional agreement also specifies the date of application of this delegated act, which shall not be earlier than 18 months from its entry into force.

17. The provisional agreement includes the non-opinion clause for all implementing acts.

18. The Commission is requested to present the evaluation report by a date set at 38 months after the date of application of the Regulation. The content of the review clause was adapted at technical level, taking into account the agreements found in other parts of the text.

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19. The date of application of the new Regulation was set at 54 months after its entry into force.

20. During the final consolidation of the text, certain recitals and provisions were adjusted slightly to align them with the final compromises found at the last trilogue[3].

III. CONCLUSION

21. The Presidency invites the Committee of Permanent Representatives to analyse and approve the compromise text resulting from the final trilogue, as set out in the Annex to this note, with a view to agreement. This approval would be conditional upon the receipt of a letter from the Chair of the European Parliament's IMCO Committee confirming that the European Parliament can accept the text as set out in the Annex to this note and that, should the Council adopt this text as its first-reading position, the European Parliament would not adopt any amendments to it in its second reading.

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[3] Recitals 18, 23, 67; Articles 17(5); 21(2) point b; 46(-1) point f; 46(6); 48(1); 48(2) point b; 49(1); 49(5); Annex II, Part III, points 7a and 7b; Annex VII; numbering in all Annexes.

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ANNEX

2023/0290 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the safety of toys and repealing Directive 2009/48/EC

(Text with EEA relevance)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2009/48/EC of the European Parliament and of the Council[2] was adopted to ensure a high level of safety of toys and their free movement on the internal market.

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1 OJ C , , p. .

2 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

(2) Children are a particularly vulnerable group. It is essential to ensure a high level of safety ***for*** 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 ***might*** contain. At the same time, compliant toys should be able to move freely across the ***Union*** without additional requirements. ***Therefore, this Regulation should contribute to strengthening the internal market and improving its functioning while providing for a high level of consumer protection. Furthermore, adaptive toys, which are modified versions of toys designed to make play accessible for those with physical or cognitive limitations, constitute an emerging and quickly developing sector, which also requires a high level of safety for children when playing with such toys. Therefore, this Regulation should also apply to these toys.***

(3) The Commission evaluation of Directive 2009/48/EC concluded that ***that*** Directive is relevant and generally effective in protecting children. However, it also identified a number of deficiencies that have emerged during the practical application of ***that*** Directive since its adoption in 2009. In particular, the evaluation identified certain shortcomings with regard to possible risks arising from harmful chemicals in toys. The evaluation also concluded that many non-compliant and unsafe toys remain on the Union market.

(4) The Chemicals Strategy for Sustainability[3] called for strengthening the protection of consumers from the most harmful chemicals and to extending the generic approach towards harmful chemicals (based on generic preventive bans) to ensure that consumers, vulnerable groups and the environment are more consistently protected. In particular, the strategy commits to strengthen Directive 2009/48/EC with regard to the protection from the risks of the most harmful chemicals and possible combination effects of chemicals.

(5) Since the rules setting out the requirements for toys, in particular the essential ***safety*** requirements and the conformity assessment procedures, need to be of uniform application across the Union, and not give room for divergent implementation by Member States, Directive 2009/48/EC should be replaced by a regulation.

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[3] COM(2020) 667 final

(6) Toys are also subject to Regulation (EU) 2023/988 on general product safety[4], which applies in a complementary manner in matters not covered by specific sectoral legislation on consumer products. In particular, Section 2 of Chapter III and Chapter IV in relation to online sales, Chapter VI on the Safety Gate Rapid Alert System and Safety Business Gateway and Chapter VIII on the right of information and remedy also apply to toys. Therefore, this Regulation does not include specific provisions on ▌ accident reporting by economic operators and the right of information and remedy but rather requires economic operators providing information on safety issues concerning toys to inform authorities and consumers ***or other end-users*** in accordance with the procedures set out in Regulation (EU) 2023/988.

(7) Regulation (EC) No 765/2008 of the European Parliament and of the Council[5] lays down rules on the accreditation of conformity assessment bodies, and lays down the general principles of the CE marking. That Regulation should be applicable to toys in order to ensure that toys benefiting from the free movement of goods within the Union fulfil requirements providing a high level of protection of health and safety of persons and in particular children.

(8) Decision No 768/2008/EC of the European Parliament and of the Council[6] lays down common principles and reference provisions intended to apply across sectoral product legislation in order to provide a coherent basis for such legislation. This Regulation should therefore ***follow***, to the extent possible, ▌ those common principles and reference provisions.

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4 Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1).

5 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

6 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(9) This Regulation should lay down essential ***safety*** 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.

(10) To facilitate the application of this Regulation ▌, its scope should be clearly defined. It should apply to all products designed or intended for use in play by children under 14 years of age. A product ***could*** be considered as a toy even if it is not exclusively intended for playing purposes and has other additional functions. Whether a product has play value depends on the use envisioned by the manufacturer or on the use of the product reasonably foreseeable by a parent or a supervisor. At the same time, it is necessary to exclude from its scope certain toys which are not intended for domestic use, such as public playground equipment or automatic machines intended for public use, or other toys equipped with combustion or steam engines, as such toys may present risks to the health and safety of children that are not addressed by this Regulation. In addition, a list of products that could be confused with toys but are not to be considered toys within the meaning of this Regulation should be provided.

(11) This Regulation should apply to ▌ new toys made by a manufacturer established in the Union ***and to*** toys, whether new or second hand, imported from a third country ***and placed on the Union market***. The safety of other second hand ***toys which were already on the Union market*** falls within the scope of Regulation (EU) 2023/988 of the European Parliament and of the Council[7].

[7] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1).

(12) To ensure adequate protection of children and other persons, this Regulation should apply to all forms of supply of toys, including distance sales as referred to in Article 6 of Regulation (EU) 2019/1020 of the European Parliament and of the Council[8].

(13) Essential safety requirements for toys should ensure protection from all relevant health and safety hazards posed by toys, for users or third parties. Particular safety requirements should cover the physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity to ensure that the safety of children is adequately protected against those specific hazards. Since it is possible that toys which present hazards that are not covered by a particular safety requirement might exist or be developed, it is necessary to maintain a general requirement of safety to ensure protection of children in respect of such toys. The safety of toys should be determined by reference to the intended use, while taking into account also the foreseeable use, and bearing in mind the behaviour of children, who do not generally show the same degree of care as the average adult user. Together, the general safety requirement and the particular safety requirements should form the essential safety requirements for toys. ***The obligation for economic operators to comply with those essential safety requirements does not affect their obligations to comply with other Union law that may be applicable to toys and which address other aspects such as cybersecurity, environmental protection, the making available of hazardous substances and mixtures, or artificial intelligence.***

(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[9]. Toys ***with digital elements are to comply with Regulation (EU) …/…[P.O. insert serial number for Regulation on horizontal cybersecurity requirements for products with digital elements].***

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8 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

9 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).

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][10]. Therefore, ***this Regulation should not lay down*** particular safety requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys.

(14a) Under Regulation (EU) 2024/1689, toys with AI systems as safety components that require third-party conformity assessment are classified as high-risk AI systems. The choice by the manufacturer of the conformity assessment procedures for such toys, where there is a possibility to opt out of third party conformity assessment where harmonised standards have been applied, should not affect this classification as high-risk AI system under Article 6(1) of the AI Act. Furthermore, under Regulation (EU) 2024/2847 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) and require a third party conformity assessment, unless the manufacturer has applied relevant harmonised standards, common specifications or European cybersecurity certification schemes at assurance level at least 'substantial'.

(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.

(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 [redacted]. 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

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[10] 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.

the European Parliament and of the Council[11]. 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. ***Specific safety requirements to cover the potential hazard associated with the ingestion of strong magnets or expanding toy material that are capable of causing intestinal perforation or blockage should be laid down.*** 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.

(15a) Some toys are designed to emit sound (percussion cap toys, cap-firing toys, drums, rattles, toys that play music/sound etc). In order to protect children from the risk of impaired hearing, maximum values should be set for both impulse noise and continuous noise emitted by toys which are designed to emit a sound. However, toys that are not clearly designed to emit sound, but do emit a reproduceable sound when a child activates a mechanism such as a trigger on a toy gun, should also be designed so as to protect children from the risk of impaired hearing. Current scientific knowledge is not sufficiently precise on the effects on health and safety of children of sound emitted from toys, but research within the World Health Organisation has demonstrated the general vulnerability of children to noise induced hearing loss and the harmful effects for the development of children when developing hearing loss. While noise limits applicable in an occupational context address a different exposure to noise than sound emitted by toys, it should nonetheless be ensured that toys do not lead to the exposure of children to higher levels of sound than the ones which require employers to take measures for workers in accordance with Directive 2003/10/EEC. The maximum values for continuous noise and impulse noise in toys should take into account the type of toy and sound produced by the toy, in view of the intended and reasonably foreseeable use.

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[11] 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).

(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[12]. Those generic prohibitions should apply to CMR substances, endocrine disruptors, respiratory sensitisers***,*** substances targeting a specific organ ***and skin sensitizers***, as soon as those substances are classified as hazardous under Regulation (EC) No 1272/2008[13]. ▌

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[12] 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).

[13] 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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(16a) In order to ensure toy safety, prohibited substances should be acceptable at trace levels, including in recycled materials, but only if their presence at such levels is technologically unavoidable with good manufacturing practices and if the toy is safe. The non-intended presence level should be as low as reasonably achievable according to the ALARA principle. Generic concentration limits triggering classification of mixtures are set in Regulation 1272/2008 at 1000 mg/kg for carcinogenic or mutagenic categories 1A or 1B substances, at 3000 mg/kg for reprotoxic category 1A or 1B substances or at 100.000 mg/kg for specific target organ toxicant category 1. These limits are not sufficiently protective for children and should not be used as a basis for enforcement of the generic ban.

(17) In order to provide for flexibility where the safety of children is not compromised ***it may*** be possible to ***wholly or partly exempt the presence of a prohibited substance*** from the generic prohibitions of ▌ substances in toys. ***Exemptions from*** generic prohibitions permitting the ***presence*** of prohibited substances should be of general application and should only be possible where the ***presence*** of the relevant substance is considered safe for children***. In addition,*** there ***should be no suitable*** alternatives ***to the presence of*** the substance ***in the toys. The assessment of the suitability of alternatives should consider whether the elimination or substitution of such prohibited substance is possible, including the availability and technical feasibility of alternatives to replace or fulfil the function of the substance in the toy, as well as the safety of any alternative identified. Finally, exemptions should only be possible*** where the use of the substance is not prohibited in consumer articles under Regulation (EC) No 1907/2006. ▌

(17a) The assessment of the safety of the substance and the availability of suitable alternatives 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 in the Union. In order to ensure that exemptions to generic bans take into account any new technical or scientific knowledge, ECHA should conduct a periodic review of the opinions provided. This periodic review should be adapted to the specific substance and exemption granted in toys. ECHA should request the person who submitted the original request or any other third party to submit the information that it considers necessary for this periodic review.

(18) Economic operators, industry associations or other interested parties should have the possibility to submit a request for assessment for a permitted use concerning a certain substance subject to a generic prohibition to ECHA. ECHA should draw up and make available the format ▌ for the submission of requests for assessment. In addition, for reasons of transparency and foreseeability, ECHA should issue technical and scientific guidance on such requests for assessment.

(18a) In recent years, ECHA has been entrusted with new tasks set out in several pieces of legislation and ad hoc agreements. Given the important and central role envisaged for ECHA under this Regulation, ECHA should have adequate resources to ensure that it can deliver timely and reliable data and scientific evaluations to support the decision-making process on the chemical safety of toys.

(19) The ***presence*** of nickel ***and cobalt*** in stainless steel and in components that transmit electric current has been considered safe in toys by the Scientific Committee on Health, Environment and Emerging risks and should be allowed. Other substances that are necessary to transmit electric current should be permitted in toys to allow for the making available of electric toys if such substances are completely inaccessible for a child playing with the toy and therefore do not present a risk.

(20) As batteries are regulated by Regulation (EU) …/…[P.O. insert serial number for Regulation on batteries and waste batteries][35], 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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(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.

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(22) Directive 2009/48/EC includes limit values for certain substances in toys intended for children under 36 months or intended to be put in the mouth. Those substances have shown to also pose a risk to older children, as they could be equally exposed to such chemicals via skin contact or inhalation. These limit values should therefore apply to all toys. Since the adoption of the limit values for bisphenol A in Directive 2009/48/EC, new scientific data has emerged. The European Food Safety Authority (EFSA) re-evaluated the risks to public health from dietary exposure to bisphenol A in April 2023 concluding that exposure to bisphenol A is a health concern for consumers across all age groups. EFSA has established a new tolerable daily intake of bisphenol A which is significantly lower than the previous one. In view of this scientific evidence, bisphenol A should fall under the generic prohibition for CMR substances in toys. ***In order to verify compliance with this prohibition and to ensure that there is no exposure to any non intended presence of bisphenol A in toys, a migration limit should be provided. The migration limit should be set based on a limit of quantification with existing testing methods. For similar reasons, migration limits should also be introduced for some of the most commonly used monomers in the production of plastics.***

(22a) To avoid situations where one hazardous bisphenol is replaced with another that may be equally harmful, ECHA assessed available evidence of bisphenols as a group. To protect people and the environment, ECHA concluded that 34 bisphenols would need further EU regulatory risk management under the EU chemicals legislation as they may interfere with endocrine systems and affect reproduction. This number may change as more information is generated for these bisphenols and others where currently available evidence is inconclusive. Given that toys are addressed to a highly vulnerable group that should be protected from the exposure to harmful bisphenols, those 34 bisphenols identified by ECHA should not be present in toys. Some of these bisphenols are subject to harmonised classification under Regulation (EC) No 1272/2008 as toxic for reproduction or as endocrine disruptors. Therefore, they are already covered by the generic ban of harmful chemicals in toys set out in this regulation. It is necessary to ban the presence of the remaining bisphenols identified by ECHA but not already covered by other provisions prohibiting their use under this Regulation. When new information will become available, the provisions of this Regulation as regards bisphenols, should be updated.

(22b) Per- and polyfluorinated alkyl substances (PFAS) are a large family of more 10 000 man-made chemicals. PFAS have been used in an increasingly wide range of products, including consumer products. The persistency of all PFAS is the core concern leading to increasing environmental concentrations. Exposure to the most studied PFAS has been associated with a range of adverse health effects. The intentional use in toys, components of toys or micro-structurally distinct parts of toys, of per- and polyfluoroalkyl substances (PFAS) should be prohibited.

(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***, including a prohibition on the intentional use of certain allergenic fragrances in toys, in particular in toys intended for use by children under 36 months or other toys intended to be placed in the mouth,*** and for the labelling of ***certain allergenic*** fragrances. The Commission should be empowered to adopt delegated acts to amend those rules to allow for adaptations to technical and scientific progress.

(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. ***Warnings should always be marked 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 should have appropriate warnings affixed to them if the surface of the toy allows. If this is not possible, the warnings should be placed on the label. Manufacturers may also include warnings in digital format through the Digital Product Passport.***

(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 ***or reasonably foreseeable*** 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.

(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 visible.

(26) Economic operators should act responsibly and in full accordance with the legal requirements applicable when placing or making toys available on the market.

(27) In order to ensure a high level of protection of the health and safety of children and fair competition on the internal market, economic operators should be responsible for the compliance of toys with this Regulation, in relation to their respective roles in the supply chain.

(28) As certain tasks can be executed only by the manufacturer, it is necessary to distinguish clearly between the obligations of the manufacturer and the operators further down the distribution chain. It is also necessary to distinguish clearly between the obligations of the importer and the distributor, as the importer introduces toys from third countries to the Union market. The importer should make sure that those toys comply with the applicable Union requirements.

(29) In order to facilitate communication between economic operators, market surveillance authorities and consumers or other end-users, manufacturers and importers should indicate a website, email address or other digital contact in addition to the postal address.

(30) The manufacturer, having detailed knowledge of the design and production process, is responsible for the compliance of the toy with the requirements of this Regulation and is best placed to carry out the complete conformity assessment procedure for toys. Conformity assessment should therefore remain the obligation of the manufacturer alone.

(31) To facilitate compliance of the manufacturers with their obligations under this Regulation, manufacturers should be allowed to appoint an authorised representative to carry out specific tasks on their behalf. Moreover, to ensure a clear and proportionate distribution of tasks between the manufacturer and the authorised representative, it is necessary to set out a list of tasks that manufacturers should be allowed to entrust the authorised representative with. Further, to ensure the enforceability and compliance with this Regulation, where a manufacturer established outside the Union appoints an authorised representative, the mandate should include the tasks set out in Article 4 of Regulation (EU) 2019/1020.

(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 ***law***.

PUBLIC

(33) It is necessary to ensure that toys from third countries entering the Union market comply with all applicable Union requirements, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those toys. Importers should therefore ensure that the toys they place on the market comply with the applicable requirements, that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the competent market surveillance authorities.

(34) When placing a toy on the market, importers should indicate on the toy their name and the address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the toy does not allow for such an indication, including where importers would have to open the packaging to put their name and address on the product. In such cases, the name and address should be indicated on the packaging or an accompanying document.

(35) As the distributor makes a toy available on the market after the toy has been placed on the market by the manufacturer or the importer, the distributor should act with due care to ensure that the handling of the toy does not adversely affect the compliance of that toy with this Regulation.

(36) Distributors and importers are close to the market place and should therefore be involved in market surveillance tasks carried out by competent national authorities, and should be required to participate actively in such tasks and to provide those authorities with all necessary information relating to the toy concerned.

(36a) In order to increase compliance with the obligations under this Regulation and to improve market surveillance, where fulfilment service providers have reason to believe, on the basis of the information provided by authorities or economic operators, that a toy is not in conformity with this Regulation, they should not support the making available of the toy on the market until it has been brought into conformity. Under this Regulation, fulfilment service providers do not bear a responsibility for the conformity assessment of the toy. However, they should act with due care and ensure that the conditions during warehousing, packaging, addressing or dispatching, do not jeopardise the toy's conformity with the essential safety requirements. The Commission may issue

guidelines to assist fulfilment service providers in the application of obligations that they are subject to under this Regulation.

(37) ***Any natural or legal person*** that either ***places*** a toy on the market under their own name or trademark or ***carries out a substantial modification of*** a toy ***already placed on the market*** 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 Regulation*** and should assume the obligations of ***manufacturer***. ***A consumer or other end-user who carries out a substantial modification to his or her toy should not be considered to be a manufacturer for the purposes of this Regulation and should not be subject to the obligations of the manufacturer.***

(37a) Information referring to an offer of toys placed on the market or made available on the market which are not compliant with this Regulation should be considered illegal content within the meaning of Regulation (EU) 2022/2065 and trigger the specific due diligence obligations set out thereto for online intermediaries. The important role played by providers of online marketplaces when intermediating the sale of products between economic operators and consumers has justified the establishment of recent sets of rules, imposing new due diligence obligations to online marketplaces. Firstly, Regulation (EU) 2022/2065 of the European Parliament and of the Council regulates the responsibility and accountability of providers of intermediary services online with regard to illegal content, including dangerous products. Secondly, Regulation (EU) 2023/988 of the European Parliament and of the Council establishes specific responsibilities in tackling the sale of dangerous products online. Building on the horizontal legal framework provided by those Regulations, this Regulation should specify the requirements, in relation to toy safety, with which providers of online marketplaces are to comply in order to ensure compliance with certain provisions of Regulation (EU) 2022/2065. Those requirements should be consistent with the horizontal framework for online marketplaces under Regulation (EU) 2022/2065 and Regulation (EU) 2023/988. Furthermore, those requirements should not affect the application of Regulation (EU) 2022/2065, which continues to apply to those providers of online marketplaces.

PUBLIC

(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 available on the market.

(38a) In order to ensure efficient market surveillance of toys made available on the market, economic operators should be required to keep the compliance information and documentation of a toy for a period of 10 years after it has been placed on the market. This overall period is considered to last until 10 years after the last item of that toy model was placed on the market.

(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***[36]*** and published in the Official Journal of the European Union.

(40) In the absence of relevant harmonised standards, the Commission should be empowered to adopt implementing acts 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 ***safety*** requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. ***If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications. With a view to establishing, in the most efficient way, common specifications that cover the essential safety requirements of this Regulation, the Commission should duly consult relevant stakeholders in the process.***

PUBLIC

(41) The CE marking, indicating the conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Specific rules governing the affixing of the CE marking with regard to toys should be laid down in this Regulation. Those rules should ensure sufficient visibility of the CE marking in order to facilitate market surveillance of toys.

(42) Manufacturers should create a ***digital*** product passport to provide information on the compliance of toys with this Regulation and with other Union ***law*** applicable to toys. ***They should keep the digital product passport up to date and make any necessary changes when required. The digital*** 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. ***Furthermore, toys may fall within the scope of other Union law which requires an EU declaration of conformity.*** In order to ***reduce administrative burden, the digital*** product passport ***under this Regulation may also be used to comply with the obligation to draw up an EU declaration of conformity for a toy under the scope of other Union law requiring an EU declaration of conformity. Where the digital product passport is used as an EU declaration of conformity under other Union law applicable*** to the toy, ***manufacturers and other*** economic operators ▌ should ***be deemed to comply with their respective obligations in relation*** to the ***EU declaration of conformity under that other Union law***.

(42a) 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.

PUBLIC

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

(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[14] also lays down requirements and technical specifications for a ***digital*** product passport, the establishment of a Commission ***digital product passport*** registry ***(the 'registry')*** where passport information is stored and the interconnection of that registry with the customs IT systems. That Regulation ***might*** 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, in particular information related to environmental sustainability***. 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.

(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 responsibility thereof.

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14 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.

(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 ***or other end-users*** regarding the different types of information that are available to them in a digital format.

(46a) Most toy manufacturers subject to the requirements of this Regulation are micro, small and medium sized enterprises (SMEs). 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 on how to perform safety assessments and create a digital product passport for the toys they produce.

(47) Chapter VII of Regulation (EU) 2019/1020, setting up the rules for of controls on products entering the Union market applies to toys. The authorities in charge of controls, which in almost all Member States are the customs authorities, are to perform them on the basis of risk analysis as referred to in Articles 46 and 47 of Regulation (EU) No 952/2013 of the European Parliament and of the Council[15], its implementing legislation and the corresponding guidance. This Regulation therefore does not modify in any way Chapter VII of Regulation (EU) 2019/1020 and the way the authorities in charge of controls on products entering the Union market organise themselves and perform their activities.

(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.

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[15] Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (recast) (OJ L 269, 10.10.2013, p. 1).

(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 ***registration*** identifier ***communicated to the economic operator by the digital*** product passport registry established under Article ***13*** of [P.O. insert serial number for Regulation (EU) …/… on Ecodesign Requirements for Sustainable Products] (the 'registry'). Customs authorities should ***verify as a minimum that*** a valid reference to ***the*** unique ***registration*** identifier ***and the relevant commodity code for the toy provided or made available to them corresponds to the data that are stored*** in the registry***. This would allow customs authorities to verify that a digital product passport for imported toy exists***. To carry out that automatic verification, the interconnection between the registry and the customs IT systems as provided for in [Article ***15*** of Regulation (EU) …/… on ecodesign requirements for sustainable products] should be used.

▌

(51) The ***data*** included in the ***digital*** product passport ***are intended to allow*** customs authorities to ***enhance*** and facilitate risk management and ***enable the*** controls at the ***border to be better targeted***. Therefore, customs authorities should have the possibility to retrieve and use the ***data*** included in the ***digital*** product passport and the ***related*** registry for carrying out their tasks in accordance with Union ***law***, including for risk management in accordance with Regulation (EU) No 952/2013.

▌

(53) The automatic verification by customs ***authorities*** 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.

(54) Children are daily exposed to a wide range of different chemicals originating from various sources ***that have negative effects as individual substances or mixtures, but also through combined exposure***. Significant progress has been made to close some knowledge gaps on the impact of the combination effect of those chemicals. However, the safety of chemicals is ***currently*** usually assessed through the evaluation of single substances and in some cases of mixtures intentionally added for particular uses***. Further efforts are needed to better understand the impact of the combination effect of chemicals***. In order to provide the highest protection for children, 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.

(55) Manufacturers should prepare the technical documentation describing all relevant aspects of toys including the safety assessment of all hazards that the toy may present and how they have been addressed, to allow market surveillance authorities to perform their tasks efficiently. The manufacturer should be required to make that technical documentation available to national authorities on request or to notified bodies in the context of the relevant conformity assessment procedure.

PUBLIC

(55b) In the safety assessment, manufacturers should assess the chemical substances present in the toy and possible non intended presence of substances subject to generic bans or other restrictions and determine whether their presence at such levels is technically unavoidable with good manufacturing practices and whether the toy is safe. The assessment should determine the scope of possible testing especially for those substances that can reasonably be expected, under good manufacturing practices, to appear in the toy, including as traces.

(56) To ensure that toys comply with the essential ***safety*** requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Internal production control based on the manufacturer's own responsibility for the conformity assessment is adequate where it has followed the harmonised standards, the reference of which has been published in the ***Official Journal of the European Union***, or common specifications covering all the particular safety requirements for the toy. In cases where such harmonised standards or common specifications do not exist, the toy should be submitted to third party verification, in this case EU-type examination. The same should apply if one or more such standards has been published with a restriction in the ***Official Journal of the European Union***, or if the manufacturer has not followed such standards or specifications completely, or only in part. The manufacturer should submit the toy to EU-type examination in cases where it considers that the nature, design, construction or purpose of the toy necessitates third party verification.

(57) Since it is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of toys throughout the Union, and since all such bodies should perform their functions to the same level and under conditions of fair competition, requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services under this Regulation.

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

(59) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should be used for the purposes of notification. In particular, transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be the only means of demonstrating the technical competence of conformity assessment bodies.

(60) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for toys to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries. In particular, excessive recourse to subsidiaries and subcontractors, in a manner that would call into question the competence of the notified body or its supervision by the notifying authority should be avoided.

(61) In order to ensure a consistent level of quality in the performance of conformity assessment of toys, it is necessary not only to consolidate the requirements that conformity assessment bodies wishing to be notified must fulfil, but also, in parallel, to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.

(62) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies. The Commission should by way of implementing acts request the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification.

(63) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies. Such coordination and cooperation should respect the Union competition rules.

(64) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Union ***law***. Regulation (EU) 2019/1020 sets out the framework for market surveillance of products subject to Union harmonisation legislation, including toys. Since this Regulation replaces Directive 2009/48/EC, the rules on market surveillance and controls on products entering the Union market set out in Regulation (EU) 2019/1020, including the specific requirement set out in Article 4 of that Regulation that toys are to be placed on the market only if there is an economic operator established in the Union responsible for the tasks specified in that Article, continue to apply to toys. Member States should therefore organise and carry out market surveillance of toys in accordance with that Regulation.

(65) Directive 2009/48/EC provides for a safeguard procedure allowing the Commission and other Member States to examine the justification for a measure taken by a Member States against toys that the Member State considers to be non-compliant. That procedure ensures that interested parties are informed of measures intended to be taken with regard to toys posing a risk to the health or safety of persons and that such toys are consistently addressed by all market surveillance authorities in the Union market The procedure should therefore be maintained.

(66) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required. Where there are objections to such a measure, the Commission should, by means of implementing acts, determine whether a national measure in respect of a toy is justified.

PUBLIC

(67) Experience with Directive 2009/48/EC has shown that new toys available on the market which were compliant with the applicable particular safety requirements when placed on the market have in specific cases posed a risk to children and therefore do not comply with the general safety requirement. Provisions should be made to ensure that market surveillance authorities can take action against any toy presenting a risk to children, even when it is compliant with the particular safety requirements. ▌

(67a) Under Regulation (EU) 2019/1020 market surveillance authorities are required to communicate, through the information and communication system on market surveillance, information on toys for which an in depth inspection has been conducted, including measures or corrective action taken as well as available information on injuries caused by such toys. Furthermore, under 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. Such information should be taken into consideration for the purposes of assessing the effectiveness of this Regulation, as part of the evaluation process.

(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.

(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 ***supplementing this Regulation by determining the technical requirements of the digital product passport, and 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.

(70) In order to facilitate the work of customs authorities in relation to toys and their compliance with the requirements set out in this Regulation, 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 the list of commodity codes and product descriptions to be used for customs controls in accordance with this Regulation on the basis of Annex I to Regulation (EEC) No 2658/87 of the European Parliament and of the Council[16].

(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[17]. 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.

(72) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission ▌ 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[18].

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16 ***[1]*** Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, OJ L 256, 7.9.1987, p. 1.

17 OJ L 123, 12.5.2016, p. 1.

18 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).

(73) Member States should provide for penalties applicable to infringements of this Regulation. Those penalties should be effective, proportionate and dissuasive.

(74) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements laid down by this Regulation, it is necessary to provide for a transitional period during which toys which comply with Directive 2009/48/EC may be placed on the market. ▌

(75) Since the objective of this Regulation, namely to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

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, ***taking due account of the precautionary principle,*** and on the free movement of toys in the Union.

Article 2

Scope

1. This Regulation applies to products which are designed or intended, whether or not exclusively, for use in play by children under 14 years of age (‘toys’).

For the purposes of this Regulation, a product shall be considered to be intended for use in play by children under 14 years of age ▌, 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 ***a*** relevant age group.

2. This Regulation does not apply to the products listed in Annex I.

3. The Commission ***is*** 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(3)***. ***The date of application of such implementing acts shall not be earlier than 18 months from its entry into force, except in duly justified cases, or except in cases where certain categories of products are deemed not to fulfil the criteria in paragraph 1, where an earlier date of application may be set.***

Article 3

Definitions

For the purposes of this Regulation the following definitions apply:

(1) 'making available on the market' means any supply of a toy for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(2) 'placing on the market' means the first making available of a toy on the Union market;

(3) 'manufacturer' means any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under that person's name or trademark;

(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***;

(5) 'importer' means any natural or legal person established within the Union who places a toy from a third country on the Union market;

(6) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a toy available on the market;

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

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

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

(10) ‘harmonised standard’ means a harmonised standard as defined in Article 2, point (1), of Regulation (EU) No 1025/2012;

(11) ‘Union harmonisation legislation’ means Union ***law*** listed in Annex I to Regulation (EU) 2019/1020 and any other Union ***law*** harmonising the conditions for the marketing of products to which that Regulation applies;

(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;

(12) ‘CE marking’ means a marking by which the manufacturer indicates that the toy is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(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;

(13) ‘toy model’ means a group of toys that meet the following conditions:

(a) they are under the responsibility of the same manufacturer,

(b) they have uniform design and technical characteristics,

(c) they are manufactured using uniform materials and manufacturing processes,

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(d) they are defined by a type number or other element allowing them to be identified as a group;

(14) 'data carrier' means ***data carrier as defined in Article 2 paragraph 1, point 29 of Regulation (EU) .../...) [OJ insert serial number for Ecodesign Requirements for Sustainable Products***;

(14a) 'digital product passport' means a set of data specific to a toy that contains the information set out in Annex VI and that is accessible via electronic means through a data carrier in accordance with Chapter IV;

(15) 'unique product identifier' means unique ***identifier as defined in Article 2 paragraph 1, point 30 of Regulation (EU) .../...) [OJ insert serial number for Ecodesign Requirements for Sustainable Products]***;

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

(16a) 'digital product passport service provider' means a natural or legal person that is an independent third-party authorised by the economic operator which is required to create a product passport for a toy and that processes the digital product passport data for that toy for the purpose of making such data available to economic operators and other relevant actors with a right to access those data under this Regulation or other Union law;

(17) 'release for free circulation' means the customs procedure laid down in Article 201 of Regulation (EU) No 952/2013;

(18) 'customs authorities' means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013;

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(19) ‘EU Customs Single Window Certificates Exchange System’ means the system referred to in Article 4 of Regulation (EU) 2022/2399 of the European Parliament and of the Council[19];

(20) ‘conformity assessment’ means the process demonstrating whether the essential ***safety*** requirements relating to a toy have been fulfilled;

(21) ‘conformity assessment body’ means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;

(22) ‘accreditation’ means accreditation as defined in Article 2, point (10), of Regulation (EC) No 765/2008;

(23) ‘national accreditation body’ means a national accreditation body as defined in Article 2, point (11), of Regulation (EC) No 765/2008;

(24) ‘hazard’ means a potential source of harm;

(25) ‘risk’ means the combination of the probability of an occurrence of a hazard and the degree of severity of the harm caused by that hazard;

(26) ‘recall’ means any measure aimed at achieving the return of a toy that has already been made available to the end user;

(27) ‘withdrawal’ means any measure aimed at preventing a toy in the supply chain from being made available on the market;

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

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[19] Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013 (OJ L 317, 9.12.2022, p. 1).

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(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;

(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 installation;

(30) 'aquatic toy' means a toy that is intended for use in shallow water and which is capable of carrying or supporting a child in the water;

(31) 'activity toy' means a toy for domestic use in which the support structure remains stationary while the activity is taking place and which is intended for climbing, jumping, swinging, sliding, rocking, spinning, crawling, creeping, or any combination thereof;

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

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

(34) 'cosmetic kit' means a toy the purpose of which is to assist a child to learn to make cosmetic products such as fragrances, soaps, creams, shampoos, conditioners, bath foams, tooth pastes as well as glosses, lipsticks***, nail polish*** and other make-up;

(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;

(35a) 'PFAS' means any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).

Article 4

Free movement

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.

2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a toy which does not comply with this Regulation, provided that a visible sign clearly indicates that the toy does not comply with this Regulation and will not be available on the market until it has been brought into conformity.

   During fairs, exhibitions and demonstrations, adequate measures shall be taken by economic operators to ensure the protection of persons.

Article 5

Essential safety **requirements** ▌

1. Toys shall only be placed on the market if they comply with the essential safety requirements which include the safety requirement set out in paragraph 2 (the 'general safety requirement') and the safety requirements set out in Annex II (the 'particular safety requirements').

2. 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 way, bearing in mind the behaviour of children.

   When assessing the risk referred to in the first subparagraph, the ability of the users and, where appropriate, their supervisors shall be taken into account. Where a toy is intended for use by children under 36 months or by another specified age groups, the ability of users in that specific age group shall be taken into account.

3. Toys placed on the market shall comply with the essential safety requirements during their foreseeable period of use.

Article 6

Warnings

1. Where necessary to ensure their safe use, toys shall bear ***warnings*** specifying appropriate user limitations. The user limitations shall 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.

2. The ▌ categories of toys ***listed in Annex III*** shall bear warnings in accordance with the rules for each category set out in ***that*** Annex**.**

▌

Toys shall not bear one or more of the warnings set out in Annex III where such warnings conflict with the intended use ***or reasonably foreseeable use*** of the toy, as determined by virtue of its function, dimension and characteristics.

3. 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 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.***

Warnings ***as set out in paragraphs 1 and 2*** shall be clearly visible to the consumer before the purchase, including in cases where the purchase is made through distance sales. Warnings shall ***comply with the*** visibility ***and legibility criteria set out in Annex III***.

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.

CHAPTER II
OBLIGATIONS OF ECONOMIC OPERATORS

PUBLIC

Article 7

Obligations of manufacturers

1. When placing toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements.

2. Before placing toys on the market, manufacturers shall draw up the required technical documentation in accordance with Article 23 and carry out the applicable conformity assessment procedure in accordance with Article 22 or have it carried out.

   Where compliance of a toy with the applicable requirements laid down in this Regulation has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall, before the toy is placed on the market:

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

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

   (c) affix the CE marking in accordance with Article 16(1);

   (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).

3. ***Manufacturers shall ensure that the technical documentation referred to in paragraph 2 is up to date. Furthermore,*** manufacturers shall keep the technical documentation and the ***digital*** product passport for a period of 10 years after the toy covered by that documentation and ***digital*** product passport has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for toys that are part of a series production to remain in conformity with this Regulation. Changes in the design or characteristics of toys, and changes in the harmonised standards referred to in Article 13 or the common specifications referred to in Article 14 by reference to which conformity of a toy is declared or by application of which its conformity is verified, shall be adequately taken into account.

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

5. Manufacturers shall ensure that toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.

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 ***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.

7. Manufacturers shall ensure that the toy is accompanied by instructions ***for use*** and 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***, including for persons with disabilities if feasible***.

7a. Manufacturers shall ensure that the toy is marked with warnings in accordance with Article 6 in a language or languages easily understood by consumers and other end-users, as determined by the Member State concerned.

PUBLIC

8. 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.

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

(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 *27* of Regulation (EU) 2023/988, giving details, in particular, of any non-compliance and of any corrective measures taken; and

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

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it, with all the information and documentation necessary to demonstrate the conformity of the toy, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

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-compliance*** that the manufacturers have identified.

The manufacturer shall ensure that the fulfilment service providers are provided with the detailed information necessary for ensuring the safe storage, packaging, addressing or dispatch.

PUBLIC

11. Manufacturers shall make publicly available ***communication channels such as*** a telephone number, an electronic address, a dedicated section of their website [redacted], 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.

12. Manufacturers shall investigate complaints and information referred to in paragraph 11 and shall keep an internal register of those complaints and that information, as well as of recalls and any other corrective measures taken to bring the toys into conformity with this Regulation.

13. The internal register referred to in paragraph 12 shall only contain personal data that are necessary for the manufacturer to investigate the complaint or the information referred to in paragraph 11. Such data shall only be kept as long as is necessary for the purpose of the investigation and, in any event, no longer than 5 years after the data have been entered in the register.

Article 8

Authorised representatives

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

2. The obligations laid down in Article 7(1), and the obligation to draw up technical documentation referred to in Article 7(2), shall not form part of the authorised representative's mandate.

3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer and shall provide a copy of the mandate to the market surveillance authorities upon their request. The mandate shall allow the authorised representative to do at least the following:

(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 toy covered by ***that documentation and that digital product passport*** has been placed on the market;

(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 a language which can be easily understood by that authority***;

(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.

(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.

4. Where a manufacturer not established in the Union appoints an authorised representative as referred to in paragraph 1 of this Article, the written mandate shall include the tasks set out in Article 4(3) of Regulation (EU) 2019/1020.

4a. Where there is reason to believe that a toy is non-compliant or presents a risk, authorised representatives shall immediately inform the market surveillance authorities thereof.

Article 9

Obligations of importers

1. Importers shall only place on the market toys complying with this Regulation.

2. Before placing toys on the market, importers shall ensure the following:

(a) the manufacturer has carried out the appropriate conformity assessment procedure and drawn up the technical documentation referred to in Article 7(2);

(b) the toy is accompanied by instructions ***for*** use and safety information in accordance with ▌ Article 7(7) ***and warnings in accordance with Article 6*** in a language or languages which can be easily understood by consumers or other end-users, as determined by the Member State concerned;

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

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

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

(f) ▌ the CE marking ***is affixed*** in accordance with Article 16;

(g) the manufacturer has complied with the requirements set out in Article 7(5) and (6).

Where importers consider, or have reason to believe, that a toy is not in conformity with ***this Regulation***, they shall ***inform the manufacturer and refrain from placing*** the toy on the market until it has been brought into conformity.

Furthermore, where importers consider, or have reason to believe, that the toy presents a risk, ***importers*** shall ▌ :

(a) ***immediately inform*** the manufacturer ***thereof***;

(b) ***ensure that*** the market surveillance authorities ***are immediately informed*** via the Safety Business Gateway referred to in Article ***27*** of Regulation (EU) 2023/988 **.**

▌

PUBLIC

3. Importers 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 ***feasible***, on its packaging or in a document accompanying the toy ***or in the digital product passport***.

4. Importers shall ensure that, while a toy is under their responsibility, their storage or transport conditions do not jeopardise the toy's compliance with the essential safety requirements.

5. When ***deemed appropriate*** with regard to the risks presented by a toy, ***importers shall,*** for the protection of health and safety of consumers or other end-users, carry out sample testing of marketed toys.

6. Where importers 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.

Furthermore, where importers consider, or have reason to believe, that a toy that they have placed on the market presents a risk ▌, they shall immediately***:***

(a) inform the manufacturer thereof;

(b) ensure that consumers or other end-users are immediately informed thereof in accordance with Article 35 or 36, or both of Regulation (EU) 2023/988;

(c) inform the market surveillance authorities via the Safety Business Gateway referred to in Article 27 of Regulation (EU) 2023/988 giving details, in particular, of the non-compliance and of any corrective measures taken.

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.

PUBLIC

8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the toy in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

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 ▌ communication ***channels are*** not available, importers shall provide for ***them***, taking into account accessibility needs for persons with disabilities.

10. Importers shall investigate complaints and information referred to in paragraph 9 of this Article that they have received via a communication channel made available by the manufacturer, or via a communication channel made available by the importers themselves, and that concern the toys which they have made available on the market. Importers shall file those complaints, as well as recalls and any other corrective measures taken to bring the toys into conformity with this Regulation, in the register referred to in Article 7(12), or in their own internal register.

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.

11. Personal data contained in the internal register of the importers referred to in paragraph 10 shall only be those personal data that are necessary for the importer to investigate the complaint or the information referred to in paragraph 9. Such data shall only be kept as long as is necessary for the purpose of the investigation and, in any event, no longer than 5 years after the data have been entered in the register.

PUBLIC

PUBLIC

Article 10

Obligations of distributors

1. When making a toy available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making a toy available on the market, distributors shall verify that the following conditions have been met:

   (a) the toy is accompanied by instructions ***for use*** and safety information ***in accordance with Article 7(7) and warnings in accordance with Article 6*** 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;

   (b) the ▌ data carrier ***is affixed*** in accordance with Article 17(5) and the CE marking in accordance with Article 16 and

   (c) the manufacturer and the importer have complied with the requirements set out in Article 7(2), second subparagraph, Article 7(5), (6) and (11) and Article 9(3) respectively.

   Where distributors consider, or have reason to believe, that a toy is not in conformity with ***this Regulation***, they shall ***inform the manufacturer or importer and refrain from making*** the toy available on the market until it has been brought into conformity.

   Where distributors consider, or have reason to believe, that the toy presents a risk, they shall ▌ :

   (a) ***immediately inform*** the manufacturer or the importer***, as applicable, thereof***;

   (b) ***ensure that*** the market surveillance authorities ***are immediately informed*** through the Safety Business Gateway referred to in Article ***27*** of Regulation (EU) 2023/988;

3. Distributors shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential safety requirement.

4. 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 ***immediately*** taken.

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

5. Distributors shall, further to a reasoned request from a competent national authority, provide it, with all the information and documentation necessary to demonstrate the conformity of the toy, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have made available on the market.

Article 10a

Obligations of fulfilment service providers

1. When contributing to the making available on the market of a toy, a fulfilment service provider shall act with due care in relation to the requirements of this Regulation.

2. A fulfilment service provider shall ensure that the conditions during warehousing, packaging, addressing or dispatching, do not jeopardise the toy's conformity with the essential safety requirements.

PUBLIC

3. ***A fulfilment service provider shall cooperate as regards product withdrawals or recalls, regardless of whether initiated by authorities, the manufacturer, the authorised representative or the importer.***

4. ***Where a fulfilment service provider considers or has reason to believe, on the basis of the information provided by authorities or economic operators, that the toy is not in conformity with this Regulation, the fulfilment service provider shall not support the making available of the toy on the market until it has been brought into conformity.***

Article 11

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

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 ***carries out a substantial modification on*** a toy already placed on the market in such a way that compliance with the applicable requirements of this Regulation may be affected ***and makes it available on the market***. ***A modification of a toy, by physical or digital means after a toy has been placed on the market, shall be deemed to be substantial where it has not been foreseen or planned by the manufacturer and it affects the safety of that toy, by creating a new hazard or by increasing an existing risk. A consumer or other end-user who carries out a substantial modification to his or her toy shall not be considered to be a manufacturer for the purposes of this Regulation and shall not be subject to the obligations on the manufacturer set out in Article 7.***

Article 12

Identification of economic operators

1. Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a toy;

(b) any economic operator to whom they have supplied a toy.

2. Economic operators shall be able to present the information referred to in the paragraph 1 for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and for a period of 10 years after they have been supplied with the toy, in the case of other economic operators.

Chapter IIa

Obligations of online marketplaces

Article 12a

Specific obligations of providers of online marketplaces related to toy safety

1. Information referring to an offer of toys sold or promoted in online marketplaces intermediating between economic operators and consumers which are not in conformity with this Regulation shall be considered illegal content for the purposes of Regulation (EU) 2022/2065 and subject to the measures established therein.

2. For the purposes of this Regulation, providers of online marketplaces shall comply with the requirements set out in Articles 30 to 32 of Regulation (EU) 2022/2065 and Article 22 of Regulation (EU) 2023/988. The compliance with such requirements shall be enforced within the enforcement structure set out in those Regulations.

3. For the purposes of compliance with Article 31(2)(c) of Regulation (EU) 2022/2065, and in addition to the information required in Article 22(9) of Regulation (EU) 2023/988, providers of online marketplaces shall ensure that their online interface is designed and organised in a way that it allows economic operators to provide:

(a) the CE marking referred to in Article 16;

(b) any warning to be clearly visible to the consumer before the purchase in accordance with Article 6(3) of this Regulation;

(c) the data carrier or weblink through which the digital product passport referred to in Article 17 is accessible.

4. Any toy that does not comply with the particular safety requirements, or that complies with the particular safety requirements but which poses a risk to the health and safety of children and other persons, shall be considered a dangerous product for the purposes of compliance with Article 22 of Regulation (EU) 2023/988.

5. The Commission may issue guidelines to assist economic operators and providers of online marketplaces in the application of paragraphs 1 and 2.

CHAPTER III
CONFORMITY OF TOYS

Article 13

Presumption of conformity *of toys*

Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the essential safety requirements to the extent that those requirements are covered by those standards or parts thereof.

Article 14

Common specifications

1. Toys which are in conformity with the common specifications referred to in paragraph 2 of this Article or parts thereof shall be presumed to be in conformity with the essential safety requirements to the extent that those requirements are covered by those common specifications or parts thereof.

2. ***In exceptional cases,*** the Commission may ***adopt*** implementing acts ***establishing*** common specifications ***covering requirements that provide a means to comply with the applicable*** essential safety requirements***.***
Those implementing acts shall only be adopted where the following conditions are fulfilled:

(a) there is no harmonised standard covering those requirements the reference of which is published in the Official Journal of the European Union ***and no such reference is expected to be published within a reasonable period***;

(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 requirements and ▌ :

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

(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:

(a) ***are not delivered*** 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.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50(3).

2a. Before preparing the draft implementing act referred to in paragraph 2, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 2 have been fulfilled.

PUBLIC

When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the Expert Group on Toys Safety and shall duly consult all relevant stakeholders.

▌

3. ***Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference*** of a harmonised standard ***is*** published in the Official Journal of the European Union, the Commission shall ***repeal or amend*** the implementing acts referred to in paragraph 2***, or parts thereof*** which cover the same essential safety ***requirements as those covered by that harmonised standard***.

4. When a Member State considers that a common specification does not entirely satisfy the essential safety requirements, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.

Article 15

General principles of the CE marking

Toys made available on the market shall bear the CE marking.

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 16

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly ***on*** the toy ***or on*** a label attached to the toy***. Where this is not possible on account of size or nature of the toy, it shall be affixed*** to the packaging***, if any, or on documentation accompanying*** the toy.

▌

Where the CE marking ▌ is not visible from outside the packaging, it shall also be affixed to the packaging.

2. The CE marking shall be affixed before the toy is placed on the market.

3. The CE marking ***may***, where applicable in accordance with Article 6, be followed by a pictogram or any other warning indicating a special risk or use.

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER IV

DIGITAL PRODUCT PASSPORT

Article 17

Digital **product passport**

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

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

(a) correspond to a specific toy model;

(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;

(c) contain at least the ***data*** set out in Part I of Annex VI;

(d) be ***accurate, complete and*** up to date;

(e) be available in the language or languages required by the Member State where the toy is made available on the market;

(f) be accessible to consumers or other end-users, market surveillance authorities, customs authorities, notified bodies, the Commission and other economic operators ***in accordance with the access rights set out pursuant to Article 46(-1) point (d)***;

(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 ***digital*** product passport;

(h) be ***connected*** through a data carrier ***to a persistent unique product identifier***;

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

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

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

4a. Where the digital product passport created in accordance with this Regulation for a toy includes all the information required for the declaration of conformity under, as applicable, Regulation (EU) 2024/2847, Regulation (EU) 2024/1689, Commission Delegated Regulation (EU) 2019/945, Directive 2014/53/EU, Directive 2014/35/EU, Directive 2014/30/EU, and/or Directive 2011/65/EU:

PUBLIC

(a) manufacturers and, where applicable, providers of high-risk AI systems, shall be deemed to comply with the obligation to draw up an EU declaration of conformity under, as applicable, Article 13(12) of Regulation (EU) 2024/2847, Article 16 (g) of Regulation (EU) 2024/1689, Article 6 (2) of Commission Delegated Regulation (EU) 2019/945, Article 10(3) of Directive 2014/53/EU, Article 6(2) of Directive 2014/35/EU, Article 7(2) of Directive 2014/30/EU, and/or Article 7(c) of Directive 2011/65/EU;

(b) manufacturers shall also be deemed to comply, where applicable, with obligation under Article 13(20) of Regulation (EU) 2024/2847, Article 6(8) of Commission Delegated Regulation (EU) 2019/945 and/or Article 10(9) of Directive 2014/53/EU;

(c) by drawing up the digital product passport, manufacturers shall assume responsibility for the compliance of the toy with the requirements laid down in the relevant Regulations and/or Directive(s);

(d) economic operators and, where applicable, providers of high-risk AI systems shall use the digital product passport to fulfil their obligations related to the declaration of conformity under, as applicable, Article 13(13), Article 18(3)(a), Article 19(2) and (6) of Regulation (EU) 2024/2847, Article 18(1)(e), Article 22(3)(a) and (b), Article 23(1)(c) and (5), and Article 24(1) of Regulation (EU) 2024/1689, Article 6(3), (4), Article 7(2)a, Article 8(8) of Commission Delegated Regulation (EU) 2019/945, Article 10(3) & (4), Article 11(2)(a) and Article 12(8) of Directive 2014/53/EU; Article 6(2) & (3), Article 7(2)(a), Article 8(8) of Directive 2014/35/EU; Article 7(2) & (3), Article 8(2)(a), Article 9(7) of Directive 2014/30/EU; and/or Article 7(c) & (d), Article 8(b) and Article 9(g) of Directive 2011/65/EU.

4b. Where manufacturers rely on the provisions set out under paragraph 4a for the purposes of fulfilling their obligations related to the declaration of conformity, the digital product passport shall contain the information set out in point (fa) of Annex VI.

PUBLIC

5. The data carrier shall be physically present on the toy or on a label attached to ***the toy. Where this is not possible on account of size or nature of the toy, it shall be affixed to the packaging, if any, or on documentation accompanying*** the toy, in accordance with the ***delegated act adopted pursuant to Article 46(-1)***. ▌ It shall be clearly visible to the consumer ***or other end-users*** before any purchase and to market surveillance authorities, including in cases where the toy is made available through distance sales.

6. Where other Union ***law*** requires information on the toy to be available via a data carrier, a single data carrier shall be used to provide the information required under this Regulation and such other Union ***law***.

7. Where other Union ***law*** applying to toys requires a ***digital*** product passport, a single ***digital*** product passport shall be created for toys containing the ***data*** required under this Regulation as well as any other ***data*** required for the ***digital*** product passport by that other Union ***law***. ***By way of derogation from paragraph 2, point (a), where that law requires that the digital product passport corresponds to a batch level, the digital product passport for the purposes of this Regulation can be issued to that level.***

▌

9. Economic operators may, in addition to the ***data*** referred to in paragraphs 6 and 7, make other information accessible through the data carrier referred to in paragraph 5. Where this is the case, that information shall be clearly separated from the information required under this Regulation and, where relevant, under other Union ***law***.

9a. The manufacturer or the digital product passport service provider shall ensure that 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 might present a risk to the health and safety of consumers is displayed when accessing the digital product passport.

▌

PUBLIC

11. The economic operator placing the toy on the market shall:

(a) provide distributors and providers of online marketplaces with a digital copy of the data carrier or the unique product identifier, as relevant, to allow them to make the data carrier or the unique product identifier accessible to potential customers where they cannot physically access the product;

(b) provide the digital copy referred to in point (a) or a webpage link free of charge promptly and in any event within 5 working days of receiving a request to do so.

12. The economic operator, when placing the toy on the market, shall make available a back-up copy of the digital product passport through a digital product passport service provider.

Article 18

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

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

2. All ***data*** included in the ***digital*** product passport shall be based on open standards developed with an interoperable format and shall be***, as appropriate,*** machine readable, structured***,*** searchable ***and transferable through an open interoperable data exchange network without vendor lock-in***.

3. Consumers or other end-users, economic operators***, competent national authorities and customs authorities, the Commission*** 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.

3a. Consumers shall not be requested to register or provide a password to access the digital product passport.

4. The ***digital*** product passport shall be stored by the economic operator responsible for its creation or by ***digital product passport service providers***.

4a. Where a new digital product passport is created for a toy that already has a digital product passport, the new digital product passport shall be linked to the original digital product passport or passports.

5. ***If the digital*** product passport is stored ***pursuant to paragraph 4 of this Article*** or otherwise processed by ***digital product passport service providers pursuant to Article 17(12), those digital product passport service providers*** shall not ▌ 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 ***unless specifically agreed with the economic operator placing the toy on the market***.

5a. Data authentication, reliability and integrity shall be ensured.

5b. Digital product passports shall be designed and operated so that a high level of security and privacy is ensured and fraud is avoided.

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 information on the ***digital*** product passport online. ***In particular, personal data related to the customer of the product shall not be stored in the digital product passport without the explicit consent of the consumer or other end-user in compliance with Article 6 of Regulation (EU) 2016/679.***

Article 18a

Data carriers and unique identifiers

1. The data carriers and the unique product identifiers required under this Regulation shall comply with the standards applicable to data carriers and unique product identifiers under Regulation (EU) 2024/1781.

PUBLIC

The unique operator identifiers required under this Regulation shall comply with the standards applicable to unique operator identifiers under Regulation (EU) 2024/1781.

2. Article 12(2) of Regulation (EU) 2024/1781 shall apply to economic operators who create or update a digital product passport under this Regulation when a unique operator identifier does not exist.

Any rules and procedures for the lifecycle management of unique identifiers and data carriers set out in delegated acts adopted pursuant to Article 12(4) of Regulation (EU) 2024/1781 shall also apply in respect of unique identifiers and data carriers under this Regulation.

3. Where a toy is subject to an obligation to provide for a digital product passport under a delegated act adopted pursuant to Article 4 of Regulation (EU) 2024/1781 or under another Union law, the unique product identifier, the unique operator identifier and the unique registration identifier shall be the same.

4. Any procedures to issue and verify digital credentials of economic operators and other relevant actors that have access rights to data included in the digital product passport set out by implementing acts adopted pursuant to Article 11 fourth paragraph of Regulation (EU) 2024/1781 shall also be applicable for the purposes of this Regulation.

5. Any requirements for digital product passport service providers to comply with in order to become such providers, and, where appropriate, for providing services, set out in delegated acts adopted pursuant to Article 11 third paragraph of Regulation (EU) 2024/1781 shall also be applicable for the purposes of this Regulation.

Article 19

***Digital* product passport registry**

1. Before placing a toy on the market, ***the*** economic ***operator placing the toy on the market*** shall upload, in the registry established under Article ***13(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. ***In the case of toys***

intended to be placed under the customs procedure 'release for free circulation', the registry shall store the commodity code of the toy.

1a. Upon the uploading by the economic operator the data referred to in paragraph 1 in the registry, the registry shall automatically communicate to that economic operator a unique registration identifier associated with the unique identifiers uploaded in the registry for a specific toy. That communication by the registry shall not be deemed to be proof of compliance with this Regulation or other Union law.

The Commission may adopt an implementing act specifying the implementation arrangements for the registry, including for the communication of the unique registration identifier referred to in this paragraph. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 50(3).

2. The Commission, ***national competent*** authorities and customs authorities shall have access to the ▌ registry ▌ for ***the purpose of*** carrying out their duties pursuant to this Regulation.

Article 20

Customs controls relating to the *digital* product passport

1. Toys entering the Union market shall be subject to verifications and other measures laid down in this Article. ***This Article is without prejudice to any other Union law, in particular Regulation (EU) 952/2013 and Chapter VII of Regulation (EU) 2019/1020.***

2. ***Any person intending to place a toy under*** the customs ***procedure*** **'**release for free circulation***' shall provide or make available to customs authorities the unique registration identifier as referred to in Article 19(1a)***.

3. Customs authorities ***may release a toy for free circulation only after having verified as a minimum that*** the unique ***registration*** identifier ***and the commodity code provided or made available to them correspond to the data stored*** in the registry***. The release for free circulation shall not be deemed to be proof of compliance with this Regulation or other Union law***.

▌

5. The ***verification*** referred to in ***paragraph 3*** shall take place electronically and automatically ***via*** the interconnection between the registry ▌ and the EU Customs Single Window Certificates Exchange System referred to in [Article ***15(3)*** of [P.O. insert serial number for Regulation (EU) …/… on Ecodesign Requirements for Sustainable Products]]. ***This verification shall take place as from the moment that interconnection is operational or the from the date of application of this Regulation, whichever is later.***

▌

7. ***The Commission and the*** customs authorities may retrieve and use the ***data*** on toys included in the ***digital*** product passport and in the registry for carrying out their duties pursuant to Union ***law***, including ▌ risk management***, customs controls and release for free circulation*** in accordance with ▌ Regulation (EU) No 952/2013.

8. The verifications and other measures laid down in this Article shall be carried out on the basis of the list of commodity codes and product descriptions set out in Annex VII.

▌

Article 20a

Assistance for SMEs

No later than ... [12 months before the date of application of this Regulation], the Commission shall provide assistance, in consultation with the relevant national authorities, to SMEs by providing them with guidelines on how to set up and operate a digital product passport for toys, in accordance with this Regulation.

PUBLIC

PUBLIC

CHAPTER V
CONFORMITY ASSESSMENT

Article 21

Safety assessment

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.

2. The safety assessment shall in particular :

   (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***. The safety assessment shall consider the possible non-intended presence of substances subject to point 4 of Part III of Annex II and shall take into account any information provided to the manufacturer as regards the presence of substances or mixtures meeting the classification criteria of the categories set out in paragraphs a) to da) of point 4 of Part III of Annex II***;

   (ba) for toys falling within the scope of Directive 2014/53/EU, Regulation (EU) 2024/2847 or Regulation (EU) 2024/1689, take account of the particular vulnerabilities of children in relation to the use of such toys as intended, when assessing and addressing the hazards that the toy may present;

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

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

Article 22

Conformity assessment procedures

1. Manufacturers shall use the conformity assessment procedures referred to in paragraphs 2 ***or*** 3.

2. If the manufacturer has applied harmonised standards, the reference of which has been published in the Official Journal of the European Union, or common specifications**,** covering all relevant safety requirements for the toy ***identified in the safety assessment referred to in Article 21***, the manufacturer shall use the internal production control procedure set out in Part I of Annex IV.

3. In the following cases, the manufacturer shall use the EU-type examination procedure set out in Part II of Annex IV together with the conformity to type procedure set out in Part III of that Annex:

(a) where harmonised standards, the reference of which has been published in the Official Journal of the European Union, or common specifications covering all relevant safety requirements for the toy, do not exist;

(b) where harmonised standards or common specifications referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;

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

(d) where the manufacturer considers that the nature, design, construction or purpose of the toy necessitates third party verification.

PUBLIC

4. The EU-type examination certificate issued in accordance with Part II, point 6, of Annex IV shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.

Article 23

Technical documentation

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that the toy complies with the essential safety requirements. It shall, in particular, contain the documents listed in Annex V.

2. The technical documentation shall be drawn up in one of the official languages of the Union.

3. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.

   When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk to health and safety.

4. If the manufacturer does not comply with the requirements set out in paragraphs 1, 2 and 3, the market surveillance authority may require the manufacturer to have a test performed by a notified body at its own expense within a specified period in order to verify compliance with the essential safety requirements.

PUBLIC

CHAPTER VI
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

PUBLIC

Article 24

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 25

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of this Regulation, and for the monitoring of notified bodies, including compliance with Article 30.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

PUBLIC

Article 26

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of their activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

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.

5. A notifying authority shall safeguard the confidentiality of the information they obtain ***in accordance with Union and national law***.

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

7. A notifying authority shall monitor the nature and amount of tasks performed by subsidiaries of or subcontractors to notified bodies in accordance with Article 30.

Article 27

Information obligation of notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 28

Requirements relating to notified bodies

1. For the purposes of notification under this Regulation, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11. It shall be accredited in accordance with Regulation (EC) No 765/2008.

2. Conformity assessment bodies shall be established under the national law of a Member State and shall have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses.

   A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered a third-party body for the purposes of the first subparagraph.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, nor the authorised representative of any of those parties. This shall not preclude use of the assessed toys that is necessary for the operations of the conformity assessment body or the use of those toys for personal purposes.

   A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of those toys, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

PUBLIC

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out the conformity assessment tasks assigned to it by Annex IV and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been notified, a conformity assessment body shall have at its disposal, or in place, the following:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and ability of reproduction of those procedures;

(c) appropriate policies and procedures that distinguish between tasks it carries out as a notified body and other activities;

(d) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

A conformity assessment body shall have the ***resources*** 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.

7. The personnel responsible for carrying out the conformity assessment activities (the 'assessment personnel') shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

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

(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;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with its national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy ***in accordance with applicable Union and national law*** 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. ***Proprietary rights,*** intellectual property rights ***and trade secrets*** shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 29

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 28 insofar as the applicable harmonised standards cover those requirements.

Article 30

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 28, and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

3. Notified bodies shall be capable of reviewing the tasks performed by the subcontractors or subsidiaries in all their elements.

4. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

5. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex IV.

PUBLIC

Article 31

Application for notification

1. A conformity assessment body shall submit an application for notification under this Regulation to the notifying authority of the Member State in which it is established.

2. The application referred to in paragraph 1 shall be accompanied by a description of the conformity assessment activities and the toys for which that body claims to be competent, as well as by an accreditation certificate issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.

Article 32

Notification procedure

1. Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 28.

2. Notifying authorities shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities and the relevant accreditation certificate. The notification shall also include information on any tasks to be performed by subsidiaries and subcontractors.

4. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two months of a notification.

   Only such a body shall be considered a notified body for the purposes of this Regulation.

5. The notifying authority shall inform the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 33

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to each notified body.

   It shall assign a single identification number even where the same body is notified under several Union acts.

2. The Commission shall make publicly available a list of bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

   The Commission shall ensure that the list is kept up to date.

Article 34

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 28, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying authorities and market surveillance authorities, at their request.

PUBLIC

Article 35

Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying authority shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet the requirements for notification, it shall, by means of an implementing act, request the notifying authority to take the necessary corrective measures, including the withdrawal of the notification if necessary.

Article 36

Operational obligations of notified bodies

1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Annex IV.

2. Notified bodies shall carry out the conformity assessment activities set out in this Regulation in a proportionate manner, avoiding unnecessary burdens for economic operators. They shall perform their activities under this Regulation taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

PUBLIC

When performing their activities, the notified bodies shall respect the degree of rigour and the level of protection required for the compliance of the toy with this Regulation.

3. Where a notified body finds that the toy does not meet the essential safety requirements, the requirements in corresponding harmonised standards, where such standards are applied or the requirements in corresponding common specifications referred to in Article 14, where such specifications are applied, it shall require that manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate as referred to in Part II, point 6, of Annex IV.

4. Where, in the course of the monitoring of conformity following the issue of a EU-type examination certificate, a notified body finds that a toy ▌ no longer ***complies***, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EU-type examination certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates, as appropriate.

6. Where a notified body is informed by a market surveillance authority that a toy for which the notified body has issued a EU-type examination certificate ***does not comply*** with the essential safety requirements, it shall withdraw the EU-type examination certificate in respect of that toy.

Article 37

Appeals against decisions of notified bodies

A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.

PUBLIC

Article 38

Information obligation of notified bodies

1. Notified bodies shall inform the notifying authority of the following:

   (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate;

   (b) any circumstances affecting the scope of and conditions for their notification;

   (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

   (d) on request, conformity assessment activities performed within the scope of their notification, and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Regulation which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

3. Notified bodies shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation that relates to any EU-type examination certificate which they have issued or withdrawn, or that relates to any refusal to issue such a certificate, including test reports, and the technical documentation referred to in Article 23.

Article 39

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

PUBLIC

Article 40

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

Notified bodies shall participate in the work of that group or groups, directly or by means of designated representatives.

CHAPTER VII
MARKET SURVEILLANCE

Article 41

Procedure for dealing with toys presenting a risk at national level

1. 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.

   Where, in the course of that evaluation, a market surveillance authority finds that a toy does not comply with the requirements laid down in this Regulation, it shall without delay require the relevant economic operator to take appropriate corrective action in accordance with Article 16(3) of Regulation (EU) 2019/1020 within a reasonable period of time prescribed by the market surveillance authority and taking into account the nature of the risk.

   The market surveillance authorities shall inform the relevant notified body accordingly.

PUBLIC

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the relevant economic operator to take.

3. The economic operator shall ensure that appropriate corrective action is taken in respect of all the concerned toys that the economic operator has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, second subparagraph, the market surveillance authorities shall take appropriate provisional measures to prohibit or restrict the toy being made available on their national market, to withdraw the toy from that market or to recall it.

   The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4, second subparagraph, shall include all available details, in particular the data necessary for the identification of the non-compliant toy including the unique product identifier, the origin of that toy, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:

   (a) failure of the toy to meet the essential safety requirements;

   (b) shortcomings in the harmonised standards referred to in Article 13;

   (c) shortcomings in the common specifications referred to in Article 14.

PUBLIC

6. Market surveillance authorities of Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within 3 months of receipt of the information referred to in paragraph 4, second subparagraph, no objection has been raised by either a market surveillance authority of a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed to be justified.

8. Market surveillance authorities of other Member States shall ensure that appropriate restrictive measures, such as withdrawal of the toy from their market, are taken without delay in respect of the toy concerned, and shall inform the Commission and the other Member States of those measures.

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.

Article 42

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 41(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission has reasons to believe that a national measure could be contrary to Union ***law***, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure.

   On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

PUBLIC

The Commission shall address its decision to all Member States and shall without delay communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant toy is withdrawn or recalled from their market, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw it.

3. Where the national measure is considered to be justified and the non-compliance of the toy is attributed to shortcomings in the harmonised standards referred to in Article 13 of this Regulation or the common specifications referred to in Article 14 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or amend the common specifications as appropriate.

Article 43

Formal non-compliance

1. Without prejudice to Article 41, where a market surveillance authority makes one of the following findings with regard to a toy, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 15 or 16;

(b) the CE marking has not been affixed;

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

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

(e) the technical documentation referred to in Article 23 is either not available or not complete.

PUBLIC

2. Where the non-compliance referred to in paragraph 1 persists, the market surveillance authority concerned shall take appropriate measures to restrict or prohibit the making available on the market of the toy, or ensure that the toy is recalled or withdrawn from the market.

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Article 45

Commission action concerning toys that present a risk

1. Where the Commission becomes aware of a toy or a specific category of toys made available on the market which presents a risk to the health and safety of persons but is nonetheless either in compliance with the particular safety requirements or raising doubts about such compliance, it is empowered to adopt implementing acts setting out measures to ensure that the toy or category of toys, when made available on the market, no longer presents that risk, to withdraw it from the market or to recall it where all of the following conditions are met:

   (a) it emerges from prior consultations with the market surveillance authorities that their approaches to dealing with the risk differ from one market surveillance authority to another;

   (b) the risk cannot, in view of its nature, be dealt with under other procedures laid down by this Regulation.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 50(3). On duly justified imperative grounds of urgency relating to the protection of the health and safety of persons, the Commission is empowered to adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 50(4).

PUBLIC

PUBLIC

CHAPTER VIII
DELEGATED POWERS AND COMMITTEE PROCEDURE

Article 46

Delegated powers

-1. The Commission is empowered to adopt delegated acts in accordance with Article 47 to supplement this Regulation by determining the technical requirements related to the digital product passport for toys. Those requirements shall cover in particular the following:

(a) one or more data carriers to be used;

(b) the layout in which the data carrier is to be presented and its positioning;

(c) the technical elements of the passport for which defined European or international standards are to be used;

(d) the actors that are to have access to data in the digital product passport and to what data they are to have access. Such access rights shall take into account the need to protect confidential business information and trade secrets in accordance with Directive (EU) 2016/943, as well as the need to ensure that consumers can easily access the information that is relevant to them;

(e) the actors that are to create a digital product passport or update the data in a digital product passport and what data they may introduce or update. Except where they act on behalf of the manufacturer, the actors that update data in a digital product passport shall be responsible for the accuracy of the data they provide;

(f) the detailed arrangements for introducing or updating data referred to in point (e).

The date of application of delegated acts under the first subparagraph shall not be earlier than 18 months from their entry into force, except in duly justified cases for the whole act or for some specific requirements, or except in cases of partial repeal or amendment of delegated acts, where an earlier date of application may be set.

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

2. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Article 19(1) by setting out that additional information among the information listed in Annex VI or that information on the non-compliance of the toy when measures are taken in accordance with Articles 41(2) or (4) and Article 44(1) is to be stored in the registry.

When adopting the delegated acts in accordance with the first subparagraph, the Commission shall take into account the following criteria:

(a) coherence with other relevant Union acts, where relevant;

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

(c) the relevance of the information for improving the efficiency and effectiveness of market surveillance checks and customs controls for toys;

(d) the need to avoid disproportionate administrative burden for economic operators ***and national authorities, including customs authorities***.

▌

4. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex VII to this Regulation in order to adapt the list of commodity codes and product descriptions to be used for the purposes of Article 20(8). Those adaptations shall be based on the list set out in Annex I to Regulation (EEC) No 2658/87.

5. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex III in order to adapt it to technical and scientific progress.

6. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Part C of the Appendix to Annex II***, while taking into account the conditions set out in Annex II, Part III, point (7a),*** in order to permit a certain ***presence*** in toys of a specific substance or mixture that is prohibited under Part III, point 4***, 4a or 4b***, of Annex II, or to ***amend or withdraw the permission of the presence of*** a certain ***substance or mixture. The Commission shall justify any exemption granted and make this publicly available in an easily accessible and user-friendly manner***.

▌

8. The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Parts A***, B and D*** of the Appendix to Annex II in order to adapt them to technical and scientific progress, by ▌ :

(a) introducing conditions for the presence of substances or mixtures in toys and, in particular, limit values for specific substances or mixtures in toys, including limit values for ***the non intended presence*** of prohibited substances or mixtures as referred to in Part III, point ***5***, of Annex II;

(b) modifying the conditions or limit values for the presence of substances and mixtures in toys.

8a. The Commission shall request an opinion from ECHA under Article 49(7) on the safety of nitrosamines and nitrosatable substances in toys, in view of the overall exposure. The Commission shall evaluate the opinion and, where necessary, in view of that opinion, adopt delegated acts in accordance with Article 47 in order to adapt the limit values for these substances in toys listed in Part A of the Appendix to Annex II.

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8b. ***The Commission shall request an opinion from ECHA under Article 49(7) on the safety of lead, cadmium, mercury and chromium vi in toys, in view of the overall exposure. The Commission shall evaluate the opinion and, where necessary, in view of that opinion, adopt delegated acts in accordance with Article 47 in order to adapt the limit values for these substances in toys listed in Part A of the Appendix to Annex II.***

9. For the purposes of paragraphs 6 and ***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.

Article 47

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 46 shall be conferred on the Commission for ***a*** period of ***five years from … [the date of entry into force of this Regulation]***. ***The Commission shall draw up a report in respect of the delegation of power not later than nine 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 not later than three months before the end of each period.***

3. The delegation of powers referred to in Article 46 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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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.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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 ***three*** months at the initiative of the European Parliament or of the Council.

Article 48

Requests for assessment for the purposes of Article 46(6)

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

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*** 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:

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(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 and the hazard class in accordance with the Annex II, Part III, point 4, where appropriate;

(c) type of toy or toy component;

3. ***Before … [the first day of the month following 12 months after the date of entry into force of this Regulation], the ECHA shall draw up and make publicly available a format 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 and on how the analysis supporting such requests should be conducted, including as regards the availability of alternatives to the substances or mixtures and how to address under this Regulation the known additional hazards from the combined exposure to the different substances and mixtures present in the toy***.

Article 49

Opinions from ECHA

1. For the purposes of Article 46(6), ECHA shall provide opinions to the Commission on the ***presence*** in toys of substances or mixtures that are prohibited under Part III, point 4***, 4a or 4b*** 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 ***Annex II, Part III, point 7a***, points (a) and (b), are met for a specific use.

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.

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.

4. That period may be extended once by a period of up to 6 months if ECHA needs to request information from a third party or if a high number of requests for assessment are submitted to ECHA under Article 48(1).

5. ECHA shall re-evaluate its opinions on the ***presence*** in toys of substances or mixtures listed in Part C of the Appendix to Annex II at least every 5 years from the date of entry into force of a delegated act adopted in accordance with Article 46(6). ***For the purposes of carrying out this re-evaluation, ECHA shall request the person submitting the original request to provide within a specified period the necessary information and documentation demonstrating that the conditions justifying the presence of the substance in toys set out in Annex II, Part III, point 7a, continue to be met. ECHA may also request any third party to submit additional information within a specified period.***

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

7. For the purposes of Article ***46(8)***, 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 ***known additional hazards from the combined exposure to the different substances and mixtures present in the toy, as well as the*** vulnerability of children.

8. When preparing an opinion in accordance with the provisions set out in this Article, ECHA shall make publicly available the information on the start of the assessment, the adoption of the opinion as well as any intermediate steps in the assessment procedure. In particular, ECHA shall make the draft opinions publicly available and provide an opportunity for any interested party to comment on those opinions within a period of at least 4 weeks.

PUBLIC

Article 50

Committee procedure

1. The Commission shall be assisted by a Committee on Toy Safety. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. ***Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER IX
CONFIDENTIALITY AND PENALTIES

Article 51

Confidentiality

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

   (a) personal data;

   (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is in the public interest.

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2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without ***prior consultation with*** the originating competent national authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, or the obligations of the persons concerned to provide information under criminal law.

4. Member States and the Commission may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements***, when those arrangements ensure that any exchange of information is in accordance with applicable Union and national law***.

Article 52

Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States by … [P.O. insert date: the first day of the month following 30 months after the date of entry into force of this Regulation] notify the Commission of those rules and shall notify it without delay of any subsequent amendment affecting them.

PUBLIC

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▌

CHAPTER X
FINAL PROVISIONS

Article 53

Repeal

Directive 2009/48/EC is repealed with effect from … [OP: please insert the date = the first day of the month following ***54 months after the date of entry into force of this Regulation***].

References to the repealed Directive 2009/48/EC shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VIII.

Article 54

Transitional provisions

1. ***Member States shall not impede the making available on the market of toys which were*** placed on the market in conformity with Directive 2009/48/EC before ***54*** months after the date of entry into force of this Regulation ▌ .

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 ***54*** 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 ***54*** months after the date of entry into force of this Regulation].

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 ***[60 months after the date of entry into force of this Regulation***], unless they expire before that date.

Article 55

Evaluation and review

1. ***By … [OP please insert the date = the first day of the month following 38 months after the date of application 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, in particular:

(a) the effectiveness of this Regulation in ensuring a high level of protection of health and safety of children;

(b) the effectiveness of this Regulation in improving the functioning of the single market, including in online sales;

(c) the efficiency of the Regulation and the impacts on competitiveness, including for SMEs.

2. Where the Commission finds it appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation.

Article 56

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

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It shall apply from … [OP please insert the date = the first day of the month following ***54 months after the date of entry into force of this Regulation***].

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***].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

PUBLIC

Annex I

PRODUCTS TO WHICH THIS REGULATION DOES NOT APPLY

PUBLIC

Part I

Toys excluded from the scope of this Regulation

1. Playground equipment intended for public use;

2. automatic playing machines, whether coin operated or not, intended for public use;

3. toy vehicles equipped with combustion engines;

4. toy steam engines.

Part II

Products that are not considered as toys within the meaning of this Regulation

1. Decorative objects for festivities and celebrations ***that do not have a play value***;

2. products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years and above. Examples of this category are:

   (a) detailed scale models;

   (b) kits for the assembly of detailed scale models;

(c) folk dolls and decorative dolls and other similar articles;

(d) historical replicas of toys; and

(e) reproductions of real fire arms;

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

4. bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark;

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;

6. electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof;

7. aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids;

8. puzzles with more than 500 pieces;

9. guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long;

10. fireworks, including percussion caps which are not specifically designed for toys;

11. products and games using sharp-pointed missiles, such as sets of darts with metallic points;

12. Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision.

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13. products intended for use for educational purposes in schools or other pedagogical contexts under the surveillance of an adult instructor, such as science equipment;

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;

15. interactive software, intended for leisure and entertainment, such as computer games, and their storage media;

16. babies' soothers;

17. ***continuously wired*** child-appealing luminaires;

18. electrical transformers for toys;

19. fashion accessories for children which are not for use in play***;***

20. paint ball equipment;

21. reading and educational books intended for children older than 36 months, that do not have a play value.

PUBLIC

Annex II

PARTICULAR SAFETY REQUIREMENTS

PUBLIC

Part I

Physical and Mechanical Properties

1. Toys and their parts and, in the case of fixed toys, their anchorages, shall have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.

2. Accessible edges, protrusions, cords, cables and fastenings on toys shall be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as much as possible.

3. Toys shall be designed and manufactured in such a way as not to present any risk to health and safety or only the minimum risk inherent to their use which could be caused by the movement of their parts.

4. (a) Toys and their parts shall not present a risk of strangulation.

   (b) Toys and their parts shall not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.

   (c) Toys and their parts shall be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(d) Toys which are clearly intended for use by children under 36 months ***and toys which, although not foodstuff, resemble foodstuff such that it is likely that they are confused with foodstuff by children***, and their component parts and any of their detachable parts, shall be of such dimensions as to prevent them being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.

(e) The packaging in which toys are contained for retail sale shall not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.

(f) Toys contained within food or co-mingled with food shall have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent it from being swallowed and/or inhaled.

(g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, shall be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in points (c) and (d).

(ha) Toys must not cause a risk to the obstruction of the intestines due to the expansion of the toy if swallowed.

5. Aquatic toys shall be designed and manufactured so as to reduce as much as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.

PUBLIC

6. Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants shall have a means of exit which the intended user can open easily from the inside.

7. Toys conferring mobility on their users shall, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy generated by it. Such a system shall be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

For electrically driven ride-on toys, the maximum representative potential operating speed determined by the design of the toy shall be limited so as to minimise the risk of injury.

8. The form and composition of projectiles and the kinetic energy they may generate when fired from a toy designed for that purpose shall be such that, taking into account the nature of the toy, there is no risk of physical injury to the user or to third parties.

9. Toys shall be manufactured so as to ensure that:

(a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched;

(b) liquids and gases contained within the toy do not reach temperatures or pressures which are such that their escape from the toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.

10. Toys ***that are designed to emit a sound and toy mechanisms that are activated by a child and emit reproduceable 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 maximum values shall not lead to an exposure of children to continuous and peak sound pressure exceeding the lower exposure action values set in Directive 2003/10/EEC. The maximum values for impulse noise and continuous noise in toys shall take into account their intended and reasonably foreseeable use in accordance with Article 5(2).***

11. ▌Toys shall be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning as much as possible. In particular, ***for activity toys*** any surface of such a toy that is accessible for one or more children to play on shall be designed to bear their load.

12. ***Toys that contain magnets or magnetic parts shall be designed and manufactured in such a way that the size and strength of the magnets do not present a risk of intestinal perforation or blockage.***

PUBLIC

Part II

▌Flammability

1. Toys shall not constitute a dangerous flammable element in the child's environment. They shall therefore be composed of materials which fulfil one or more of the following conditions:

   (a) they do not burn if directly exposed to a flame or spark or other potential source of fire;

   (b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);

   (c) if they do ignite, they burn slowly and present a low rate of spread of the flame;

   (d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

   Combustible materials in the toy shall not constitute a risk of ignition for other materials used in the toy.

2. ***Toys, in particular toys containing materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography, toy foam soap or similar activities,*** shall not, as such, contain substances or mixtures which may become flammable due to the loss of non-flammable volatile components.

▌

3. Toys other than toy percussion caps shall not be explosive or contain elements or substances likely to explode when used as specified in Article 5(2), first subparagraph.

4. Toys and, in particular, chemical games and toys, shall not contain as such substances or mixtures:

(a) which, when mixed together, may explode through chemical reaction or through heating;

(b) which may explode when mixed with oxidizing substances; or

(c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

Part III

▌Chemical Properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain, when the toys are used as specified in Article 5(2), first subparagraph.

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Toys shall comply with the relevant Union legislation relating to certain categories of products or to restrictions for certain substances and mixtures. Toys or their parts and their packaging that can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use, shall also comply with Regulation (EC) No 1935/2004.

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

3. Toys shall comply with the specific requirements and conditions for chemical substances set out in part A of the Appendix and with the labelling requirements set out in part B of the Appendix.

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

(a) carcinogenicity, germ cell mutagenicity or reproductive toxicity (CMR) category 1A, 1B or 2;

(b) endocrine disruption ***for human health*** category 1 or 2;

(c) specific target organ toxicity category 1, either in single exposure or in repeated exposure;

(d) respiratory sensitisation category 1.

(da) skin sensitizers category 1A.

▌

4a. The intentional use in toys, components of toys or micro-structurally distinct parts of toys, of per- and polyfluoroalkyl substances (PFAS) is prohibited.

PUBLIC

4b. ***The presence in toys, components of toys or micro-structurally distinct parts of toys, of the bisphenols included in part D of the Appendix is prohibited.***

5. The non-intended presence of a substance or mixture referred to in point 4***, 4a or 4b*** that stems from impurities of natural or synthetic ingredients, or from the manufacturing process and that is technically unavoidable in good manufacturing practice, shall be permitted provided that, despite such presence, toys remain in conformity with the general safety requirement.

6. By way of derogation from point 4, ***4a and 4b*** substances or mixtures prohibited under that point may be used in toys if they are listed in Part C of the Appendix, under the conditions specified therein.

7. Points 4 to 6 shall not apply to:

(a) materials that comply with the conditions set out for specific substances in Part A of the Appendix, as regards those substances;

(b) batteries in toys; or

(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)***.

(ca) materials that comply with a substance specific restriction for toys in Annex XVII of Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) under the conditions specified therein, as regards those substances, unless a more protective restriction is set out for that substance for toys in the Appendix.

7a. ***By way of derogation to point 4, 4a or 4b, the presence in toys of a prohibited substance or mixture may only be permitted when all of the following conditions are met:***

PUBLIC

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(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, 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) there are no suitable alternatives available to the presence of the substances or mixtures in the toy, including via technical alternatives, as established by ECHA based on an analysis of alternatives. This assessment shall consider as a priority the safety of any alternative identified and also consider its technical feasibility and availability;

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

7b. Restrictions or prohibitions on the use of PFAS laid down in accordance with Regulations (EC) No 1907/2006, or (EU) 2019/1021, shall take precedence over paragraph 4a.

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[1].

9. Toys shall not:

(a) have a biocidal function insofar as the toy would thereby be considered a biocidal product according to the definition set out in Article 3(a) of Regulation (EU) 528/2012, or

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[1] 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).

(b) be treated with, or intentionally incorporate, one or more biocidal products, as defined in Article 3(a) of Regulation (EU) 528/2012.

By way of derogation to point b), toys intended to be permanently placed outdoors may be treated with, or intentionally incorporate, one or more biocidal products provided that all active substances contained in the biocidal products that it was treated with or incorporates are included in the list drawn up in accordance with Article 9(2) Regulation (EU) No 528/2012 for the relevant product-type of preservatives falling in the main group 2 of Annex V to that Regulation, or in Annex I, and any relevant conditions or restrictions specified therein are met, or under assessment in the work programme for the systematic evaluation of all existing active substances set up in accordance with Article 89 of Regulation (EU) No 528/2012 for the relevant product-type falling in the main group 2 of Annex V to Regulation (EU) No 528/2012.

10. By way of derogation from points 4 and 9, preservatives may be used in toys where the preservative is allowed for use in leave-on cosmetics as listed in Annex V of Regulation (EC) 1223/2009 on cosmetic products in accordance with the conditions set out in that Annex, except those that are not to be used for children under 3 or 10 years of age, or those that are not allowed to be used in products applied on mucous membranes or for which contact with the eyes should be avoided.

Part IV

▌Electrical Properties

1. Toys shall not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts shall not exceed 24 volts DC or the equivalent AC voltage.

   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 ***harmful*** electric shock, even when the toy is broken.

2. Parts of toys which are connected to, or liable to come into contact with, a source of electricity capable of causing electric shock, and any cables or other conductors through which electricity is conveyed to such parts shall be properly insulated and mechanically protected so as to prevent the risk of such a shock.

3. Electric toys shall be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

4. Under foreseeable fault conditions, toys shall provide protection against electrical hazards arising from an electrical power source.

5. Electric toys shall provide adequate protection against fire hazards.

6. Electric toys shall be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the toy, are limited to the extent necessary for the operation of the toy, and shall operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Union measures.

7. Toys which have an electronic control system shall be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor.

8. Toys shall be designed and manufactured in such a way that they do not present any health hazards, or risk of injury to eyes or skin, from lasers, light-emitting diodes (LEDs) or any other type of radiation.

9. The electrical transformer of a toy shall not be an integral part of the toy.

10. Electric toys with batteries that constitute small parts shall be designed and manufactured in such a way as to ensure that access to the battery is prevented by requiring the use of a tool. Where the size or nature of the toy so requires, a rechargeable battery may instead be made inaccessible, and removable or replaceable only by independent professionals.

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Part V

▌Hygiene

1. Toys shall be designed and manufactured in such a way with regards to their hygiene and cleanliness that they do not present any risk of infection, sickness or contamination.

2. A toy intended for use by children under 36 months ***or intended to be put in the mouth*** shall be designed and 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 soak washed. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

3. Toys with accessible aqueous materials shall be designed and manufactured in such a way as to ensure that they do not present a microbiological risk.

Part VI

▌Radioactivity

Toys shall comply with all relevant measures adopted under Chapter III of the Treaty establishing the European Atomic Energy Community.

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Appendix

Specific conditions for the presence of certain chemical substances or mixtures in toys

Part A. Substances subject to specific limit values

1. The following migration limits, from toys, components of toys or micro-structurally distinct parts of toys, shall not be exceeded:

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

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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

These limit values shall not apply to toys or components of toys or micro-structurally distinct parts of toys which, due to their accessibility, function, volume or mass, clearly exclude any risk due to sucking, licking, swallowing or prolonged contact with skin when used as specified in Article 5(2), first subparagraph.

2. ***N-nitrosamines and N-nitrosatable*** substances are prohibited in ***the following toys*** where the migration of those substances is ▌ higher than***:***

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

3. The following limit values, in toys or components of toys or micro-structurally distinct parts of toys, shall not be exceeded:

Substance	CAS No	Limit value and conditions for application
TCEP	115-96-8	5 mg/kg (content limit)
TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Formamide	75-12-7	20 µg/m3 (emission limit) after a maximum of 28 days from the start of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content)
1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit) in aqueous toy materials ▌
▌	▌	▌
5-Chloro-2-methyl-isothiazolin-3(2H)-one	26172-55-4	0,75 mg/kg (content limit) in aqueous toy materials
▌	▌	▌
Phenol	108-95-2	5 mg/l (migration limit) in polymeric materials 10 mg/kg (content limit) as a preservative ▌
Formaldehyde	50-00-0	1,5 mg/l (migration limit) in polymeric toy material 0,062 mg/m3 (emission limit) in wood toy material 30 mg/kg (content limit) in textile toy material

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		30 mg/kg (content limit) in leather toy material 30 mg/kg (content limit) in paper toy material 10 mg/kg (content limit) in water-based toy material
Aniline	62-53-3	30 mg/kg (content limit) after reductive cleavage in textile toy material and leather toy material 10 mg/kg (content limit) as free aniline in finger paints 30 mg/kg (content limit) after reductive cleavage in finger paints
Styrene	***100-42-5***	***0,77 mg/l (migration limit) in polymeric toy materials***
Bisphenol A	***80-05-7***	***0,005 mg/l (migration limit)***
Acrylonitrile	***107-13-1***	***0,01 mg/l (migration limit) in polymeric toy materials***
Butadiene	***106-99-0***	***0,07 mg/l (migration limit) in polymeric toy materials***
Vinyl chloride	***75-01-4***	***0,01 mg/l (migration limit) in polymeric toy materials***

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:

No	***Chemical*** name ▌	***Common name***	CAS number
(1)	Alanroot oil (Inula helenium ***L.***)		97676-35-2

(2)	***Allyl isothiocyanate***		57-06-7
(3)	Benzyl cyanide		140-29-4
(4)	4-tert-Butylphenol		98-54-4
(5)	Chenopodium ***ambrosioides L. (essential oil)***	***Chenopodium oil***	8006-99-3
(6)	Cyclamen alcohol		4756-19-8
(7)	Diethyl maleate		141-05-9
(8)	***3,4-*** Dihydrocoumarin		119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde		6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)		40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin		17874-34-9
(12)	Dimethyl citraconate		617-54-9
(13)	7,11-Dimethyl-***4,6,10***-dodecatrien-3-one	***Pseudomethyl-ionone***	26651-96-7
(14)	6,10-Dimethyl-***3,5,9***-undecatrien-2-one	***Pseudoionone***	141-10-6
(15)	Diphenylamine		122-39-4
(16)	Ethyl acrylate		140-88-5

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(17)	Fig leaf ***absolute (Ficus carica L.)***		68916-52-9
(18)	trans-2-Heptenal		18829-55-5
(19)	trans-2-Hexenal diethyl acetal		67746-30-9
(20)	trans-2-Hexenal dimethyl acetal		18318-83-7
(21)	Hydroabietyl alcohol		13393-93-6
(22)	***4-Benzyloxyphenol and*** 4-Ethoxy-phenol		***103-16-2;*** 622-62-8
(23)	6-lsopropyl-2-decahydronaphthalenol		34131-99-2
(24)	7-Methoxycoumarin		531-59-9
(25)	***Hydroquinone methylether;Mequinol***	***p-Hydroxyanisol***	150-76-5
(26)	4-(***4-Methoxyphenyl***)-3-butene-2-one	***Anisylidene Acetone***	943-88-4
(27)	1-(***4-Methoxyphenyl***)-1-penten-3-one	***alpha-Methylanisylideneacetone***	104-27-8
(28)	Methyl trans-2-butenoate		623-43-8
(29)	6-Methylcoumarin		92-48-8
(30)	7-Methylcoumarin		2445-83-2
(31)	5-Methyl-2,3-hexanedione	***Acetyl isovaleryl***	13706-86-0

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(32)	Costus root oil (Saussurea lappa Clarke)		8023-88-9
(33)	7-Ethoxy-4-methylcoumarin		87-05-8
(34)	Hexahydrocoumarin		700-82-3
(35)	Exudation of Myroxylon pereirae (Royle) Klotzsch ***(Peru balsam, crude***)		8007-00-9
(36)	2-Pentylidene-cyclohexanone		25677-40-1
(37)	***3,6,10***-Trimethyl-***3,5,9***-undecatrien-2-one	***Pseudo-Isomethyl ionone***	1117-41-5
(38)	Verbena ***essential oils*** (Lippia citriodora Kunth) ***and derivatives other than absolute***		8024-12-2
(39)	▌4-tert-Butyl-3-methoxy-2,6-dinitrotoluene▐	***Musk ambrette***	83-66-9
(40)	4-***Phenylbut-3-en***-2-one	***Benzylidene acetone***	122-57-6
(41)	***2-Benzylideneheptanal***	***Amyl cinnamal***	122-40-7
(42)	***2-Pentyl-3-phenylprop-2-en-1-ol***	***Amylcinnamyl alcohol***	101-85-9
(43)	Benzyl alcohol		100-51-6
(44)	Benzyl salicylate		118-58-1

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(45)	Cinnamyl alcohol		104-54-1
(46)	***2-Propenal, 3-phenyl-***	***Cinnamal***	104-55-2
(47)	***3,7-Dimethyl-2,6-octadienal***	***Citral***	5392-40-5
(48)	***2H-1-Benzopyran-2-one***	***Coumarin***	91-64-5
(49)	***Phenol, 2-methoxy-4-(2-propenyl)***	***Eugenol***	97-53-0
(50)	***2,6-Octadien-1-ol, 3,7-dimethyl-, (2E)-***	***Geraniol***	106-24-1
(51)	***7-***Hydroxy-citronellal	***Hydroxycitronellal***	107-75-5
(52)	***3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde***	***HICC***	***51414-25-6;*** 31906-04-4
(53)	***Phenol, 2-methoxy-4-(1-propenyl)***	***Isoeugenol***	97-54-1
(54)	Oakmoss ***extract***	***Evernia prunastri extract***	90028-68-5
(55)	Treemoss ***extract***	***Evernia furfuracea extract***	90028-67-4
(56)	▌2,6-Dihydroxy-4-methyl-benzaldehyde▐	***Atranol***	526-37-4
(57)	▌3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde▐	***Chloratranol***	57074-21-2

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(58)	***Methyl Oct-2-ynoate (***Methyl heptine carbonate***)***	***Methyl 2-Octynoate***	111-12-6
(59)	***2-(4-tert-butylbenzyl) propionaldehyde***	***Butylphenyl methylpropional***	***80-54-6***

5. Toys intended for use by children under 36 months or other toys intended to be placed in the mouth shall not contain the fragrance allergens listed in Annex II, Appendix, Part B, point 1, unless their presence in the toy is technically unavoidable under good manufacturing practice and does not exceed 10 mg/kg.

Part B. Substances subject to specific labelling requirements

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 present in the toy or any component thereof at concentrations exceeding ***10*** mg/kg:

The information mentioned shall be expressed by using the common ingredient name or a term as contained in a generally accepted nomenclature.

No	***Chemical*** name▌	***Common name***	CAS number
(1)	***4-Methoxybenzyl*** alcohol	***Anise alcohol***	105-13-5
(2)	Benzyl benzoate	***Benzyl benzoate***	120-51-4
(3)	***2-Propenoic acid, 3-phenyl-, phenylmethyl ester***	***Benzyl cinnamate***	103-41-3

(4)	***3,7-Dimethyl-6-octen-1-ol (3R)-3,7-dimethyloct-6-en-1- ol (D-Citronellol) (3S)-3,7-dimethyloct-6-en-1- ol (L-Citronellol)***	***Citronellol***	106-22-9***; 26489-01-0***; 1117-61-9; 7540-51-4
(5)	***2,6,10-Dodecatrien-1-ol, 3,7,11-trimethyl***	***Farnesol***	4602-84-0
(6)	***2-Benzylide-neoctanal***	***Hexyl cinnamaldehyde***	101-86-0
▌	▌		▌
(8)	***1-methyl-4-prop-1- en-2-yl-cyclohexene; dl-limonene (racemic); Dipentene (R)-p-mentha-1,8-diene; (d-limonene) (S)-p-mentha-1,8-diene; (l-limonene)***	***Limonene***	***138-86-3; 7705-14-8;*** 5989-27-5***; 5989-54-8***
(9)	***1,6-Octadien-3-ol,3,7-dimethyl***	***Linalool***	78-70-6
(10)	3-Methyl-4-(***2,6,6***-trimethyl-2-***cyclo-hexen***-1-yl)-3-buten-2-one	***alpha-Isomethyl ionone***	127-51-5
(11)	***[3R-(3α,3aβ,7β,8aα)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-***	***Acetyl Cedrene***	32388-55-9

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	tetramethyl-1H-3a,7-methanoazulen-5- yl)ethan-1-one		
(12)	***Pentyl-2-hydroxy-benzoate***	***Amyl Salicylate***	2050-08-0
(13)	***1-Methoxy-4-(1E)- 1-propen-1-yl-benzene (***trans-Anethole***)***	***Anethole***	***104-46-1;*** 4180-23-8
(14)	Benzaldehyde	***Benzaldehyde***	100-52-7
(15)	***Bornan-2-one; 1,7,7-Trimethylbi-cyclo[2.2.1]-2-hept-anone***	***Camphor***	76-22-2***; 21368-68-3***; 464-49-3***; 464-48-2***
(16)	***2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one (5R)-2-Methyl-5-prop-1-en-2-ylcyclohex-2-en-1- one (5S)-2-Methyl-5-prop-1-en-2-ylcyclohex-2-en-1-one***	***Carvone***	99-49-0; 6485-40-1; 2244-16-8
(17)	(***1R,4E,9S***)-***4,11,11-Trimethyl-8-methylenebi-cyclo[7.2.0]undec-4-Ene***	***beta-Caryophyllene***	87-44-5
(18)	***1-(2,6,6-Trimethyl-cyclohexa-1,3-dien-1-yl)-2-buten-1-one***	***Rose ketone-4 (Damascone)***	23696-85-7

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(19)	***1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one***	***alpha-Damascone; cis-Rose ketone 1; trans-Rose ketone 1***	43052-87-5; 23726-94-5***; 24720-09-0***
(20)	***(Z)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one***	***cis-Rose ketone 2 (cis-beta-Damascone)***	23726-92-3
	(E)-1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one	***trans-Rose ketone 2 (trans-beta-Damascone)***	***23726-91-2***
(21)	***1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one***	***Rose ketone 3 (delta-Damascone)***	57378-68-4
	1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)- 2-buten-1-one	***trans-Rose ketone 3***	***71048-82-3***
(22)	***2-Methyl-1-phenyl-2-propyl acetate;***Dimethylbenzyl Carbinyl Acetate	***Dimethyl Phenethyl Acetate (DMBCA)***	151-05-3
(23)	***Oxacycloheptadecan-2-one***	***Hexadecanolactone***	109-29-5
(24)	***1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-γ-2-benzopyran***	***Hexamethylindanopyran***	1222-05-5
(25)			

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(26)	***3,7-Dimethyl octa-1,6-diene-3-yl*** acetate	***Linayl acetate***	115-95-7
(27)	***dl-Menthol (***Menthol ***racemic) Menthol l-menthol (Levomenthol) d-menthol***	***Menthol***	1490-04-6; 89-78-1; 2216-51-5***; 15356-60-2***
(28)	Methyl ***2-hydroxybenzoate***	***Methyl salicylate***	119-36-8
(29)	3-Methyl-5-(2,2,3-trimethyl-3-***cyclopentenyl***)pent-4-en-2-ol ***l***	***Trimethylcyclopentenyl Methylisopentenol***	67801-20-1
(30)	***2,6,6-Trimethylbicyclo[3.1.1]hept-2-ene (***alpha-Pinene***); 6,6-Dimethyl- 2-Methylenebicyclo[3.1.1]heptane (beta-Pinene)***	***Pinene***	80-56-8***; 7785-70-8; 127-91-3; 18172-67-3***
▌	▌		▌
(32)	***3-***Propylidene***-1(3H)-isobenzofuranone***	***3-Propylidenephthalide***	17369-59-4
(33)	***o-Hydroxy-benzaldehyde***	***Salicylaldehyde***	90-02-8
(34)	***5-(2,3-Dimethyltricyclo[2.2.1.02,6]-hept-3-yl)-2-methylpent-2-en-1-ol ;***Alpha-Santalol***; (1S-(1a,2a(Z),4a))-***	***Santalol***	***11031-45-1;*** 115-71-9***; 77-42-9***

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	2-Methyl-5-(2-methyl-3-methylenebicyclo[2.2.1]hept-2-yl)-2-penten-1-ol (beta-Santalol)		
▌	▌		▌
(36)	***[1R-(1α)]-α-Ethenyldecahydro-2-hydroxy-α,2,5,5,8a-pentamethyl-1-naphthalenepropanol***	***Sclareol***	515-03-7
(37)	***2-(4-methylcyclohex-3-en-1-yl)propan-2-ol; p-Menth-1-en-8-ol (***alpha-Terpineol***); 1-methyl-4-(1-methyl-vinyl)cyclohexan-1-ol (beta-Terpineol); 1-methyl-4-(1-methylethylidene)cyclohexan-1-ol (gamma-Terpineol)***	***Terpineol***	***8000-41-***798-55-5***; 138-87-4; 586-81-2;***
	▌		▌
(39)	***p-Mentha-1,4(8)-diene***	***Terpinolene***	586-62-9
(40)	***1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-***tetramethyl-***2-naphthyl)ethan-1-one; 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-***	***Tetramethyl acetyloctahydronaphthalenes***	54464-57-2; 54464-59-4; 68155-66-8; 68155-67-9

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	tetramethyl-2-naphthyl)ethan-1-one; 1-(1,2,3,5,6,7,8,8a octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one; 1-(1,2,3,4,6,7,8,8a octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one		
(41)	***3-(2,2-Dimethyl-3-hydroxypropyl)toluene***	***Trimethyl benzenepropanol***	103694-68-4
(42)	***4-Hydroxy-3-methoxybenzaldehyde***	***Vanillin***	121-33-5
(43)	Cananga odorata ***flower oil and extract; Ylang Ylang flower oil and extract***	***Cananga Odorata Flower Extract; Cananga Odorata Flower Oil***	83863-30-3; 8006-81-3***; 68606-83-7; 93686-30-7***
(44)	Cedrus atlantica ▌ oil ***and extract***	***Cedrus Atlantica Bark Extract; Cedrus Atlantica Bark Oil; Cedrus Atlantica Bark Water; Cedrus Atlantica Leaf Extract; Cedrus Atlantica Wood Extract; Cedrus Atlantica Wood Oil***	92201-55-3; ***8023-85-6***
(45)	Cinnamomum cassia leaf oil		8007-80-5***; 84961-46-6***

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(46)	Cinnamomum zeylanicum bark oil		84649-98-9***;*** ***8015-91-6***
(47)	Citrus aurantium ***dulcis*** flower oil	***Citrus aurantium dulcis flower oil***	8016-38-4***;*** ***8028-48-6***
	Citrus aurantium dulcis peel oil	***Citrus aurantium dulcis peel oil***	***97766-30-8*** ***8028-48-6***
		Citrus Sinensis Peel Oil	***8008-57-9***
(48)	Citrus aurantium amara ***flower*** oil	***Citrus aurantium amara flower oil***	72968-50-4
	Citrus aurantium amara peel oil	***Citrus aurantium amara peel oil***	***68916-04-1*** ***72968-50-4***
(49)	Citrus ***aurantium*** bergamia ***oil***	***Citrus Aurantium Bergamia Peel Oil***	89957-91-5***;*** ***8007-75-8;*** ***68648-33-9;*** ***8007-75-8;*** ***85049-52-1***
(50)	Citrus ***limon oil***	***Citrus limonum peel oil***	84929-31-7***;*** ***8008-56-8***
(51)	[redacted]		[redacted]
(52)	***Cymbopogon Schoenanthus Oil*** ***Cymbopogon Flexuosus Oil***Cymbopogon Citratus ***Oil***	***Cymbopogon Schoenanthus Oil;*** ***Cymbopogon Flexuosus Oil;*** ***Cymbopogon Citratus Leaf Oil***	***8007-02-1***; 89998-16-3***;*** ***91844-92-7***
(53)	Eucalyptus ***Globulus*** Oil	***Eucalyptus Globulus Leaf Oil; Eucalyptus***	***97926-40-4***; [redacted] 8000-48-4

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		Globulus Leaf/Twig Oil	
(54)	Eugenia Caryophyllus ▌ Oil	***Eugenia Caryophyllus Leaf Oil; Eugenia Caryophyllus Flower Oil; Eugenia Caryophyllus Stem oil; Eugenia Caryophyllus Bud oil***	8000-34-8***; 8015-97-2; 84961-50-2 84961-50-2 84961-50-2 84961-50-2***
(55)	Jasminum Grandiflorum / ▌ Officinale ***Oil and Extract***	***Jasminum Grandiflorum Flower Extract; Jasminum Officinale Oil; Jasminum Officinale Flower Extract***	84776-64-7; 90045-94-6; 8022-96-6***; 8024-43-9; 90045-94-6***
(56)	Juniperus Virginiana ***Oil***	***Juniperus Virginiana Oil Juniperus Virginiana Wood Oil***	8000-27-9; 85085-41-2
(57)	Laurus nobilis ▌ oil	***Laurus nobilis leaf oil***	8007-48-5***; 8002-41-3; 84603-73-6***
▌	▌		▌
▌	▌		▌
(60)	Lavandula Hybrida ***Oil/Extract;*** ***Lavandula Intermedia Oil/Extract;***	***Lavandula Hybrida Oil Lavandula Hybrida Extract; Lavandula Hybrida Flower Extract; Lavandula Intermedia Flower/Leaf/Stem Extract;***	91722-69-9***; 8022-15-9; 93455-96-0; 93455-97-1; 92623-76-2; 84776-65-8; 8000-28-0; 90063-37-9; 84776-65-8;***

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	Lavandula Angustifolia Oil Extract	***Lavandula Intermedia Flower/Leaf/Stem Oil; Lavandula Intermedia Oil; Lavandula Angustifolia Oil; Lavandula Angustifolia Flower/Leaf/Stem Extract***	***8000-28-0; 90063-37-9***
▌	▌		▌
(62)	Mentha piperita ***oil***		8006-90-4; 84082-70-2
(63)	Mentha spicata ***oil (spearmint oil)***	***Mentha Viridis Leaf Oil***	84696-51-5***; 8008-79-5***
(64)	Narcissus ***Poeticus / Pseudonarcissus / Jonquilla / Tazetta Extract***	***Narcissus Poeticus Extract Narcissus Pseudonarcissus Flower Extract Narcissus Jonquilla Extract Narcissus Tazetta Extract***	***90064-26-9; 68917-12-4 90064-27-0 90064-25-8***
(65)	Pelargonium graveolens ***oil***	***Pelargonium graveolens flower oil***	90082-51-2; 8000-46-2
(66)	Pinus Mugo ***Leaf Oil; Pinus Mugo Twig Leaf Extract; Pinus Mugo Twig Oil***		90082-72-7
(67)	Pinus Pumila ***Needle Extract; Pinus Pumila Twig Leaf Extract; Pinus***		97676-05-6

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	Pumila Twig Leaf Oil		
(68)	Pogostemon cablin ***oil***		8014-09-03; 84238-39-1
(69)	***Rosa Damascena Flower Oil; Rosa Damascena Flower Extract; Rosa Alba Flower Oil; Rosa Alba Flower Extract; Rosa Canina Flower Oil; Rosa Centifolia Flower Oil; Rosa Centifolia Flower Extract; Rosa Gallica Flower Oil; Rosa Moschata Flower Oil; Rosa Rugosa*** Flower Oil ▌		***8007-01-0; 90106-38-0 93334-48-6 84696-47-9; 84604-12-6; 84604-13-7; 92347-25-6***
(70)	Santalum album ***oil***		84787-70-2; 8006-87-9
(71)	Turpentine ***gum (Pinus spp.); Turpentine oil and rectified oil; Turpentine, steam distilled (Pinus spp.***)	***Turpentine***	8006-64-2; 9005-90-7; 8052-14-0

2. The use of fragrances referred to in entries 41 ***to 51 and 53*** to 55 in the table in Part A, point 4, and of fragrances referred to in points 1 to ***9*** in the table in point 1 of this Part shall be allowed in olfactory board games, cosmetic kits and gustative games, under the following conditions:

(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;

(b) where applicable, the resulting products made by the child in accordance with the manufacturer's instructions comply with Regulation (EC) No 1223/2009; and

(c) where applicable, the fragrances comply with the relevant Union ***law*** on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 2 of Annex III.

PUBLIC

Part C. Permitted *presence* of substances subject to generic prohibitions under Part III, point 4, of Annex II

Substance	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.
Cobalt	***Carc 1B, Muta 2, Repr 1B***	***In metal toy components intended to conduct electric current.*** ***[In metal toy components that serve a function other than electrical conductance such as metal toys, toy jewellery, fidget spinners, magnets.]***[2]

[2] ***The permitted use will be adapted at a later stage, following Chemicals Working Group Meeting.***

Part D. Bisphenols prohibited in toys

No	*Substance name*	*CAS number*	*EC Number*
1	*4,4'-(1-methylpropylidene)bisphenol; bisphenol B*	*77-40-7*	*201-025-1*
2	*4,4'-isopropylidenedi-o-cresol;*	*79-97-0*	*201-240-0*
3	*6,6'-di-tert-butyl-4,4'- butylidenedi-m-cresol*	*85-60-9*	*201-618-5*
4	*2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol; TBMD*	*118-82-1*	*204-279-1*
5	*4,4'-isopropylidenebis[2-allylphenol],*	*1745-89-7*	*217-121-1*
6	*4,4'-isopropylidenedi-2,6-xylol,*	*5613-46-7*	*227-033-5*
7	*2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bisethyl diacetate*	*19224-29-4*	*242-895-2*
8	*(1-methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate;*	*27689-12-9*	*248-607-1*
9	*4-(4-isopropoxyphenylsulfonyl)phenol*	*95235-30-6*	*405-520-5*
10	*2,2'-diallyl-4,4'-sulfonyldiphenol; TG-SA*	*41481-66-7*	*411-570-9*

PUBLIC

Annex III

WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS

PUBLIC

1. General rules - presentation

All warnings shall be preceded by the word 'Warning' or, ***in the form of following*** generic pictogram***, which shall be displayed in a prominent way, without the obligation to repeat it before each warning***:



The pictogram size shall be at least 10 mm in black triangle, yellow background and black exclamation mark.
Warnings shall be printed in characters using a font size where the x-height is equal to or greater than 1,2 mm and with sufficient contrast between the print and the background to ensure their visibility and legibility, without prejudice to the minimum height of pictograms, which shall be not less than 10 mm. In case of packaging or containers the largest surface of which has an area of less than 80 cm^2, the x-height of the font size shall be equal to or greater than 0,9 mm.

2. Toys not intended for use by children under 36 months

Toys which might be dangerous for children under 36 months shall bear a warning ▌ 'Not suitable for children under 36 months' or 'Not suitable for children under three years' or a warning in the form of the following pictogram:



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.

This point shall not apply to toys which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months.

3. Activity toys

Activity toys shall bear the following warning:

'Only for domestic use.'

Activity toys attached to a crossbeam as well as other activity toys, where appropriate, shall be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at certain intervals, and pointing out that the toy may cause a fall or overturn if such checks are not carried out.

Instructions shall also be given as to the correct assembly of the toy, indicating those parts which can present a danger if incorrectly assembled. Specific information regarding a suitable surface on which to place the toy shall be given.

4. Functional toys

Functional toys shall bear the following warning:

'To be used under the direct supervision of an adult.'

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In addition, functional toys shall be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to follow such working instructions or take such precautions will expose the user to the hazards normally associated with the appliance or product of which the toy is a scale model or imitation. Those hazards shall be specified in the warning. It shall also be indicated that the toy is to be kept out of the reach of children under a certain age, which shall be specified by the manufacturer.

5. Chemical toys

Without prejudice to the application of the provisions laid down in applicable Union legislation on the classification, packaging and labelling of certain substances or mixtures, the instructions for use of toys containing inherently ***hazardous*** substances or mixtures shall bear a warning of the ***hazardous*** nature of those substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them. These precautions shall be specified concisely and shall relate to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of the relevant type of toy shall also be mentioned. It shall also be stated that the toy is to be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

In addition to the instructions referred to in the first subparagraph, chemical toys shall bear the following warning on their packaging:

'Not suitable for children under …[1] years. For use under adult supervision.'

6. Skates, roller skates, inline skates, skateboards, scooters and toy bicycles

Where skates, roller skates, inline skates, skateboards, scooters and toy bicycles are offered for sale as toys, they shall bear the following warning:

'Protective equipment should be worn. Not to be used in traffic.'

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[1] Age to be specified by the manufacturer.

The instructions for use shall contain a reminder that the toy is to be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user or third parties. Indications shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

7. Aquatic toys

Aquatic toys shall bear the following warning:

'Only to be used in water in which the child is within ***its*** depth and under adult supervision ▌ '**.**

8. Toys in food

Packaging of food containing toys or packaging of food co-mingled with ***toys*** shall bear the following warning***, which shall be visible before the purchase***:

'Toy inside. Adult supervision recommended.'

9. Imitations of protective masks and helmets

Where imitations of protective masks and helmets are offered for sale as toys, they shall bear the following warning:

'This toy does not provide protection.'

10. Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps

For toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps, the following warning shall be given on the packaging of the toy and shall be permanently marked on the toy:

'To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees ▌ '**.**

PUBLIC

11. Packaging for fragrances in olfactory board games, cosmetic kits and gustative games

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain fragrances referred to in entries 41 to ***51 and 53 to*** 55 in the table in Part A, point 4, of the Appendix to Annex II and of fragrances referred to in entries ***1 to 9*** in the table in Part B, point 1, of that Appendix shall contain the following warning:

'Contains fragrances that may cause allergies.'

PUBLIC

Annex IV

CONFORMITY ASSESSMENT PROCEDURES

Part I

Module A: Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares, on the manufacturer's sole responsibility, that the toy satisfies the requirements of this Regulation.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, to the extent relevant for the assessment, the design, manufacture and operation of the toy. The technical documentation shall contain at least the elements set out in Annex V.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Regulation.

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

4.1. The manufacturer shall affix the CE marking to each individual toy that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall ***create the digital*** 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 the market. The ***digital*** product passport shall identify the toy for which it has been ***created***.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

PUBLIC

Part II

▌Module B : EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a toy and verifies and attests that the technical design of the toy meets the requirements of this Regulation.

2. EU-type examination may be carried out in any of the following manners:

(a) examination of a specimen, representative of the production envisaged, of the complete toy (production type),

(b) assessment of the adequacy of the technical design of the toy through an examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the toy (combination of production type and design type),

(c) assessment of the adequacy of the technical design of the toy through an examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of the manufacturer's choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, as well as the name and address of that representative,

(b) a written declaration that the same application has not been lodged with any other notified body,

(c) the technical documentation, which is to make it possible to assess the product's conformity with the applicable requirements of this Regulation and is to include an adequate analysis and assessment of the risk(s), including the safety assessment referred to in Article 21; it is to specify the applicable requirements and cover, to the extent relevant for the assessment, the design, manufacture and operation of the toy; and it is to contain at least the elements set out in Annex V,

(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,

(e) the supporting evidence for the adequacy of the technical design solution; it is to mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full; and it is to include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

4. The notified body shall:

For the toy:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of its technical design;

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For the specimen:

4.2. verify that the specimen has been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or common specifications, as well as the elements which have been designed without applying the relevant provisions of those standards ***and/or common specifications***;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or common specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or common specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential ***safety*** requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 as well as their results. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Regulation, the notified body shall issue an EU-type examination certificate to the manufacturer. The EU type examination certificate shall include a reference to this Regulation, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference of the relevant test report. The certificate shall contain the name and address of the manufacturer, an indication of the place of manufacture, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have annexes attached.

PUBLIC

The certificate and the annexes thereto shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type might no longer comply with this Regulation, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the toy with the essential ***safety*** requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities of the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

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Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

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.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Part III

Module C: Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

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The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements of the legislative instrument that apply to them.

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

3.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the legislative instrument.

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

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

PUBLIC

Annex V

ELEMENTS TO BE INCLUDED IN THE TECHNICAL DOCUMENTATION (as referred to in Article 23)

(1) A detailed description of the design and manufacture, including a list of components and materials used in the toy as well as ***a list of*** the substances and mixtures used, ***including the safety data sheets,*** to be obtained from the chemical suppliers;

(2) The safety assessment(s) carried out in accordance with Article 21;

(3) A description of the conformity assessment procedure followed;

(4) The addresses of the places of manufacture and storage;

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

(6) Test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards ***or common specifications***, if the manufacturer followed the internal production control procedure referred to in Article 22(2); and

(7) a copy of the EU-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EU-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EU-type examination and followed the conformity to type procedure referred to in Article 22(3).

PUBLIC

Annex VI

DIGITAL PRODUCT PASSPORT

PUBLIC

Part I

Information to be included in the *digital* product passport

(a) unique product identifier of the toy;

(b) name and address of the manufacturer ***and, when applicable,*** of the manufacturer's authorised representative, as well as the unique operator identifier;

(c) name and address of the economic operator responsible for carrying out the tasks set out in Article 4 of Regulation (EU) 2019/1020, as well as the unique operator identifier;

(ca) the mention that this passport is issued under the sole responsibility of the manufacturer;

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

(e) ***where applicable,*** the commodity code***, as defined in Council Regulation (EEC) No 2658/87***[1] under which the toy is classified at the moment the passport is created***;***

(f) references to all Union ***law*** that the toy complies with;

(fa) where applicable, the mention that this Digital Product Passport replaces the EU Declaration of conformity under Regulation (EU) 2024/2847, Regulation (EU) 2024/1689, Commission Delegated Regulation (EU) 2019/945, Directive 2014/53/EU, Directive 2014/35/EU, Directive 2014/30/EU, or Directive 2011/65/EU;

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1 ***[1]*** Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

(g) references to the relevant harmonised standards used, or references to common specifications in relation to which conformity is declared;

(h) where applicable: the notified body name and number which has intervened in the conformity assessment procedure and issued a certificate, as well as the reference to the certificate;

(i) the CE marking;

(j) a list of allergenic fragrances that are present in the toy and that are subject to specific labelling requirements as set out in Part B, point 1, of the Appendix to Annex II;

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

(l) the reference of the digital product passport service provider hosting the back-up copy of the digital product passport.

Part II

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

(a) safety information and warnings;

(b) instructions of use.

PUBLIC

Annex VII

LIST OF COMMODITY CODES AND PRODUCT DESCRIPTIONS FOR THE PURPOSES OF ARTICLE 20(8)

1	*ex 3213: Artists', students' or signboard painters' colours, modifying tints, amusement colours and the like, in tablets, tubes, jars, bottles, pans or in similar forms or packings for use by children*
2	*ex 3407: Modelling pastes put up for children's amusement*
3	*ex 4903: Children's picture, drawing or colouring books, excluding books intended for children older than 36 months*
4	*ex 61, ex 62: Fancy dresses for children under 14 years of age, excluding goods classified under 6111, 6112, 6115, 6116, 6209, 6211, 6212, 6213, 6216*
5	*ex 8711 60: Children's cycles (with a maximum saddle height not exceeding 435 mm) fitted with an auxiliary motor, with electric motor for propulsion, not intended for travel in public roads* *ex 8712, ex 8714: Children's cycles (with a maximum saddle height not exceeding 435 mm), not motorised, and parts thereof*
6	*ex 9503: Tricycles, scooters, pedal cars and similar wheeled toys; dolls' carriages; dolls; other toys; reduced-size ('scale') models and similar recreational models, working or not; puzzles with 500 pieces or less*
7	*ex 9504 40 00: Playing cards* *ex 9504 90 10: Electric car racing sets, having the character of competitive games* *ex 9504 90 80: Other, table or parlour games*
8	*ex 9505 90 00: Carnival or other entertainment articles, including conjuring tricks and novelty jokes for use by children*
9	*ex 9506 70 30: Roller skates and inlane skates for children with a body mass not exceeding 20 kg*
10	*ex 9506 99 90: Skateboards intended for children with a body mass not exceeding 20 kg*
11	*ex 9506 99 90: Inflatable paddling pools for children*
12	*ex 9506 69 90: Other balls for children's amusement, like 'juggling balls' and 'anti-stress balls' for children*
13	*ex 9506 99 90: Frisbees*
14	*ex 9603 30: Artists' brushes for use by children*
15	*ex 9609: Pencils (other than pencils of heading 9608), crayons, pencil leads, pastels, drawing charcoals, writing or drawing chalks and tailors' chalks for children*

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16	***ex 9610 00 00: Slates and boards, with writing or drawing surfaces, whether or not framed for use in play by children***

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Annex VIII

CORRELATION TABLE

Directive 2009/48/EC	This Regulation
Article 1	Article 1
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Article 3(25)	Article 3(35)
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